Osseointegrated, percutaneously derived implants for rehabilitation after the transfemoral amputation - via the endo-exo implant system

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Abstract

Osseointegrated, percutaneously guided implants - so called endo-exo prosthetics (EEP) - have been used to a limited extent since 1999 for rehabilitation after major amputation. Meanwhile, implant survival times of more than 15 years have been achieved. The obligatory colonization of the skin penetration site of the implant does not necessarily lead to an intramedullary, periprosthetic infection. This circumstance can be explained by the interconnectivity ingrowth of the bone into the three-dimensionally structured implant surface. This sufficiently prevents the formation of an infection promoting connective tissue layer between bone and metal. A total of 110 EE femoral prostheses were implanted (6 x bilaterally amputated) in 104 patients between August 1999 and October 2016. The implant is produced by casting from a CoCrMo alloy coated with titanium nitride. The first step is the implantation of the intramedullary module with subsequent wound closure. After safe osseointegration of the endomodule after 6 weeks, the skin was penetrated with docking of the components receiving the exoprosthetics in a second surgical step.

Keywords: Osseointegrated, endomodule.

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Introduction

Osseointegrated, percutaneously guided implants - so called endo-exo prosthetics (EEP) - have been used to a limited extent since 1999 for rehabilitation after major amputation. Meanwhile, implant survival times of more than 15 years have been achieved. The obligatory colonization of the skin penetration site of the implant does not necessarily lead to an intramedullary, periprosthetic infection. This circumstance can be explained by the interconnectivity ingrowth of the bone into the three-dimensionally structured implant surface. This sufficiently prevents the formation of an infectionpromoting connective tissue layer between bone and metal.

A total of 110 EE femoral prostheses were implanted (6 x bilaterally amputated) in 104 patients between August 1999 and October 2016. The implant is produced by casting from a CoCrMo alloy coated with titanium nitride. The first step is the implantation of the intramedullary module with subsequent wound closure. After safe osseointegration of the endomodule after 6 weeks, the skin was penetrated with docking of the components receiving the exoprosthetics in a second surgical step.

The retrospective analysis shows that a total of 324 operations were required for the 110 implantations performed. Of these, 220 operations were performed using the two-stage implant procedure. The remaining 104 surgical interventions were soft tissue problems at the skin interface, 7 fracture restorations, 8 explantations with 3 reimplantations and minor corrections to the prosthetic components. The initial infection problem with severe soft tissue irritations at the skin interface could be effectively countered by changing the design of the components. From January 2010 - October 2016, only 12 surgical procedures were necessary. It has also been shown that even prolonged soft tissue infections involving the distal end of the femur do not necessarily lead to an ascending periprosthetic infection. Patient satisfaction was predominantly high. Regarding to the wearing and operating comfort of the prosthetics, the recovery of a tactile sensation, the so-called “osseoperception”, and the considerable increase in mobility are these very positive aspects. When using the bone-guided prosthesis, special attention must be paid to the orthopaedic technical treatment. In particular, the axial alignment of the prosthesis abutment requires specific handling in order to achieve an optimal walking pattern and to prevent possible consequential damage to the hip joint and spine.

Bone guided percutaneous prosthetics for rehabilitation after transfemoral amputation can be considered sufficiently safe according to the available data. Therefore it represents a valuable treatment option for patients after

transfemoral amputation who would otherwise not be able to rehabilitate satisfactorily.

This is the first prospective study to look at quality of life, function, and complications after patients with TFA were treated with an osseointegrated percutaneous prosthetic implant. We discovered a two-year cumulative survival rate of 92 percent, which contrasts with previous reports of direct skeletal attachment for prostheses, which have shown limited prosthetic function in dogs and goats due to implant loosening or infection, or have only been used for almost unloaded implants in humans. Brnemark pioneered the concept of osseointegration, which has revolutionised dental treatment and is now widely employed in hearing aids, craniofacial prosthesis, and thumb prostheses. 8 The application of this notion to TFA patients is a step forward in this direction. A research on a German concept for percutaneous prosthesis fixed to bone for transfemoral amputees showed promising outcomes, despite the absence of prospective short and medium follow-up on implant survival, infection rates, and revision rates. 20 Between 1990 and 2010, 30 of 37 patients who had arm amputations at various levels and were treated with implants continued to use the implant successfully, and a case report using the British osseocutaneous ITAP system in a patient with transhumeral amputation has survived two years without any reported signs of failure. There are numerous lower limb amputees around the world, many of whom are young, and TFA prostheses have typically used suspended sockets. However, because of inadequate suspension and fit, local pain, skin ulceration, and general discomfort, problems with the socket are widespread. Patients with a short stump or insufficient soft tissues may opt to forego using their prosthesis altogether. 4 Hoaglund et al2 found a significant rate of persistent discomfort in Vietnam war veterans with amputations in the United States. A survey of 97 TFA patients in Sweden found that 72 percent had heat and sweating of the stump, 62 percent had sores/chafing/skin irritation, 61 percent had mobility issues, 51 percent had stump discomfort when standing or walking, and 44 percent were uncomfortable sitting with the stump. This was a prospective, single-center, nonrandomized study that received ethical approval in compliance with the European standard for clinical trials of medical devices (EN-540) (R402-98). A formal consent form was signed by all of the patients. The following inclusion criteria were used to select patients: Transfemoral amputees (ages 20 to 70) with problems with conventional socket-suspended prostheses, or who are unable to use or do not use a prosthesis, and who are likely to comply with treatment and follow-up requirements as determined by the treatment team, which includes experienced orthopaedic surgeons, physiotherapists, and prosthetists. Amputation owing to severe peripheral vascular disease and/or diabetes mellitus, skin disorders on the severed leg, pregnancy, and current therapy with systemic corticosteroids, chemotherapeutic agents, or other medicines that cause amputation were all considered exclusion criteria.

References

1. Hoaglund FT, Jergesen HE, Wilson L, Lamoreux LW, Roberts R: Evaluation of problems and needs of veteran lower-limb amputees in the San Francisco Bay Area during the period 1977-1980. J Rehabil R D 1983;20:57-71.

2. Hagberg K, Brånemark R: Consequences of non-vascular trans-femoral amputation: A survey of quality of life, prosthetic use and problems. Prosthet Orthot Int 2001;25:186-194.

3. Ghoseiri K, Safari MR: Prevalence of heat and perspiration discomfort inside prostheses: Literature review. J Rehabil Res Dev 2014;51:855-868.

4. Mooney V, Preecki P, Renning J, Gray J: Skeletal extension of limb prosthetic attachments–problems in tissue reaction. J Biomed Mater Res Symp 1971;2:143-159.

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