OSSEO
INTEGRATION

Direct Skeletal Prosthesis

OSSEOINTEGRATION GROUP OF AUSTRALIA

CONTENTS

INTRODUCTION

What is osseointegration?
Osseointegration is derived from the Greek word "osteon" meaning bone, and the Latin "integrare", which means to make whole. The term is defined as the direct contact between living bone and the surface of a synthetic, often titanium based, load bearing implant.

Osseointegration's original application was in bone and joint replacement surgeries and not only has it dramatically enhanced these surgeries and their outcomes, but now it is also used to vastly improve the quality of life for amputees.

Sir John Charnley pioneered hip replacement surgery in 1962. His design and approach involved attaching the replacement prosthesis to the bone, which he based on a dental practice that utilized bone cement. His revolutionary technique is still used today.

The concept of osseointegration in dentistry first started in 1965 with Professor Per-Ingvar Branemark who threaded trans-oral titanium implants into the mandible and maxilla (the bones of the upper and lower jaw) to act as anchorage for dental prostheses.

In 1990, based on a successful technique developed by his father, Rickard Branemark performed the first transcutaneous femoral intramedullary osseointegration surgery on an above knee amputee with a 12-cm screw-fixation titanium threaded device. A non weight-bearing period of six to twelve months was applied to allow proper osseointegration.

Osseointegration for amputees has been in clinical use since 1995 utilizing a skeletally integrated titanium implant, which is connected through an opening (stoma) in the residual limb to an external prosthetic limb. The socket component of the traditional prosthesis is no longer required. Attachment between the external portion of the implant and the prosthetic knee is achieved via a torque controlled knee connector. This allows direct contact to the ground, which provides greater stability, more control, and minimizes energy consumption.

Say goodbye to your socket!

OGAAP-OPL: The Osseointegration Group of Australia (OGA) is an organization founded by Sydney orthopedic surgeon Associate Professor Munjed Al Muderis. The group consists of a team of highly qualified medical professionals offering support before, during, and after osseointegration surgery. Using a multi-disciplinary team approach, the group provides those with amputations the possibility of improved mobility utilizing the newest innovation in the field of osseointegration.

Imagine a prosthesis that isn't bulky, cumbersome, and didn't cause rubbing due to poor fit. With the Osseointegration Group of Australia Accelerated Protocol – Osseointegration Prosthetic Limb (OGAAP-OPL), mobility is restored as close as possible to that of an able-bodied person and life as an amputee is dramatically changed for the better.

THE SURGEON

Associate Professor Munjed Al Muderis is an Australian trained orthopedic surgeon and a squadron leader in the Australian Air Force Reserve. He is also an ambassador for the Australian Red Cross, human rights activist, and a refugee who fled to Australia by boat.

Born in Baghdad, at the age of 27, A/Prof Al Muderis escaped from Iraq as a young doctor, having refused the orders of Saddam Hussein to mutilate the ears of army deserters. He endured a life-threatening journey to Australia. After spending 10 months in Curtin Detention Centre, upon his release, he embarked on a mission to become an orthopedic surgeon.

A/Prof Al Muderis is now one of three surgeons world wide pioneering the revolutionary technology known as osseointegration. As a leading surgeon in this complex reconstructive and robotic surgery, he has helped hundreds of amputees from around the world to improve mobility, reduce pain, and enhance their overall quality of life.

A/Prof Al Muderis' day-to-day work as an orthopedic surgeon involves hip and knee arthroplasty and major reconstructive surgery. He teaches at Notre Dame and Macquarie Universities, and trains local and international surgeons, registrars, and medical students.

Apart from his academic and clinical roles, A/Prof Al Muderis is heavily involved in humanitarian work, volunteering his time as a surgeon and as a human rights advocate. He has affiliations with Amnesty International, United Nations High Commissioner for Refugees (UNHCR) and represents the Australian Red Cross.

A/Prof Al Muderis studied medicine at Baghdad University from 1991 to 1997. His first job in Australia was at Mildura Base Hospital as an Emergency Unit and Orthopedic Resident. Four months later, he moved to Melbourne as a Surgical Registrar at the Austin Repatriation Hospital. He then went to Wollongong Hospital where he spent a year as an unaccredited Orthopedic Registrar and another year at Canberra Hospital. He joined the Australian Orthopedic Training Program in 2004 as part of the Sydney NSW Orthopedic Training Scheme and obtained his surgical fellowship, FRACS (Orth), in 2008.

A/Prof Al Muderis went on to complete three post specialization fellowships. First, he attended a six month national fellowship in Sydney with Dr. Ali Gursel on Lower Limb Arthroplasty at the Sydney Adventist and Baulkham Hills Hospitals. Then he moved overseas to Berlin, Germany, where he completed a nine month fellowship in Hip and Knee Arthroplasty with Prof Dr. Med Jorg Scholz at the Emil von Behring Hospital, a Teaching Hospital of the Charite Medical School. His third post was a three month Trauma Fellowship with Prof. Dr. Med. Axel Ekkernkamp at the Unfallkrankenhaus Berlin (UKB), also a Teaching Hospital of the Charite Medical School.

During A/Prof Al Muderis' time in Europe, he attended several short-term courses and workshops including:

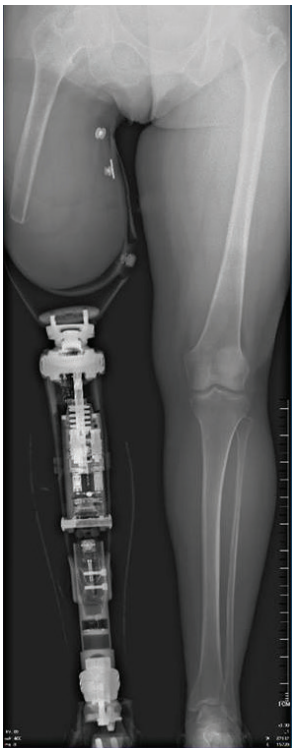
- A two week intensive workshop on hip resurfacing with Dr. Gerdesmyer – major designer of the Onlay Hip Resurfacing System at the Sankt Elisabeth Kranhenhaus Kiel, Germany
- The Anterior Approach Hip Arthroplasty Using Harmonic Scalpel workshop with Dr. Marcus Michek – the designer of the MIS Anterior Approach of Hip Arthroplasty in Bern, Switzerland
- The Anterior Approach Hip Arthroplasty Hip Surgery Using Traction Device workshop with Dr. Stephane Denjean in Lyon, France
- The Endo-Exo Prosthesis workshop with Dr. Grundi and Dr. H. Aschoff in Lubeck, Germany
- The Total Femur Replacement and Tumour Prosthesis Implantation Techniques workshop with Professor Ashel in Nuremburg, Germany

INNOVATION

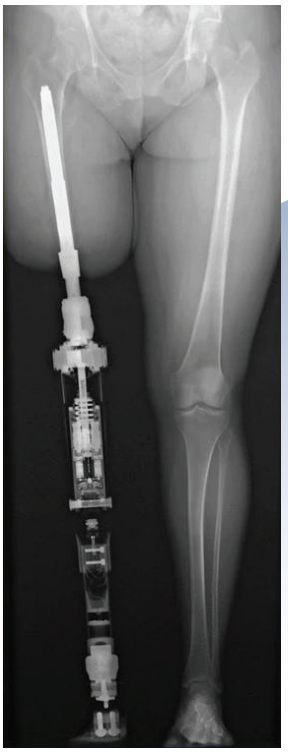
What is the OGAAP-OPL?

The OGAAP-OPL is a revolutionary type of prosthesis for both upper and lower extremity amputees that makes a conventional socket unnecessary. Problems associated with conventional sockets such as rubbing, chaffing, and pressure sores have remained largely unsolved despite extensive and continuing research in socket design and manufacturing. A/Prof Al Muderis (who is the OGAAP-OPL designer), along with the manufacturers, have many years of experience in the field of internal prosthesis design and production. They used evidence of proven clinical history to deliver a safe result that enables mobility and movement without a suction prosthesis.

What makes the OGAAP-OPL so innovative is the fact that it is modeled on the anatomy of the human body and takes the load back directly to the bone and the associated muscles. The OGAAP-OPL is implanted directly into the bone, and actually encourages bone growth. Once integrated, it allows for a simple, quick, and safe connection between the residual limb and the lower prosthesis. No longer is the prosthesis merely attached to the person via a socket, but it becomes part of the person's bone structure, resulting in greater comfort and walking control.



BEFORE: Unnatural position of the femur in a socket prosthesis



AFTER: Femur position is more anatomically correct

ADVANTAGES

What are the benefits of the OGAAP-OPL?

NO SOCKET

The major advantage of the OGAAP-OPL is the absence of a socket. This ensures the prosthesis always fits comfortably, always attaches correctly, and is always held firmly in place regardless of activity level, fluid fluctuations, perspiration levels, or weight loss/gain. It also allows for a natural streamlined look in clothing.

COST SAVINGS

With the OGAAP-OPL, the need for frequent sockets and associated supplies is eliminated, which represents significant cost benefits.

EASY ATTACHMENT

With osseointegration, taking the prosthesis on and off involves little more than tightening/loosening a single adapter screw.

INCREASED MOBILITY

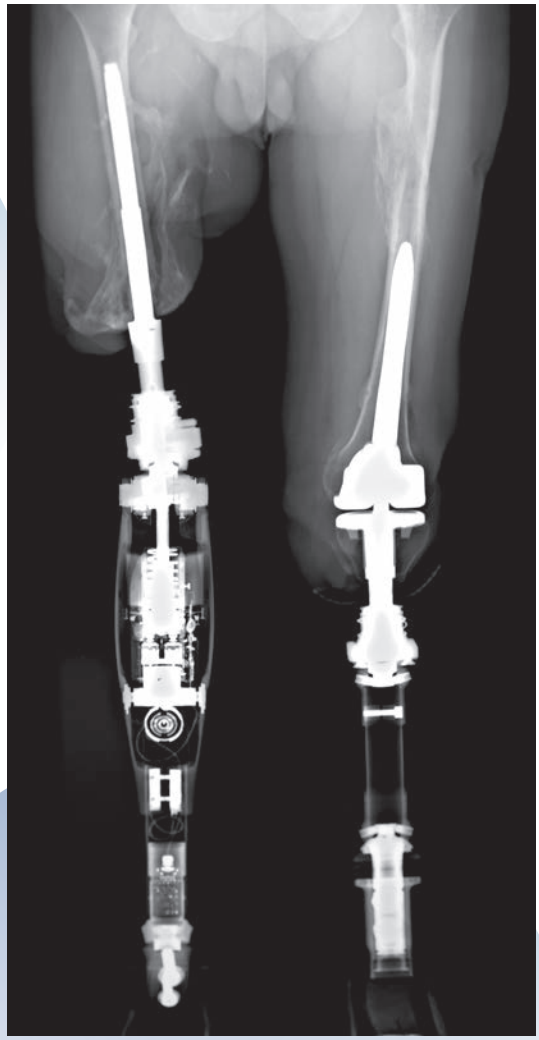
Osseointegration allows for full freedom of movement from walking to cycling and recreational activities. Movement is no longer restricted by the protruding edges of a socket, allowing for greater ease and comfort when sitting, standing, walking, or engaging in vigorous sports activities such as speed cycling or rowing.

IMPROVED GAIT

Following osseointegration, increased muscle use and control frequently results in a more natural walking gait. Improvements in range of movement and natural pivoting in the hip and knees also contributes to an improved gait.

MUSCLE & BONE STRENGTH

Walking with the OGAAP-OPL allows for natural loading of the hip joint and the femur, which encourages bone growth. Muscle strength is developed freely and walking requires significantly less physical exertion.

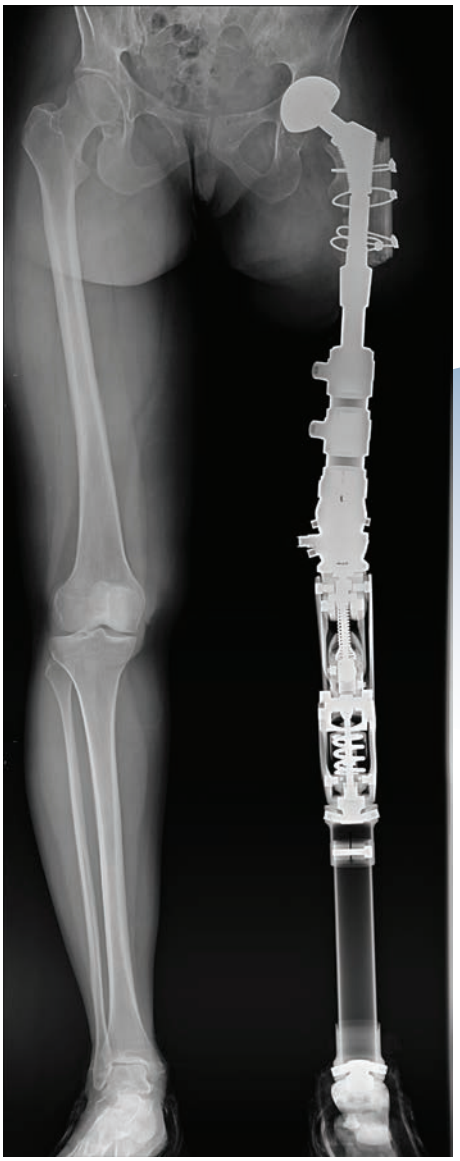


ABOVE LEFT:
Above knee osseointegration

ABOVE RIGHT:
Knee replacement with osseointegration

LEFT:
Below knee osseointegration

BELOW:
Hip replacement with osseointegration



WHY OSSEOINTEGRATION?

Improved quality of life: People with above or below knee amputations seek to return to a mobile lifestyle. Conventional rehabilitation uses a socket prosthesis, which is fixed to the soft tissue of the remaining residual limb using suction or vacuum. The artificial knee joint and/or lower leg prosthesis is then attached to the socket. This enables the patient to walk without aids, but there are several challenges in the use of a suction prosthesis. One important factor is the length of the remaining limb, as it determines the lever arm and the force, which has to be applied for conducting, guiding, and controlling the prosthesis. If the socket does not fit properly, it can create skin irritations of the soft tissue which may lead to sores, ulcers, and chronic inflammation with abscesses and pain.

Moreover, the remaining stump length correlates with the energy expenditure during walking. On average, an amputee uses 70% more energy than an able-bodied person. These difficulties can result in a poor gait with negative effects on the remaining musculosketal system. This often leads amputees to utilize walking aids or even a wheelchair.

Hence, a prosthesis that avoids the skin and soft tissue interface eliminates:

- Skin irritation due to friction, chaffing, and squeezing
- Increased sweating and heat rashes
- Inflammation, bruises and hematoma, pressure marks, and even deep skin injuries
- Dissatisfying fit of the prosthesis due to variation of weight and stump volume
- Pain and discomfort even while sitting
- Hygiene problems

For many amputees, it is difficult to find a way back into an active lifestyle or to the working force. Often they cannot perform activities or sports, and have to rely on the help of others during everyday life.

People with upper limb (humerus) amputations can also benefit from osseointegration. While the majority of surgeries performed to date by A/Prof Munjed Al Muderis have been on lower limb amputees, he has also performed multiple surgeries for upper limb amputees.

Compare Options - Two Systems Commercially Available Today

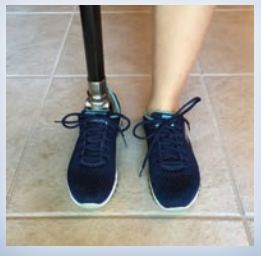
	Osseointegration Group of Australia **OPL - Osseointegration Prosthetic Limb**	Integrum OPRA **Osseointegrated Prosthesis for the Rehabilitation of Amputees**
Implant Design	Titanium Press Fit Solid Core Custom Sizes Used since 1999 for amputees Based on joint replacement technology  	Titanium Screw Fixation Hollow Core Limited Sizes Used since 1990 for amputees Based on dental implant technology  
Bone Interface	Bony In-Growth Bone grows into the implant. 	Bony On-Growth Bone grows onto the implant. 
Rehabilitation	3 Months (mobilizing in 10-14 days)	6-12 Months
Surgery Stages	Single-Stage Surgery	Two-Stage Surgery
Surgical Intervention	No Maintenance	Maintenance
Patient Care	Team-Centered	Team-Centered

OSSEOPERCEPTION

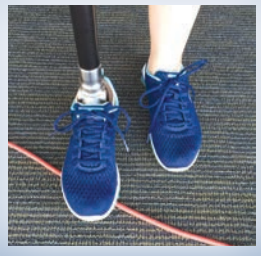
Following osseointegration surgery, the patient regains their sense of proprioception, which is the unconscious perception of the position of the body, movement, and spatial orientation in relation to the external environment. Patients regain the ability to feel the ground beneath them as they walk and differentiate between different surfaces, as depicted below. This allows for safer and more confident movement even in unfamiliar areas or dim light.

Carpet

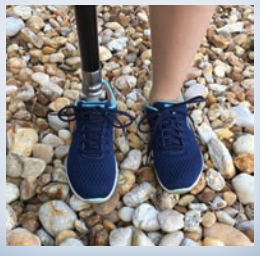
Grass



Tile



Uneven Ground



Gravel

IMPLANT TECHNOLOGY

How does the OGAAP-OPL work?

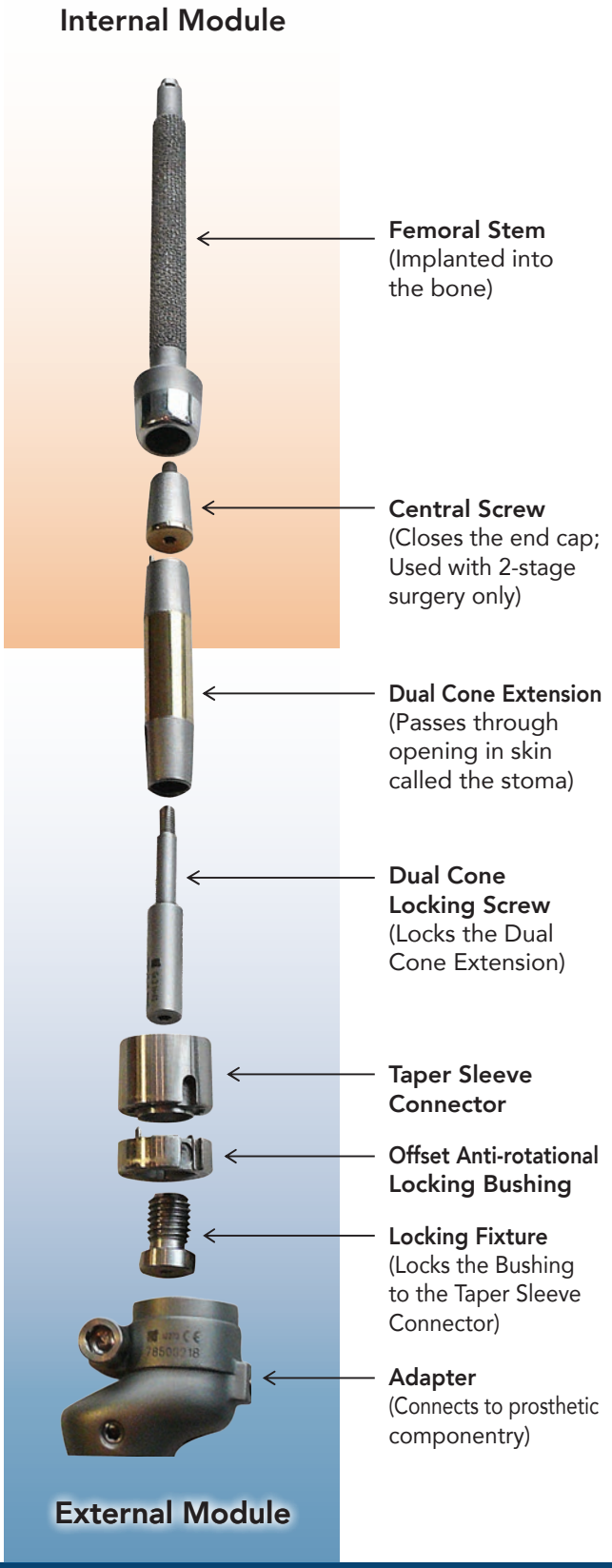
The OGAAP-OPL is made up of several different components that can be divided into an internal (endo) module and an external (exo) module. The endo module, a titanium stem, is directly implanted into the bone. There are a range of implants to meet the needs of varying patients.

The implant surface is highly porous titanium, which allows initial stability and long-term bone integration (in-growth). This technology has been successful in clinical use around the world for more than 30 years in joint replacement surgery. The biocompatibility of the titanium implant allows the bone to grow inside the surface of the prosthesis, which makes the bone-implant structure one solid unit. This is known as osseointegration.

A dual cone extension connects the internal implant to the external prosthesis. This extension has a highly polished smooth surface to minimize soft tissue friction. It is also coated with a titanium niobium, which has antibacterial properties. This passes through a small opening in the skin known as the stoma.

Externally, the dual cone extension is fixed to a torque controlled safety device comprised of a taper sleeve connector and an anti-rotational locking bushing that are held together by a locking fixture. This further connects to an adapter that then connects to the lower prosthetic limb.

There are different adapters available, with different features, yet all are compatible with the various prosthetic componentry in today's market.



Osseointegration Prosthetic Limb (OPL) Implants

Below Knee Implant

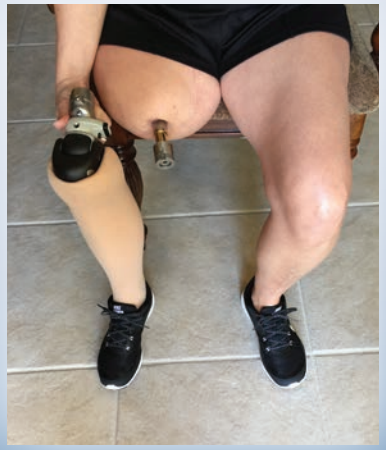
Above Knee Implant

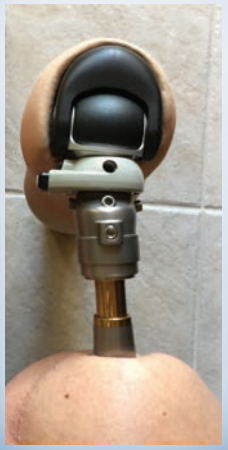
Above Knee Implant

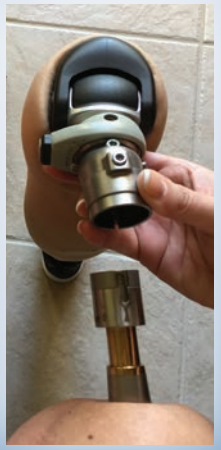
EASY ATTACHEMENT

Donning and doffing the prosthesis is very easy and takes less than ten seconds. Due to the solid fixture to the bone, it accurately connects to the exact spot each and every time the prosthesis is attached. The OGAAP-OPL can be used with all types of prosthetic componentry.

Gone are the days of fiddling around with time consuming and cumbersome suction, sockets, and liners.







TEAM APPROACH

The Osseointegration Group of Australia (OGA) was established in 2010 and the first osseointegration surgery was undertaken in March, 2011. The OGA provides a team approach to assist amputees with the possibility of greater and more effortless mobility by utilizing the latest innovation in the field of prosthetics. The team consists of experts in a variety of fields, each with vast experience working with amputees. They understand every situation and every patient is unique. By utilizing a combined team approach, they work together to assess and determine the best possible treatment for each patient.

The team cares for their patients emotionally and physically from the first meeting. Open communication is a vital part of the osseointegration procedure performed by the OGA team. They offer support and expert guidance through all stages of the osseointegration process; from choosing to undergo surgery, to the surgery itself, through after care in pain management, physiotherapy, and prosthetic adjustments that are best suited to the patient.

The OGA team is made up the following medical professionals:

- Orthopedic Surgeon (A/Prof Munjed Al Muderis)
- Practice Nurse / Surgical Assistant
- Prosthetist
- Acute Care Nurse
- Physiotherapists
- Rehabilitation Physician
- Anesthetist
- Patient Advocates
- Biomedical Engineer
- Psychologist
- Patient Coordinator

Your desire for improved mobility, comfort, freedom, and active participation in all areas of life is our number one priority.

FACILITIES

The team works out of four state of the art facilities in Australia: Norwest Private Hospital, Macquarie University Hospital, Sydney Adventist Hospital, and Hurstville Private Hospital. International patients are typically treated at the Norwest Private Hospital, Hurstville Private Hospital, or Macquarie University Hospital.

Pre-surgery and post-surgery clinics are scheduled at periodic intervals. Non-local patients unable to attend clinics in person are followed-up with remotely.

Norwest Clinic
Suite G3B,
Norwest Private Hospital
9 Norbrik Drive
Bella Vista NSW 2153

Macquarie Clinic
Level 3, Suite 303
2 Technology Place
Macquarie University NSW 2109

Drummoyne Clinic
Level 2
169 Victoria Road
Drummoyne NSW 2047

Hurstville Clinic
Level 2, Suite 4
37 Gloucester Road
Hurstville NSW 2220

GETTING STARTED

Who is a candidate for osseointegration?

Referrals of prospective patients are commonly provided through rehabilitation physicians, specialists, general practitioners or prosthetists, or arise from direct enquiries. All prospective patients are directed to complete a secure online enquiry form available on the OGA website at:
www.osseointegrationaustralia.com.au

The completed form is then reviewed by core members of the team and a phone call is made to the candidate to enable preliminary screening. Information that indicates a candidate's potential exclusion is obtained during this initial phone call.

Exclusion Criteria

- Peripheral Vascular Disease
- Receiving Chemotherapy
- Receiving Irradiation
- Mentally Unstable
- Unrealistic Expectations
- Smoking*
- Growing Skeleton*
- Non-compliance

* Candidates initially excluded may be reconsidered if circumstances change.

At this stage, further information and questionnaires are sent to the candidate, who is also invited to send any specialist's reports, x-ray images or scans for review. A/Prof Al Muderis and members of his team will review all available information to evaluate the initial suitability of the candidate and a plan for the individual will be agreed upon. A clinical coordinator will then contact the individual to arrange for the patient to attend an osseointegration clinic. Preferably, international patients should allow 5-7 days for pre-operative consultation, flight recovery, and clinic attendance if the dates coincide.

During clinic, the team will consult with the candidate, assess the case, answer all questions and discuss the procedure and post-surgery physiotherapy. The clinic is also a chance to meet other amputees who are at various stages of the osseointegration journey.

The candidate will be sent for x-rays and scans in order for A/Prof Al Muderis to be able to make a thorough assessment of the individual situation.

The candidate will have a session with the team's psychologist, who will discuss the process, the candidate's thoughts, and the reasons for wanting the surgery.

Once all assessments have been carried out, the team will discuss the candidate's case and make the decision whether or not to proceed with surgery.

The candidate will meet with the team's prosthetist, who will conduct a series of gait measurements, tests, and assessments. The team's physiotherapist will run through a series of pre-surgery strengthening exercises to do prior to surgery.

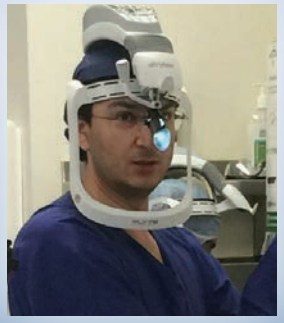
A/Prof Al Muderis and his surgical team will then make the necessary preparations for surgery. The anesthetist and pain management specialist will consult with the patient about what anesthetic will be best and run through the post-surgery pain management protocol.

There is a good chance that you may be a candidate for osseointegration!

ABOVE: All x-rays and scans are thoroughly reviewed by A/Prof Al Muderis in order to properly assess the candidate's case and make comprehensive decisions on the implant and surgical steps needed. Additional needs of the patient are considered and any potential complications of the procedure are assessed.

PRE-SURGERY

Hospital admission: The patient is admitted to the hospital on the night before or on the same day of the surgery. It is extremely important for the patient to bring all x-rays, CT scans, and MRIs applicable to the operation during admission. Patients are advised to bring a family member or friend with them for support.



SURGERY

What happens during the operation?

The surgical procedure involves permanent insertion of an osseointegration implant into the residual bone of the operated limb.

The OGA team originally developed the OGAAP-1 osseointegration protocol which revolves around a two-stage surgery with a 4-6 week interval between the two stages. Until very recently, the vast majority of osseointegration procedures worldwide have been performed in two stages. From the time of initial surgery, these procedures typically required up to 12-18 months for the completion of reconstruction and rehabilitation, and at least 4-5 months even under the OGAAP-1 protocol. Since April 2014, however, the OGA team has developed and routinely performs a single surgery under the OGAAP-2 protocol. This protocol reduces the overall time required for reconstruction and rehabilitation to approximately 3-6 weeks, which is substantially shorter than the two-stage surgery. A single surgery also minimizes the risks associated with multiple surgeries, reduces time away from work and family, and reduces costs. However, no two osseointegration patients are identical, and while single-stage surgery may be suitable for some people, two-stage surgery may be the best solution for others.

Patients are selected for either procedure by the OGA team based on pre-operative assessments, and the surgical process varies slightly from patient to patient depending on their existing condition and needs.

During the surgical procedure:

- The soft tissue is managed and redundant skin and soft tissue fat are removed in order to minimize the bone to skin distance. This leads to a reduced chance of complications. The muscle groups are rearranged to serve a functional purpose in operating the leg and the soft tissue facial layer is reorganized around the stem.
- The bone canal is prepared using a specialized instrument. The internal component of the implant is press-fitted into the bone canal securing early stability and future bone in-growth.
- If there is a neuroma causing nerve pain, the nerves involved are addressed surgically by excision of the painful neuroma and deep positioning of the residual nerve into the fat tissue to minimize future nerve issues.
- The stump is refashioned in a cosmetic manner and the wound is closed in layers.
- A circular skin opening (the stoma) is created at the base of the limb. Through this opening, the dual cone extension is connected to the internal stem, which is already integrated in the bone. The remaining components of the prosthesis are then attached externally.

Partial weight-bearing and the fitting of the lower prosthesis can take place as early as a few days after the surgery. This is done under careful supervision of the team. It is now that the rehabilitation stage and gait training can begin, which will enable the earliest possible return to daily activities.

POST-SURGERY

How is pain managed?

The surgery is usually performed under a combined spinal/epidural and general anesthesia to achieve optimal pain management post-surgery. However, this may change depending on the patient's medical condition or suitability for certain anesthetic modalities. Ongoing intravenous infusion of pain medications continues for the first three days post-surgery. Once these are removed, the patient is assessed for commencement of rehabilitation procedures and discharge from the hospital. Upon release from the hospital, it is important to continue with oral medications as instructed by the anesthetist/pain specialist. The regime is designed to minimize not only surgical pain, but also to minimize any phantom/referred/neurogenic limb pain.

LEFT: Initial use of an abutment attached to the OGAAP-OPL in order to load weight

BELOW: Initial use of a light-weight prosthesis for walking

How long before walking can commence?

Approximately 3-5 days post-surgery, the patient begins a static weight-loading regime. Weight loading starts at a relatively small amount of weight for a short period of time and increases daily until approximately 50% of the patient's body weight is reached. After reaching the target loading weight (10-14 days post-surgery), the patient is fitted with a temporary light-weight prosthesis and walking commences with the use of aids. Once walking unassisted with crutches and pain is well controlled, the patient can start walking using a definitive prosthesis, first on two crutches for 6 weeks, then on a single crutch for another 6 weeks, and unaided thereafter.

STOMA CARE

How is the stoma cared for?

Following surgery, there will be a metal abutment protruding from the skin with a dry gauze dressing that should be changed daily or as needed if excessive discharge is present.

The stoma area should be kept clean and dry for two weeks post-surgery and protected with waterproof materials when showering. After two weeks, the area should be washed twice daily with warm tap water and soap, and pat dry. Staples are used to close the skin and are removed 14-16 days post-surgery.

Continued discharge from the stoma is common and varies from patient to patient, while some people have none at all. Discharge accumulated on the abutment should be removed with a soft shaving brush or tooth brush on an ongoing basis. Brushes should be replaced at least once a month.

BELOW: Example of a stoma at 14 months post-surgery

FACTORS TO CONSIDER

There are hundreds of satisfied osseointegration users with this type of prosthesis who can testify that this technology offers significant and unparalleled advantages compared to a traditional socket prosthesis. For many who were unable to use a socket prosthesis, osseointegration has allowed them to walk again after years of being bound to a wheelchair or crutches.

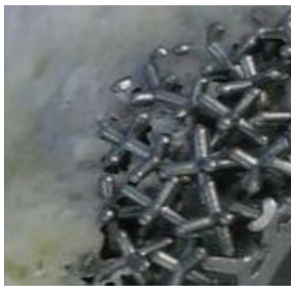
Sensible handling of the prosthesis and simple common sense can prevent any chance of future problems. To ensure the implant is safely integrated into the bone, patients are required to only partial weight-bear for the first 12 weeks. This means walking with at least one crutch or walking stick for this time period.

While it is a very exciting time and the urge to push oneself is often strong, it is recommended that the patient slowly build up to walking to avoid any injuries caused by pushing too hard, too soon.

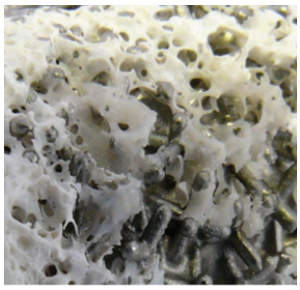
As a general rule, excessive rotation such as pivoting and sharp twisting should be avoided. However, if high levels of strain should occur, the safety shear pins in the external implant system will break to protect against a bone fracture occurring. The system yields and the bone remains undamaged. Safety is a priority and the system has been designed to protect the bone during any large strain or vigorous movements.

BONE PENETRATION

Images depicting bony in-growth



Immediate post-surgery



6 weeks post-surgery

PATIENT PROFILE - 1

Fred Hernandez

Fred Hernandez was 17 when his life changed in an instant. He was a typical teenager growing up in Southern California during the 1980s. He lived an active life and spent a lot of time socializing with his friends.

But all that changed one late Friday night in 1985 when he fell asleep at the wheel of his car. He ended up underneath a semitrailer on the interstate. His legs were burnt, his pelvis broken; he had collapsed lungs, a ruptured spleen, and numerous internal injuries. A week later, his right leg had to be amputated due to gangrene infection. It took a year of rehab before he could be fitted with a traditional socket prosthesis. Despite his disability, Fred tried as best he could to not let his leg, or lack thereof, limit him. He never wanted to be seen as disabled and got on with his life as best he could.

But it wasn't easy. Like most amputees, Fred struggled with pain and sometimes sores that formed from the socket rubbing against his skin. Due to his hips being broken in the accident, his alignment was not correct and his "good leg" was injured so badly he had to wear an ankle foot orthoses due to the trauma and missing muscle tissue. The combination resulted in a very painful, uneven gait.

But osseointegration would change all of that. After researching the procedure, Fred knew it was something he wanted. In 2013, he traveled to Australia to have the surgery and he was the first American to be fitted with the OGAAP-OPL prosthesis.

The moment Fred took his first steps with his new leg, it was an incredible feeling. He felt like he had his "real" leg back. While there was some muscle pain from utilizing muscles that had been dormant for 28 years, the feeling of being back on his feet and able to walk without the restrictive nature of a socket could not be put into words.

For Fred, it's the little things that are the most exciting. Things people may take for granted, like being able to sit down comfortably, not having his pants pull to one side, and not constantly banging the leg on everything he comes near. Not to mention never having to deal with a heat rash or rub again.

For most of his life Fred never had any interest in amputee or disability matters unless it related to getting fitted for a new leg or issues related to easing pain. Contact with the amputee community was limited, as being an amputee never defined who he was.

But osseointegration has changed that and has opened up a whole new world where Fred has been able to finally embrace his disability as a part of who he is. He now has a career in the field and is passionate about inspiring others and spreading the message of this revolutionary surgery in order to help as many amputees as he possibly can.

For more on Fred's story, visit his website at:
www.AmputeeImplant.com

PATIENT PROFILE - 2

Kathy Wilcheck

Kathy Wilcheck was 39 years old when her life changed forever. Jokingly, she wrote on social networks that she had the impression of dying because of a nasty flu. Little did she know, but she was right.

Kathy was admitted to the hospital on December 31, 2013, struck by the flesh-eating bacterium on her lungs. With only a five percent chance of survival, the doctors offered to give her comfort care so she would leave the world peacefully. But giving up was not an option.

Kathy's spouse, Frank, wanted to save her. The doctors tried to give her different treatments, but her blood was no longer circulating in the extremities of her body. Discussions about the amputations of her two legs and the tips of her fingers began, but no one dared to make that decision for her. They took her out of her artificial coma and the doctors asked her the dreadful question. With a nod, she agreed. It was the only solution if she wanted to live. Both her legs were amputated above her knees on January 11, 2013. Her fingertips were spared, and she survived.

The mourning of her two legs was long and Kathy misses them to this day. She took very little time to be able to stand up, only 11 months, but it felt like an eternity for her and it took even longer for her to manage to walk. Her first prostheses allowed her to stand only a few minutes. Being an amputee is a daunting challenge and it becomes even more complex when you are a double amputee above the knees. Kathy could not imagine how much she liked to do the little tasks that normally overwhelmed her, until the day she could no longer do them because she lost her legs.

Kathy embodies perseverance and independence. She was determined to remain a strong and active woman. She did not identify with an invalid person and she did not want to sit in a wheelchair. Her goal became simple; she wanted to walk in order to regain a normal life. For two years, Kathy tried different sockets that did not allow her to walk and regain her independence; these sockets were never properly adjusted. They were either too tight or painful, or far too large. Kathy and Frank were searching for something that would allow her to walk freely and go about her regular routine.

Kathy tried to smile everyday regardless of what life had taken away from her, but without her legs, without being able to walk, without her independence, there was always a bit of sadness behind her beautiful smile.

Osseointegration seemed to be the solution. Kathy and Frank obtained information from several people, and discovered the operation was not being practiced in Canada. They had to go to Australia to have access to it. A trip of more than a month had to be planned in order for Kathy to have the operation.

At the beginning of February, 2016, Kathy and Frank left for Australia for her to become the first osseointegration patient from Quebec and her life changed once more. Five days later, Kathy was walking again. Never again will she have to try to wear painful sockets which are far too hot in the summer. Above all, she can go about her business and be fully present for her family which keeps growing.

Kathy now identifies herself as Quebec's first osseointegration patient and would like the surgery to be accessible to other amputees in her country. Her life has changed for the better thanks to osseointegration and she wants everyone to have that opportunity.

PATIENT PROFILE - 3

Miranda Cashin

When Miranda Cashin was five, while learning to surf with her dad, she was attacked by a shark. It ripped her right leg clean off. No, her Dad didn't punch the shark in the nose, nor does she know how big it was and she doesn't have it's head on her wall as a trophy.

In fact, this "shark attack" story isn't actually true, but for many years it was the line Miranda peddled to people when they asked about her leg. The truth is, she was amputated at 14 months as the result of a birth defect. As part of the condition, she is also missing her right hip joint.

But growing up, Miranda never wanted to be seen as "the disabled girl", and she still doesn't. She never wanted to be treated differently because she happened to be missing a limb, nor did she like to think of it as defining her identity. Her Mum taught her that the only limitations her disability had on her life were those that she placed upon herself. Miranda body-boarded, skied, rock-climbed, abseiled, kayaked, bushwalked, and beat able-bodies kids at swimming carnivals. At school camps, the instructors would often eye her leg nervously and offer for her to sit the activity out. "I don't think so", she'd respond. She'd give anything a go.

Miranda tried as best as she could not to let her leg limit her. But in saying that, it was still tough. The hardest thing was living with the constant rubbing and pain that came with wearing a traditional suction prosthesis. At times, the pain was so bad she would limit the amount of times she went to the bathroom at work, as the short walk was akin to a Tough Mudder event.

Then it all changed one day in May of 2012 when she stumbled upon a brochure on osseointegration and the OGAAP-OPL implant. Miranda was sold immediately. Following her surgery, Miranda barely slept the night before she took her first steps with the new leg. In a way, Miranda had been waiting for this moment her entire life. To walk without pain. To walk as close as possible to an able-bodied person. When it came time to take her first steps she could barely breathe. It felt amazing. Someone commented that her grin was so huge you could see it from behind.

Miranda's five weeks in rehab were the hardest, most grueling physical, emotional, and mental challenge she had ever faced, but the rewards, triumphs, and personal growth has been incredible.

In terms of life changing experiences, they don't come much bigger than this. With osseointegration, Miranda has been awarded a new physical lease on life. There are many pinch herself moments that come with the realization that she will never have to wear a socket again and the freedom that comes with that. Like being able to wear exercise tights, sit comfortably for hours, and never have another painful rub again.

After her time in rehab, she was inspired to return to university to study to become a physiotherapist so she can help as many people as she can to live their best life, just like she is now doing.

For more on Miranda's story visit her blog at:
www.TheGirlWithTheCyborgLeg.wordpress.com

PATIENT PROFILE - 4

Matt Boiteau

He will never forget September 21, 2011; it was an ordinary day for Matt Boiteau. He woke up, walked his dog Molson, and started to get ready for work. Matt was 29 years old when he jumped on his motorcycle that day. Little did he know he was in for the fight of his life if he ever wanted to see his best friend, Molson, again. An hour into his drive, Matt came upon a hill on a road he had driven a thousand times before. Though it happened too quickly to avoid, he can still recall the silhouette of the approaching vehicle cresting that hill towards him. With nowhere to go, he closed his eyes and said "Goodbye".

Over in the ditch, Matt kept his eyes closed so he wouldn't fully understand his injuries. He began focusing on those in his life who would be affected should he ultimately give into the pain and let go. Then as if by miracle, a farm dog started barking in the distance and he was reminded of Molson. It gave him the reason to keep fighting through the agony as the paramedics arrived. It wasn't until his dad reached the ambulance doors, Matt finally opened his eyes and simply said, "I love you, Dad".

Levels were critical. His right leg had been crushed below the knee and with the main arteries sliced, amputation was inevitable. His right hand had been forced back into his arm, shattering the radius and ulna in 20+ pieces. In Matt's early 20's, he fixed up houses and rental properties, and studied hard at school, earning his way up to a great job. He could often be found working on his cars over the weekends. Now, he was bed-ridden while his body recovered and his mind tried to make peace with his new life.

His leg was fitted for a prosthetic socket a year later. Matt's motivation had been the thought of his life returning back to normal with the abilities to do everything he had done before. Boy, was he wrong. He soon learned that these dreams would be crushed by nerve pain, bruising, burning, sores, cuts, blisters, pinching, infections, and so on. The endless discomfort, irritation, and soreness had him reevaluating every step he took and reconsidering every plan he made. The constant pain caused limited use of his prosthetic and he would once again be confined to a lifestyle of limited mobility. He dedicated countless hours over more than 4 years to researching and investing in different prosthetics, from different countries. 40+ test sockets later, he knew there had to be a better way… somehow, somewhere, someone.

It all started when he found A/Prof Munjed Al Muderis. Matt awoke from the procedure known as osseointegration surgery on April 6, 2016. The doctor tapped the newly external portion of the implanted device and Matt instantly felt a shockwave through his spine. He could feel again! 10 days later, when taking his first steps following the surgery, he realized these were his first steps to a new life he could now look forward to.

Matt was able to follow the rehabilitation protocol to a tee at home thanks to his mom, a physiotherapist. The pain of a socket no longer held him back and his new leg could be securely attached in a matter of seconds. His gait and posture improved so well, people are now shocked to learn that he has an artificial leg.

Matt would simply sum up osseointegration as "Life-changing".

PATIENT PROFILE - 5

Joe Yantz

Joe Yantz was injured while serving in Afghanistan when he was only 21 years old. He was deployed with the 82nd Airborne and was hit by an improvised explosive device blast while on foot patrol in 2010. As a result, his right leg was amputated just below his hip.

The road to recovery was a long and difficult one for Joe. He had been working with traditional prosthetics for nearly five years with no success, and was forced to use crutches most of the time.

Joe learned about osseointegration shortly after getting hurt and knew it was the best solution considering how high his amputation was and how difficult it was to wear a traditional prosthesis. He began looking for a surgeon that could perform the surgery and found A/Prof Munjed Al Muderis and the OGA. The surgery was performed in Australia in August, 2015, making Joe the first United States veteran to have the procedure. Within a few months of the surgery, he was able to walk without the use of any crutches or canes. He is now able to go hunting, hiking, swimming, and most importantly, live a normal life with his wife.

PATIENT PROFILE - 6

Melissa Lowrance

In May of 2014, Melissa Lowrance had it all. For many years she was a full time mail carrier and had been making plans for a great future for her family. With one doctor visit that was all ripped away. It was discovered that she had cancer in her knee and amputation was her best chance of surviving.

So in June, 2014, she underwent amputation surgery. Even after the amputation, she was determined to have that great future; job included. But she struggled for months with a socket and no amount of determination made those sockets comfortable or usable. As the weeks passed by, once again she saw her dreams dissolving. She had heard about osseointegration but hadn't taken it seriously. Once she realized that a socket wasn't an option for her and she was going to be on crutches for the rest of her life, she started thoroughly researching the osseointegration technology.

She traveled to Australia in June, 2015 to get the implant and as a direct result, she got her life back. She went back to work four months after the osseointegration surgery and she hasn't slowed down since.

FREQUENTLY ASKED QUESTIONS

How much does it cost?

The cost varies based on the particular situation and needs of each patient. Completing an online enquiry form is the first step to receiving a price quote.
www.osseointegrationaustralia.com.au

ONLINE ENQUIRY
Click Here

Australian Private Health Insurance covers most of the cost involved with OGAAP-OPL prosthesis surgery. However, some items necessary for treatment may not be covered under some health funds such as physiotherapy, medications, or x-rays. This will vary from company to company and policy to policy.

The price quoted for overseas patients covers hospital fees, doctors'/specialists' fees, medications, medical supplies, transportation to/from the airport and appointments, and accommodations. Patients should be aware of currency exchange rates.

Additionally, all patients are responsible for airfare (if needed), food outside of the hospital or rehab facility, and personal entertainment. It should be noted that the price quoted is an estimate of fees and the actual cost may vary in the case of the occurrence of unexpected challenges or variation from the initial clinical and radiology assessment that may involve further intervention to optimize the care. However, this is not expected to occur routinely.

What are the risks of infection?

As with any surgical or invasive procedure, there is always the risk of infection, however, long term antibiotic therapy is not required for patients receiving the OGAAP-OPL. The intraoperative protocol for osseointegration surgery is similar to that used for joint replacement procedures. This consists of a few doses of intravenous antibiotics over the first two days until the catheter and drains are removed.

The patient will then commence on a one-week course of oral antibiotics. The patient may develop a minor infection at the skin-implant interface at approximately six weeks post-surgery. In the case of a suspected infection, the patient is advised to visit a general practitioner and obtain a culture swab of the wound. The general practitioner will then prescribe the appropriate antibiotic treatment for the patient.

Superficial irritation may occur from time to time but should not be a cause of concern unless infection is suspected. Most minor infections can easily be managed with oral antibiotics, and patients are advised to consult the general practitioner whenever required.

Patients may contact the OGA team directly for a suspected infection following osseointegration surgery. The patient will be asked to answer a series of questions to help determine if an infection is present, and if so, a course of action will be advised.

How long is the operation?

The surgery usually takes 1-2 hours, however the entire time in the operating theatre may last up to 4-5 hours.

Can I go swimming after osseointegration?

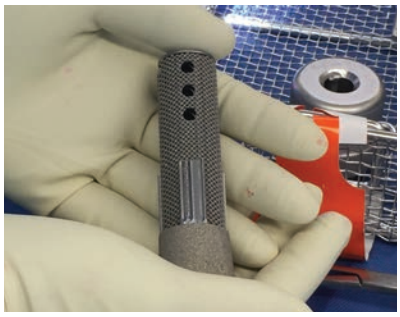
Swimming in a pool, especially salt water or the sea, is highly recommended, as it helps to maintain stoma health. However, patients should minimize swimming in public pools, particularly those that are at risk of children defecating or urinating inside. Patients who swim in a public pool should ensure that the stoma is well rinsed when leaving the pool. Taking a soaking bath with salts is recommended from time to time, as this helps to treat muscle pain and prevent the accumulation of debris.

Will there be discharge?

Clear mucous secretions from the stoma site are normal, and can increase with higher activity levels and alcohol consumption. However, milky discharge accompanied by pain is often a sign of infection. Certain people can also manifest lack of secretion and dry crust formation at the stoma site, which needs to be cleaned regularly to prevent infection.

Is the OGAAP-OPL available for below-knee amputees?

Yes. A tibial implant (seen below) designed especially for the anatomical shape of the tibia can be inserted into the tibia and functions the same way as the above-knee prosthesis. In selected cases, patients are given total knee replacement with the patient specific tibial implant.



Have there been any failures?

There are only a handful of cases reported worldwide that required replacement or removal of the implant. To date, there has been no single case that resulted in the loss of the rest of the limb or bone of any patient. If the surgery does not work for some reason, the patient can always return to a socket prosthesis. It's important to note that any surgery could potentially result in a devastating complication including death, however, osseointegration carries the same risk as any medium complexity type surgery and to date, no such complication has been reported.

What has been the experience with phantom limb pain?

Patients who suffer from this pain have had, in many occasions, significant relief from this condition. This is due to a combination of pharmaceutical and surgical intervention.

How soon after amputation can the surgery be performed?

Each situation is unique and is assessed in order to make the best decision for the patient. Some patients can go straight from amputation to implantation of the OGAAP-OPL.

Is running allowed?

For the first 12 months following osseointegration surgery, patients are strongly advised against high impact activities such as running, or any activities that may result in a fall. Due to the affected limb being under-used prior to surgery, a period of at least 12 months is required for the development of bone strength to a level suitable for impact activities. Premature overloading of the bone will result in a greater risk of femoral neck fractures and other injuries. The patient is required to consult the principle surgeon before commencing any activities which may increase the risk of injury.

What is the implant made of and is it affected by heat or cold?

The implant is made of titanium that is coated with a rough surface of a plasma spray which allows the bone to grow into it. These materials are extremely biocompatible in endoprosthetics. The body will not reject the implant and there is no permanent medication required. Patients report no internal sensitivity to either hot or cold climates.

Where does rehabilitation occur and how long does it take?

The length of rehabilitation and the techniques used are tailored to each patient's situation, however, there are generally two options:

Option 1 – In-patient Rehabilitation
The Hills Private Hospital for 1-2 weeks followed by local rehabilitation with own prosthetists and physiotherapists.

Option 2 – Out-patient Rehabilitation
The Clinic Physiotherapy, Macquarie University Hospital for 3-5 days per week for 1-2 weeks (1 session per day).

Where can I find more information?

Additional information can be found at the following websites:
www.osseointegrationaustralia.com.au
www.almuderis.com.au

Many osseointegration patients can be contacted to answer questions via the Osseointegration Peer Support Group on Facebook, and there are numerous videos available for viewing on YouTube – simply search on Osseointegration Australia.

Contact the Osseointegration Group of Australia by phone at:
1800 907 905.

Scan the QR codes with a smartphone to view online information.

Osseointegration Australia Website

3D Animation of Osseointegration Surgery

Osseointegration Group of Australia Experience

Disclaimer: Information provided is for educational and communication purposes only. The material presented is neither intended to convey the only, nor necessarily the best, method or procedure, but rather represents techniques and procedures used by the Osseointegration Group of Australia.

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

Any surgical or invasive procedure carries serious risks. Before proceeding, you should seek medical advice regarding your personal condition and situation and if you require, seek a second opinion from an appropriately qualified health practitioner.

This device is not approved by the Food and Drug Administration (FDA) for use in the United States.