THE OSSEOINTEGRATION GROUP OF AUSTRALIA

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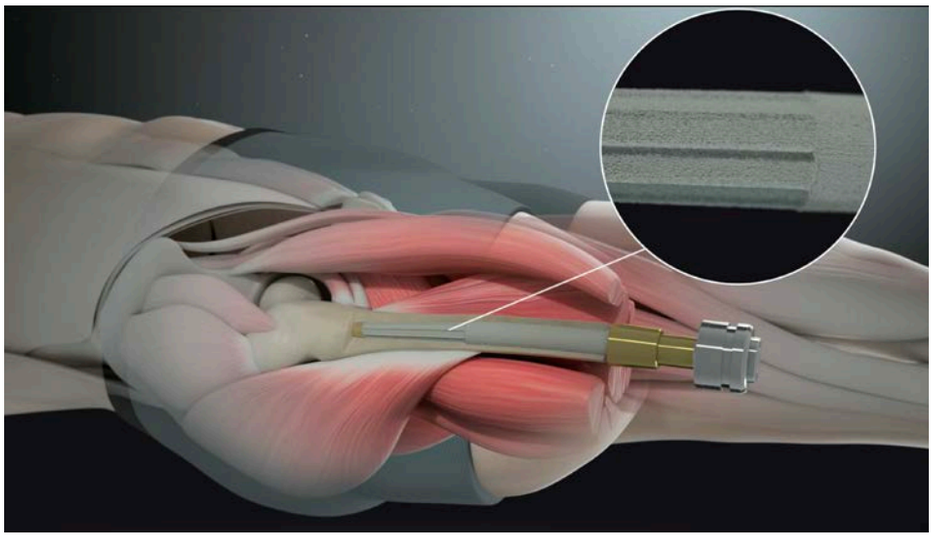
# Osseointegration Surgery

A GUIDE FOR PATIENTS

Osseointegration is a revolutionary technology for both upper and lower limb amputees, offering a viable solution for patients experiencing problems with a traditional socket mounted prosthesis. This technology originated in the 1990's with only a few surgeons performing the procedure. However, the number of centres performing this surgery has expanded dramatically since 2010 due to improvements in surgical techniques and implant design. It is expected that this technology will become the treatment of choice for a large proportion of amputees in the near future.



Contrary to socket mounted prostheses, the osseointegration implant is directly attached to the skeleton, restoring the mechanical axis of the limb close to natural physiological conditions. This allows for freedom of movement, greater control of the limb and reduced overall pain. Once fully integrated, the system enables a simple, quick, and safe connection between the residual limb and the prosthesis.

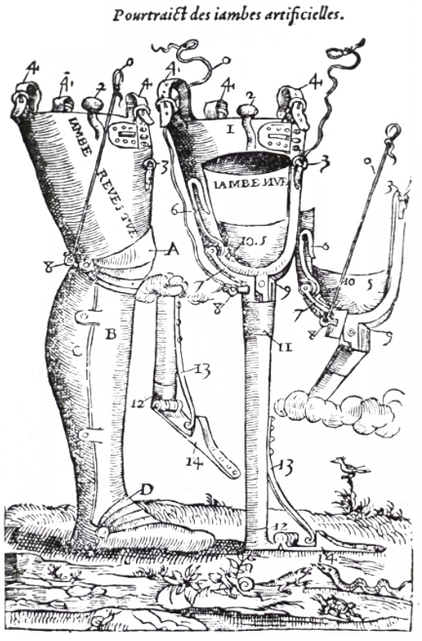
The Osseointegration Group of Australia was established in 2010. A multidisciplinary approach was developed to provide amputees with the best outcome. This technology has only become possible through an extensive collaboration between clinicians, scientists and engineers, all aiming to help patients regain their freedom of movement. Building on past experiences and a futuristic vision towards new technology such as targeted muscle reinnervation and implantable electrodes, the team strives to allow amputees to operate an osseointegrated robotic limb by mind control. The technology continues to evolve; with the application of 3D-printing and surface coating utilising antimicrobial nano-particles to improve clinical outcomes and reduce the long term complication rates.

## AMPUTATION AND THE SOCKET-MOUNTED PROSTHESIS

An amputation refers to the loss of the whole or part of an extremity. It can occur after an injury (traumatic amputation) or deliberately during surgery. Amputees represent 1 out of every 1000 individuals across Australia. In addition, there are an estimated 185,000 amputations performed yearly in the United States.

The majority of amputations are performed to treat complications arising from peripheral vascular disease (PVD) or diabetes. The next most common cause of amputations are traumatic events, such as motor vehicle collisions or military casualties. Less commonly, patients undergo amputation for treatment of a tumour in the extremity, infection or for a congenital condition.

Socket mounted prostheses are the current standard rehabilitation method for limb loss patients. Although significant advances have been made in prosthetic technology, the fitting of a socket remains challenging and often represents one of the most difficult aspects of the rehabilitation process. Achieving an optimal fit without pressure points, the appropriate amount of flexibility versus rigidity, and longevity remains elusive for a large percentage of patients. Despite continued research in socket and liner technologies, the modern socket remains the main reason many amputees cannot improve mobility, independence, and quality of life.




*The basic design of a socket-mounted prosthesis has not changed much since it was first invented by Ambroise Paré in 1525.*

### Osseointegration Information Pamphlet

DEAR SURGEON: Please discuss this pamplet with your patient and record this event on the patient's electronic medical history file. This will confirm that the information has been provided.

Patient's Name:_____

Clinic Location:_____

Doctor's Name:_____

Date: (day)_____ (month)_____ (year)_____

Edition number: 1

## INDICATION FOR SURGERY

Today, osseointegration technology is available as a treatment for above knee, below knee, above elbow, below elbow, thumb and finger amputations. Surgery may be suggested by your clinician if you have problems using a conventional socket prosthesis. You may have failed to utilise a socket-mounted prostheses due to problems such as:

- Pain in the stump or lower back
- Recurrent skin infections and ulcerations in the contact area
- A short stump preventing the successful use of socket prostheses
- Volume fluctuation in the stump
- Extensive scarring or skin grafting
- Excessive perspiration
- Overall restricted mobility

### Surgical criteria may include:

- Compliance with the protocol
- Proper understanding of the benefits and risks associated with this procedure
- BMI < 40 (A small number of patients with morbid obesity were successfully treated as a last resort as they could not wear a socket)
- Well controlled blood sugar levels especially for diabetic patients
- No smoking for at least 3 months prior to surgery

### Contraindications include:

- Active infection in the residual limb
- Radiation to the affected bone
- Pregnancy
- Psychological instability

## YOUR DECISION TO HAVE TREATMENT

The decision to have surgery is ultimately yours. Only make the decision when you are satisfied with the information you received and believe you have been well informed. Keep in mind that your surgeon cannot guarantee that the surgery will meet all of your expectations. In order to make an informed decision it is paramount that you have peer support discussions, clinical team assessment and undergo the proper investigations.

**Patient peer support:** Speaking with someone who has been through the surgery can play an important part in your preparation, recovery and rehabilitation. Many patients feel more comfortable discussing personal issues with someone who understands what they are going through, someone who has experience and can appreciate how you feel. Osseointegration clinics are usually operated in an open environment which may provide you with the opportunity to share concerns and ask questions that only someone who has been through limb loss can answer.

**Clinical team support:** From the decision to have surgery through to after care in pain management, physiotherapy and prosthetic limb adjustments, the surgery requires a multi-disciplinary team approach. The clinical team is here to assess conditions and determine an optimum treatment plan for you. Open communication is a vital part of your success. You will have a patient liaison assigned to you who will look after your entire journey.

**Investigations:** To obtain necessary information to assist with your decision and ongoing care, you will be required to undergo several objective, subjective and radiology tests before your surgery and regularly throughout your post-operative journey.

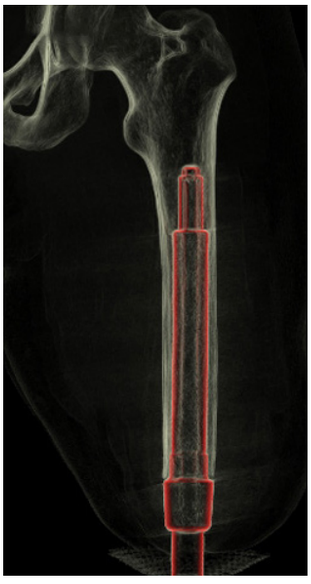
**Realistic expectations:** It is important to understand that not everyone will get the same results. Patients who have realistic expectations about what the surgery can achieve are suitable for osseointegration surgery.

**Consent form:** If you decide to have treatment, your surgeon will ask you to sign a consent form. Read it carefully. If you have questions, ask your surgeon.

## BEFORE YOUR SURGERY

Your surgeon will need to know your medical history to plan the best treatment. Fully disclose any health problems you may have had. Tell your surgeon if you have any allergies, prolonged bleeding, problems with blood clots or psychological illnesses. If you have diabetes, speak to your doctor about your blood sugar control before the surgery.

**Radiology assessments:** To assist with the management plan, your surgeon will require specific X-rays, CT and DEXA (bone density) scans for examination. If you have any X-ray films of your stump, please bring them with you to the clinic and hospital.



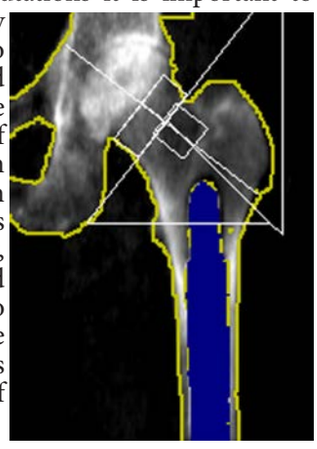
**Custom implants:** On occasions, your surgeon may request a custom implant to be made to ensure a precise adaptation of the implant to your stump. Custom implants are specifically designed based on your anatomy and will be an exact fit to your bone. Custom implants require extra planning and time for manufacturing. Your surgeon will determine if this is required.

**Travelling:** If you are travelling for surgery, you should plan to arrive a few days prior to the procedure. It is advisable that a support person, usually a family member, accompanies you. This time frame will allow you to settle and familiarise yourself with the new surroundings.

**Stump skin conditions:** It is advisable to optimise your skin condition prior to surgery. Please avoid excessive use of your socket in the two weeks prior to your surgery as this may result in sores, pimples or ulcers. If you have an infected area near your incision site, inform the team as this may result in a delay of your surgery.

**Pre-admission check-up:** You may be asked to have a check-up with a physician or attend a pre-admission clinic to ensure your condition is optimised for the operation.

**Pre-operative conditioning:** Some patients may be advised to undertake a pre-operative conditioning program. Upper body and core strength optimisation may be necessary. In the case of lower limb amputations it is important to learn how to use crutches. Any flexion deformity should also be identified and addressed accordingly. DEXA scans are vital to assess the degree of osteoporosis and the resorption of the affected bone. Patients can vary in their level of osteoporosis depending on their age, sex, time since amputation and activity. Advice can be given to use supplements and encourage exercise. The level of osteoporosis will also determine the speed of post-operative rehabilitation.



## THE SURGICAL PROCEDURE

The surgical procedure is usually performed as a single operation. Historically, a 2-stage procedure was performed with a gap of 4 to 6 weeks between stages. A single-stage surgical approach was introduced in 2014 to facilitate faster patient rehabilitation and minimise risks associated with multiple surgeries. On the rare occasion, multiple staged procedures may still be required.

Anaesthesia: The surgery is usually performed under a spinal or epidural block that stops pain and feeling from the waist down, supplemented with sedation. Modern anaesthesia is safe and effective, but it does have risks. Your anaesthetist will speak to you before surgery.

The Surgery: An incision will be made at the distal end of your stump. The wound is then opened in layers to expose the end of your residual bone. Utilising special instruments, the end of the bone is prepared by removing any unwanted spurs. Your surgeon will then explore and remove any neuromas if encountered. Your muscles will be re-organised and grouped in a circumferential manner using special sutures by attaching them directly to your bone. This will allow you to control the prosthesis with your muscles in the future.

Insertion of the Implant: The bone canal is then prepared by sequential reaming with special reamers which converts the bone canal from an oval to a cylindrical shape. Broaches are then utilised to match the shape and cut the desirable fins for your implant. All of the extracted bone is carefully harvested to be used as bone graft. Once the desirable implant size is reached, the bone graft will be inserted in the cavity and the implant is carefully press-fitted in the canal.

Surgical closure: A soft tissue flap is prepared by removing excess subcutaneous tissue fat. This flap is then used to cover the muscles, the implant and is secured in place using surgical staples. A circular opening is created in the skin at the tip of the implant. The percutaneous prosthesis is carefully attached to the implant through this opening. Following this, the wound dressing is applied.

## RECOVERY AND REHABILITATION

After surgery, you will receive a combination of pain medications depending on your specific needs. This is based on a balanced analgesic protocol, allowing you to control your muscles and maintain good cognitive status so that you can commence rehabilitation with adequate pain relief. The hospital stay is usually between 3-5 days and after that you will be discharged to continue rehabilitation.

Wound care: After removal of the surgical dressings, your wound will be cleaned and allowed to air-out. A simple 4x4 gauze is encouraged as a non-occlusive dressing. The goal is to allow the seepage to clear out rather than accumulate inside the wound. Instead of covering your wound at all times, you should aim to keep your wound dry and expose it to the sun to allow UV light to kill any bacteria. Skin staples are typically removed partially at 3 weeks and completely at 4 weeks.

Limb pain can be due to many factors and treatment needs to be targeted at the root cause. It is expected that **muscular pain** will increase in the initial stages after surgery. This is due to the fact that these muscles in the limb are recruited for the first time since the initial amputation. This pain will vary in severity and duration based on the activity level, the degree of muscle wasting and the time required to build these muscles back. Pain due to **bone spurs** will be eliminated by surgically removing them as part of the surgery. It is expected that **skin irritation pain** due to the socket will be completely eliminated. However it maybe replaced by a different type of pain at the opening where the implant protrudes which can be treated by a numbing cream or topical oil. **Neuroma pain** is normally treated either through a local excision during the surgery or later down the track with injections or pain killers. **Phantom limb pain** is the most complex to treat. Though it is likely that phantom limb pain will reduce after osseointegration, we do not know the exact mechanism and phenomena behind the causes. Pain management specialists utilise a multi-faceted approach which varies from medications to nerve stimulators.

Rehabilitation generally involves 3 phases. You will be given thorough information pre-operatively and be guided throughout your rehabilitation program. **Phase 1** involves the loading of a static weight by standing on a bathroom scale using a loading device attached to your implant. Loading takes place over a 20 minute period twice a day. This may commence as soon as the next day after surgery and continues until you achieve 50% of your bodyweight or 50kg. You will begin loading at 5kg with the speed of advancement determined by your bone quality measured through pre-operative DEXA scans and intra-operative bone quality assessments. **Phase 2** applies only to above-knee amputees and involves getting fitted with a light leg for gait training. You will start taking your first steps aided by parallel bars and when it is safe, progress to using two crutches. **Phase 3** involves the fitting and alignment of your definitive prosthesis. Once fitted, you will be allowed to walk with two crutches for 6 weeks, followed by one crutch for another 6 weeks then unaided thereafter. This is necessary to minimise the risk of falls and prevent premature overloading of the implant.

Recovery takes time: You should avoid performing high impact activities for the first 12 months post surgery.

## ONGOING CARE

At about 3-4 months after surgery most patients will have completed rehabilitation, and will be walking without any assistive devices. However, it is important that you visit your prosthetist and physiotherapist regularly as you will continue to improve your gait and balance over time. Your prosthetist will also instruct you on how the safety mechanism works and how to correctly replace it should it break in a fall or accident.

**Excessive discharge** from the stoma site following surgery is very normal and will usually lessen 3-6 months after your surgery. Females, short residuum and overweight patients are expected to have higher levels of secretion than others. This natural secretion is normally golden or clear in colour. To prevent dripping, you may apply split gauze dressings around your percutaneous adaptor and gently tape them to the metal components. Warm salt water baths can also effectively reduce the amount of discharge.

**Daily cleaning**: Once you leave the hospital, you should begin showering daily. Using your hands, gently wash the stump with soap and water. It is ideal to use a hand held shower head to rinse off your stoma daily. It is also recommended that you use a very basic soap that does not contain perfumes or moisturisers. To remove dried blood and discharge from the metal components, you may use a clean soft baby toothbrush while showering. To aid healing, you should aim to keep your stoma dry and uncovered.

**Swimming** in a salt water pool or the ocean is highly recommended. You should rinse your percutaneous opening after swimming, especially in rivers or public pools.

**Know your components** The osseointegrated prosthesis is designed to become a permanent extension of your skeletal structure and you should learn how they are designed to function. The team will explain how each component works, including any regular maintenance and services required. As you increase your activity levels, the components may gradually become loose and you will need to re-tighten them regularly every 3 months.

**Infection management:** Despite a significant reduction in infection rates after the introduction of single stage surgery and refinements in surgical techniques, infection still remains a major risk associated with this procedure. If you suspect that you have an infection (pain, redness, fever or unusual discharge), please contact the team immediately. Describe your condition in as much detail as possible and send photos to the team to assist with the diagnosis. Avoid taking random swab cultures around the stoma skin area and do not begin any antibiotic treatments until you know what type of infection you are treating. The team will guide you on the best route of management.

**Support network:** Osseointegration surgery is a life-long commitment. The international osseointegration network is constantly training new clinicians from centres all across the world. We endeavour to provide all patients around the world with local support. Should you have any questions or concerns, simply reach out to any member of the osseointegration network.

## POSSIBLE COMPLICATIONS

As with all surgical procedures, osseointegration surgery does have risks, despite the highest standard of practice. It is important that you have enough information about possible complications to fully weigh up the benefits, risks and limitations of the treatment. Serious complications are uncommon. The following possible complications are listed to inform, not alarm you.

### Associated risks may include:

- Death.
- Severe systemic infection.
- Loss of the remainder of the limb.
- Blood clots that form in deep veins which can be life threatening.
- Fractures of the implant or related components.
- Bone fracture around the implant.
- Reaction to anaesthetics, antibiotics, sutures or dressing materials.
- Temporary or permanent injury to nerves or blood vessels close to the surgical area.
- Chronic infections that may require oral, intravenous antibiotics or even removal of the implant and conversion back to socket.

These complications are rare, and there may be other complications not listed which are less likely to occur. The most common complication is infection and is discussed below:

- The risk of minor infections was common. However, this has dramatically reduced with the introduction of the single-stage surgery and refinement in surgery techniques.
- Infection may occur at any time, even months after the operation. The most common time of infection is 2-3 weeks after surgery and the frequency reduces as time goes by. To treat infections, most of the time a course of oral antibiotics will be sufficient.
- In rare cases there may be a need for intravenous antibiotics or surgical debridement of the infected tissue.
- In extreme cases, a second operation may be needed to remove the implant, followed by a third operation to re-insert it.
- The implant may become loose over time due to infection, trauma, overloading or in some cases no known reason.

### Dental work or surgery

If you have dental work or any other surgeries, even minor, please let your dentist or surgeon know about your osseointegrated implant. You may need to take prophylactic antibiotics prior to and after the procedure to reduce the risks of infection around the prosthesis.

## REPORT TO YOUR TEAM

Contact your osseointegration team or local doctor immediately if you develop any of the following conditions:

- Temperature higher than 38.5 °C (fever) or chills
- Severe pain or tenderness
- Heavy bleeding from the incision
- Spreading redness around stoma
- Nausea or vomiting
- Worsening flexibility or inability to bear weight through the implant
- Traumatic incidents such as a fall
- Any other concerns you may have regarding your surgery

## COSTS OF TREATMENT

Your surgeon will provide an estimate of fees. This is an estimate because the actual treatment may differ from the initial proposal. It is important to note that no two patients are the same and it is impossible to evaluate treatment costs without a thorough clinical assessment of your condition. Ask your surgeon about costs that may be covered by private health funds. There will also be ongoing costs involved in the replacements of consumable components. Discuss costs before the treatment rather than afterwards. If complications occur, more surgery may be needed. This may lead to more costs and inconvenience.

## YOUR OSSEOINTEGRATION TEAM CONTACT

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