

Percutaneous Osseointegrated Prosthesis (POP) for Above Knee Amputation

Category: Amputation Care

Description: The POP device is a metal implant that is surgically inserted into the femur (the long bone in the thigh), enabling a prosthetic leg to be directly attached to the bone and pass through the skin. Participants will be randomly assigned to a surgery group OR a control group to improve the function of their current prosthesis (with an option to undergo surgery after a year). Everyone will participate in face-to-face assessments periodically at one of five designated research sites for up to 3 years (travel and lodging covered by the study).

Study Duration: 2 years for surgery group participants; up to 3 years for control group participants.

Who can participate?

You may be eligible to participate in this study if you:

- Have a transfemoral (above-the-knee) amputation
- Are least 18 years of age or older
- Have previously worn a socket prosthesis
- Are willing, able, and committed to participating in in-person evaluations for the entire duration
- Agree to comply with study physician instructions and recommendations

Note: This study has additional eligibility requirements. A screening visit will determine if you qualify.

What is Involved?

Time Commitment: Telephone follow-ups and approximately 7-11 face to face assessments over 2-3 years, depending on group assignment.

Participation may include:

- Health screenings and physical exams
- Lab tests (blood, urine, imaging)
- Questionnaires and surveys
- Surgical implantation of investigational device
- Follow-up visits

Compensation: You will not be paid for participating in this study. Travel and lodging required face-to-face study visits will be paid for by the study. A daily allowance will be provided to participants.

Contact: Name: National Call Center (NCC) Phone: 1-833-412-9359

Investigator: John Hermansen, MD

*IRB of Record: VA Central IRB
IRBNET #: 1794608
IRB Approval Date: 1/6/2025*

Version 2: Dated 10/21/2025