Informed Consent - Osseointegration used for electronic reporting and for patient.

Treatment

- Placement of an osseointegration implant with one or two operations, followed by rehabilitation.

Indication

- Upper or lower leg amputation.
- Restrictions concerning mobility, daily activities and quality of life.

Intended objective of treatment

- Improvement of mobility, daily activities and quality of life with a prosthetic leg.

Possible disadvantages and complications

Surgery

- The osseointegration treatment is relatively new and the surgical technique is constantly evolving. This means that risks may be associated with this treatment that are not yet known to us. Logically, we cannot inform you about these unknown risks.
- For people with a long femoral stump, the stump sometimes needs to be shortened considerably.
- During the implantation process, the bone can crack or facture, which will result in a modified rehabilitation program.
- A wound infection might occur after the first operation. The surgeon can then choose to perform the second operation sooner than originally planned. A wound infection might also occur after a second operation.
- In patients whose bone is poorly covered by muscles, skin and other soft tissue, the first and second operations are sometimes performed together.

Rehabilitation

- With an osseointegration prosthesis, the risk of fractures from accidental falls is higher due to osteoporosis of the stump bone. These fractures can be treated with or without surgery.
- Pain in stump muscles/muscle attachments is common during the rehabilitation phase in the first year after implantation. The pain will decrease as soon as the stump muscles become stronger.
- Knee pain/groin pain can occur after implantation during the rehabilitation phase. The pain often disappears following a modified rehabilitation program and/or an adjustment to the prosthetic alignment.

Components

- The first generation of implants was made from a different type of metal than the current implants. Such first-generation implants were more susceptible to breakage. Titanium implants have been used since 2015 and have not broken to date. If an implant breaks, the remaining piece of the implant is surgically removed and if possible, a new implant will be placed.
- The double cone adapter (adapter between implant and connector) can break. In the event of a fall, safety weak points can break, and the adapter itself can break. If the adapter breaks, the component will be removed, on an outpatient basis if possible, and a new one will be installed.
- If the double cone adapter breaks, AOFE clinics cannot be held liable for this.
- The osseointegration prosthesis is suitable for normal daily activities. Excessive loading on the osseointegration prosthesis due to activities such as contact sports, running or lifting heavy objects (cupboards, furniture, etc.) must be avoided.
- Mechanical failure of the various components may occur as a result of overloading and/or as a result of incorrect choice of components. The manufacturer of the implant specifies in the instructions which parts must be used. Do not try to repair or adjust parts yourself but ask your doctor or the osseointegration specialist at your prosthetist's office for information.
- In approximately 2% of all cases, the implant can come loose from the bone, with or without infection. If this happens the implant has to be removed and if possible, a new implant will be placed.

General aspects

- Infection or irritation of the stoma (the opening in the skin through which the osseointegration material emerges) occurs regularly in the first year after implantation. This is treated with stoma gel or antibiotics. Bacteria are always present in and around the stoma, but normal bacterial growth does not usually cause any problems. By thoroughly cleaning the stoma twice a day, extreme bacterial growth and stoma infection or irritation can often be prevented.
- Risk factors for stoma infections or irritation include inadequate cleaning of the stoma, excessive subcutaneous fatty tissue at the site of the stoma and smoking.
- With a recurrent stoma infection or irritation, a re-operation may sometimes be required to remove excessive subcutaneous fatty tissue at the site of the stoma. Nowadays, this fatty tissue is removed as much as possible during the first operation, to prevent re-operations as much as possible.
- Phantom pain and/or neuropathic pain may develop or worsen after the implant is inserted. Existing phantom pain and neuropathic pain may also disappear or subside after implantation. If nerve nodes (neuromata) are found during the operation, they will be removed to prevent pain.
- Chronic stump pain without clear cause may occur. In that case, adequate treatment is not always possible and may be a reason to close the skin over the implant or remove the osseointegration implant. This is always done in consultation with the patient. In some cases, the stump bone then needs to be shortened, which in some cases means that a socket prosthesis will no longer be possible.
- You can still undergo an MRI scan with the implant, double-cone adapter and male part of osseointegration connector. However, the implant can cause interference with MRI images.
- The implant can be detected by surveillance systems at airports, for example.
- AOFE clinics is not responsible for irresponsible use of the dual cone adapter.
- AOFE clinics is not responsible for cracks, breaks due to incorrect use or mismatched connector on connection of the dual cone adapter.
- AOFE clinics is only responsible for the surgical procedure and can therefore not be held responsible for adjusting the prosthesis on the dual cone connector.

<u>Estimation of outcome or chance of success</u>

- Current research has shown that patients wear their prosthesis 80% more than before osseointegration, that patients can walk 32% further during a 6-minute test and that walking require 18% less energy. Osseointegration patients report an improvement in their quality of life of 62%. Of all patients who underwent the surgery, 2% were not satisfied with the osseointegration. All percentages mentioned above are averages.

<u>Alternatives</u>

- Continuation of the current situation.
- Alternative modification of your socket prosthesis.

<u>Online information</u>

- The above information can also be found on the AOFE clinics website.

<u>Who performs treatment?</u>

- Operation: orthopedic surgeon or surgeon in training under the supervision of a surgeon.
- Rehabilitation: rehabilitation physician.
- The prosthetist's office is responsible for choosing the type of connector, adjusting the prosthesis and for maintenance and any required repairs of the connector and prosthesis.

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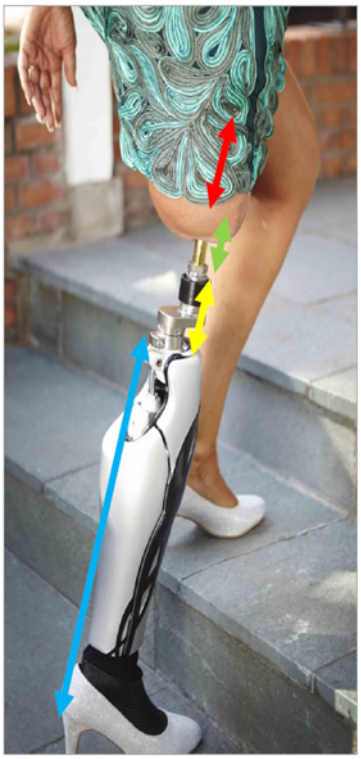

Het implantaat (ook wel de pin of het intramedullaire component); hetgeen in het bot wordt geplaatst
Soms foutief prothese genoemd

De adapter (ook wel dual cone adaptor of transcutane dubbel conus); verbindt het implantaat met de connector

De connector: verbindt de adapter met de prothese

De prothese