REQUEST FOR PILOT GRANT PROPOSALS IN NINE POTENTIAL AREAS OF ORTHOTIC AND PROSTHETIC (O&P) RESEARCH

(This form should be used as the first page of your application.)

The Center has identified nine areas for potential submission of proposals.

Areas for submission are:

a. Microprocessor Knee – Stumble Recovery Benefit for Non-Variable Cadence Ambulators, and Does Restricted Access for K-1 and K-2 to Hydraulic Controls Adversely Impact Patient Safety?
b. TLSO/LSO: Utilization and comparative effectiveness of TLSO/LSO. Pre and post operative use. Efficacy of custom vs OTS relating to clinical outcome, analyses of providers credential.
c. Socket Interface: Methods for Measuring Proper Socket Fit and Alignment.
d. Vacuum-Assisted Socket Suspension Systems
e. AFO/KAFO: Utilization and comparative effectiveness of custom vs OTS AFOs and KAFOs. Investigation and analyses of patients who receive custom orthosis subsequent to OTS AFO fitting.
f. L0631 bracing—Performance and Outcomes Data That Differentiate Patient Results from What Could be Achieved with an OTS Orthosis that is Provided without any Fitting, Trimming or Clinical Care?
g. Quality of Life, Wellness, Patient Satisfaction and/or Outcomes Studies of Patients Who Have Received O&P Care vs. Those Who Have Not.
h. Outcomes Measures, Evaluation and Quality of Life Metrics Related to Orthotic Management (Note: Submissions Should be Pathology and/or Condition Related,.e.g. Stroke, Cerebral Palsy, Multiple Sclerosis, Polio, OA)
(i.) Open Topics – Beyond the Above Priorities, Top Quality Clinical O&P Research Topics Considered

AOPA reserves the right not to select for funding any of the proposals received. While funding is available, decisions will be made on the merits of the proposals.

TITLE OF PROJECT: Efficacy of a Functional Resistance Device for Tri-planar Control of the Foot and Ankle: A Pilot Study

INVESTIGATORS:

Name(s): (list Principal investigator on line 1)
1. Kimberly Reed CO, MBA
2. Cheryl Barkey BS
3. Beth Toth PT
4. Janice Cox PTA

FUNDS REQUESTED: $15,000

NAME OF RESPONSIBLE INVESTIGATOR: Kimberly Reed CO, MBA
(to be completed if Principal Investigator is a trainee)

IRB STATUS:

Approved	Pending	Approval Not Required

CONFLICT OF INTEREST:

None	Potential	Yes

As the principal (or responsible investigator, if applicable), I agree that if this grant proposal is funded, I will acknowledge the *AOPA*'s support in all publications that arise from the research. I also will submit to AOPA a final report within 12 months after the date of the award.

Signature of Principal Investigator: Kimberly Reed CO, MBA

Signature of Responsible Investigator (required if Principal Investigator is a trainee):

_____

Institution: MEDICAL DEVICE CONSULTING
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2015

Request for Proposal: Bid Number EBP-043015

Efficacy of a Functional Resistance Device for Tri-planar Control of the Foot and Ankle: A Pilot Study

A PROPOSAL TO: ***Evaluate the efficacy of a functional resistance device for tri-planar control of the foot and ankle in ambulatory patients with a lack of dynamic ankle and forefoot rocker.***

Date: March 30, 2015

Principle Investigators: Kimberly Reed CO, MBA
Cheryl Barkey BS
Beth Toth PT
Janice Cox PTA

A commercial party having a direct financial interest in the results of the research supporting this article has conferred or will confer a financial benefit on the author or one or more of the authors. Reed and Barkey are employees of Medical Device Consulting, which manufactures the functional resistance device; Reed and Barkey receive sales proceeds from the purchase of the device. A Design Patent Application has been filed with The United States Patent and Trademark Office and the device is Patent Pending 62/125,553.

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Efficacy of a Functional Resistance Device for Tri-planar Control of the Foot and Ankle: A Pilot Study

SPECIFIC AIMS

Investigating the relationship between a functional resistance system (The Gait Balancer) and Zero Drop Shoes. The Gait Balancer affects patients with joint replacements in the long term, after all rehabilitation measures have been exhausted. We theorize that continued use of The Gait Balancer re-establishing Ankle Rocker mechanics, will lead to less chance of knee revisions or subsequent contralateral knee or hip replacements, due simply to the fact that The Gait Balancer is re-engaging the hip extensor mechanism and decreasing a quadriceps dependent gait.

Abstract

Evaluate several mechanisms to explain the improvement of quantitative gait performance and energy efficiency between The Gait Balancer-off and The Gait Balancer-on evaluations in ambulatory patients with a lack of dynamic ankle and forefoot rockers across a spectrum of diagnoses. Obtain objective gait data regarding the biomechanical quality of gait while using The Gait Balancer, including all gait parameters within the OptoGait Technology system, specifically Phase Coordination Index (PCI) on the affected and unaffected side with The Gait Balancer use.

We hypothesize that improvement in gait pattern is likely to reduce musculoskeletal stress on the joints and to improve the ease of walking as The Gait Balancer increases the energetic efficiency of gait through proper foot alignment, mobility and function in stance phase.

We can also hypothesize that the improvement in lower-extremity strength (tested without The Gait Balancer at all visits), will most likely contribute to the improvement in gait speed and endurance through the functional resistance provided by the device.

Gait tests will be performed on our OptoGait Technology, single meter system. For this reason, one may question the real effectiveness of The Gait Balancer on the ability to perform mobility-related ADLs, but we plan to address dynamic ambulation improvements through use of the functional resistance device.

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BACKGROUND

We have spent the last two years specializing in home health care for seniors, post-op joint replacements, post-op spinal surgeries. We have made a significant impact in analyzing and changing the way patients are walking. Enhancing walking safety and working to prevent falls by changing footwear and utilizing our Patent Pending Gait Balancer. Low cost, innovative analysis and solutions helping patients walk with better balance, stability and confidence. We work with physical and occupational therapists and assistants to enhance their therapy initiatives by giving the patient a stable base of support through footwear and a if required, ankle devices to improve ankle range of motion and forefoot propulsion.

Research Plan

Fourteen week pre- and post-intervention uncontrolled trial.

Setting

Private orthotic center with OptoGait Technology.

Participants

Ambulatory patients with unilateral (or unilateral predominant) lack of dynamic ankle and forefoot rocker.

Intervention

Subjects will be fit with the functional resistance device (The Gait Balancer) on the weaker side, trained to use the device, and given a wear schedule. Subjects will complete 10 baseline evaluations and follow-up testing at 2, 4, 6, 8, 10 and 12 weeks.

Main Outcome Measures

Lower-extremity manual muscle testing, pain, and gait performance (OptoGait Technology). Subject satisfaction will be evaluated by using a 10-item custom questionnaire.

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Budget

We request a total of **$15,000** to undertake the study described above. The majority of funds will go towards personnel expenses for the essential but time-consuming activities of conducting and analyzing full biomechanical and gait evaluations. This includes compensation for sub-contractors to conduct the biomechanical and gait evaluations, a clinical release for the Principal Investigator, Co-Principle Investigator, and support for a Physical Therapist and Physical Therapist Assistant. The Principal Investigator will be responsible for the successful execution of the project. The Principle Investigator and the Co-Principle Investigator will conduct the biomechanical and gait evaluations and, along with the Physical Therapist and Physical Therapist Assistant, code and analyze the OptoGait data generated from these biomechanical and gait evaluations and work on the publications that this research will generate. The Principle Investigator and Co-Principle Investigator will also provide intensive administrative and research support for the project. The total *personnel* costs are estimated to be *$12,000* . The estimated *direct expenses* for the project are *$1,400* and include the costs of transcription and supplies. In addition to the above, we also request a 10% overhead to cover facilities and other support provided by our facility at *$1,600.*

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