



## THE FUTURE OF AMPUTEE REHABILITATION

Imagine a life without a socket. A leg that is not bulky, cumbersome, that didn't cause rubbing due to poor fit. A fit that is so close to normality it is changing lives for the better.



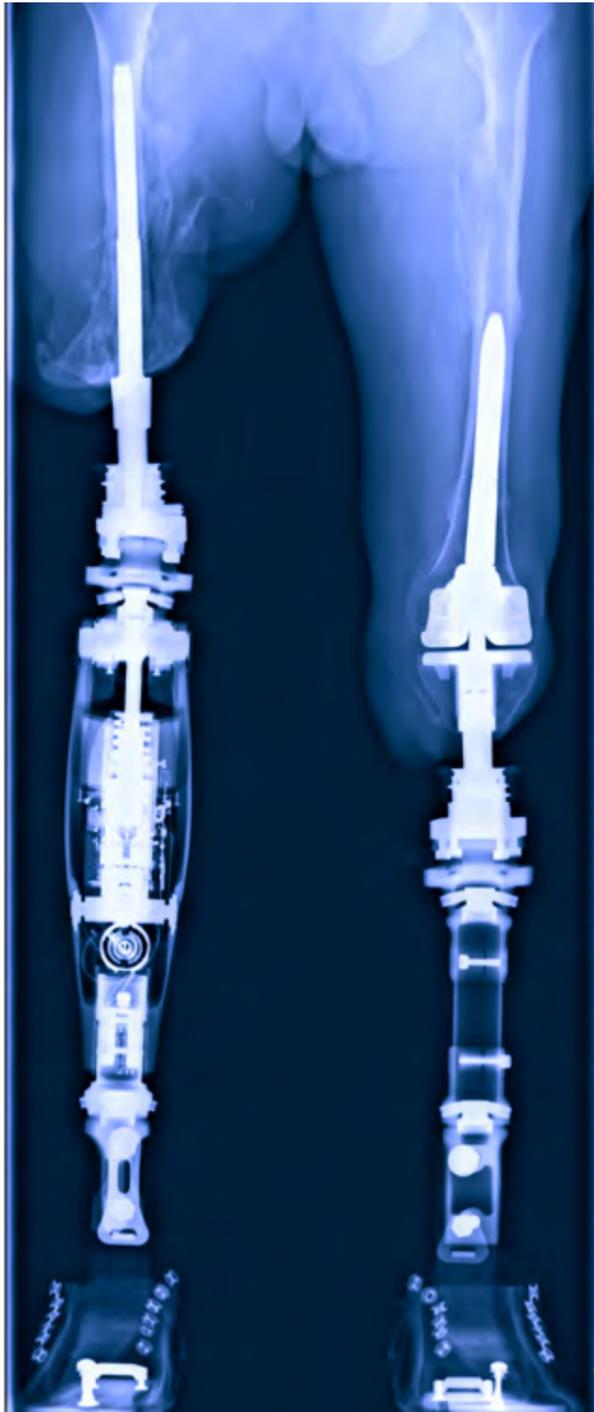
# OSSEOINTEGRATION SURGERY FOR AMPUTEES



## THE OSSEOINTEGRATION GROUP OF AUSTRALIA

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# A REVOLUTION IN AMPUTEE REHABILITATION



## A/Prof Munjed Al Muderis

Munjed is an Australian trained orthopaedic surgeon and a squadron leader in the Australian Air Force Reserve. He is also an ambassador for the Australian Red Cross, a human rights activist, and a refugee who fled to Australia by boat. At the age of 27, Munjed escaped from Iraq and embarked on a life-threatening journey to Australia to realise his lifelong goal of becoming an orthopaedic surgeon.

rate of success. We established “The Osseointegration Group of Australia”, in Sydney, and adopted a multidisciplinary approach to provide amputees with the best chance at attaining greater and more efficient mobility. This technology has recently expanded to include below elbow, below knee, and digital amputations. With advancements in robotic technology, targeted muscle reinnervation, and implantable sensory electrodes, the current state-of-the-art technology allows amputees to operate an osseointegrated robotic limb by mind control.

Osseointegration is able to restore the mechanical axis of the limb to pre-amputation conditions, allowing for correct anatomical alignment. This is in contrast to the malposition of the residual limb tends to take inside a socket prosthesis. This leads to significant impairment in mobility and discomfort due to the poor fit and pistoning of the stump within the socket, potentially causing deleterious outcomes on the hip and spine. An Osseointegration implant rigidly attaches to the limb with virtually no unwanted movement, which minimises any friction on the soft tissue and

provides the patient with a high degree of freedom and comfort. This technology has only become possible through an extensive collaboration between clinicians and engineers; all aiming to help our patients regain their freedom of movement, pain-free.

Today, the technology continues to evolve. Surface coatings embedded with antibacterial nanoparticles and fully customisable 3D printed implants continue to improve clinical outcomes and reduce complications. Osseointegration technology has already proven its short and long term success. It will continue to expand, and I foresee a future where this technology becomes the standard practice to treat limb loss, helping a wider group of amputees to live more vibrant, agile, and fulfilling lives.

**A/Prof Munjed Al Muderis**  
Founder & Chairman of the OGA

# Empowering Amputees with Freedom, Mobility, and Comfort.

# 500+

## Successful Cases Performed

Following the growing body of positive clinical evidence, more and more amputees are travelling to Sydney to enhance their mobility and improve their quality of life.



## MS KATHY W.

For two years I tried different sockets that did not allow me to walk and regain independence; these sockets were never properly adjusted. They were either too tight or painful, or far too large. My husband and I were constantly searching for something that would allow me to walk freely and go about our regular routine.



## MR FRED H.

I struggled with pain and sores that formed from the socket rubbing against my skin. Due to my hips being broken in the accident, my alignment was incorrect and my “good leg” was injured so badly I had to wear an ankle orthosis due to the missing muscle tissue. The combination resulted in a very painful, uneven gait.

# AMPUTATION THE FACTS

- Amputations occur at a rate of 185,000 /year in the US alone and can result from trauma, vascular disease, tumor, infection or congenital anomalies<sup>1</sup>.
- The current standard for the treatment of lost limbs is the socket mounted prosthesis. Despite improvements in socket designs, amputees continue to suffer from problems such as discomfort, pain, pistoning and lack of proprioception.

An amputation refers to the removal of the whole or part of the upper or lower extremity. Amputations can occur after an injury (traumatic amputation) or deliberately in surgery. Historians have identified artificial limbs over 2000 years old and amputations are generally regarded as one of the oldest surgical procedures. Today amputees are highly prevalent, and represent 1 out of every 1000 individuals across Australia; additionally, there are an estimated 185,000 amputations performed yearly in the US<sup>1</sup>.

In most countries, the majority of amputations are performed to treat the complications arising from peripheral vascular disease (PVD). In fact, up to 70% of patients undergoing amputation have a history of diabetes or PVD<sup>2</sup>. Diabetes, high blood pressure, high cholesterol level, smoking, and kidney failure are common risk factors associated with PVD.

The next most common cause of limb loss is trauma, such as motor vehicle collisions or military casualties. Less commonly,

patients undergo amputation for treatment of a tumor in an extremity or for a congenital abnormality of the limb. It is more common for amputations secondary to trauma, cancer or congenital deformations to occur in younger patients which can generate large family and socio-economic burdens due to their disability.

Socket mounted prostheses are the current standard of care for limb loss patients. Although significant advances have been made in prosthetic technology, the fitting of a socket remains challenging and often represents one of the most difficult aspects of the rehabilitation process. Achieving an optimal fit without pressure points, the appropriate amount of flexibility versus rigidity, and longevity remains elusive for a large percentage of patients. Despite continued research in socket and liner technologies, the modern socket remains the reason many amputees are unable to increase mobility, independence, and quality of life.

# 30<sup>+</sup> Million Amputees

The World Health Organization estimates 30 million amputees populate developing countries alone<sup>3</sup>.



## The Original Socket

*The overall design for socket mounted prostheses has changed marginally since it was invented by the French military surgeon Ambroise Paré in 1525<sup>4</sup>.*

## Problems with the Socket Mounted Prostheses

Although it has been in use for over 500 years, the traditional socket prosthesis is still associated with significant limiting factors that can be problematic for the amputee.

Amputees often experience poor socket fit that is exacerbated by slight changes in weight. The use of fabric and silicone liners often causes excessive sweating and rubbing, which leads to chaffing, blistering and skin infections.

Summarised below are some of the reasons why so many patients are only able to wear socket mounted prostheses for short periods of time, or in some cases not able to wear them at all. Sockets can often hinder mobility, which has been identified as the most important outcome for amputees. This is particularly true for bilateral transfemoral amputees in which over 90% of them end up being confined to a wheelchair<sup>5</sup>.



### MECHANICAL ISSUES

The non-physiological loading of a limb through layers of soft tissue can lead to problems such as progressive osteoporosis, which greatly increases the risks of future fractures.

### POOR GAIT

The effect of abnormal loading of the limb and poor fitting of the stump often hinders the amputee from walking with a normal gait, increasing the risk of joint & spine problems in the future.

### HIGH ENERGY CONSUMPTION

Socket users have higher energy requirements (up to 200%) compared to a non-amputee. The significant time required during donning and doffing also impacts their daily living activities.

### RESTRICTIVE LIFESTYLE

Activities such as sitting on a chair or toilet seat, accessing a vehicle, ascending and descending stairs or ramps, kneeling, cycling, and other activities can be very challenging, if not impossible.

### INTERFACE ISSUES

Rotational instability and axial pistoning during walking, daily body volume fluctuations due to weather and weight changes make perfect fitting of the socket impossible.

### SKIN ISSUES

These are very difficult to manage and may include friction, heat, chafing, sweating, ingrown hair, infections or allergic reaction to the liners, further limiting socket use.

### PRESSURE ISSUES

Pressure points created by the socket often develop into sores and ulcers that are difficult to treat, occasionally requiring re-surgery or a higher level of amputation.

### PSYCHOLOGICAL ISSUES

Amputees often show their disappointment and frustration with the socket prosthesis, especially with the advancement of robotic knee joint technology, which is hindered by the archaic interface with the stump.



30+ MILLION  
AMPUTEES



70% DUE TO  
VASCULAR CAUSES



EXPECTED TO  
DOUBLE BY 2050



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## THE HISTORY OF OSSEOINTEGRATION

The concept of osseointegration originated in 1965 by Professor Per-Ingvar Branemark who threaded trans-oral titanium implants into the mandible and maxilla to act as anchorage for dental prostheses. In 1990, his son Rickard Branemark performed the first transcutaneous femoral intramedullary osseointegration surgery on an above knee amputee with a 12-cm screw fixated titanium threaded device. Osseointegration for amputees has now been used clinically since 1995 utilising a skeletally integrated titanium implant, connected through an opening (stoma) in the residual limb to an external prosthetic limb.

# OSSEOINTEGRATION SURGERY & DEVICES

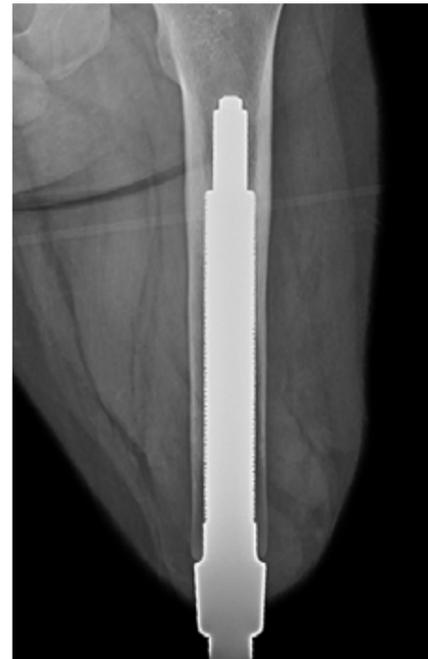
The surgical procedure is performed in a single surgery or in two separate surgeries depending on patient suitability. The bone canal is prepared using specialised instruments to accommodate the implant. The implant is then press-fitted into the canal tightly to achieve initial stability, which enables accelerated rehabilitation. The majority of the surgery involves soft tissue management where redundant

skin, soft tissue, and fat are removed to minimise the bone to skin distance and reduce the risk of complications. Muscle groups are reoriented to serve a functional purpose in the leg, and the soft tissue fascial layer is approximated around the stem in a deliberate fashion. A layered closure provides the outcome of a refashioned stump with improved cosmesis. The surgeons then create a

circular skin opening (the stoma) at the base of the stump overlying the tip of the implant. Through this opening, the dual cone adaptor is connected to the implant, which enables the remaining components and prosthetic limb to be attached externally. Loading through the implant begins a few days post-surgery, and the rehabilitation progresses to gait training shortly thereafter.

## PATIENT ELIGIBILITY

All amputees are potential candidates for osseointegration. However, certain conditions such as age, smoking, ongoing chemotherapy, irradiated bone, ongoing infections, pregnancy, and psychological instability are regarded as additional risk factors to this procedure. Precautions must also be taken when considering patients with diabetes and peripheral vascular disease.



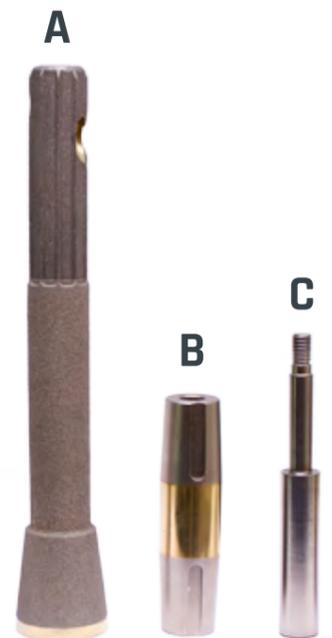
## THE OSSEOINTEGRATED PROSTHETIC LIMB (OPL)

The OPL system is made up of multiple components which can be divided into implantable or non-implantable modules. The implantable module, a porous coated titanium stem (A), is directly implanted into the residual bone of the amputee.

The implant surface is finished with a highly porous plasma sprayed coating. This offers immediate post-operative stability and enables long term biological bony in-growth. This is the same proven technology successfully utilised in modern joint arthroplasty devices for more than 30 years. The macroporus titanium surface has been optimised for excellent biocompatibility and promotes bone to grow into the rough surface of the implant. The bone-implant

interface becomes a single solid unit with potential for a lifelong bond.

A dual cone adaptor (B) connects the implant to the external prosthesis, which is further secured by an internal locking screw (C). This adaptor features a highly polished smooth surface to minimise soft tissue friction. It is also coated with Titanium Niobium for antibacterial properties and passes through a small opening in the skin. Externally, the adaptor is fixed to a torque controlled safety device, which further connects to the prosthetic limb. Donning and doffing the prosthesis is very easy and requires less than 10 seconds. This device is designed so that it can be used with all types of common prosthetics.



**>98%**  
SUCCESS RATE

The revision rate of the OGA osseointegrated femur is currently less than 2%.



## GLOBAL DEVICE AVAILABILITY

The Osseointegrated Prosthetic Limb is approved and available in the following countries: Australia, New Zealand, Canada, the Netherlands, the United Kingdom, and Germany. Ongoing clinical trials and regulatory applications are under way in the United States, Mexico, Taiwan, Poland, Jordan and South Africa.

## AUSTRALIAN TGA REGISTRATION & REBATE

The Osseointegrated Prosthetic Limb (OPL; Permedica s.p.a; Milan, Italy) and the Integral Leg Prosthesis (ILP; Orthodynamics GmbH; Lübeck, Germany) both contain implantable components under the regulation by the Australian Therapeutic Goods Administration (TGA), and have been approved since 2012 (ARTG numbers: 190214, 195008, 195009, 228038, 229715, 229716 & 229734). Australian health care rebates are available for eligible patients.



## MS MARGUERITE M.

The biggest impact is the feeling of complete freedom. Now I never take my leg off during the day, whereas with my socket I would take it off several times to be more comfortable. To never have to deal with the socket discomfort again is amazing.

# CONFIRMED CLINICAL RESULTS

- The original Integral Leg Prosthesis (ILP) device has been utilised for more than 17 years<sup>1</sup>. Recent clinical studies verify the improved mobility and quality of life among patients, with an acceptable risk of infection and complications.
- Preliminary results from ongoing clinical studies suggest that similar results are attainable in patients with peripheral vascular diseases (PVD) or diabetes, potentially allowing a much wider patient cohort to consider osseointegration.

In 2016, the OGA, along with partnering centers published an article in the prestigious Journal of Bone and Joint Surgery (JBJS American) revealing the safety and complication rates<sup>2</sup>. The multi-centre study followed 86 patients who had their osseointegrated device for a minimum of 2 years. It was concluded that while mild infections and irritations can occur, they are easily resolved through oral antibiotics. Severe infections resulting in septic implant loosening were rare.

The team also published the 1 year follow-up results of 5 limb loss patients with PVD who underwent osseointegrated

reconstruction as an attempt to preserve their mobility<sup>3</sup>. All patients were mobilising well at follow-up, which was a substantial outcome considering the 1-year post amputation mortality rate of PVD patients can reach 48%<sup>4</sup>. Until now, PVD has been seen as a contraindication to performing osseointegration.

These results suggest that the procedure is safe and effective. In fact, among all femoral procedures performed in Australia, none required a revision due to infection. The overall complication rate can be considered comparable to common joint arthroplasty procedures.



# 17+ YEARS Results

The original ILP device was first introduced in 1999 with great clinical results. The refinements of the OPL device and associated rehab protocols continue to improve clinical outcomes<sup>1</sup>.

- No more sockets
- Easy limb attachment
- Osseoperception
- Improved gait
- Improved mobility
- Reduced pain
- Cost savings
- Improved bone strength
- Improved quality of life
- Freedom

## 500+ Lives changed

Many patients who have been long term amputees are now able to walk again for the first time in decades. For amputees this is certainly a life changing technology.



## THE OGAAP-1 & OGAAP-2 PROTOCOLS

The Osseointegration Group of Australia Accelerated Protocols 1 & 2 describe the two-stage and single-stage surgery and rehabilitation protocols in full detail. The OGA has published and released these rehabilitation protocols in renowned medical journals, and welcomes the input and comments of other medical professionals to achieve better outcomes for patients.

# SINGLE STAGE SURGERY & REHAB

- In contrast to the 2-stage protocol required by a screw fixation device, which can take up to 12-18 months, the press-fit design ensures that bone integration occurs rapidly with a consolidation phase of 4-6 weeks. This allowed the OGA to dramatically shorten the 2 stage protocol (OGAAP-1).
- Recent advancements in implant design and refinements in surgical techniques further enabled the OGA to perform the procedure in a single stage, shortening the overall surgery & rehabilitation time to 3-6 weeks total (OGAAP-2).

Until very recently, the vast majority of osseointegration procedures worldwide have been performed in 2 stages. From the time of the initial surgery, these procedures typically require up to 12-18 months for the completion of reconstruction and rehabilitation with screw fixation implants. The use of press-fit technology in osseointegration devices provided the early stability required for accelerated loading. The OGAAP-1 protocol greatly reduced the gap in between the stages to at least 4-6 weeks, reducing the total rehabilitation time by more than half<sup>5</sup>.

Since April 2014, a single-stage procedure

has been routinely performed by the OGA under a further refined OGAAP-2 protocol<sup>6</sup>. This reduces the overall time required for the definitive osseointegrated reconstruction and rehabilitation of lower limb amputees to 3-6 weeks, which is substantially shorter compared with any currently available two-stage protocol.

Preliminary data suggests that the single stage OGAAP-2 protocol not only saves the patient time and money, but also lowers the risk of infections, and reduces the chances of the patient requiring a future soft tissue refashioning procedure.



# 3-6 WEEK Rehab Program

The majority of our patients are able to be fitted with their definitive prosthesis to ambulate using crutches by 3-6 weeks and walk independently in approximately 3 months.

Rehab is performed in 3 stages:

- Phase 1 (Days 3-10): Initial loading until the target loading weight (50kg) or half the patient's body weight is achieved.
- Phase 2 (Weeks 2-3): Fitting of a light training prosthesis and initiation of gait training exercises.
- Phase 3 (Weeks 3-6): Fitting of the definitive prosthesis, continuation of gait training exercises and mobilisation with crutches.

Our single-stage approach greatly reduces hospital and rehabilitation costs and allows patients to gain independence in less time.



## LOW RISK & COMPLICATION

Hundreds of amputees have already benefited from osseointegration technology. Clinical studies confirm that the complication risks are comparable to common joint replacements.



## IMPROVED MOBILITY

Enabling full freedom of movement from walking to cycling and recreational activities. Movement is no longer restricted by the protruding edges of a socket.



## MORE COST EFFECTIVE

With an osseointegrated implant, the need for frequent sockets and associated supplies is eliminated, which potentially reduces the long-term costs.



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3. Atallah, Robin, et al. "Osseointegrated Transtibial Implants in Patients with Peripheral Vascular Disease: A Multicenter Case Series of 5 Patients with 1-Year Follow-up." JBJS 99.18 (2017): 1516-1523.
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5. Al Muderis, M., et al. "The Osseointegration Group of Australia Accelerated Protocol (OGAAP-1) for two-stage osseointegrated reconstruction of amputated limbs." Bone Joint J 98.7 (2016): 952-960.
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The information provided here is accurate as of October 2017.

For the most up-to-date data and figures, please contact the OGA team at [info@osseointegrationaustralia.com.au](mailto:info@osseointegrationaustralia.com.au).



### MR PHILIP V.

Having osseointegration has returned me to 99% of the person I was before I lost my leg. To try and explain fully the benefits and the positives would take days. At the beginning, I was hesitant and nervous about the procedure; however now, nearly 3 years later, I tell myself that I should have done it much sooner.

# NUMBERS & STATISTICS



**GLOBAL: 600+**

**8** Global centres.  
More opening soon.

The majority of patients currently treated have travelled to Sydney Australia or Nijmegen, the Netherlands to receive their surgery. Currently the procedure is performed in the following cities: Sydney, Adelaide, Melbourne, Perth, Christchurch, Nijmegen, Rotterdam, and Birmingham.

**NORTH AMERICA: 100+**

Patients from Canada and USA have been travelling to Sydney Australia to receive their surgery.

**OCEANIA: 240+**

There are currently 4 osseointegration centres operated in Australia and 1 center in New Zealand.

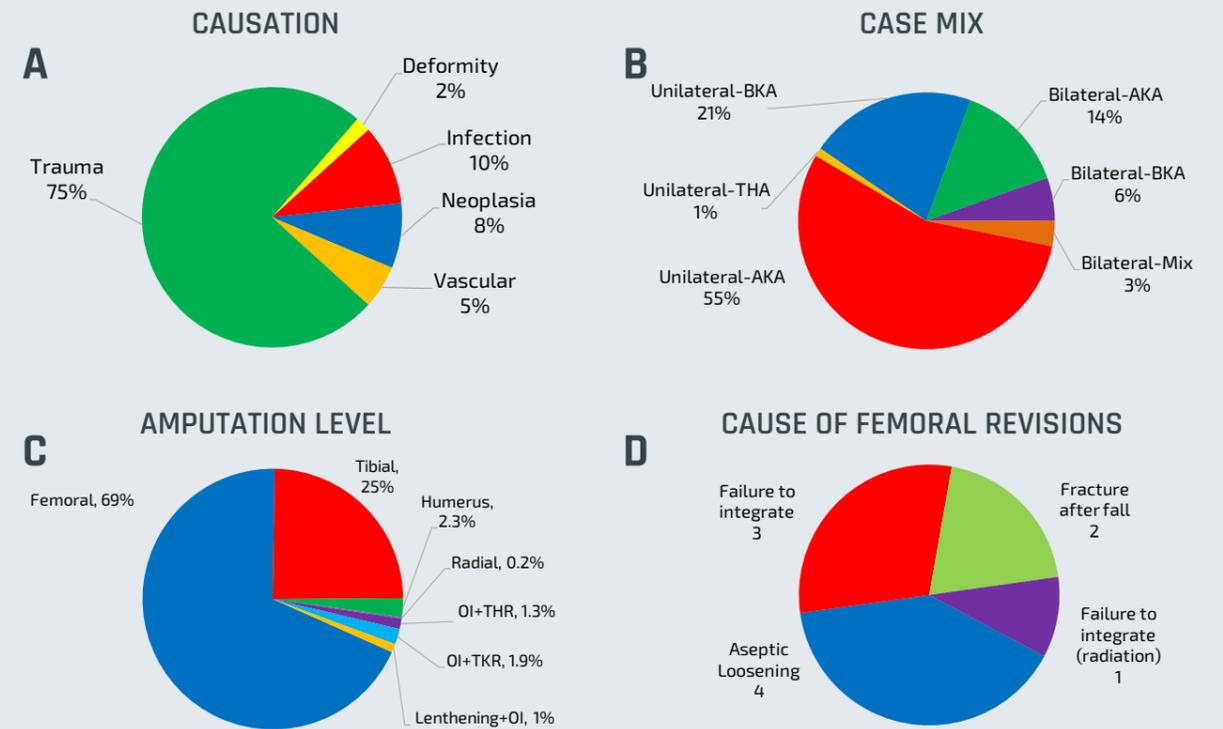
**EUROPE & ASIA: 170+**

The surgery is currently available in the UK, the Netherlands, and Germany.

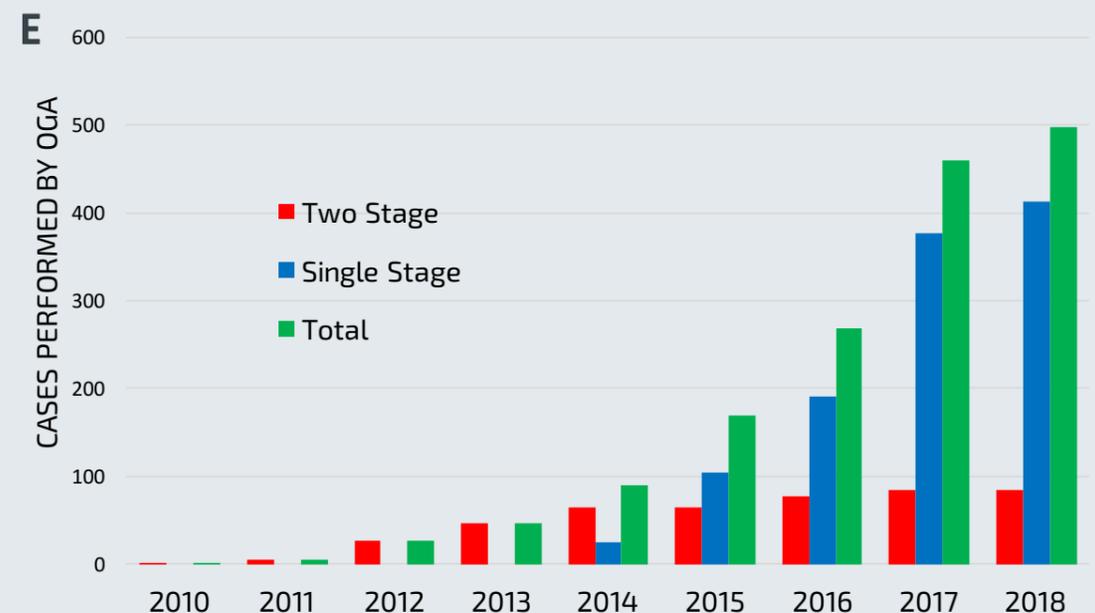
**MIDDLE EAST: 100+**

The OGA is active in humanitarian projects throughout the Middle East region.

A/Prof Al Muderis is currently offering the world's only fellowship program (officially accredited by the Australian Orthopaedic Association) specific for osseointegration surgery. Clinicians are welcome to attend the fellowship program to learn more about the technology or become an OGA certified partner centre.



**A:** Most of our patients lost their limbs due to trauma, however, a few were due to vascular causes. **B:** A substantial proportion of our patients are bilateral amputees in which most were wheelchair bound. **C:** The majority of surgeries were performed on transfemoral amputees. **D:** Total femoral revision rate is approximately 2%. There were no revision cases due to severe infections.



**E:** The OGA performed all initial surgeries using the OGAAP-1 two-stage surgery. However, since the introduction of the OGAAP-2 single stage protocol in 2014, the majority of surgeries are now being performed in a single stage.



### MS NIKKI C.

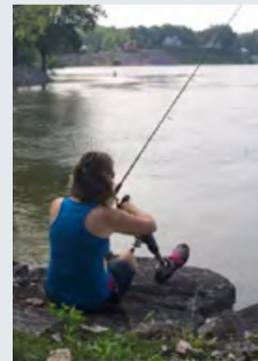
Amazing! This has given me far greater freedom because of the absolute ease of walking. I no longer have to park as close as possible to sporting venues or shopping centres etc. I take the dog for a 3km walk every day and more! I have also managed to get my golf handicap down to 11! The daily comfort is 100% better.



### MRS DIANE C.

Before osseointegration I could not walk or stand for more than 10 minutes. If I was grocery shopping I would have to abandon my trolley and get to the car to take my leg off and massage it until the pain subsided. I can now garden, walk and stand without pain. It has made so much difference to my life.

## MELISSA L. PATIENT STORY



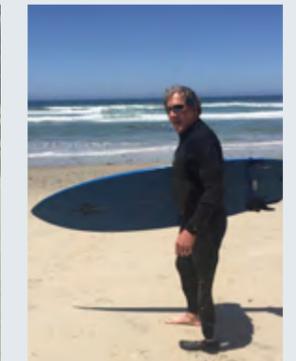
For many years Melissa was a mail carrier who relied on full use of her legs. She had plans for a great future for herself and her family. However, with one doctor visit, everything changed. She was diagnosed with cancer in her right leg, and she would need an amputation to save her life. Although it was an incredibly difficult decision, she knew she had to fight, and in June, 2014, she underwent above knee amputation surgery. Even after the amputation, she was determined to have that great future.

Unfortunately, she struggled for months with a socket and came to the harsh realisation that no amount of determination would make those sockets comfortable or usable for her. As time passed, Melissa was cancer free, but she began to lose motivation. She had heard about osseointegration, but she initially failed to see the potential benefit it could provide for her.

It soon became apparent that her socket prosthesis had become more of a burden than she could bear.

Once she realised she would be on crutches or in a wheelchair for life, she gave osseointegration technology another look. After thorough research, osseointegration suddenly became the answer she was looking for. In order to save her life for a second time, she traveled to Australia to have the surgery. Osseointegration brought her independence again and put her back on a path to the bright future she wanted with her family. She went back to work four months after the surgery and she hasn't slowed down since.

## VICTOR W. PATIENT STORY



Victor has always had the high-flying life Hollywood movies are made about. A former fighter jet pilot who became the trusted airline captain taking passengers across oceans to exotic locations, he had it all figured out. When, in the blink of an eye, everything changed: a motorbike accident left him struggling for his life. His strong will kept him alive, but he lost his leg due to his severe injuries and became a transfemoral amputee during his hospitalisation. He was able to rehabilitate and ultimately returned

to his job with his commercial airline company, but he had significant problems with his socket prosthesis. He was unable to sit for long periods of time and was unable to pass flight requirements, which forced him to leave the skies and take a desk job. However, he refused to quit aiming high, he did his research, and he learnt that osseointegration could be the solution.

In January, 2017, Victor underwent the surgery in Australia. As a man

accustomed to tough situations, he took the challenge head on. It was one of the hardest periods of his life, but osseointegration surgery and rehabilitation ultimately became his biggest reward. The next time he came to Australia he flew himself just 2 months after surgery, as the captain of a commercial jet. He is back to all of his activities and couldn't imagine his life without osseointegration.

Osseointegration gave me a second chance at life to feel fully human again.

Rowena M.

The freedom from socket and liners had a huge impact on my life.

Mike H.

**Patient-Centered Outcomes Research**  
 The OGA adopts a Patient-Centered Outcomes Research (PCOR) philosophy to help patients communicate and make informed healthcare decisions, allowing their voices to be heard in assessing the value of healthcare options.

# THE OGA NETWORK AND PARTNERS

**An ever expanding network of clinics, rehabilitation centers, and medical device companies involving multi-disciplinary experts dedicated to advancing the field of limb loss science.**

The Osseointegration Group of Australia team consists of experts in a variety of fields, each with vast experience working with amputees. We appreciate that every situation and patient is unique, and a multidisciplinary team approach is the best way to assess and determine the optimal treatment plan for our patients.

Each patient is viewed through the lens of the various specialties that comprise the OGA team, and a comprehensive plan is developed through collaborative discussion. If you are interested to learn more about the surgical procedure or implant system, you are welcome to arrange a visit to our Sydney centre where you can see how this technology changes people's lives. Not only will patients have

the opportunity to meet the dedicated professionals of the OGA team, they can also choose to participate in group discussion sessions with other patients considering surgery and those who have already undergone osseointegration.

The OGA cares for our patients both emotionally and physically throughout the process. From helping patients make the best decision for their situation, through to surgery and after care in pain management, physiotherapy and prosthesis adjustments. At all stages we are committed to making sure our patients have the best possible outcome. As our network continues to grow within Australia and internationally our ability to care for the needs of our patients will only grow stronger.

## WE WELCOME ALL COLLABORATIVE OPPORTUNITIES

Our team makes advances through international collaboration between clinicians, biomedical engineers, researchers and allied health professionals. Please contact us at [research@osseointegrationaustralia.com.au](mailto:research@osseointegrationaustralia.com.au).



And many more...

## DISCLAIMERS

The testimonials contained in this booklet are the personal opinions held by those giving the testimonials. No reliance should be placed on the testimonials and all patients should make their own enquiries and obtain their own medical advice about the procedures and their suitability to those described in this website.

Any surgical or invasive procedure carries serious risks. Before proceeding, patients should seek medical advice on their personal condition and seek a second opinion from an appropriately qualified health practitioner.



#### DISCLAIMERS

Any medical information contained in this brochure is not intended as a substitute for informed medical advice. The Osseointegration Group of Australia and Osseointegration International Pty Ltd cannot answer any unsolicited queries relating to personal healthcare issues. Information on the products mentioned may also vary by country. Patients and healthcare professionals should check with local medical resources and regulatory authorities for information appropriate to their country.