AOPA 2020-2021 COPL Pilot Grant Award Report

After receiving 26 proposals for the 2020-2021 COPL Pilot Grant cycle, 10 studies received very high scores and were recommended by individual reviewers for funding. The COPL Board met on July 7th the discuss the eligible proposals in detail and determine which studies should be funded within the available budget.

As a result of a vibrant and detailed discussion, COPL recommended funding of the following six studies totaling $94,040.

Develop Evidence-Based Clinical Practice Guidelines for Vacuum-Assisted Socket Suspension Systems **for the amount of $6,000; Investigator Sarah R. Chang, PhD**

Prosthetic sockets are a key component in connecting the user's body with the prosthesis. The socket fit is critical for enabling prosthesis users to effectively complete activities of daily living. Fluctuations in residual limb volume affect the fit between the residual limb and the prosthetic socket. Vacuum-assisted socket system (VASS) technology, also known as elevated vacuum, is a form of socket suspension commonly used by prosthesis users to maintain this fit. Prior VASS research has indicated benefits for prosthetic socket fit, residual limb volume management, and outcomes as compared to other suspension systems. Clinical practice guidelines on VASS technology have not been developed based on the latest evidence.

The purpose of this research is to develop clinical practice guidelines for vacuum- assisted socket suspension systems based upon the best available evidence evaluated in a systematic review. Results from the systematic review are used to develop the clinical practice guidelines and also prepared for publication in a peer-reviewed journal. An evidence table to assist clinical case managers at insurance companies will also be developed with the systematic review evidence. The clinical practice guidelines provide clinical recommendation statements to support prosthetists with evidence-based decisions regarding VASS technology for their patients.

Development of a Customizable Outcome Measures Electronic Toolkit (COMET) **for the amount of $15,000; Investigator Natalie Harold, CPO**

This proposal will develop a customizable electronic toolkit of outcome measures in a mobile application, called COMET, for increased utilization and easy implementation in orthotic and prosthetic (O&P) clinics. There has been increasing demand on O&P professionals to implement evidence-based practices, and it appears that most have been convinced of the need to do so. Yet, the majority of clinicians still struggle with how to implement outcome measures into their practices. Why is it so challenging to implement? Is it hard deciding which is the right outcome measure to use? Are they too time-consuming to complete or too difficult to score? Is the information difficult to collect, analyze or interpret? All of these barriers to implementation have been identified by O&P providers as reasons why outcome measures are underutilized.

Outcomes and Products: By creating a standardized process for implementing outcome measures we can enable practitioners to easily select the appropriate measure, administer the test, and use that data immediately to inform clinical decisions, often within the same clinic visit. The COMET mobile application can encourage an evidence-based approach to patient care, increase utilization of outcome measures, improve clinical documentation for insurance reimbursement, all without increased burden on the patient or practitioner.

***Non-invasive method for quantifying progress of healing after transtibial amputation: a pilot study* for the amount of $29,895; Investigator Jonathan D. Day**

Purpose: The purpose of this proposal is to examine relationships between clinical judgement and weekly measures of $TcPO_2$ (mmHg), StO_2 (%), and changes in the speckle pattern over time using Transcutaneous Oxygen Perfusion ($TcPO_2$), Near Infrared Spectroscopy (NIRS) and Laser Speckle Contrast Imaging (LSCI) during first 16 weeks post-transtibial amputation.

Design: A single-center longitudinal observational pilot study. Subjects: Thirty adults with unilateral transtibial amputation will be conveniently sampled from one

medical center. Up to five physicians and 50 prosthetists will be concurrently surveyed. Approach: Aim 1: $TcPO_2$, NIRS and LSCI data from photographed distal residuum of thirty □a□□□c□□a□□□□ healing suture line will be collected weekly over the first 16-weeks post-amputation. Surveyed expert physicians will determine aggregated percentage healing by rating photographed surgical closure. Weekly correlation and multivariable model analyses will determine the best technique(s) to track healing. Aim 2: Participants (patients and clinicians) will be surveyed to determine feasibility and clinical acceptability of best technique(s) to track residuum healing post-transtibial amputation. Expected Results: Results will provide preliminary data on the best technique(s) to monitor healing progression post-amputation, informing future study across postoperative management strategies. Prosthetists can apply this tracking method to expedite prosthetic application and rehabilitation.

***The Effect of Osteoarthritis Bracing on Community Involvement, A Pilot Study* for the amount of $15,000; Investigator Erik Hansen, MD**

The purpose of this study is to investigate how an unloader knee orthosis (KO) influences community activity and quality of life for people with symptomatic unilateral compartment knee osteoarthritis (OA). We hypothesize that activity levels will increase and quality of life will improve with the use of an unloader KO. The current scientific evidence on the benefits of unloader KOs shows how they impact pain levels, static alignment of the knee joint, in-clinic functional testing, and patient reported outcomes. There is a dearth in the literature focusing on activity levels outside of the controlled clinic or research lab environments. Real-world data is necessary to ensure clinical assessments correlate to activities in patients' daily lives. This

research project will provide clearer quantitative measures for the effect of unloader KOs on community activity levels using the Actigraph activity monitor to measure daily activity as well as validated outcome measures including the Visual Analog Scale for Pain, Knee Injury and Osteoarthritis Outcome Score, 6 Minute Walk Test, Stair Climb Test, and 30 Second Chair Stand Test. Our goal is to demonstrate the positive effects of unloader KOs on quality of life and activity level in the community.

Describe the population receiving orthotic/prosthetic services using telehealth, and their experience and satisfaction with those services **for the amount of $14,028; Investigator Michael Dillon, PhD**

Background*:* It will be difficult for the orthotic/prosthetic workforce to meet rising demands for clinical services given the growing, workforce shortage and a concentration of clinical services in metropolitan and large regional centres.

As a result of the COVID-19 pandemic, there is an opportunity to learn more about the use of telehealth services for orthotics/prosthetics, in particular, consumer experience and satisfaction.

Aim*:* Describe the population receiving orthotic/prosthetic services using telehealth, and their experience and satisfaction with those services.

Method*:* Study design: Mixed-methods. A non-probability sample of orthotic/prosthetic consumers who have just completed a telehealth consultation will be invited to complete an online survey about their demographics, health condition, and the type of clinical service. *Orthotic Prosthetic Users Survey - Satisfaction with Services module (OPUS-SSM)* and *Telehealth Satisfaction Scale (TeSS)* will be used to quantify satisfaction. Semi- structured interviews will be undertaken with a purposively sampled group of consumers to explore their experience with telehealth for orthotic/prosthetic services.

Results*:* Data describing participant demographics, health condition, and type of clinical service will be summarised. Data from the OPUS-SSM and TeSS will be summed and transformed as appropriate. Audio recorded interviews will be transcribed verbatim and data analysed using thematic inductive analysis.

Prosthetic, functional, and clinical outcomes among female amputees: A scoping project o include a systematic review and 10-year retrospective record review of female Veterans with limb loss **for the amount of $14,117; Investigator Rebecca M. Miro, PhD, CP, MBA, CRA**

Despite known anatomic, anthropometric, and physiologic differences between males and females, and the considerable existing female amputee demographic, research specific to

females with limb loss remains limited. The purpose of this project is to: (1) evaluate the quality, quantity, and consistency of existing available female amputee literature by conducting a systematic review of the literature; and (2) analyze existing retrospective clinical hospital data, using a cross sectional design and analysis to produce a comparative and descriptive summary of female Veteran amputee characteristics, relative to their male counterparts, and between female subset groups. The aim is to begin to fill knowledge gaps, develop strategic objectives for future research, knowledge translation and clinical implementation efforts related to female amputees and potentially related secondary comorbidities, functional consequences and other factors. Dedicated, focused research will begin to provide an evidentiary basis to inform truly patient-centered care which could lead to more gender-specific component design, more favorable prosthetic fit outcomes, and potentially increased satisfaction and quality of life.