

GAP Proposal: Splinting for Treatment of Peripheral Artery Disease

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The Problem

Peripheral arterial disease (PAD) affects 8.5 million Americans and over 200 million worldwide. PAD prevalence increases with age, affecting 12-30% of patients age 65 or older. Patients with peripheral arterial disease (PAD) often have walking impairment due to insufficient oxygen supply to skeletal muscle, most often in the lower leg. Although walking programs are safe and may improve symptoms, they are often difficult to adhere to over the long-term, especially in elderly patients in whom frailty, arthritis, and other symptoms limit patient compliance. There is an unmet need to provide relief from symptoms and improve mobility and quality of life in PAD patients, even if walking has become problematic or not possible.

A program of supervised exercise training is recommended as an initial treatment. However, participation rates are low in elderly PAD patients, and as many as 1/3 of these older patients drop out of exercise programs because they are difficult or painful to maintain. This lack of exercise allows progression of PAD, leading to surgery, amputation, or death. In the US and Europe, PAD is responsible for 240,000 amputations each year. As the American population ages, PAD rates are climbing.

The Potential Solution

Our initial clinical study demonstrates improved patient symptoms when a therapeutic splint is used at home by the patient. The splint holds the foot at a 15 degree angle relative to the leg, and is worn for 30 minutes a day each day for a 4 week period. This short period of stress induces microchanges and growth within the muscle tissue. Our study links this passive stretching to measured improvements in blood vessel formation and improvement of pain levels during walking. Improved walking leads to better outcomes in many other aspects of health.

Our Novel Technology

Our proposed splinting device holds the foot in the desired position at 15 degrees relative to the calf. This angle may be pre-set and the flexion accomplished after the brace is put on. The splint is low cost, safe and is designed for at-home self-application which renders it suitable for a broad range of patients with PAD. Currently, no brace exists for automated control of ankle flexion. There are also no static stretching devices indicated for the treatment of PAD. Our splint is strapped to the leg and a programmed angle setting to move the foot to the 15 degrees of flexion of the foot relative to the calf. The patient can use the splint at home from their bed or couch, or within a hospital or specialized care facility.

The convenience, effectiveness, safety and low cost of this simple intervention render it attractive for commercialization.

The Market

Our results and the existing body of research suggest that the splint therapy would be inexpensive to implement and broadly applicable to this large, growing market. Patients' greater capacity for exercise leads to an overall improvement in health and life for elderly or frail patients in many cases. Given these far-reaching benefits and minimal incremental cost/expertise required to implement our procedure, we believe that following further clinical trials/research, this intervention and device will ultimately be widely adopted by physicians, benefit patients, and be lucrative for FSU – below, we provide a high-level summary of the facts upon which we predicate that assertion.

The US Center for Medicare and Medicaid Services reports that approximately 8.5 million Americans above the age of 40 are affected by PAD – this is after revascularization or false-negative results with ABI, which is in-line with estimates of prevalence of PAD based on nationwide claims data from large employers' health plans and from Medicare and Medicaid programs between 2003 and 2008. Of this 8.5 million, 60% experience leg pain as a symptom, leaving a population of patients 'at risk' of non-compliance with a walking program at approximately 5.1 million. Private practitioners estimate that 30% of elderly PAD patients fail to adhere to their prescribed walking regimens specifically because of this leg pain. This has also been borne out in multiple academic studies¹, where the rate of program drop-out due to leg pain has been as high as 20%, irregardless of age. We conservatively estimate that 2 million patients fail to complete their prescribed walking programs due to the physical discomfort accompanying walking, etc. These rates are similar for both at-home and supervised populations, indicating that the level of pain remains a robust predictor of walking program success.

A \$100 marginal expenditure per patient² associated with incorporating our splint and other modifications could significantly reduce the rate of program drop-out for a population as great as 1 million. It would also extend the potential duration of patient walking during their exercise therapy³ and generally improve efficacy of PAD treatment programs for the broader population of 8.5 million. Given that this a fraction of the cost necessary for these programs, it seems likely that private insurers and government providers of care would be likely to both cover and recommend (if not require) patients utilize such a splint as a part of their treatment program – as such, we believe the potential addressable market could generate as much as \$50 million per year in the US alone.

¹ <https://www.cardiosmart.org/News-and-Events/2011/02/Exercise-for-PAD-Trying-it-at-Home>

² The retail cost of the splint can be seen [here](#).

³ A [meta-analysis](#) conducted by Lane et al concluded that “The optimal exercise program for improving claudication pain distances in patients with peripheral arterial disease uses intermittent walking to near-maximal pain during a program of at least 6 months”

Potential Commercialization Partners

We have contacted a number of physicians who enthusiastically support this endeavor, as evidenced by the letters included in the Supporting Letters of Interest section of this proposal. As key opinion leaders, their endorsement is a critical component to establishing commercialization partners within either the vascular intervention market or the orthopedic brace market.

We believe companies currently offering device-oriented PAD treatments would be interested, such as Medtronic, Johnson and Johnson, and ProMedica. Additionally, we expect to attract attention from traditional orthopedic brace companies because our splint design would allow access to a huge, entirely new cardiovascular market. These companies include DonJoy Aircast, Breg, Hanger, and FLA Orthopedics, among others.

Proposed Use of GAP Funding

The GAP funding would be used to pay for the hardware, software and research labor needed to develop a working prototype of the therapeutic splint.

The Phase I design incorporates best practices in patient interactions based on our previous study. It is simple and accommodates a large range of patient body types. Materials are inexpensive. ABS plastic in an additive manufacturing model will allow rapid prototyping of the device geometry while other materials are considered for strength and functionality. Hinges present in the heel area of the splint allow various dorsiflexion angles to be measured and held. Phase II allows feedback to the design process by allowing patients to try and give feedback on the device. The Phase III model involves automation of the dorsiflexion angle. With the push of a button on the brace or a remote, the angle is adjusted via a motor. Other features may include bracing behind the knee to ensure the limb is straightened during the treatment period.

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Professional Biography

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November 9, 2017

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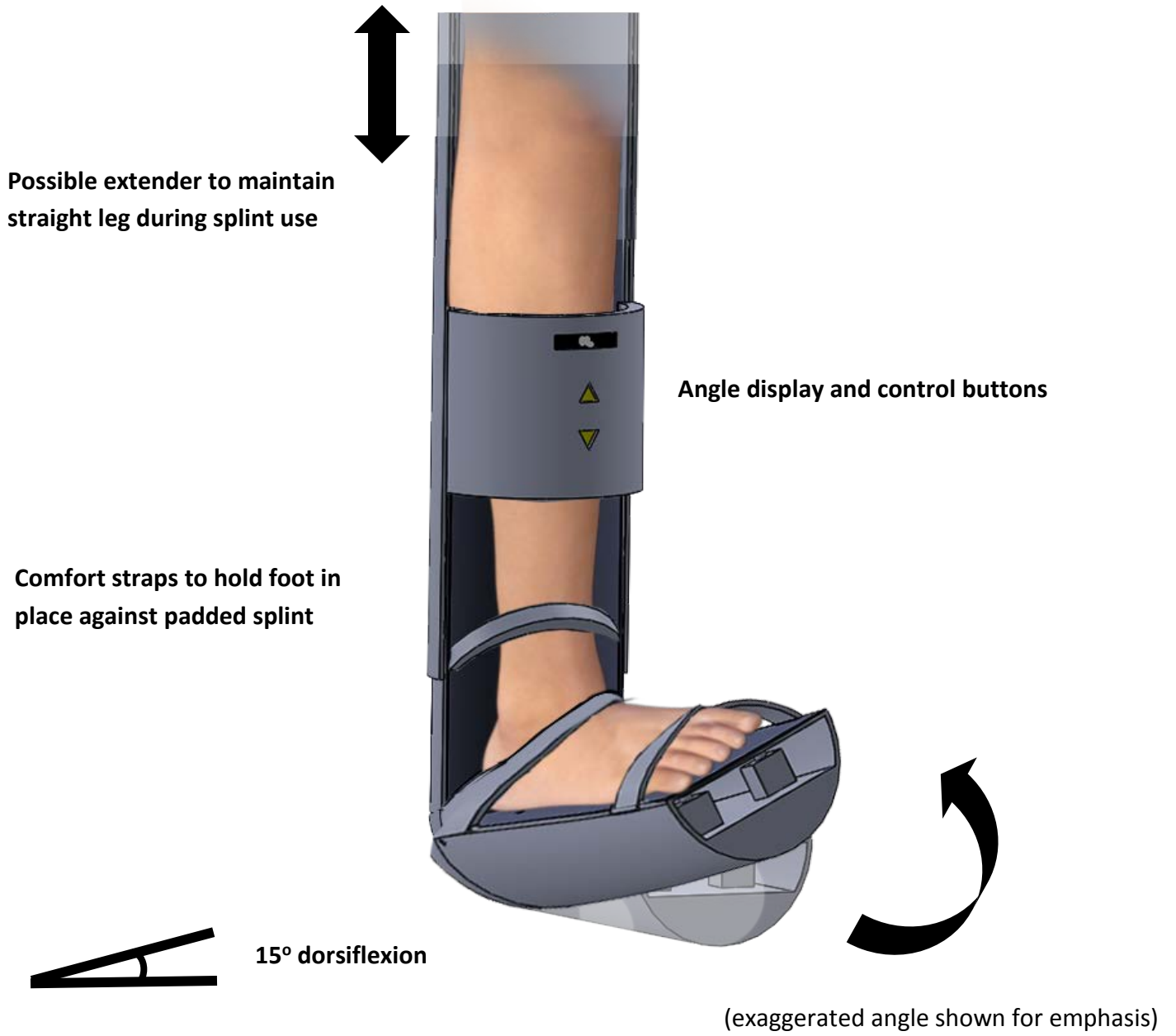
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Diagrams and Device Drawings

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Cost and Activities Plan

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Phased Implementation Plan

The GAP funding would be used to pay for the hardware, software and research labor needed to develop a working prototype of the therapeutic splint.

Phase I. Development of manual clinical therapeutic splint prototype

Objective: The Phase I design incorporates best practices in patient interactions based on our previous study. It is simple and accommodates a large range of patient body types. Materials are inexpensive. ABS plastic in an additive manufacturing model will allow rapid prototyping of the device. Hinges present in the heel area of the splint allow various dorsiflexion angles to be measured and held.

Timetable: January 5, 2018 – March 17, 2018

Required funding: \$8,160

Failure point: Ability of the splint to withstand stresses of 15 degrees dorsiflexion of the foot.

If successful, proceed to Phases II and III.

Phase II. Therapeutic splint use-case tests.

Objective: “Customer” survey and use-case tests to refine splint design.

Timetable: March 17, 2018 – May 15, 2018

Required funding: \$2,280

Failure point: N/A

The design feedback from Phase II should be incorporated as design changes to Phase III.

Phase III. Development of automated therapeutic splint.

Objective: This model involves automation of the dorsiflexion angle to allow the physician to prescribe a value or series of values over the treatment period. With the push of a button on the brace or a remote, the angle is adjusted via a motor. Other features may include bracing behind the knee to ensure the limb is straightened during the treatment period.

Timetable: March 17, 2018 – December 31, 2018

Required funding: \$26,240

Failure point: Splint should vary the angle of the splint to a set value and withstand stresses due to up to 15 degrees dorsiflexion of the foot.

If successful, move to find manufacturing partner.

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Supporting Letters of Interest

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