

Direct Skeletal Prosthesis Osseointegration

Dr Munjed Al Muder

Advanced Prosthetics

- **No more socket problems**
- **Freedom of Mobility**
- **Easy Attachment**
- **Perfect fit every time**
- **Osseoperception - Sensory Feedback**



Contents



**Dr Munded Al Munjed Almuderis. Chairman of
The Osseointegration Group of Australia
Page 4**



**History of Osseointegration
Page 5**



**Implant patients
Pages 9 - 12**

Osseointegration International.....3

Why Osseointegration?.....7

Innovation.....8

 No more suction prosthesis
 How does the OGAP-OPL work?

What is the OGAP-OPL Prosthesis?.....14

 The OGAP-OPL Prosthesis consists of
 Three main components.
 What are the advantages of the OGAP-OPL?

Freedom of Mobility.....15

 Easy attachment and fit
 Osseoperception

Surgery and Care.....16

 How does the operation take place?

Stoma Care.....17

 Factors to be considered
 Further Information
 How soon after amputation can the surgery be
 performed?

Treatment Pathway.....18

We take care of your mobility.....19

 Osseointegration Group of Australia Team Approach

Meet the OGAP team.....20

OGAP Pre-operative Pathway (Background).....21

What are the different modalities of OI.....22

Bony On-growth / In-growth & Penetration?.....23

What does Bony Penetration look like?.....24

Most common applications for implants.....25

 What is a stoma?

Is Osseointegration right for you?.....26



Osseointegration International Pty Ltd

Incorporating the Osseointegration Group of Australia

We take care of your mobility

The Osseointegration Group of Australia 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 OGAP-OPL implant.

Through Osseointegration surgery, Dr Al Muderis and The Osseointegration Group of Australia Team provide upper and lower limb amputees with extremity replacement by using the OGAP-OPL implant. The surgery involves a titanium implant being directly inserted into an amputee's skeletal system and is designed to be as close to the human anatomy as possible. Once integrated with the bone, the device allows for a simple, quick and safe connection between the stump and prosthesis. Osseointegration surgery provides amputees with greater mobility, range of motion, comfort and quality of life.

Benefits of a Direct Skeletal Attachment

- Increased range of motion
- Eliminates pressure, sores and pain caused by the socket
- Stable attachment
- Easy attachment and detachment
- Better walking ability
- Improved osseoperception (sensory feedback)
- Can be worn all day, every day
- Improved sitting comfort
- No socket adjustments required
- Suitable for short amputation stumps





Associate Professor Munjed Al Muderis

A/Prof Munjed Al Muderis is an orthopaedic surgeon and a clinical lecturer at Macquarie University and The Australian School Of Advanced Medicine. He specialises in hip, knee, trauma and osseointegration surgery. He is a fellow of the Royal Australasian College of Surgeons and Chairman of the Osseointegration Group of Australia.

A/Prof Al Muderis graduated from Baghdad College High School (The American Jesuit) in 1991. He studied medicine at Baghdad University from 1991 to 1997.

As a first year resident A/Prof Al Muderis was forced to flee Iraq as he refused Saddam's regime brutal orders to surgically remove the ears of soldiers who had escaped from the army.

He ended up on a flimsy wooden boat heading to his new home, Australia.

A/Prof Al Muderis' first job in Australia was at Mildura Base Hospital as an Emergency Unit and Orthopaedic Resident. Four months later he moved to Melbourne as a Surgical Registrar at the Austin Repatriation Hospital. His career next took him to Wollongong Hospital where he spent a year as an unaccredited Orthopaedic Registrar and then a year at Canberra Hospital.

A/Prof Al Muderis joined the Australian Orthopaedic Training Program in 2004 as part of the Sydney NSW Orthopaedic Training Scheme and obtained his surgical fellowship, FRACS (Orth), in 2008.

A/Prof Al Muderis went on to complete three post specialisation fellowships. First he attended a six month national fellowship in Sydney with Dr Ali Gursel in 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 Krankenhaus Kiel, Germany
- The Anterior Approach Hip Arthroplasty Using Harmonic Scalpel workshop with Dr. Marcus Michel - the designer of the MIS Anterior Approach of Hip Arthroplasty in Bern, Switzerland
- The Anterior Approach Hip Arthroplasty Hip Surgery workshop using traction device with Dr Stephane Denjean in Lyon, France
- The Endo-Exo Prosthesis workshop with Dr. Grundt and Dr. H Aschoff in Lubeck, Germany
- The Total Femur Replacement and Tumour Prosthesis Implantation Techniques workshop with Professor Ashel in Nuremburg, Germany A/Prof Al Muderis commenced his private practice in 2010 and is currently appointed as a Clinical Lecturer at Macquarie University Hospital and The Australian School of Advanced Medicine. He also have appointments at The Sydney Adventist Hospital and Norwest Private Hospital.

A/Prof Al Muderis sees patients at his Macquarie University, Bella Vista, Drummoyne and Sydney Adventist Hospital clinics.

He specialises in **hip, knee and trauma surgery** with particular interest in **hip arthroscopy, resurfacing, arthroplasty, knee arthroplasty** and reconstruction of recurrent patellar dislocations. He is also a world leading surgeon in the field of osseointegration surgery.

In 2014 his memoir *Walking Free*, was published by Allen and Unwin.

He lives in Sydney with his wife Irina, a GP, and their daughter Sophia and poodle Mozart.

History of Osseointegration

Osseointegration is derived from the Greek 'osteon' meaning bone, and the Latin 'integrare', which means to make whole. It is defined as the direct contact between living bone and the surface of synthetic, often titanium based, 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 fixing the replacement prosthesis to the bone, which he based on a dental practice of using bone cement. His revolutionary technique is still used today.

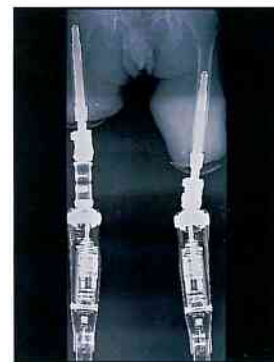
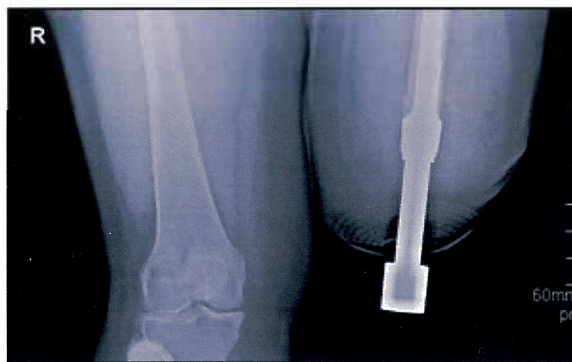
The concept of osseointegration in dentistry first started in 1965 with Professor Per-Ingvar Brånemark who threaded trans-oral titanium implants into the mandible and maxilla (the bones of the upper and lower jaw) to act as anchorage for dental prostheses.

In 1990, based on a successful technique developed by his father, Brånemark performed the first transcutaneous femoral intramedullary prosthesis on an above knee amputee with an A 12-cm screw-fixation titanium threaded device.

A non weight-bearing period of six to 12 months was applied to allow proper osseointegration.

Clinically osseointegration for amputees has been used since 1995, utilising a skeletally integrated titanium implant, which is connected through an opening in the stump (stoma) to an external prosthetic limb. The traditional suction prosthesis is no longer required and perfect fit is achieved via a torque controlled knee connector.

This allows for direct contact to the ground, which provides greater stability, more control and minimizes energy exerted.





**Why settle for anything less than complete
comfort for your mobility?**

Why Osseointegration?

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 amputation stump via suction or vacuum. The artificial knee joint and or lower leg prosthesis can then be attached to the socket. This enables the patients 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 stump because 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, chronic inflammation with abscesses and pain.

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

Hence a prosthesis that avoids the skin and soft tissue interface is desirable for different reasons:

- skin irritation due to friction, chaffing and squeezing
- an increase in 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 missing comfort also during sitting
- hygienic problems

For a lot of amputees it is therefore difficult to find their way back into an active lifestyle or to the working force. Often they cannot perform the kind of activity and sports, which they would like to enjoy and they have to rely on the help of others during everyday life. Because of the mentioned difficulties some single-side or bilateral amputees even depend on a wheelchair permanently.



Dr Munjed Al Muderis and Phil Coulson. New Zealand's First Osseointegration patient

Innovation

No more Suction Prosthesis!

The OGAP-OPL is a revolutionary type of prosthesis for amputees where a conventional socket becomes unnecessary.

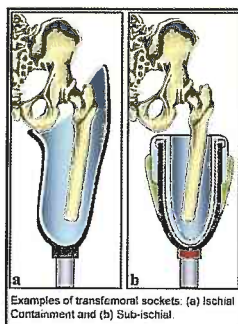
What makes the OGAP-OPL so innovative is it is modeled on the anatomy of the human body and takes the load back directly to the bone, the joint above and the associated muscles.

The OGAP-OPL is implanted directly into the skeletal system and when integrated with the bone it allows for a simple, quick and safe connection between the stump and the prosthesis.

No longer is the prosthesis merely attached to you but it becomes a part of you, resulting in greater comfort and control.

One of the major differences between the bone anchored OGAP-OPL prosthesis and a conventional prosthesis is the absence of a socket. This ensures the prosthesis always fits comfortably regardless of fluid fluctuations of the stump. It also ensures it always attaches correctly and is always held firmly in place regardless of activity or sweat levels.

The absence of a socket also eliminates other associated problems that accompany the use of a socket such as rubbing, chaffing and pressure sores.



How does the OGAP-OPL Work?

The OGAP-OPL is made up of several components which can be divided into an inner (endo) module and an external (exo) module. The endo module, a titanium stem, is directly implanted into the bone.

The implant surface is highly porous titanium which allows initial stability and long term bone integration (ingrowth). 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 adaptor connects the internal implant to the external prosthesis. This adaptor 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 adaptor is fixed to a torque control safety device which further connects to the prosthetic limb. Taking on and off the prosthesis is very easy and takes less than ten seconds. Due to the solid fixture to the bone it accurately connects in the exact spot each and every time you attach the prosthesis. This device can be used with all types of prosthetic componentry.

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



Brendan Burkett - Australia's first Osseointegration Patient

Biomechanics Professor, Paralympic Champion, World Champion, World Record holder, Commonwealth Games and Australian multiple medalist.

Brendan Burkett always loved sport. Hailing from Tannum Sands near Gladstone he was captain of his local rugby league team and loved to swim.

But his dreams to play league at a professional level came to a violent halt in 1985 when a car smashed into him while Brendon was riding his motorbike. Shattered in 13 places his right leg was amputated above the knee.

While his life changed dramatically in an instant for Brendon it was just a case of pursuing a different dream. Swimming became his focus and he went on to compete and win multiple medals at the four Paralympics between 1988 and 2000 as well as becoming the recipient of a variety of prestigious awards including Order of Australia in 1997.

Combining his love of engineering and sport he is currently a Professor of Sports Science at The Sunshine Coast University after five years as a consulting engineer which included a year working on the oil rigs in the North Sea which he was the first person with a disability to pass the medical and work on the rigs.

It was through his line of work he came across a research article on osseointegration back in 1990. At that stage it was only being preformed in Europe and the UK. He was immediately interested in the technology and during his travels with the Australian swim team used every opportunity to meet with patients, surgeons and pioneers of the technology in England, Germany and Sweden.

But it was chance encounter a little more than two years ago that indicated that finally it could be a reality for Brendan.

He was having a routine visit to his prosthetist in Brisbane when he happened to notice a brochure sitting on the bench. He acted immediately, calling Dr Al Muderis on his drive home to the Sunshine Coast. As a biomechanical engineer he preferred the OGAP-OPL system as opposed to the Branemark implant being used in Melbourne.

He would be the first OGAP-OPL in Australia and with a femur left bent from his accident he was a far from a straightforward first patient for Dr Al Muderis. But challenge is Dr Al Muderis's middle name and Brendan wasn't worried in the slightest. He had complete faith in the process and a life without constant rubbing, blistering and sweat was a key motivator. Comfort and function were his main dreams. Despite the pain and discomfort the socket caused him Brendan wore his leg everyday, it was simply what had to be done in order to walk and live the life he wanted. It was just the way of life and he simply got on with it.

The day he took his first steps after his surgery he was filled with a mixture of anxiety, nerves and excitement. What would it feel like? Would it be as amazing as he thought it would be? He wasn't disappointed in the slightest. He went in to hospital on crutches and was determined to walk out and taking those steps out the door was akin to winning a medal.

In terms of comfort and functionality his new leg and way of walking has far exceeded his expectations.

Gone are the days of constant sweating, pinching and pulling. He can sit in a chair comfortably without something digging into his groin and if he feels like going for a walk for pleasure he can and now walks 1.5km a day.

That was something he would never have done before, unless his life depended on it.

But it's the little things he didn't expect, like the ease he has slipping the leg back on after a shower or a swim in the pool. Before after a swim putting the leg back on was fraught with difficulties and it never fit properly on the damp skin. Now it's as simple as a turn of a screw.

He advocates amputees coming to their own decision as to whether the surgery is right for them but for Brendon it is the perfect fit.

Fred Hernandez - Australia's first American Osseointegration patient

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 that all changed one late Friday night in 1985 when he fell asleep behind the wheel of his car. He ended up underneath a semi trailer on the interstate. His legs were burnt, his pelvis broken; he had collapsed lungs, a ruptured spleen as well as numerous internal injuries. A week later his right leg had to be amputated due to a gangrene infection.

It took a year of rehab until he could be fitted with a traditional suction prosthesis. But despite his disability he tried as best as he could not to let his leg, or lack thereof limit him. He never wanted to be seen as the disabled guy and just got on with life the best he could. Many people he has worked with over the years didn't even realize he was missing a leg.

But it wasn't easy. Like most amputees Fred struggled with pain and sometimes sores associated with the socket rubbing against his skin. His accident resulted in his hips being broken, so his alignment was never quite correct and his 'good leg' was injured so badly that he wears an AFO due to 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 had to have. In 2013 he travelled to Australia to have the surgery and is the first American to be fitted with an OGAP-OPL prosthesis.

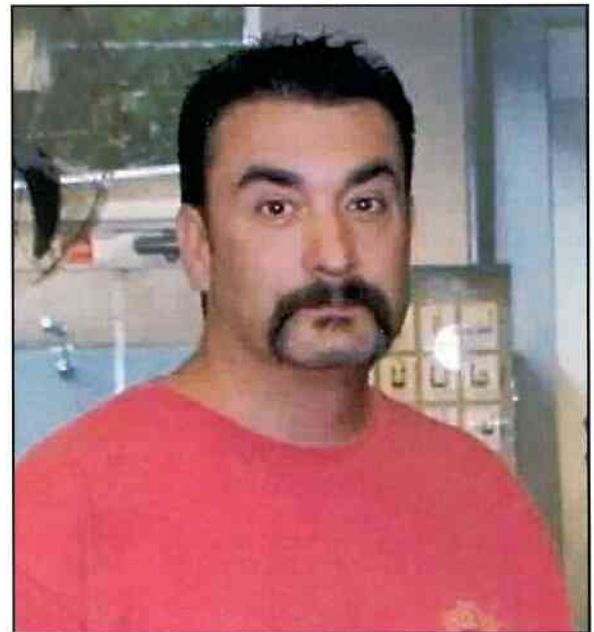
The moment Fred took his first steps with his new leg was an incredible feeling. He felt like he had his 'real' leg back. While there was some muscle pain from utilizing muscles that have sat dormant for 28 years, the feeling to not only be back on his feet but being able to walk without the restrictive nature of a socket can not be put into words. There was no wiping the grin off his face. It felt so normal and natural.

For Fred the sheer feeling of freedom is the most exciting thing about the process. He no longer feels like he has a foreign object attached to his body in order to walk. All of his life he was always aware of the leg but now it isn't even a factor nor does he give it a second thought.

But for Fred it's the little things that are the most exciting. Things people may take for granted like being able to sit down on your backside 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 so much so he now desires a future 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 www.AmputeeImplant.com

Miranda Cashin

When Miranda Cashin was five, while learning to surf with her dad at Lennox Head 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. 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', 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 has body-boarded, skied, rock-climbed, abseiled, kayaked and bushwalked and beat able-bodied kids at swimming carnivals. On 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 best as she could not to let her leg limit her. But in saying that, it has still been tough.

The hardest thing was living with the constant rubbing and pain that came with wearing the 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 OGAP-OPL implant. Miranda was sold immediately without a moment's hesitation. It would change her life dramatically and how could she live with herself passing up that opportunity?

Like a kid on Christmas Eve awaiting a sack full of presents from Santa, she barely slept the night before she

took her first steps with the new leg. All night she had butterflies, every nerve pulsating with anticipation. 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 was 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. The Miranda of a year ago is a completely different person.

With this procedure she has been awarded a new physical lease on life and while this journey is far from over, there is much work to be done, the future looks glittering and shiny with possibility and holds so much potential. Miranda plans to make the most of her new physical capabilities and to use it to open up doors of activities previously shut to her. She has already ticked off her first goal and completed her first 5km fun run/walk and while crossing that finishing line was an incredible feeling, just walking without pain was the true reward.

She often catches herself smiling to that walking could feel this good, that she could be this happy and 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 Lorna Jane exercise tights, sitting comfortably for hours and never having another painful rub again.

After her time in rehab she has been inspired to return to university to study to become a physio 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:
www.TheGirlWithTheCyborgLeg.wordpress.com

Mitch Grant

On December 31st 2008 Mitch Grant was involved in a motorbike accident. As a result his left leg was amputated above the knee; he suffered a brachial plexus injury, which resulted in a loss of function to his left arm, and several other injuries to his right leg. Mitch was a patient at Royal North Shore for 4 months following the accident and underwent over 13 operations in the course of 18 months. He was only 21 years of age.

Prior to the accident taking place Mitch was a lively 21 year old, who enjoyed leading a fit and healthy lifestyle. Being out and about, spending time with friends and family was extremely important to him. Mitch loved participating in most sports, particularly swimming and rugby, and also spent a lot of time training hard at the gym and keeping in shape. He pursued a career as a carpenter and found the combination of manual labor and being outdoors the perfect fit. Although after the accident took place it was clear that Mitch's life had changed forever.

For the first 11 months after the accident, Mitch was unable to be fitted with a prosthesis due to the extent of his injuries and having to undergo a considerable amount of operations. After finally being fitted, Mitch still endured several further operations in the following 6 - 7 months. Throughout this time Mitch was also in the process of undergoing rehabilitation. This included ongoing physiotherapy and the process of learning to walk again using his newly fitted prosthetic leg.

After 18 months of back to back operations, Mitch could now finally concentrate on recovery. As soon as he could, Mitch jumped back into the pool and started swimming again with his main goal being to increase his strength and stamina.

With recovery now well underway Mitch was focused on getting his life back on track. As he was unable to continue working as a carpenter anymore, he knew he had to look for an alternate job. Considering Mitch still wanted to lead an active, healthy lifestyle, after much deliberation, Mitch decided to open a 24 hour gym.

In May 2011, Good Vibes Fitness at Macquarie Park opened. With Mitch now able to walk using his prosthetic leg he was able to run the gym and, for the most part, get back to his busy, active lifestyle. However, despite never complaining, it was evident that simple everyday tasks were sometimes a burden. Mitch was grateful for the increased mobility that his prosthetic leg provided, however he was now faced with a lot of personal problems from the socket system. The main problems faced included difficulty sitting, phantom pain, challenges putting the leg on and off and maneuverability. There was also a lot of frustration with the heat, including extreme perspiration with the socket and rubbing and chafing.



It was in late 2011 that Mitch first heard about Osseointegration. Initially Mitch wasn't too interested and didn't really think it was the best option. At that particular moment in time, the last thing Mitch wanted to do was go back into hospital let alone spend time away from his new business. However, once meeting with Brendan (Australia's first Osseointegration patient) Mitch instantly saw the benefits and decided to book in for the operation. The operation took place in late September 2011 and the recovery time was extremely short. Post recovery Mitch soon discovered most of the problems he was experiencing with the socket were no longer an issue. It was much easier to take on and off and the issue of overheating and perspiring was no longer of concern. Mitch would put the leg on in the morning and didn't take it off until his day was over. Not only were most of the personal frustrations with the socket system eliminated for Mitch, but the implant also

helped improve his gate and overall posture. Mitch couldn't have been more pleased with how the operation went and found himself back at the gym, working on expanding his business and training hard, in no time at all. When asked, Mitch would confidently say that undergoing this procedure changed his life for the better.

Mitch now not only manages Good Vibes Fitness but is also a part of the Osseointegration Team which involves presenting to amputees, doctors and physiotherapists from a patients perspective. More recently Mitch has started running motivational talks to help inspire oth-

The Sydney team works out of two state of the art facilities in Australia



Macquarie University Hospital is Australia's first and only private not-for-profit teaching hospital on a university campus. Located on the leafy grounds of Macquarie University



Norwest Private Hospital is located in Bella Vista and provides excellence in medical services and patient care to Western Sydney.

What is the OGAP-OPL Prosthesis?

The OGAP-OPL is a new type of prosthesis for both upper and lower extremity amputees that makes a conventional suction prosthesis unnecessary.

The OGAP-OPL is modeled on the anatomy of the human body and takes the load back to the skeletal system where it belongs.

Both Dr Al Muderis (who is also the designer), along with the manufacturers, have many years of experience in the field of internal prosthesis design and production. They use evidence of proven clinical history to deliver a safe result that enables mobility and movement without a suction prosthesis.

The OGAP-OPL is implanted directly into the bone, which enables a safe and secure connection between the patient and the prosthesis. This same connection has been in clinical use in Total hip Replacement surgery with successful outcomes for more than 30 years.

The OGAP-OPL prosthesis consists of three main components:

- A titanium rod that has a thick porous coating. This porous coating is used in hip replacement surgery with excellent results. It facilitates the bone to grow into the titanium rod and results in the implant and bone becoming one.
- A highly polished transcutaneous connector with an anti-microbial coating that links the internal osseointegrated prosthesis to the knee safety connector.
- The quick release knee torque connector that connects the implant to the knee.



What are the advantages of the OGAP-OPL?

No Socket!

- Walking with the OGAP-OPL allows for natural loading of the hip joint and the femur. This encourages bone growth, creates a more natural gait and requires less physical exertion.
- Any weight or fluid variations of the stump have no effect on fit or functionality.
- No bulky socket which provides a natural streamlined look in clothes



Freedom of Mobility

- Allows for full freedom of movement in activities ranging from walking to cycling, recreational activities and physical work.
- Muscular strength is developed freely which minimises muscle wastage of the stump.
- Movement is not restricted by the protruding edges of a socket. This allows for greater ease and comfort while engaging in daily activities.
- The direct connection between bone, implant and implant enables free, natural pivoting movements.



Easy Attachment and Fit

The prosthesis can be easily attached and removed with ease within just a few seconds.

Osseoperception

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. This means the patient regains the ability to feel the ground beneath them as they walk and can differentiate between different surfaces such as carpet, grass, tiles and uneven ground. This allows for safer and more confident movement even in unfamiliar areas or dim light.



Osseintegration patients Mitch Grant and Fred Hernandez



Patients can actually feel the ground beneath their feet

Surgery and Care

How does the operation take place?

The implantation of the OGAP-OPL is performed in either a single surgery or in two stages depending on the patient's existing conditions and suitability.

No two osseointegration patients are identical, the surgical process will vary slightly from patient to patient depending on their condition and needs.

In saying that, the first stage will generally involve:

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 residuum is reshaped and any bone spurs are removed.
- 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 ingrowth.
- If there is a neuroma causing nerve pain the nerves involved will be addressed surgically by excision of the painful neuroma and deep positioning of the residual nerve into the muscle group to minimize future nerve issues.
- The stump is refashioned in a cosmetic manner and the wound is closed in layers.
- A period of six to eight weeks takes place after the first stage to allow for osseointegration. This is then followed by the second stage.

Involved in the second stage is:

- The creation of a circular skin opening (the stoma) at the base of the stump. Through this opening the dual cone adaptor is connected to the internal stem, which is already integrated in the bone. The remaining components of the prosthesis can then be attached externally.

If the surgery is performed in a single stage, all of the above will take place during the one procedure.

Partial weight-bearing and the fitting of the lower prosthesis can take place as early as a few days after the second surgery. This is done under careful supervision of the team. It is now that the rehabilitation stage and gait training can begin.



Stoma Care

Care should be paid to the opening (stoma) through which the external adaptor passes out of the stump. There will be a small amount of discharge from the stoma. This amount varies from patient to patient and some have none at all.

With normal daily hygiene the risk of infection is very low. Washing once a day in the shower, paying attention to the stump and stoma is all that is needed.



Example of a Stoma at 14 months Post Op

Factors to be considered

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.

In order to ensure the implant is safely integrated into the bone you 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 yourself is often strong, it is recommended that you build up your walking slowly to avoid any injuries caused by pushing yourself 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. The safety pins are easily exchanged by the prosthetist and in the near future there is the possibility they will be able to be replaced by the patient.

The implant is made of titanium, which is coated with a rough surface of a plasma spray which allows for the bone to grow into. In addition there is a layer of hydroxyapatite coating which attracts bone cells to adhere and grow into. These materials are extremely biocompatible in endoprosthetics. The body will not reject the implant and there is no permanent medication required.

Further Information

Clinics are held the first Thursday of the month in Sydney where patients are invited to meet with the surgeon and the team consisting of prosthetists, physiotherapists, rehabilitation specialists and a psychologist. Patients will also have the chance to meet and chat with other OGAP-OPL users who are at a variety of stages in the process from having had the first surgery to walking with the prosthesis for two years.

US clinics will be offered from time to time and interested patients can enquire about when the next clinic is nearest to them through the website.

How soon after amputation can the surgery be performed?

Each situation is unique and will be assessed to make the best decision for you. It differs from person to person, one patient has gone straight from amputation to the OGAP-OPL while another was a user of the traditional suction prosthesis for 28 years prior.

Treatment Pathway

Meet with the Osseointegration Group of Australia team at the monthly Osseointegration Clinic: The team will consult with you, assess your case, answer all of your questions and discuss the procedure and post-op physio and care with you. The clinic is also a chance to meet other amputees who are at various stages of the osseointegration journey.

A/Prof Al Muderis refers patient for pre-op assessment: You will be sent for x-rays and scans in order for A/Prof Al Muderis to be able make a thorough assessment of your individual situation.

Psychologist review: You will have a one on one session with the team's psychologist Dr Chris Basten, who will chat with you about the process, your thoughts about it and your reasons for wanting the surgery.

Group agrees to proceed: Once all assessments have been carried out the team will discuss your case and make the decision whether or not to proceed with surgery.

Prosthetics/Physio complete pre-op build up and muscle rehab: Meet with the team's prosthetist, Stefan Laux who will conduct a series of gait measurements, tests and assessments. Sarah Benson, the team's physiotherapist will run through a series of pre-op strengthening exercises for you to do prior to surgery.

Operative planning: A/Prof Al Muderis and his surgical team will make the necessary preparations for surgery.

Pain management/Anesthetist: Anesthetist Ajay Kumar and Pain Management Specialist Dr Andrew Paterson will consult with you about what anesthetic will be best and the to run through the post-op pain management protocol.

Hospitalisation – Acute nurse physio care: If you are undergoing the surgery at Macquarie University Hospital you will be under the care of Jennifer Martin who is the Acute Care Nurse; Nurse Unit Manager and has vast experience with osseointegration. If the surgery is being performed at Norwest you will be under the care of specialty acute care nursing staff who also have a great deal of osseointegration patient experience.

Prosthetics/Physio for rehab and follow up: Partial weight-bearing and the fitting of the lower prosthesis can take place as early as a few days after the second surgery or first surgery if you undergo a single stage procedure. This is done under careful supervision of the team physios. They will guide you through the weight loading stage. Once you have reached and can comfortably load at a weight of half your body weight prosthetist Stefan Laux will fit you with a light leg and gait training can commence.



We take care of your mobility

An amputation is a devastating moment in anybody's life and has a significant impact on all areas of an individual's life. For this reason the desire for greater and more effortless mobility allowing for active participation in all areas of life is the Osseointegration Group of Australia's top priority.

Prosthetic care plays a vital role in fulfilling these wishes and recovering with unrestricted comfort and mobility.

We would like to introduce our response to your needs. A team approach from the initial meeting, to surgery, then quality after care with rehabilitation, physiotherapy and pain management that is best suited to you. This is done using the latest innovation in the field of prosthetics, the OGAP-OPL implant.

Osseointegration Group of Australia Team Approach

The Osseointegration Group of Australia team consists of experts in a variety of fields each with vast experience of working with amputees. They understand every situation and patient is unique. By utilizing a combined team approach they work together to assess and determine the best possible treatment for you.

The team cares for you emotionally and physically from the first meeting, offering 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.

Meet the OGAP Team



- **A/Prof Al Muderis** - Orthopaedic Surgeon
- **Stefan Laux** - Prosthetist (APC Prosthetics)
- **Jennifer Martin** - Acute Care Nurse; Unit Manager, Macquarie University Hospital
- **Sarah Benson** - Physiotherapist, Macquarie University
- **Cathy Howells** – Physiotherapist
- **Dr Simon Chan** - Rehabilitation Physician
- **Dr Ajay Kumar** - Anesthetist
- **Mitchell Grant** - Patient Advocate
- **Deborah Vickers** - Biomedical Engineer
- **Dr Chris Basten** - Psychologist
- **Barry Leech** - Prosthetist/Orthotist (Queensland)
- **Shona Wilmont** - Osseointegration Australia Coordinator



The Osseointegration Group of Australia OGAAP & Osseointegration Group of Australia pre-operative pathway OGAAP-ROM

The Osseointegration Group of Australia (OGA)[®] was developed in 2010 under the Chairmanship of A/Prof Munjed Al Muderis, an Orthopaedic Surgeon trained in Sydney, Australia. The desire to improve the choices and quality of care for amputees in Australia came about after A/Prof Al Muderis returned to Sydney having completed a post-graduate fellowship in Germany. During this fellowship he was able to participate in the Osseointegration process. Having then examined the Swedish (Branemark - OPRA) ¹⁻⁸ and German (Endo Exo - ILP) ^{9,10} methods it was decided that this technology did have a place in Australia and that the optimal way of bringing this technology to the Australian amputee community was by creating a multi-disciplinary team, which would together examine applicants and determine their suitability for surgery. In December of 2010 the first planning meeting of OGA[®] was held and the first osseointegration surgery was undertaken in March 2011.

Patient-centered care is widely recognized as a core dimension of a quality modern health service. Informed decision-making; a two-way dialogue between patients and their health practitioners, examining the benefits, risks and alternatives of treatment, taking into account the patient's personal circumstances, beliefs and priorities; is vital to truly patient-centered care. A well-informed patient can be an active partner in decision-making about

their care. Having realistic expectations about the likely or potential outcomes of their treatment provides an additional layer of vigilance and protection against errors or adverse events. Performed well, the informed decision-making process builds trust, prevents harm and reduces surprise and distress if complications or adverse events occur. Open communication is a vital part of the Osseointegration process. On presentation to an osseointegration clinic, each patient is advised on the format of these clinics and our care. Patients are invited to engage in the open forums provided at each clinic if they choose. It is with these principles in mind that the OGA team embarked.

The Osseointegration group of Australia team initially started with A/Prof Munjed Al Muderis, Dr. Simon Chan, Rehabilitation Physician, Stefan Laux, Prosthetist, and Jennifer Martin, NUM and since, it has expanded to a larger number of people in multiple cities around Australia. Currently the OGA[®] has a strong partnership with the Osseointegration team at Radboud University medical centre, Nijmegen, The Netherlands, where they started an Osseointegration program in 2011 and have now adopted the OGA model ¹¹.

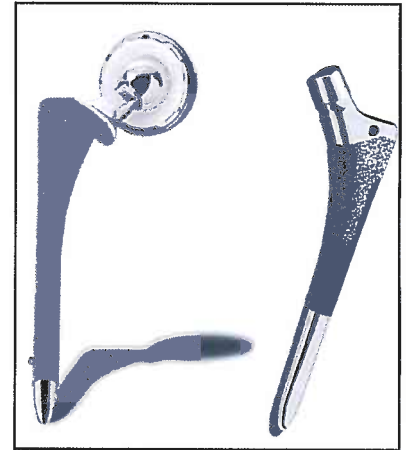


What are the different modalities of Osseointegration?

One Dimensional Bony On-growth



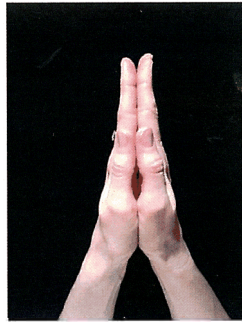
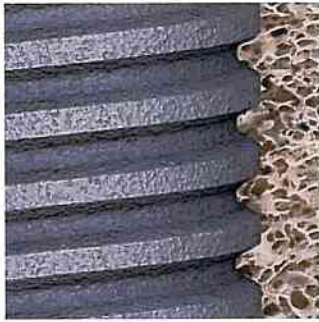
Two Dimensional Bony In-growth



Three Dimensional Bony Penetration

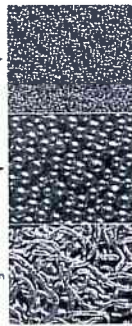


What is Bony On-growth?



Kerstin Hagberg, RPT, PhD; Rickard Brånemark, MD, PhD. One hundred patients treated with osseointegrated transfemoral amputation prostheses—Rehabilitation perspective.

What is Bony In-growth?



J. D. . Bobyn, R. M. . Pilliar, H. U. Cameron, G. C. Weatherly, 1980 The optimum pore size for the fixation of porous-surfaced metal implants by the ingrowth of bone. *Clinical Orthopaedics and Related Research*, 150 263-270

What is Bone Penetration?

Immediate post surgery

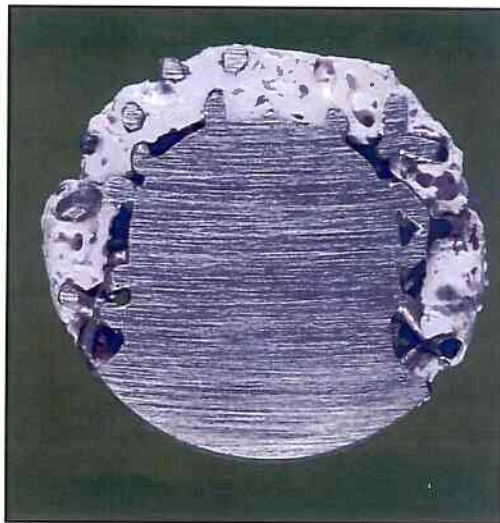


Six weeks later



* O, Dufek P. Biological fixation and clinical results of the cement-free Lübecker total endoprosthesis made from spongiosa metal. *Orthop Ihre Grenzgeb.* 1993 Nov-Dec;31(6):524-31

What does Bony Penetration look like?



Most common applications for implants

Teeth Implants

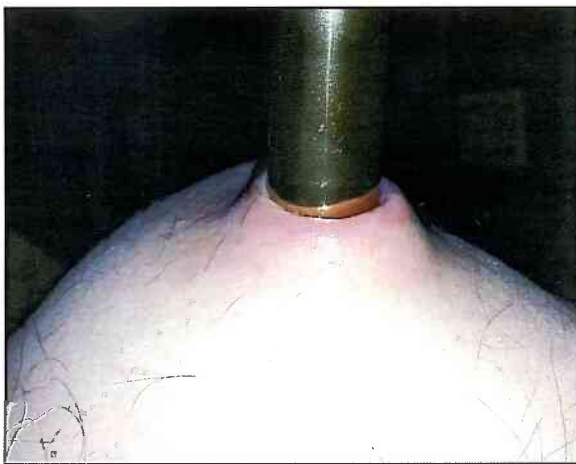


Total Hip Replacement



What is a Stoma?

A Stoma is the interface between the implant and skin. Similar to what we see in various types of body piercings.



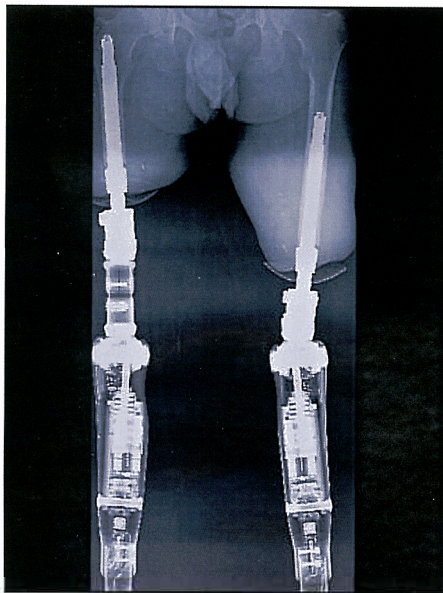
Is Osseointegration right for you?

A Direct Skeletal Prosthesis offers significant and unparalleled advantages compared to a traditional suction prosthesis. The technology has allowed a number of amputees world wide to regain both their mobility and quality of life.

There is a good chance that you are a candidate

Exclusion Criteria

- Peripheral Vascular Disease
- Receiving Irradiation
- Mentally Unstable
- Smoker
- Growing Skeletal System
- Non Compliance



Michael Swain's Post Op X-ray



Dr Munjed Al Muderis and Bilateral Ak Amputee Michael Swain. The UK Military's first Osseo patient

Please visit the following website for additional information:

www.OsseoInternational.com





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 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 brochure.

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



Scan for patient inquiry