Complications Associated with Use of the OPRA™ Protocol for Treatment of Transfemoral Amputation

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Clinical Question: What are the complications for patients using the OPRA™ protocol for bone-anchored suspension in the prosthetic treatment of transfemoral amputation?

Background: The OPRA protocol for the utilization of bone-anchored suspension has been approved by the FDA for use in the prosthetic treatment of transfemoral amputation in the United States. Studies evaluating the benefits of using the OPRA protocol for bone-anchored prostheses have shown statistically significant improvement in quality of life (QoL) in patients who transitioned from conventional socket prostheses to a bone-anchored device after reported difficulties with conventional socket devices,[1,2] comparable general QoL scores for patients with a bone-anchored prosthesis when evaluated against a matched group of patients utilizing conventional socket prostheses,[3] increased prosthesis use after implantation,[1,4,5] less patient-reported prosthesis associated problems compared to patients using conventional socket prostheses,[3] improved spatiotemporal parameters compared to socket prostheses,[6] and patient-reported improvements in their cognitive integration with their prosthesis following transition to a bone-anchored device.[7] These findings are noteworthy suggesting bone-anchored prostheses are a viable alternative to socket prostheses for patients with transfemoral amputation. Recent research has also suggested that these improvements in QoL are sustained through long-term follow-up.[4] However, studies have also reported various complications during the treatment and rehabilitation process. Practitioners need to be aware of these complications to maximize treatment outcomes, prevent barriers to bone-anchored prosthesis use, and reduce or avoid negative impacts on patient health.

Search Strategy:
Databases Searched/Search Approach: PubMed, SCOPUS, O&P iQ. Controlled vocabulary (MeSH) and title/abstract keywords related to osseointegration, bone-anchored prostheses, and OPRA implants/protocols were combined using Boolean Operators.
Search Terms*:
PubMed: MeSH and title/abstract terms for Osseointegration AND prosthetic implants/devices AND OPRA.
SCOPUS: Title/abstract keywords for Osseointegration AND prosthetic implants/devices AND OPRA.
O&P iQ: osseointegration transfemoral.
Inclusion/Exclusion Criteria: Original peer-reviewed research; No reviews or case studies; English Language; published in last 10 years; OPRA protocol required; Transfemoral amputation; Complications recorded.

Synthesis of Results: Five studies were identified (see Evidence Table). Brånemark et al.[1] identified superficial infection, fixture removal, surgical revisions of the residual limb, deep infections, exchange of abutment and abutment screws, and accidental overload leading to abutment bending as complications during their five-year follow-up. Hagberg et al.[5] identified more than half of their patients had a mechanical complication after 15 years, with more active patients having higher incidence of mechanical complications. Hagberg et al.[8] identified an increase in Severe Adverse Events (SAEs), events requiring medical treatment or hospitalization, in the second 5-year period of a 10 year follow-up, and more active patients had a higher incidence of mechanical complications. Voigt et al.[9] identified increased cost of care based on Quality Adjusted Life Years (QALY), an evaluation based on cost effectiveness of medical interventions. However, they did indicate that using the OPRA protocol is a cost-efficient alternative to conventional socket prostheses. Tillander et al.[10] identified an estimated risk of osteomyelitis of 20% over 10 years, with an estimated implant removal risk of 9%.

Clinical Message: While the reported benefits of the OPRA protocol are well documented, complications associated with the OPRA protocol are not uncommon and may be severe. Clinicians should understand these risks when discussing the OPRA protocol and when treating patients who have undergone the procedure.

*Author can be contacted for exact search string

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Evidence Table

	Brånemark et al., 2019[1]	Hagberg et al., 2020[5]	Hagberg et al., 2023[8]	Voigt et al., 2024[9]	Tillander et al., 2017[10]
Population	51 patients and 55 total limbs treated with the OPRA implant system at Sahlgrenska University Hospital. 45 patients passed 2-year follow up with 40 patients being followed up with at 5 years.	111 patients with a unilateral transfemoral amputation treated with OPRA implant system, 70% male with a mean age of 45 (17 to 70).	51 Patients treated with the OPRA implant system at the transfemoral level. 28 men and 23 women, 45 with unilateral amputation and six with bilateral amputation.	Patients assumed to be physically active, middle aged (46 years) healthy males with unilateral transfemoral amputation.	First 96 patients treated at osseointegration center in Gothenburg between May 1990 and January 2010.
Study Design	Prospective Non-Randomized Cohort Study	Longitudinal Cohort Study	Non-Randomized Prospective and Retrospective Clinical Study	Retrospective Comparison Using Markov Modeling	Retrospective Cohort Study
Intervention	OPRA implant system for a bone-anchored prosthesis for prosthetic treatment of transfemoral amputation.	OPRA implant system for a bone-anchored prosthesis for prosthetic treatment of transfemoral amputation	OPRA implant system for a bone-anchored prosthesis for prosthetic treatment of transfemoral amputation	OPRA implant system for a bone-anchored prosthesis for prosthetic treatment of transfemoral amputation and socket prosthesis for prosthetic treatment of transfemoral amputation	Intramedullary transcutaneous titanium implants for prosthetic treatment of transfemoral amputation. 69 treated within OPRA protocol
Comparison	Compared to preoperative baseline measures	Compared to preoperative baseline measures	Compared to preoperative baseline measures	Cost of patients with a socket prosthesis compared to treatment- naïve patients (considered to not be able to use a socket prosthesis and treated with an OPRA device) and treatment-refractory patients (patients who switched from a socket prosthesis to OPRA device)	No Comparison
Methodology	Clinical examinations and safety assessments were made at 3, 6, 12, and 24 months after implantation. Any complication was registered. At 5 year follow up, radiographs were performed and patient-reported outcome	After procedure for OPRA implant, patients were followed up with at two, five, seven, ten, and 15 years for evaluation	Clinical data was collected prospectively during the first two years following OPRA implant surgery. Clinical data in years 3-10 was collected	Q-TFA data were used from published studies along with health care reimbursement data through Medicare along several different health states to create a Markov Model to compare cost	Time from implant insertion to diagnosis of osteomyelitis and/or extraction caused by infection was registered. Mean observation time was 7.9 years. Infection

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	measures were taken with adverse events. (AEs) being registered.		retrospectively from the medical record.	effectiveness along different health states.	was identified through percutaneous bone biopsy or aspirated bone marrow cultures.
Outcomes	Questionnaire for persons with Transfemoral Amputation (Q-TFA) and Short Form 36 Health Survey (SF-36) were administered with all adverse events also being recorded.	Complications were registered, Q-TFA was administered, Prosthetic Activity Grades were given	Adverse Events (AEs) and Severe Adverse Effects (SAEs) were documented. Q-TFA and the SF-36 survey were administered over the ten year period.	Q-TFA data over time was used to assign scores along different health states to evaluate medical costs per Quality-Adjusted-Life-Years to determine overall cost effectiveness.	Infection was classified as definitive, probable, or possible. Time to infection was evaluated from implantation date.
Key Findings	5-year fixture survival rate was 92%. Revision free rate was 45%. Most common AE was superficial infection which occurred 70 times in 34 patients. Total of 85 serious AEs reported in 26 patients. Removal of the fixture, stump revisions, deep infections, exchange of abutment and/or abutment screw were examples of serious AEs. 43 mechanical complications occurred in 15 patients. Accidental overload after falling or stumbling causing abutment bending was cause in 16 abutments.	55% of patients had at least one mechanical complication, with 19% having six or more events. Patients with mechanical complications had a higher activity grade, higher mobility, and health scores. The highest number of mechanical incidents per patient year occurred after eight years. Mechanical complications can be expected, especially several years after implantation and in patients with higher mobility needs.	83% implant survival rate after ten years, which is worse than the statistics at the five year follow up mark (92%) with a larger number of mechanical complications after five years which could indicate a problem with sustainability of the implant system for patients with higher levels of prosthetic mobility. Incidence of SAEs also increased significantly between the first and second 5 year periods, while AEs did not increase in frequency.	Patients treated with the OPRA protocol improved QOL at a slightly increased yearly cost of $279/QALY for treatment-refractory patients and $273/QALY for treatment-naïve patients. These findings suggest that use of an OPRA prosthesis for active patients with transfemoral amputation is a cost-effective alternative to a socket prosthesis.	Estimated risk of osteomyelitis reached 20% by 10 years of evaluation. Median time was 2.6 years. 16 patients (16.7%) were observed with osteomyelitis with 10 instances resulting in extraction of the implant (9%). It is worth noting that the authors stated that outcomes significantly improved with the standardized protocol, and some of the data collection was occurring as the protocol was being refined.
Study Limitations	No controls of patients with transfemoral amputation used for comparison. Subject demographics are not included in this paper limiting ability to generalize the results. The follow-up period is mid-term, not long-term. Patients were only treated at a single location.	No controls of patients with transfemoral amputation not treated with the OPRA implant were used for comparison. Patients treated at a single hospital.	No controls of patients with transfemoral amputation not treated with the OPRA implant were used for comparison. Patients were treated at a single location.	Only active, healthy, middle-aged males were included as participants in this study. Patients with additional comorbidities may have been included, which may skew results toward higher incidence of complications and costs. Hagberg et al., 2020[5] is	Data were taken before and after the implementation of the OPRA protocol which could have led to increased likelihood for infection in the early group. As these were the first 96 patients treated there could be improvement in outcomes

	Brånemark et al., 2019[1]	Hagberg et al., 2020[5]	Hagberg et al., 2023[8]	Voigt et al., 2024[9]	Tillander et al., 2017[10]
	This location was also used in Hagberg et al., 2020[5] and Hagberg et al., 2023[8] and the timelines of these studies overlap. The populations that have been studied using osseointegrated prostheses are limited making the ability to generalize to a larger population limited.			referenced in this article. Research is limited on Osseointegrated prostheses and there is still need for more extensive research on more expansive populations.	from these measures with the standardized protocol.