An Osseointegrated Percutaneous Prosthetic System for Treatment of Transfemoral Amputees: Medium and Projected Long-Term Follow-Up

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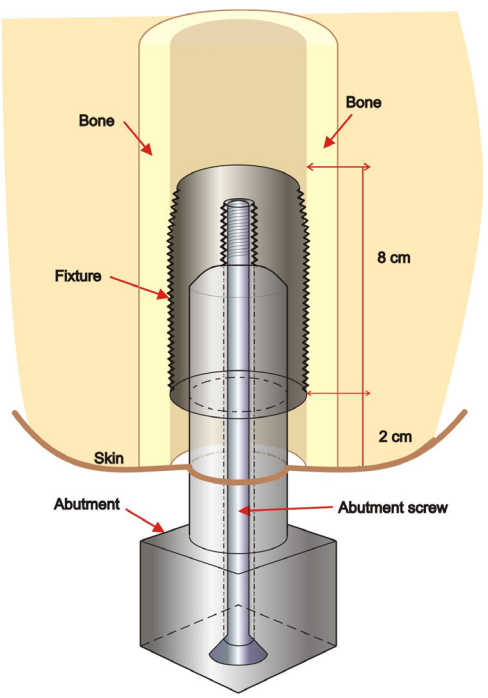
Purpose: In 2014 we published the first prospective study on the results of bone-anchored amputation prostheses in transfemoral amputees (TFAs). The OPRA study (Osseointegrated Prosthesis for the Rehabilitation of Amputees) includes 51 patients with 55 implants recruited from 1999 to 2007. At the 2-year follow-up (FU) in May 2010, 3 patients were excluded (1 dead, 1 lost to FU, 1 withdrawn due to contralateral extremity problems). The aim of the current study is to report on the clinical outcome with a minimum of 5-year FU with this technique, and projected 10-year results.

Methods: The surgery consists of a two-stage procedure. First a titanium screw (fixture - F) is inserted intramedullary into the remaining skeleton (S1 operation). Six months later a transdermal implant (abutment - A) is inserted into the fixture (S2 operation). The abutment is secured to the fixture by an abutment screw (AS).

Results: At 2-year FU 4 implants had been removed due to loosening (3) or infection (1), leaving 44 remaining patients (48 implants) in the study. The cumulative implant survival was 92%. The patients had an average of one superficial infection every 2 years, successfully treated conservatively with peroral or local antibiotics in all cases. There were 6 deep infections in 4 patients. All but one were successfully treated by conservative means. Four patients had 9 mechanical complications (bent or fractured As or ASs) and 3 skeletal fractures occurred. Prosthetic use, prosthetic functions, and global quality of life were all significantly improved ($P<0.001$). At 5-year FU no additional fixture losses were reported, but another patient had passed away unrelated to the procedure (43 patients/47 implants). Hence the implant survival rate remains stable at 92%. Between the 2- and 5-year FU superficial and deep infections occurred in 22 and 7 patients, respectively. Another 8 patients had bent or fractured As or ASs after trauma, and 15 patients had other mechanical problems due to wear leading to change of the A or AS. No F has been removed between the 2- and 5-year FU.



Conclusion: The observed cumulative success rate of 92% at 2-year FU remains stable at 5-year FU. Despite the general belief in the orthopaedic

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community, deep infection does not correspond to loosening of the implant, and neither does a superficial infection necessarily continue to develop into a deep infection. Patients using the OPRA implant report stable improvements in prosthetic function at 2- and 5-year FU as compared to baseline, and preliminary results indicate that this improvement is stable until 10-year FU. However the mechanical issues are of concern in a long-term perspective and need to be continuously monitored. So far these issues have been successfully addressed and solved.