

# QUANTIFYING PROSTHESIS ALIGNMENT IN TRANSTIBIAL BONE-ANCHORED PROSTHESIS USERS

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Other condition
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON52260

### Source

ToetsingOnline

### Brief title

Optimizing BAP Alignment

### Condition

- Other condition

### Synonym

bone-anchored prosthesis, Osseointegration

### Health condition

Bot-verankerde prothesegebruikers

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Radboudumc Nijmegen

**Source(s) of monetary or material Support:** Ministerie van OC&W, Subsidie van Stichting ZiektekostenVerzekering Krijgsmacht

## Intervention

**Keyword:** Alignment, Bone-anchored, Osseo-intergration, Prosthesis

## Outcome measures

### Primary outcome

The level of symmetry in moments around the hip and knee between the residual limb and the sound limb. This data will be collected at self-selected comfortable walking speed, and we will compare baseline alignment condition to the WBL alignment condition within the participants.

### Secondary outcome

Investigating the relationship between a structural change in alignment and the change in knee, hip and implant moments in trans-tibial bone-anchored prosthetic users in the frontal plane. Thereby, we investigate if the weight-bearingline alignment method results in short term (within 2 weeks) physical complaints

## Study description

### Background summary

We aim to investigate whether a standing x-ray has the potential to being used for optimizing prosthetic alignment. In clinical practice, frontal prosthetic alignment adjustments are often made to help solve the frequently present knee pain in transtibial bone-anchored prosthetic (BAP) users. Knee pain limits activity and participation level in the short term, and in the long term may ultimately lead to permanent damage in the knee, such as knee osteoarthritis.

Currently, optimizing prosthetic alignment is an iterative process and although it often results in fewer complaints, it is still unclear which alignment is most optimal for BAP users. Additionally, we lack insight into the impact of prosthetic alignment on the implant and on other joints. We hypothesize that a symmetric weight-bearing line alignment results in more symmetrical frontal plane hip- and knee moments during gait. A standing x-ray is a tool for obtaining this weight-bearing line and may therefore be a useful tool to optimize prosthetic alignment in BAP users. By respecting the individual anatomy, we expect that this alignment strategy has a preventive effect on the development of knee pain. Secondly, we hypothesize that imposed systematic alignment adjustments result in a structural change on knee and hip and implant moments. This relation is of clinical importance, since it could be used to determine the necessary prosthetic alignment adjustments for BAP users who present themselves with pain or discomfort within clinical practice. Since it is important to translate the knowledge of the weight bearing line in a x-ray, towards widely accessible resources, we introduce a tertiary purpose. We will investigate if the accessible tools for the Prosthetic and Orthotic Industry, such as the LASAR 3D and 3D motion capture, will be of use to implement findings of this study. While these systems are widely accepted, the use of the LASAR3D has not been validated. It is therefore necessary to investigate the clinimetric properties of the LASAR3D and its potential role in optimizing and monitoring the prosthetic alignment in transtibial BAP users. A better understanding of alignment and developing a more objective alignment approach will result in shift from a reactive treatment towards a proactive treatment strategy within prosthetic facilities. It has the potential to prevent or reduce prosthetic related problems limiting health-related quality of life.

## **Study objective**

The primary aim is to investigate if the weightbearing line alignment using a full-leg radiographic image results in more symmetrical frontal plane hip- and knee moments during gait. As a secondary aim, we will evaluate a) the relationship between imposed systematic changes in alignment and knee, hip, and implant moments and b) the effects of weight-bearing line alignment method on short term (within 2 weeks) physical complaints. The tertiary aim is to investigate the correlation between the weight-bearing line in a radiographic image and a weight-bearing line that can be obtained using 3D motion capture. Additionally, we will investigate the clinimetric properties of the LASAR3D.

## **Study design**

A mono-center cross-sectional study.

## **Study burden and risks**

The burden or risks associated with this research are limited and are not basically different from the risks and burden of patients visiting a rehabilitation facility for regular bone anchored prosthetic adjustments. Standing x-rays and alignment changes are routinely conducted during rehabilitation and follow-ups for bone-anchored prosthetic users at the Radboudumc. The participants of this study may benefit from an optimized alignment. In general, a better understanding of prosthetic alignment potentially prevents BAP users from experiencing pain and discomfort during prosthetic use and may lead to preventing permanent damage of the knee.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Persons will be eligible for the study if they use a unilateral trans-tibial

bone-anchored prosthesis for at least one year. They need to be able to walk without additional assistive devices during the measurements. An activity level of K3-K4 is required and all participants should be over 18 years of age.

## Exclusion criteria

Persons with cognitive or communicative limitations or visual limitations as well as physical co-morbidity, that would hinder smooth locomotion and save locomotion during the measurements, will be excluded from participation in this study .

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 23-06-2022

Enrollment: 27

Type: Actual

### Medical products/devices used

Generic name: Bone anchored transtibial prosthesis and LASAR3D

Registration: No

## Ethics review

Approved WMO

Date: 17-05-2022

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-11-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-02-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL78861.091.22