OP Solutions

is recruiting subjects for a research study titled

Prosthetic Smart Socket Technology to Improve Patient Interaction, Usability, Comfort, Fit, and Function

PURPOSE The purpose of this study is to determine whether a prosthetic socket that notifies its user via smartphone prompt of excessive distal pressure will improve user socket compliance. Once prompted the user knows to adjust the socket which they are using, potentially decreasing distal pressure, reducing skin and functional problems more effectively than relying upon the usual feedback and standard prosthetic fit protocols and practices.

INCLUSION CRITERIA

1. Unilateral transtibial amputation
2. Must be primary or revision amputation
3. Candidate for intermediate stage socket fitting, not yet fit into their first socket
4. Male or female, of any ethnicity
5. 18-60 yrs. of age (active military age)
6. 100-275 lbs

TIME COMMITMENT Complete participation in the study lasts 120 days. After fitting the new prosthesis there will be 4 data collections following the fitting at 30, 60, 90 and 120 days.

LOCATION The prosthetic clinic where the subject receives normal care.

BENEFITS OF PARTICIPATION There is no cost to participate in this study. Subjects can receive up to $500 for their participation and the benefit of an Alps iForce. The prosthetist will receive the prosthesis at no cost. This includes a Variflex foot, a finished flex interface graphite frame socket, iForce, 2 liners, 2 suspension sleeves, and 12 socks. You will have access to the data for clinical use after the data collection is complete.

IF YOU ARE INTERESTED IN PARTICIPATING Contact us with a prospective subject. We will provide an informed consent document and discuss all the risks and rewards with the subject. Once they have provided informed consent, proceed with fitting into the check socket. We will ship all components and fabricate the socket with the iForce within 7 business days. Once the socket is fit, you will log into the data collection site and proceed with data collection.

If you are a Prosthetist who has a subject interested in participating in this study or more information, please contact:

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