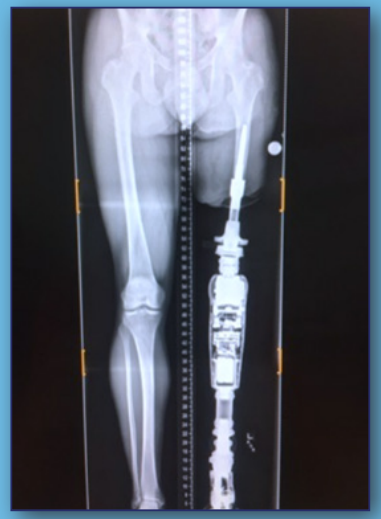
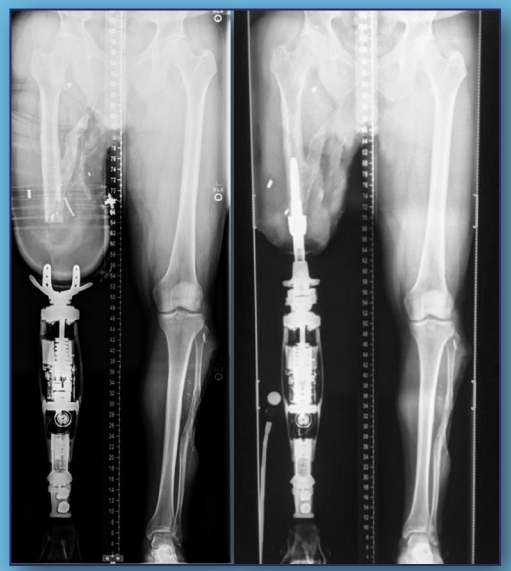




Principal Investigator

Sarina Sinclair, PhD

Contact Information:

Osseointegration Research Team
1-833-412-9359

https://www.vacsp.research.va.gov/CSP-OI-Study/

Participate in VA Research

Do you have an above-knee amputation?

We Need Your Help!

Percutaneous Osseointegrated Prosthesis (POP)

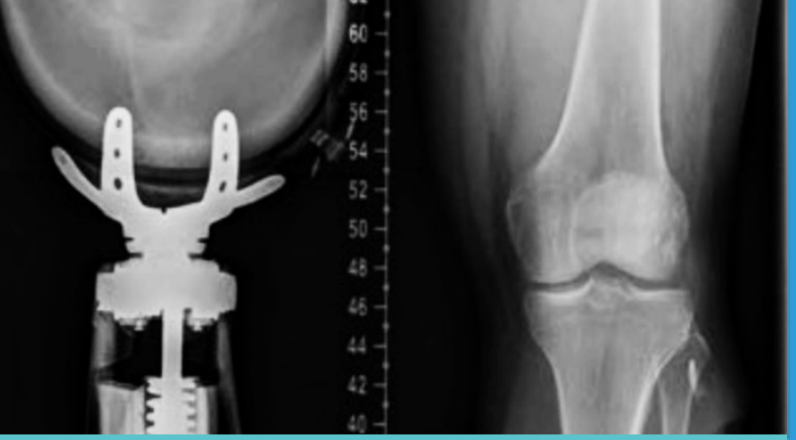
A Clinical Trial

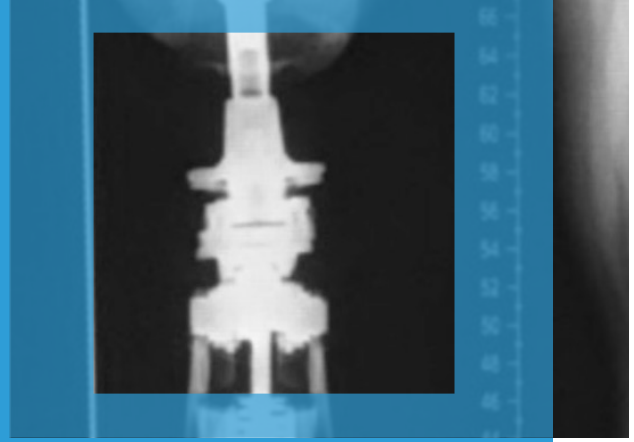
VA | U.S. Department of Veterans Affairs
Veterans Health Administration
Office of Research and Development
Cooperative Studies Program

Version Date: 02/03/2025

VA | U.S. Department of Veterans Affairs
Veterans Health Administration
Office of Research and Development
Cooperative Studies Program

VA Central IRB
Effective Date: February 24, 2025





WHAT IS THE POP DEVICE?

The POP device is a metal implant, like the implants used in hip and knee replacements. It is surgically implanted into the femur (long bone) of the leg allowing a prosthetic leg to be directly attached to the implant and requires two separate surgical procedures.

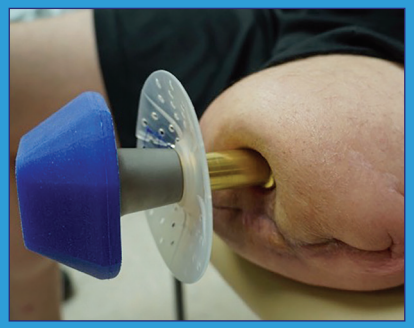
WHAT ARE THE GOALS OF THE POP STUDY?

- To study the safety of a new prosthetic device for Veterans with lower limb amputation
- To determine how effective the POP device is for prosthetic limb function

WHO CAN PARTICIPATE?

Any Veteran who:

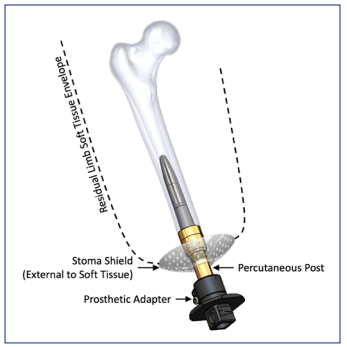
- Has a transfemoral (above-the-knee) amputation
- Is at least 18 years of age or older
- Has previously worn a socket prosthesis
- Is willing, able, and committed to participating in in-person evaluations for the entire duration of the study (~ 2 years)
- Agrees to comply with study physician instructions and recommendations



WHAT IS INVOLVED IF YOU PARTICIPATE?

If you are interested and meet initial crIteria for the study,

- you will be asked to visit a designated VA medical center for further screening
- your consent to participate will be required
- you will be assigned to one of two study groups randomly, like the flip of a coin
  - **POP group**: Will undergo surgery at the designated VA to have the new prosthetic device implanted into their residual limb
  - **SOCKOPT group**: Will continue to wear one's own socket prosthetic and will undergo further evaluation at the designated VA medical center
- you will undergo in-person assessments throughout the year at one of six designated research sites
- you will agree to follow study physician instructions and recommendations
- At month 12, participants will be allowed to switch to the POP group if you were originally assigned the SOCKOPT group



HOW DO YOU ENROLL?

If you are interested in learning more and to find out if you might be eligible, please call 1-833-412-9359.

VA Central IRB
Effective Date: February 24, 2025