



THE AMERICAN ORTHOTIC & PROSTHETIC ASSOCIATION

Title: Orthotic Treatment for Stroke Patients: Addressing Prospects for Improved Gait Mechanics, Balance, Increased Aerobic Activity/Mobility, Stability, Reduction in Falls and Prospects for Lower Recurrence Rate with Use of Ankle-Foot Orthoses (AFOs)

Research Objectives

The purpose of this funding opportunity is to encourage clinical research proposals as to treatment of post-stroke patients that can assess the role of orthotic bracing (specifically ankle-foot orthoses, potentially by comparison with other therapies) in multi-faceted patient mobility outcomes, likelihood of fall injuries and reduced stroke recurrence.

Overview and Background

Ankle Foot Orthoses

Economics and patient-reported quality of life outcomes have driven changes in what is delivered to patients (Medicare beneficiaries and others) and how it is delivered. Some economic data point to the need for prospective clinical and comparative effectiveness studies relating to ankle-foot orthoses in the treatment of post-stroke patients.

We know that, across a range of 20+ etiologies of predisposing conditions, the cost of providing Medicare patients with an ankle-foot orthosis comprises less than roughly 1% of the total average Medicare payments for a beneficiary's episode of care, which on average costs in the range of \$170,000. This is 0.3% of the total episode expenditures of \$230,000 for Medicare patients with acute cerebrovascular disease. Payers largely focus on patient recorded satisfaction and quality of life. This is obviously important, but what if there were markers for payment that could relate post-stroke mobility to likelihood of complications, such as injurious falls, and even more importantly, stroke recurrence. Are these appropriate measures? Appropriate outcome measures might relate to restoration of function, gait mechanics, balance, increased aerobic activity/mobility, stability, and as previously noted, reduction in injurious falls and less prospects for stroke recurrence. Prospective clinical, or comparative effectiveness studies could help us determine whether some of these conclusions are either possible or accurate.

Research Objectives and Scope

This RFP invites proposals for clinical and/or comparative effectiveness studies relating to patient treatment post stroke, treatment by orthopedic bracing, i.e. ankle-foot orthoses and resulting patient outcomes. Key questions that might be addressed by such a study might include the following:

- Is orthotic intervention with an AFO associated with increased activity compared to other post-stroke patients who do not receive treatment with an AFO?

- Is orthotic intervention with an AFO associated with cost savings and economic benefit and quality of life improvements compared to other post-stroke patients who do not receive treatment with an AFO?
- A literature search for existing studies that have looked at hospital re-admissions or falls, and their costs, as relates to AFO intervention might mark a potential pathway for the proposed study to measure and help define the important relationship, if there is any, between AFO treatment, stroke recurrence falls, and hospital re-admissions.
- There is anecdotal evidence that walking speed, gait and number of steps per day should be recognized as the “sixth vital sign.” The proposed study should at least take cognizance of this literature as part of an assessment, hopefully by the measurement of clinical factors, to related mobility with improved patient outcomes, and whether orthotic intervention results in relative increase in activity and mobility, compared to other post-stroke patients who do not receive treatment with an AFO?
- A structure for the study that would assess clinically: (a) does AFO intervention have a positive effect on patient outcome; (b) is AFO use associated with decreased fall risk; and (c) is AFO use associated with increased mobility, and is improved mobility associated with reduced likelihood for stroke recurrence.
- What are patient outcome measures relating to restoration of function with AFO use? A review of the Medicare claims data for AFO usage across a range of conditions predisposing to lower limb orthotic/AFO intervention have identified the following claims-based factors. As compared to their non-treated counterparts, study group patients who receive lower extremity orthoses had the following outcomes:
 - fewer falls and fractures
 - fewer emergency room admissions
 - fewer inpatient admissions with shorter lengths of stay
 - higher home-based care
 - lower mortality rate
 - lower Part D drug spending
 - more rehabilitation
 - Medicare 18-month episode payments were \$1,939 (or 8 percent) less for the study group’s patients who receive lower extremity orthotic care than the comparison group

Study Subjects

Suggested Protocol Considerations—Investigators are encouraged to consider the following factors; though these are not requirements, they may enhance value:

Literature Review

A comprehensive review of the literature is recommended.

Award Information

This AOPA RFP solicits, and will consider high-quality, cost-efficient proposals for a single project with a one-time award up to \$75,000 (total of **all** costs). The study must be completed within six months of the date of the award, pending manuscript submission for publication. Funding of the requested proposals is at the discretion of AOPA, which reserves the right not to fund any proposals submitted in response to this RFP. Results should be suitable for submission for publication in peer-reviewed literature, to achieve robust results within a realistic budgetary structure.

Eligibility

Responsive grant applications must involve a formal collaboration with a healthcare provider or other healthcare organization serving a lower limb limitation population. Note that physicians, prosthetists, orthotists, occupational therapists, physical therapists, engineers, and others (e.g. non-profits, and educational institutions) with suitable experience in physical or biological sciences (ideally, applications from those in engineering and science fields will include at least one investigator who has attained a Ph.D. in the appropriate discipline), as well as those in training (interns, residents, fellows) are eligible to apply provided that the work is conducted under the preceptorship of a more senior or experienced investigator (as determined by AOPA). Successful applicants must agree to acknowledge AOPA support in any publications that result from the research, and to submit a final report within 6 months of receipt of funding. The awardees are required to provide a midterm report on the progress of the research.

Selection Criteria

Awardees will be selected based on feasibility, scientific and clinical significance, originality, and anticipated contribution of the research to clinical practice. Applications will also be evaluated on the availability of adequate resources, including personnel and facilities.

Review Process

A Research Committee, or other body constituted or designated by AOPA will review the grant proposals.

Deadline

[Submit your proposal online](#) by April 30, 2018. Successful applicants will be notified by June 20, 2018, with availability of this support to begin approximately July 1, 2018 contingent on necessary IRB, and related documentation. For research involving human subjects, Institutional Review Board (“IRB”) approval must be obtained prior to onset of research. AOPA reserves the right to consider timeline extensions related to IRB review. See A. 4.

Application Instructions

ASSEMBLE THE APPLICATION MATERIALS IN THE ORDER LISTED BELOW. BEGIN WITH ITEM A (TITLE PAGE), AND END WITH ITEM I (APPENDICES).

A. Title Page

1. Use the attached form as a cover page. Type the responses.
2. List the Principal Investigator and all Co-Investigators, including credentials. List any collaborating healthcare providers or organizations.
3. In the case in which a trainee is listed as the Principal Investigator, indicate the name of the responsible investigator. This individual agrees to serve as the trainee’s preceptor and to be responsible for scientific and administrative oversight of the project.
4. Institutional Review Board status — Include the IRB approval letter in the application (see below). If IRB approval is pending at the time of submission and the grant proposal is subsequently approved for funding, funds will not be released until the IRB approval letter is received by AOPA. If the proposal is requesting funds for reimbursement of human subjects, a copy of the IRB approved consent form is required prior to funding as well.
5. Conflict of interest — A potential conflict of interest exists when the research involves a device from which any investigator(s) or a company may benefit. A conflict of interest exists if any investigator holds or has submitted a patent on a device or is a major shareholder in a company involved in the research. If applicable, attach a detailed letter of explanation (see below). It is the responsibility of the Principal Investigator to inform

AOPA of any changes to conflicts during the conduct of the study. AOPA reserves the right to evaluate said conflicts to determine appropriateness of PI and/or affected research staff with apparent or perceived conflicts.

B. Abstract

Put on a separate page immediately following the title page. Limit to 200 words. Use the abstract to summarize the proposed research.

C. Research Grant Proposal

Begin on a separate page immediately following the abstract. Limit to 8 pages (excluding references and budget). Use 1" margins with font size no smaller than 11 point. ASSEMBLE THE GRANT PROPOSAL AS DIRECTED BELOW, IN THE ORDER LISTED BELOW. FAILURE TO ADHERE TO THESE INSTRUCTIONS WILL CAUSE THE GRANT APPLICATION TO BE RETURNED UNREVIEWED.

Specific Aims — Provide a clear description of the study objectives.

Background/Significance — State how the proposed work bears on prior work and indicate how it will extend the boundaries of current knowledge. Include a current literature review relating to the rationale for the proposed research.

Research Plan — Give the details of the research plan, including the inclusion/exclusion criteria for enrollment, scientific methods to be used, examples of data that are to be collected, and how these data will be analyzed. Provide detailed sample size estimates and action plan on obtaining the appropriate sample size

References — Begin on a separate page. Be judicious in the use of references.

Budget — Begin on a separate page. Indicate how the funds will be allocated and justify each budget item, including facility fees if funds are requested for this purpose. Salary support will be provided for other personnel (research nurse, computer programmer) if adequately justified. Support will be provided for supplies and equipment. In general, major equipment acquisitions are not supported. Travel and manuscript preparation costs are not supported. Indirect costs (i.e., university overhead) are limited so as to constitute no more than 10% of the total budget/requested grant amount. Include facility overhead and fringe rates (if applicable).

D. Other Support

For each investigator, list the title, funding agency, total direct costs, dates (including expected dates of notification) of all active awards and pending funding. Use NIH format (available at <http://grants.nih.gov/grants/oer.htm>). Indicate whether any scientific or budgetary overlap exists, and if so, indicate how this will be addressed.

E. IRB Approval Letter

Include (see above).

F. Conflict of Interest Statement

Include, if applicable (see above).

G. Curriculum Vitae

Provide for principal investigator, and co-investigators. Use NIH format and adhere to the NIH 2-page limit.

H. Supporting Letters

Provide letters from collaborators, such as those supplying patient referrals, if applicable. Applications in which a physician in training, or individual who a resident in a prosthetics training program serves as Principal Investigator must be accompanied by a supporting letter from the individual's program director.

I. Appendices

Use (if needed) for data collection forms. Do not use to expand Section C (above).

J. Facilities and Resources

Your proposal should document how the facilities at the host institution match with the needs of the project, unique resources and talents that could be deployed in support of the project, including any assurance of how dedicated time would be allocated to the investigator(s) in the event that the application is accepted.

Closing Comments and Caveats

Finally, this RFP includes many suggestions, recommendations and listings to help assure that applicants have a clear understanding of the target of this project. Surely there are other good and responsive ideas which are not specifically referred to in this RFP.

[Submit your proposal online](#) by April 30, 2018

American Orthotic & Prosthetic Association
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Suite 200
Alexandria, VA 22314

Title: Orthotic Treatment for Stroke Patients: Addressing Prospects for Improved Gait Mechanics, Balance, Increased Aerobic Activity/Mobility, Stability, Reduction in Falls and Prospects for Lower Recurrence Rate with Use of Ankle-Foot Orthoses (AFOs)

The American Orthotic & Prosthetic Association is interested in promoting research focused on improving knowledge about ankle-foot orthotic bracing, specifically to encourage clinical research proposals as to treatment of post-stroke patients that can assess the role of orthotic bracing (specifically ankle-foot orthoses, potentially in comparison to other therapies) in multi-faceted patient mobility outcomes and likelihood of fall injuries and reduced stroke recurrence.

TITLE OF PROJECT: _____

INVESTIGATORS:

Name(s): (list Principal investigator on line 1)				
1.				
2.				
3.				
4.				

FUNDS REQUESTED: _____

NAME OF RESPONSIBLE INVESTIGATOR: _____
 (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 the AOPA Research Committee, or other entity so designated, a final report 18 months after the receipt of funding.

Signature of Principal Investigator: _____

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

Institution: _____

Address: _____

Address: _____

City: _____ State: _____ Zip: _____ Country: _____

Phone: _____ Fax: _____

E-mail: _____