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Original Research

Considerations for Implementation of an Ankle-Foot Orthosis to Improve Mobility in Peripheral Artery Disease



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KEYWORDS

Foot orthosis;
Patient reported
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Abstract Objective: To explore the perceptions of wearing an ankle-foot orthosis (AFO) in patients with peripheral artery disease (PAD) who did and did not adopt the AFO intervention. This follows a clinical trial of the effectiveness of an AFO in improving walking distances for patients with PAD-related claudication.

Design: A randomized crossover trial of standard of care and an AFO for 3 months. Semistructured interviews were conducted 1.5 months into the AFO intervention to understand acceptability, demand, implementation, and practicality. Data were analyzed using a summative content analysis approach.

Setting: Vascular surgery clinic and biomechanics research laboratory.

Participants: Patients (N=15; male, 100%; age, 71.9±6.7y; body mass index [calculated as weight in kilograms divided by height in meters squared], 29.0±5.5; ankle brachial index: AFO intervention withdrawal, 0.543; AFO intervention completion, 0.740) with claudication completed the study, and 6 withdrew prior to intervention completion.

Interventions: A certified orthotist fit participants with an AFO that was worn for 3 months.

Main Outcome Measures: Qualitative analysis of the semistructured interviews.

Results: Key differences were reported between AFO intervention completion and AFO intervention withdrawal. Six of 14 of AFO intervention completion participants described their

List of abbreviations: AFO, ankle-foot orthosis; PAD, peripheral artery disease.

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initial reactions to the AFO as negative vs 3 of 6 AFO intervention withdrawal participants. Only 5 of 15 AFO intervention completion participants reported minimal use of the AFO compared with 5 of 6 AFO intervention withdrawal participants. The AFO intervention withdrawal group reported higher levels of physical discomfort with the use of the AFO (4/6 vs 7/15) and preexisting health issues becoming a barrier to the use of the AFO (3/6 vs 5/15). Positive aspects reported included ease in standing and walking for AFO intervention withdrawal (4/6) and AFO intervention completion groups (13/15) as well as walking straighter and longer with less pain for AFO intervention withdrawal (3/6) and AFO intervention completion groups (9/15). *Conclusions:* Patients withdrawing prior to completion of AFO intervention tended to have more negative perceptions, more comorbidities, and more physical discomfort than those completing the intervention. Both groups reported positive aspects of the AFO. Implementation studies are needed to address barriers to AFO adoption.

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Lower extremity peripheral artery disease (PAD) is a manifestation of systemic atherosclerosis, characterized by atherosclerotic blockages of the arteries supplying the legs.¹ Claudication, or pain in the legs precipitated by activity such as walking, is the most common symptom of PAD. Patients with PAD experience reduced mobility, reduced physical functioning, poor health outcomes, and increased risk of falls. Research in our laboratory has documented significant deficits in the ankle plantar flexors to generate normal torque and power during walking in patients with PAD.² Further, affected legs demonstrate a change in muscle physiology that prevents normal muscle function.^{2,3} Supervised exercise therapy is deemed to provide lower extremity functional benefits and increases the distances these patients can walk.^{4,5} Therefore, incorporating a device to support an active lifestyle pattern that prolongs disease progression appears to be desirable and beneficial.^{4,5}

An ankle-foot orthosis (AFO) is an orthotic device indicated for individuals with muscle weakness. Carbon-composite AFOs can offset ankle plantar flexor torque and power and decrease blood flow demand and muscular stress during walking.⁵ The springlike properties of carbon composite AFOs allow energy storage at weight acceptance and energy return during push off. The notion is that the AFO immediately improves walking performance by substituting stored energy for required muscle force. Our pilot work, along with another recent study, has shown that walking with a carbon-composite AFO delays claudication onset by 30% and improves peak walking distance 35% (peak walking distance) in patients with PAD, as much as 6 months of pharmacotherapy.^{6,7} However, for the AFO to be an effective intervention, it must be widely adopted by patients with PAD. Our initial 3-month AFO intervention included patient interviews at 1.5 and 3 months. Six of 21 participants decided prior to the 1.5-month interview that they did not want to continue wearing the AFO. Our goal in this qualitative study is to assess the unique patient perceptions regarding AFO use, particularly to determine factors that contributed to patients completing the AFO study vs withdrawing early from the study.

Methods

Institutional review board approval was obtained from the affiliated institutions. All patients gave informed consent before enrollment. Patients with PAD (n=21) were recruited from an established vascular surgery clinic and consented to wear an AFO for 3 months. A certified orthotist fit each participant with one of the 2 carbon-fiber AFOs^{a,b} after the clinical evaluation. These AFOs were chosen based on the stiffness characteristics of the strut. The participants were assessed for early (prior to 1.5-mo assessment) withdrawal and completion of the intervention.

Study participants

At entry into the study, all participants (1) were able to give written informed consent; (2) demonstrated positive history of chronic claudication; (3) demonstrated exercise limiting claudication, established by history and direct observation during a screening walking test administered by the evaluating vascular surgeon; (4) had an ankle/brachial index <0.90 at rest (the range for an individual without PAD is 1.0-1.4); and (5) had a stable blood pressure lipid, diabetes, and risk factor control regimen for 6 weeks. Participants were not required to be naive to AFO use. Any potential participants were excluded if they had (1) rest pain or tissue loss due to PAD (Fontaine stages III and IV), (2) acute lower extremity ischemic event secondary to thromboembolic disease or acute trauma, or (3) walking capacity limited by conditions other than claudication.⁸

Semistructured interviews

Semistructured interviews were conducted at 1.5 months. The interview guide was developed following the standards of Bowen et al for feasibility studies.⁹ Interviews were conducted via telephone by a trained qualitative researcher with over 10 years of research experience ([supplemental appendix S1](http://www.archives-pmr.org/), available online only at <http://www.archives-pmr.org/>).

Data analysis

The semistructured interviews were transcribed and analyzed by the research team in NVivo 12^c using a summative content analysis approach.¹⁰ The researcher independently coded transcripts to reach major data themes. Emerging themes were identified by constant comparison. This approach allowed for the development of explanations through patterns but also allowed the coder to harness theory and prior knowledge or research to answer research questions.¹⁰ Responses were compared between AFO intervention completion and AFO intervention withdrawal, and only key themes were used for reporting. Clustered bar graphs were created between the 2 groups using SPSS software.^d

Results

Fifteen patients (male, 100%; age, 71.9±6.7y, body mass index [calculated as weight in kilograms divided by height in meters squared], 29.0±5.5; ankle brachial index: AFO intervention withdrawal, 0.543; AFO intervention completion, 0.740) with claudication completed the 3-month study, and 6 participants withdrew prior to 1.5 months. Key differences in several themes between AFO intervention completion and AFO intervention withdrawal responses were found. Six of 15 patients in the AFO intervention completion group described negative initial reactions, while 3 of 6 AFO intervention withdrawal participants described their initial reactions to AFO as negative (fig 1). Regarding the amount of time they wore the AFO, 5 of 15 participants of the AFO intervention completion group reported minimal use compared with 5 of 6 in the AFO intervention withdrawal group. Positive aspects reported

included ease in standing and walking for AFO intervention withdrawal (4/6) and AFO intervention completion groups (13/15) as well as walking straighter and longer with less pain for AFO intervention withdrawal (3/6) and AFO intervention completion groups (9/15).

Differences in barriers to wearing the AFO were also observed between AFO intervention completion and AFO intervention withdrawal patients. Compared with the patients in the AFO intervention completion group, the AFO intervention withdrawal patients reported higher levels of physical discomfort with the use of the AFO (4/6 vs 7/15, respectively) and preexisting health issues becoming a barrier to the use of the AFO (3/6 vs 5/15, respectively). Examples of actual responses related to the themes of "Minimal use," "Perceptions," "Barriers," "Physical discomfort," and "Poor Health" are presented in table 1.

Discussion

This study explored differences in patient perspective between those who did and did not complete an AFO intervention. We were expecting the AFO intervention would be feasible to implement for 3 months in patients with PAD. However, the results of this study indicate patients have barriers that make them chose not to wear the AFO. The main barriers are related to discomfort associated with the use of the device and with the poor overall health of the patients. Specifically, discomfort occurred because of some characteristics of the device because patients made statements such as, "It cuts my foot," and "They are uncomfortable and hurt the bottom of my feet" (see table 1). Furthermore, for some patients, poor health was a barrier because patients mentioned issues with their diabetes and foot neuropathy, other comorbidities, and health

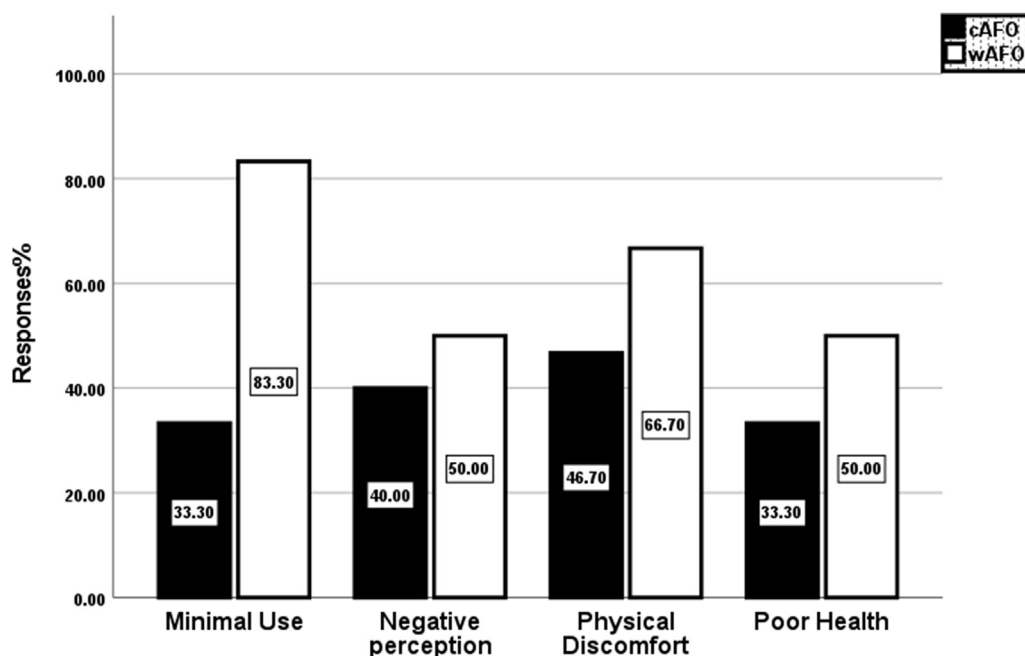


Fig 1 Clustered bar graph of cAFO and wAFO comparing the areas of focus in the implementation/acceptability domains of minimal use, negative perception, physical discomfort, and poor health.

Table 1 Themes with differences by patient group and sample quotes

Theme	Example Patient Quotes (Participant Type) cAFO	Example Patient Quotes (Participant Type) wAFO
Minimal use	"So, I wear them every day, but I only do it for about 15 minutes at night when I use the treadmill."	"If I don't need them, I don't wear them. Like when I'm around the house I don't wear them."
Perceptions	"Uh they're uh very uncomfortable and they hurt the bottom on my feet. So, I didn't wear them at all yesterday."	"They're a bit tedious with some stair steps. And a bit tedious driving, but nothing I can't handle."
Barriers: physical discomfort and poor health	"It cuts the inside of my foot." "I pretty much stayed in bed all day yesterday."	"Yeah, I could try them more often but I, they still hurt my feet a lot. It ain't really working for me."
Positive effects	"It seems to help me walk a little better and feels more comfortable to walk."	"But yeah, the walking I can go a little bit further with these on. So they do help. And plus, ya know, they do help me stand up straight." "I don't know why, but it does. And uh, I can walk straighter. I can walk a straight line."

Abbreviations: cAFO, ankle-foot orthosis intervention completion; wAFO, ankle-foot orthosis intervention withdrawal.

complications requiring their attention and physician care kept them from wearing the AFO. Our study confirms findings from previous studies that showed dissatisfaction with their orthosis led to patients to not wear the device within 2 weeks of receiving the device.^{11,12} These studies indicated that patients need support when trying the device for the first time because many viewed it as cumbersome, uncomfortable, and unsightly. In addition to adjusting to altered self-image, the participants needed education about how to don/doff the AFO, how the orthotic device will help their symptoms, and how long they need to wear it before noticing positive effects.^{11,12}

Patients also mentioned positive aspects of the AFO, including ease in standing and walking as well as walking straighter and longer with less pain (see [table 1](#)). It is possible that training and patient education could optimize AFO use and help patients meet functional goals.¹¹ While some of the issues that these patients experience might not be resolved, it is important to assess long-term feasibility of wear for those who completed the intervention. This subset of preliminary data from the AFO intervention provides important insights for assessing overall feasibility of the intervention. Additional implementation studies are needed to guide the design of the "next generation" devices and minimize barriers. Increasing feasibility and use of assistive devices will maximize improvement in physical activity and quality of life using assistive devices for patients with PAD.

Study limitations

The limitations of the study include a small sample size; however, this initial group provides important insights. In addition, we limited the AFOs to 2 similar carbon fiber devices that would provide the energy storage and return desired to help push off. It is possible that other devices would increase the potential for finding a comfortable AFO. With these limitations in mind, a follow-up study will be

conducted to assess quality of life and physical activity levels to understand longer-term benefits of using an AFO.

Conclusions

Participants who withdrew from the intervention wore the device less, had greater initial negative perception of the AFO, had higher levels of physical discomfort while wearing the AFO, and more frequently reported preexisting health issues as barriers to using the AFO compared with the completers. Most of the patients from the AFO intervention withdrawal and AFO intervention completion groups acknowledged positive aspects of the intervention. The responses of the AFO intervention withdrawal group helped identify barriers to AFO adoption, which should be the topic of future studies.

Suppliers

- Ottobock, LLC.
- Trulife.
- NVivo 12; QSR International Pty.
- SPSS version 27; IBM.

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