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Patient Compliance With Wearing Lower Limb Assistive Devices: A Scoping Review

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ABSTRACT

Objective: The aim of this scoping review was to identify information on compliance with wearing orthoses and other supportive devices, to discuss the barriers to adherence, and to suggest strategies for improvement based on these findings.

Methods: Online databases of PubMed, Web of Science, and the Cochrane Library were searched for articles about patients' compliance with regard to lower limb assistive devices. In addition, a methodological quality control process was conducted. Studies were included if in the English language and related to compliance and adherence to the lower limb assistive device. Exclusion was based on first reading the abstract and then the full manuscript confirming content was not related to orthotic devices and compliance. **Results:** Twelve studies were included. The data revealed between 6% and 80% of patients were not using a prescribed device. Barriers to the use of the orthotic device included medical, functional, device properties and lack of proper fit.

Strategies for improved compliance included better communication between patient and clinician, patient education, and improved comfort and device esthetics. **Conclusions:** Individualized orthotic adjustments, rehabilitation, and patient education were promising for increasing adherence. Despite positive aspects of improvements in gait, balance in elderly, and a sense of security produced by using assistive devices, compliance remains less than ideal due to barriers. As compliance in recent studies has not improved, continued work in this area is essential to realize the benefits of technological advances in orthotic and assistive devices. (J Manipulative Physiol Ther 2022;45:114-126)

Key Indexing Terms:

Orthotic Devices; Foot Orthosis; Patient Compliance; Lower Extremities

INTRODUCTION

Orthotic devices play a crucial role in promoting, maintaining, and enhancing the physical and psychological health and well-being of many patients in need of leg support.^{1,2,3} The patients using these devices may have one of a wide spectrum of pathological conditions that restrict ambulation, limit activities, and influence participation in daily life, including neuromuscular disorders like cerebral palsy, poliomyelitis, Charcot-Marie-Tooth disease, inclusion body myositis, myotonic dystrophy, multiple sclerosis, stroke, peripheral nerve injury, rheumatological diseases, musculoskeletal and degenerative joint disorders, complications of diabetes and peripheral artery disease (PAD).^{1,2-4}

In current clinical practice, a wide spectrum of off-the-shelf and custom-made assistive devices are prescribed to patients with gait and mobility problems.^{1,2,5,6} There are a variety of lower limb orthotic and assistive devices available, and our review concentrates on ankle-foot orthoses (AFOs), knee-ankle-foot orthoses (KAFO), and orthopedic shoes.^{1,2,5,6} An AFO is a support device intended to control the position and motion of the ankle, compensate for weakness, or correct deformities.^{6,2} Therefore, AFOs have been prescribed for patients experiencing various lower limb and ankle disorders, including rheumatoid arthritis (reduce fore-foot plantar pressure or forefoot pain) and PAD (assist the failing posterior calf muscles).^{5,2,3,7-9} Knee-ankle-foot orthoses are more often prescribed when proximal lower limb weakness contributes to knee instability (eg, weakness of the quadriceps).^{1,2} Knee-ankle-foot orthoses may also help patients with neurological diseases and muscular diseases, such as post-polio syndrome, spinal cord injury, trauma, multiple sclerosis, muscular dystrophy, and similar pathologies who experience quadriceps weakness.^{3,4} In these instances, a KAFO, aligns the knee, ankle, and foot to mitigate abnormal walking patterns caused by the quadriceps failure. Combination therapy with both AFOs and KAFOs has led to improvements in walking ability in several patient populations with impaired ambulation (eg, those with stroke or cerebral palsy).^{2,3,6,7} Custom-made orthopedic shoes help alleviate pain in the heels, feet, knees, hips, and lower back and contribute towards improving patient mobility and stability, for example, by reducing pain in the feet or ankles or preventing ulcer formation.^{2,3} Orthopedic shoes are prescribed for the elderly population as well as patients with a wide range of pathologies, such as diabetes, rheumatoid disorders, and degenerative foot disorders.^{3,4}

These assistive devices are intended to help with enabling patients to work, engage in family life, and enjoy social activities.^{1,5} However, to achieve the positive impact of these devices, patients must wear them. Unfortunately, compliance to orthotic devices varies greatly. Studies have reported varied compliance ranges. The most recent systematic review conducted in 2015 examining patient compliance to wearing an orthotic device or shoe found 6% to 80% of patients did not use the device in studies published prior to 2010.^{6,2}

Some studies describe a lack of patient compliance.^{2,4} Previous research has found dissatisfaction with the assistive devices, poor adherence, and compliance issues to wearing orthotic and/or assistive devices due to reasons such as they were not effective in improving outcomes of interest to the patient.^{2,7} Evidence on the effectiveness of orthotic devices is limited, especially in relation to the outcomes that are important to users.^{2,7} There are very few studies related to the compliance of patients with PAD demonstrated in their use of assistive devices. In addition, there are limited studies related to use and disuse of orthotic devices in aging patients or patients who have a neurological deficit or who experienced a stroke; while limited studies have examined adherence to diabetic or orthopedic shoes, etc, in patients with diabetes and those with diabetic complications like neuropathy.^{4,8} These studies also shed some light on the manufacturing, comfort, and design of the assistive devices that are deemed to improve compliance.^{2,3}

However, these papers do not give us an understanding of the compliance issues and perceptions related to lower limb assistive devices.⁴ There have been many advancements in lower extremity assistive devices since the previous review's literature search.² Therefore, the purpose of this scoping review was to analyze compliance with wearing orthoses and other supportive devices in recent years and to discuss the barriers and strategies for improvement based on these findings.

METHODS

This report was written in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines; following the PRISMA Extension for Scoping Reviews by Tricco et al.⁹ The review protocol was prospectively registered in the PROSPERO database (ID:CRD4202020214081). The methods and search strategy consisted of various stages in this scoping review. The population was patients in need of assistance with lower limb functionality. The intervention was assistive devices for lower limb. The comparison and context were compliance to the device. The research question, which was the basis for the search terms, was the following: *What is the compliance of patients wearing an assistive device?*

Search Strategy

To make the review current with recent devices and build on the last review from 2015,² we did not include articles before 2005 because devices have substantially improved since that time. Three databases were searched for relevant articles from 2005 to April 31, 2021, in the databases of PubMed, Web of Science, and Cochrane Library. The MeSH terms "orthotic devices," "foot orthosis," "orthotic shoes," "patient compliance," and "lower extremities" were used. Afterward, the reference lists from included articles were searched for any additional articles relevant to the topic. The search yielded 36 articles.

Inclusion and Exclusion Criteria

Studies were included if in the English language and related to compliance and adherence to the lower limb assistive device or shoes (for example, frequency of use, barriers to wear, users and non-users of the device, etc.). Exclusion was based on first reading the abstract and then the full manuscript confirming content was not related to orthotic devices and compliance. The review was not limited by study design.

Quality Control

The examination of the methodological quality of each article was conducted using the methodological checklist “Critical review form quantitative studies” (Evidence-based rehabilitation, 2008) (see Supplemental file).¹⁰ The articles were analyzed for reasons of use and lack of use of the device and the findings and proposed solutions presented in these studies will be summarized.

RESULTS

Keyword searches in the identified databases yielded 36 potential articles (Fig 1). After selection on title, abstract, and full content, 10 articles remained. Additionally, by searching reference lists and reading related articles, 2 additional articles were included, for a total of 12 studies (Table 1). Figure 1 gives insight into the search strategy. The PRISMA requirements for scoping reviews by Tricco et al are included in the supplementary materials. In general, the papers included design, sample size, and proper analysis methods (see Supplemental file); therefore, we included all 12 articles in the review after quality control analysis.

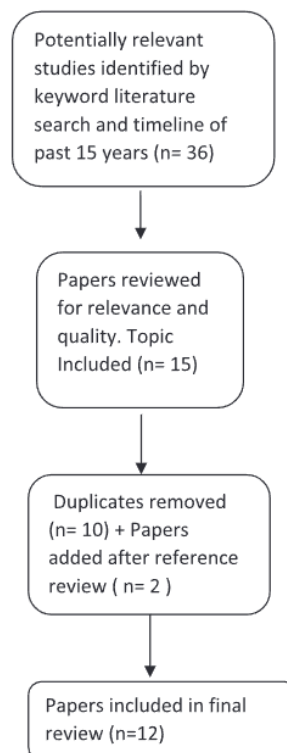


Fig 1. Flow chart that describes the search strategy.

Descriptive Analysis

Table 1 describes the content of the included studies. Only the outcome with respect to compliance is explained in Table 1. If reported, reasons for use or non-use were also described.

The sample size reported in each of the studies ranged from 10 to 339 patients. Four studies assessed adherence to orthopedic shoes, 2 included orthopedic shoes and insoles, 7 studies included AFOs, and 2 studied KAFOs, with 1 of those investigating both KAFO and AFO compliance. Questionnaires, focus groups, and interviews were used to measure and describe the compliance. Common outcomes included frequency of wear, duration of use, and included users and non-users of the assistive devices. A detailed description of the measured parameters for each study is reported and summarized below (Table 2).

Patient Population and Devices

The studies where orthopedic shoes were evaluated included patients with rheumatoid arthritis (n = 132)¹² and patients with diabetes (n = 107).⁴ The studies that evaluated AFOs included patients with neurological (post-stroke deficiency) (n = 64),⁹ patients with Charcot-Marie-Tooth (n=32),¹⁵ and patients with rheumatological symptoms (n = 269) (Table 1).^{10,18} Seven studies involved AFOs for patients with a range of conditions, including elderly patients with balance impairments or who had experienced falls, patients with post-stroke ambulatory deficits, and patients with peripheral artery disease (Table 1). Twenty-five patients with severe bilateral foot drop caused by Charcot-Marie-Tooth disease with a prescribed AFO for at least 4 months were included in 1 study.⁶ It has been previously reported that this break-in period of 3 months was necessary for collecting data about compliance of footwear, which is observed in most of these studies.^{2,4,15,16,17}

Outcome

The primary focus of this study is compliance, as noted by frequency of use. In all studies, individuals were classified as users (of the orthotic device) or non-users (of the orthotic device). We sought to understand barriers to use as well as the reasons for which the individuals decided to use the device. Additionally, we described potential solutions to decrease barriers and increase use based on findings and suggestions in the articles reviewed. Emerging barriers to orthotic device compliance and/or adherence, some related to quality of life and activities of daily living, are mentioned in the manuscript (Table 2).

Frequency of Use

The articles we have analyzed reported patient compliance to the device that ranged between 20%⁶ and 94%.¹⁹ Choma et al reported 70% users and 30% non-users of the AFO¹¹; Yuzer et al reported that the orthosis frequency of use was every day in 38 (59.4%) patients and 1 to 7 times a week in 7 (10.9%) patients, whereas 19 (29.7%)

did not use them.⁸ The study conducted by Vinci and Gargiulo⁶ indicated 5 patients (20%) were users and 20 (80%) were non-users, while Menz et al (2018) consisted of 153 participants, with 134 users (87.6%), and 19 (12.4%) non-users.¹⁴ In the study conducted by Ramdharry et al, 21 out of 32 were non-users of the AFO intervention (66%), while 11 were users (34%).¹⁵ In the study conducted by Koyuncu et al, 25.8% were reported as non-users of the orthotic device, and 1 in 4 devices failed to facilitate the daily life activities of the patient.¹³

The highest percentages of non-users were found for AFO's in severe bilateral foot drop patients with Charcot-Marie-Tooth disease,⁶ while the majority of the rheumatoid arthritis patients were wearing their orthopedic shoes daily as shown by the Van Netten et al studies, which only reported 6% non-users.^{17,19}

Table 1. Reference Table: Characteristics (Summary and Details) of the Articles Included (Data Extraction Table)⁹

Article	Sample (n)	Type of Study	Device and Patient Information	Methods	Results (Usage Duration)	Summary and/or Outcomes
Choma et al ¹¹	10	Qualitative study	Ten patients with PAD, ankle foot orthosis (AFO) 12-week intervention, community-based program. AFO used to mitigate calf pain while walking.	Focus group, semi-structured interviews. Analysis by standard qualitative coding software (NVivo, v11.3).	Seventy percent users and 30% non-users. Participants decreased or stopped device use during or after the study because of other conditions, including infection of the toe, diabetes, and skin condition.	Supports the use of AFO as an effective tool for reducing claudication symptoms from the patient perspective.
De Boer et al ¹²	132	Cross-sectional study	One hundred thirty-two patients with rheumatoid arthritis. Thirty-one men and 101 women. Mean age: 63 years. Orthopedic shoes (OS) (n = 91) and orthopedic insoles (n = 53), assessed for usage of assistive device in 3 months. The OS and insoles are prescribed to improve functional ability and comfort while walking.	Questionnaire and semi-structured interviews. Frequency of use in the past 3 months: 8 predefined categories. Individual mean reasons for usage and non-usage: Open ended questions; categories defined afterwards.	Orthopedic shoes: 72 (80%) daily, 6 (7%) weekly, 12 (13%) monthly or never. Orthopedic insoles: 43 (81%) daily, 4 (8%) weekly, 6 (11%) monthly or never. Reasons for using: Enabling activities, pain, fatigue, swelling or reduced strength, joint protection or support; recommended by physician and/or health professional; safety. Reasons for not using: aesthetics; wearing device doesn't correct limitation; device not necessary.	Fewer than 23% of the devices in possession were abandoned, and satisfaction with the devices was high. Factors associated with usage varied among categories and variables related to health status, aspects of satisfaction with the device, or self-efficacy (related to the person's ability to continue using the device).
Koyuncu et al ¹³	62	Retrospective descriptive study	Sixty-two patients with spinal cord injury (SCI). Used knee-ankle-foot orthosis (KAFO) for standing and ambulation. Divided into 2 groups based on duration (0-12 minutes and more than 12 minutes). Patients discharged from the hospital between 2012-2014, recruited.	Patients interviewed as part of the retrospective orthotic compliance study.	Of the patients, 25.8% did not use KAFO. Due to failure to facilitate daily life activities of the patient, the difficulties in putting them on and taking them off, the belief that it is unnecessary, the pressure effects as well as discomfort.	At least 1 in 4 patients with SCI did not use the lower extremity orthoses recommended. Patient training and follow-up are important for increased frequency of orthosis usage.
Menz et al ¹⁴	153	Randomized control trial	Home-based program of foot and ankle exercises, assistance with the purchase of safe footwear when necessary, and provision of prefabricated foot orthoses, to prevent falls in elderly (average age 74 years).	Questionnaires were filled, 134 (87.6%) attended 6-month follow-up assessment and completed questionnaire.	One hundred and fifty-three participants, 134 users (87.6%) and 19 non-users (12.4%). Adherence to intervention results are exercise, 72%; footwear, 54%; and foot orthoses, 69%.	Most were satisfied with improvement in posture, exercise, and the device suitability. No specific results about balance. Dissatisfaction was reported by 34 (25.4%), the shoes had to be replaced, comfort cost and aesthetics were some issues.

(continued)

Table 1. (Continued)

Article	Sample (n)	Type of Study	Device and Patient Information	Methods	Results (Usage Duration)	Summary and/or Outcomes
Swinnen et al ²	N/A review	Systematic review	Orthotic devices, including AFO, orthopedic shoes worn by different patient populations, such as patients with neurological and rheumatoid arthritis. Average age = 74 years	Systematic review, including 10 studies. Four databases were searched for relevant articles (last search in June 2014): PubMed, Web of Science, Pedro, and Cochrane Library (a methodological quality control was conducted).	The data revealed between 6%-80% non-users. Compliance depended on types of patients (severity of the disease).	Several reasons for not using the orthotic device were described (eg, pain, discomfort, and cosmetically unacceptable). The low compliance of orthotic devices leads to a high financial loss for the patients and society. Reasons for use are improvements in walking, sense of independence, and security.
Swinnen et al ³	33	Observational study	Thirty-three patients with neurological disorders (Stroke, etc) participated. Of the participants, 53% were men; 28 patients wore AFO, 3 KAFO, and 2 wore a knee brace.	Questionnaires were used to assess acceptance and user satisfaction related to an orthotic device.	Of the patients, 86% were (very) satisfied about their OD. Comfort, safety, effectiveness, and ease of use, help with alignment and mobility were some benefits.	Different devices and proper fitting should be tried by the orthotist to improve compliance. Compared to male patients more female patients reported if they perceived OD as unsafe they will not use it.
Ramdhary et al ¹⁵	32	Comparative study	Thirty-two patients with Charcot-Marie-Tooth. Eleven patients wore various types of AFOs bilaterally to treat foot drop and diminish compensatory activity of proximal muscles (AFO group), and 21 did not (never wore AFO group) for comparison purposes.	Primary measures of gait function were 10 minute walk (maximum speed) and 6-minute walk test. Means compared by independent <i>t</i> tests. Secondary measures were disease severity, muscle strength, sensory impairment, walking effort, fatigue severity, and perceived walking ability.	Twenty-one out of 32 non-users (66%) and 11 users (34%). AFO wearers walked slower with higher effort, had greater disease severity, weaker leg muscles, and perceived greater walking difficulty. The group that never wore AFO had the most common and demyelinating form of Charcot-Marie-Tooth, type 1A; the AFO group had more disease severity was a more mixed group with demyelinating and axonal variants of the condition.	Users of AFOs complained of lack of choice and discomfort but also highlighted benefits such as prevention of falls, improved walking ability, support, and greater independence.

(continued)

Table 1. (Continued)

Article	Sample (n)	Type of Study	Device and Patient Information	Methods	Results (Usage Duration)	Summary and/or Outcomes
Van Netten et al ¹⁶	339	Prospective cohort with internal comparison	Three hundred and thirty-nine patients, 85 diabetics, 60 with rheumatoid arthritis, 237 with (unspecified) foot disorder, 23 with muscular disease, 104 other disorders (stroke, PAD, etc), wore custom OS for 6 months to help diminish foot and/or ankle issues or to improve gait.	Questionnaires used 3 months after OS shoes delivery.	Two hundred and seventy-five frequent users (4-7 days/week): 65 (24%) >12 hours, 93 (34%) 8-12 hours, 83 (30%) 4-8 hours, 29 (11%) 1-4 hours, 1 (0.5%) <1 hours, 4 (0.5%) missing. Forty-three occasional users (1-3 days a week): 2 (5%) >12 hours, 1 (2%) 8-12 hours, 14 (33%) 4-8 hours, 20 (46%) 1-4 hours, 6 (14%) <1 hours, 0 (0%) missing. Twenty-one non-users (not using orthopedic shoes).	Patients with worse short-term usability outcomes for their OS are more likely to use their OS only occasionally or not at all at long-term follow-up.
Van Netten ¹⁷	269	Longitudinal study	This is the 1.5 year or 18 months follow up study of the prior Van Netten study. Out of 339 patients, only 269 participated in the follow up. Sixty-three had diabetes mellitus, 46 rheumatoid arthritis, 196 an unspecified foot disorder, 17 a muscular disease, and 86 another disorder (stroke, etc).	Out of 339 patients, 269 participated in this 18-month follow up questionnaire study about OS (custom made orthopedic shoes).	Two hundred and eleven frequent users, 81 (39%) >12 hours, 66 (31%) 8-2 hours, 47 (22%) 4-8 hours, 17 (8%) 1-4 hours. Twenty-three occasional users, 1 (4%) >12 hours, 2 (9%) 8-12 hours, 6 (26%) 4-8 hours, 14 (61%) 1-4 hours. Thirteen non-users (not using orthopedic shoes). Reasons for nonuse: Dissatisfaction with usability: effectiveness (n = 6, 17%), comfort (n = 14, 40%) Physical changes: positive (n = 6, 17%), negative (n = 8, 23%).	This follow-up study found that 87% of the patients who used their OS at short term still used their OS after 1.5 years, and 13 percent of the patients ceased using their OS. Among the non-users after 1.5 years, 57% was due to dissatisfaction with the usability of the OS.

(continued)

Table 1. (Continued)

Article	Sample (n)	Type of Study	Device and Patient Information	Methods	Results (Usage Duration)	Summary and/or Outcomes
Vince and Garguilo ⁶	25	Comparative/Qualitative study	AFO for 25 patients (8 men, 17 women) with Charcot Mary Tooth disease (prescribed for at least 4 months). AFO was prescribed to treat foot drop.	Qualitative audio-recorded interviews were conducted with the aid of an interview guide; then the interviews were transcribed and analyzed (4 months after prescription).	Data revealed 5 (20%) users and 20 (80%) non users. Patients who perceived them as less attractive were less compliant.	Patient (users and non-users) perceptions: AFO's: reasons for not using the orthotic device were described (eg, discomfort and cosmetically unacceptable). Reasons to use were prevent falls, it increased mobility and helped on uneven ground and dark places
Waaijman et al ⁴	107	Randomized controlled trial	One hundred and seven patients with diabetic neuropathy. Footwear use was measured during 7 days using a shoe-worn, temperature based monitor. Fully custom-made footwear (custom insoles in shoes) (n = 89, 83%) or semi-custom made footwear (ie, custom insoles in off-the shelf extra-depth shoes) (n = 18, 17%) .	Daily step count measured using ankle activity monitor. Patients logged time away from home. Adherence was calculated as the % of steps that footwear was worn. Determinants of adherence were evaluated a minimum of 3 months after footwear delivery.	Mean \pm SD adherence was 71 \pm 25%. Adherence at home was 61 \pm 32%, over 3959 \pm 2594 steps, and away from home 87 \pm 26%, over 2,604 \pm 2,507 steps. Wearing time was 59 \pm 27% of daytime, while (29% patients wore it >80% daytime).	Patients with diabetic foot ulcerations wear their offloading devices insufficiently. There is lack of adherence to the intervention particularly at home where they walk most, which precipitates re-ulceration. Orthotist should choose the suitable device and follow up and educate patient and maybe prescribe separate indoor footwear.
Yüzer et al ⁸	64	Retrospective descriptive study	Sixty-four patients post-stroke, 6 months after discharge from rehab. Fifty-four patients were treated with an AFO and 10 with a KAFO to facilitate ambulation.	Qualitative analysis of orthosis use and disuse on 64 (43 men and 21 women) patients.	The orthosis frequency of use was every day in 38 (59.4%) patients and 1-7 times a week in 7 (10.9%) patients, whereas 19 patients (29.7%) did not use them.	Reasons for orthosis decreased use and/or non-use: finding them unnecessary, 7 (27%), usage difficulties in 6 (19.2%), pressure sensation in 5 (19.2%), the belief that they did not make life easier in 5 (19.2%), lack of a suitable environment in 1 (3.8%), orthosis wear in 1 (3.8%) and systemic disease in 1 (3.8%) patient. Reasons for use: helps in balance and ambulation.

AFO, ankle foot orthosis; KAFO, knee-ankle-orthosis; OS, orthopedic shoes; PAD, peripheral artery disease; SCI, spinal cord injury; SD, standard deviation.

Table 2. Reported Reasons for Orthotic Device Non-Compliance

Article	Medical	Functional	Device Properties	Esthetic	Fit
Choma et al ¹¹	Three individuals either decreased or completely stopped device use during or after the study because of other existing lower extremity conditions.	The device was impractical during certain activities, such as golfing, driving, hiking uphill, squatting, and using stairs. Took extra time to put on the device.	Stiffness of the device material, especially at the ankle, altered gait patterns and may have led to a sense of awkwardness that was described as less than optimal.	Some patients discussed only certain footwear or socks could be worn with the AFO, which could be a deterrent to wear.	Initial discomfort related to the fit of the AFO was resolved by individualized modifications made by the orthotist.
De Boer et al ¹²	The device did not help with reduction of pain, fatigue, swelling, or compensation for reduced strength.	No impairment or activity limitation that requires use of the device.	Did not meet expectation and not easy to use.	Disliked the appearance, other people's negative opinion.	Lack of fit or comfort related to device.
Koyuncu et al ¹³	Pressure sensation and systemic disease.	Lack of suitable environment, failure to facilitate daily life.	Device considered unnecessary and difficult to use.	Cosmetically unacceptable.	Difficult to wear, does not fit properly.
Menz et al ¹⁴	Elderly patients with toe deformities.	Lack of proper shoes.	Dissatisfaction with device and shoes (7%).	Shoes were aesthetically undesirable and expensive.	Hard to fit the orthosis and the shoes they want to wear.
Swinnen et al, ² Swinnen et al ³	Ulcers on foot, skin allergies.	Deterioration in walking and reduced walking capability.	Too heavy, cumbersome, not easy to use.	Bad look and cosmetically unacceptable.	Need a proper fit of shoe, as rubs and pressure on foot, also too much waiting at orthotist office.
Ramdhary et al ¹⁵	Fatigue and muscular weakness not improved by device.	Deterioration in walking speed and restricting movement.	Uncomfortable and heavy.	Lack of device choice.	Different devices and proper fitting should be tried by the orthotist to improve compliance.
Van Notten et al ¹⁶	Muscular pain and skin irritation.	Dissatisfaction with usability.	Heavy and not easy to use.	Cosmetic appearance.	Communication with the medical specialist and the shoe technician to improve fit.
Van Notten ¹⁷	Physical changes and amputation in 1 patient.	Dissatisfaction with usability.	Pain, weight of the OS, and discomfort.	Cosmetic appearance.	Communication with the medical specialist and the shoe technician to improve fit.
Vince and Gargiulo ⁶	Pressure sensation and painful for some patients.	Can still manage without them for a while.	Discomfort and pain because it pushed on the leg.	Ugly and aesthetically unpleasing, cannot find shoes of choice.	Complained about difficulties to get modified properly by orthotist.

(continued)

Table 2 (Continued)

Article	Medical	Functional	Device Properties	Esthetic	Fit
Wazajman et al ⁸	Ulceration in the foot, obesity led to lower adherence.	N/A	Discomfort due to diabetic ulcerations on foot.	Patients who perceived them as less attractive were less compliant.	Orthotist should prescribe custom made comfortable shoes to wear at home.
Yüzer et al ⁸	Pressure sensation and discomfort.	Lack of suitable environment, did not make life easy.	Some patients found it unnecessary, usage difficulty.	N/A	Orthotist should choose the suitable device and follow up and educate patient.

AFO, ankle foot orthosis; OS, orthopedic shoes.

Barriers

The barriers to wear that were reported to contribute to lack of compliance (Table 2) are described in detail below.

Medical Reasons. In Swinnen et al, 2 out of 49 individuals either decreased or completely stopped the use of the device during or after the study because of discomfort in the lower extremities due to local wounds and skin irritation. In the study by Koyuncu et al, 19 out of 64 individuals either decreased or completely stopped the use of the device during or after the study because of issues related to failure to facilitate daily life activities, discomfort, pressure, and difficulty while wearing.^{15,18} Wearing the device can add discomfort in patients experiencing skin conditions, allergies, or local ulcers in the part of the foot or leg used by the assistive device, and this frequently led to discontinuation of device use.^{4,18,16,17,19}

Reasons Related to Function. Patients complained of a lack of suitable everyday environment to wear the assistive device.^{10,12} Patients found it hard to facilitate activities of daily life and found the device impractical during certain activities, such as golfing, driving, hiking uphill, squatting, and using stairs.^{10,12}

Reasons Related to Device. Patients in some studies complained about the stiffness of the device material (AFO and KAFO), leading to a sense of awkwardness, discomfort, and skin irritation that was described as less than optimal.^{12,13} Some patients considered the device unnecessary and difficult to use, as well as uncomfortable, hard to don and doff, and cumbersome.^{11-14,17,19}

Esthetic Reasons. Patients who perceived the shoes or device as less attractive were less compliant.^{6,4} Some patients mentioned that they found the device ugly, felt that other people were formulating a poor opinion about them because they were using an assistive device, and felt self-conscious by others staring at them.^{2,11,12} Patients also mentioned that only certain footwear or socks could be worn with the device, which, along with the extra time to put on the device, could be a deterrent to wear.^{12,14,15}

Reasons Related to Orthotic Fitting. Patients frequently mentioned the need for better communication with the medical specialist and the shoe technician to improve fit.^{17,19} Patients reported a desire for orthotists to be more accessible after prescribing the suitable device and stated there is a need for scheduled follow-up to resolve issues related to device fit and comfort.^{6,4,10} Initial discomfort related to the fit of the AFO was frequently resolved by individualized modifications made by the orthotist, and easy access to the orthotist for appropriate device alterations appears to improve compliance in the long term.^{11,13,14,19}

Reasons for Use. Eight out of the 12 papers focused on reasons for use or positive outcomes of the device. These papers were searched mainly for the lack of compliance. The emerging themes of use are summarized here.

Comfort and Safety of Device. “Comfort,” “safety,” “effectiveness,” and “ease of use” were reported as most important characteristics of the device.^{2,3,12} Patients experiencing multiple sclerosis or having post-stroke neurological deficits indicated that safety was the main advantage of wearing an assistive device.^{3,9}

Improvements in Gait. Patients enrolled in various studies, including post-stroke and patients with PAD, mentioned how the devices help them improve their walking and regain freedom and independence.^{6,19} For example, an AFO helps in ambulation of post-stroke patients, and AFOs may be used to supplement unstructured community-based PAD walking programs, decreasing the claudication symptoms and improving walking capacity in this patient population.^{5,11,13}

Helpful in Daily Activities. Orthotic devices are enhancing participation in meaningful daily and recreational activities.^{12,13} In 1 study, patients expressed satisfaction and a sense of security as they felt the orthopedic device helped their mobility and the performance of household and personal care activities.¹²

Balance Support. The assistive devices were deemed to be helpful in balance and ambulation, especially in elderly populations and those with neurological symptoms (including post-stroke, Charcot-Marie-Tooth, and foot drop).^{8,14} Patients post-stroke and those experiencing multiple sclerosis indicated that the improvement in walking ability and safety was the main advantage of wearing an assistive device.^{3,9}

Quality of Life Enhancement. Patients with PAD who wore an assistive device perceived improvements in their overall quality of life.^{5,18}

Suggestions to Improve Compliance

Orthotic Visit and Fitting. In some instances, poor attention and responsiveness by the orthotists to the complaints of the patients produced persistent problems, which ultimately contributed to decreased compliance or disuse. Patients identified the difficulty of scheduling an appointment (sometimes a few weeks or a month) and the lack of availability of drop-in clinics as key problems.^{2,19} Hence, proper communication between patient and the orthotist and prompt attention to fit and comfort issues by the orthotist would increase the use of the device.

Lighter and Comfortable Device. Patients report that if the device is bulky, heavy, and uncomfortable, they do not like to use it.^{6,2} Finding a lighter, easy to don and/or doff device would increase the comfort level and help patients comply with the intervention.^{15-17,19}

Rehabilitation, Patient Education and Psychological Support. The severity of mobility problems causes by the condition, such as whether patients are in a rehabilitation center or hospital or living at home and level of social life participation, all contribute to use and disuse and lack of compliance to assistive devices.^{2,20,21} Patient education, motivation, and awareness are important, particularly when the device is first prescribed and to improve patient compliance. Psychological, social, and health care support when starting to wear the orthotic device is beneficial. The ability to modify an AFO is an important benefit, which is unavailable in invasive interventions like surgery.^{4,20}

DISCUSSION

Our study sought to examine recent literature on compliance with orthotic assistive devices. A previous review included 10 studies from a search performed in June 2014 and found a range of compliance from 6% to 80%.² The current study focused on 12 new articles and provided an analysis context regarding barriers faced by patients to use assistive devices. In addition, we have mentioned the positive aspects of assistive device use as well as solutions to the potential barriers which has not been addressed previously.² Since adherence to therapy is a primary determinant of treatment success, it is important to analyze dissatisfaction with the intervention, identify specific barriers to wearing orthotic and/or assistive devices, and develop recommendations for compliance improvement.

The papers we reviewed indicate that a large number of patients never wore their assistive devices. Our study found a range between 6% and 80% of the patients not using their devices at all, which is very similar to the previously reported range.² The highest percentages of non-users were found for AFOs in severe bilateral foot drop patients with Charcot-Marie-Tooth disease,⁶ while we noted that the majority of patients with rheumatoid arthritis were wearing their orthopedic shoes and insoles daily.^{17,19} It seems that when patients deem the device as unnecessary, they are able to manage without them, and, therefore, they are not using assistive devices.^{6,21}

We identified a number of barriers to wear and the main orthotics included the following: medical, functional, device properties, esthetic, and orthotic fit. Some patients were unable to continue wearing the device due to other health-related conditions.^{2,11} The patients who ended up not using the prescribed device frequently complained of the device being uncomfortable, that it did not fit well, or it was heavy, cumbersome, and interfered with daily activities^{19,22} or themselves or others (whose opinion they value) felt that the appearance of the device was unattractive.^{11,13,14,19}

The issues we identified as barriers for the use of assistive devices were found across all the studies we reviewed. At the same time, several contradictory comments related to activities of daily living while wearing the AFOs suggested barriers, fit, and use can be quite different between patients. For example, in 1 study, many patients found the device cumbersome while driving and made statements like “did not feel confident to drive. . .because feet felt very hot and cumbersome,; yet others reported how it helped them drive better and stated “. . .excellent articulation for driving” and “good for driving, as it provides more useful feelings for the feet as well as flexibility.”²⁰

Positive aspects that contributed to use were also identified. Patients mentioned how the devices help them walk better, retain balance, and regain freedom and peace of mind.^{6,19} Older patients, as well as patients with neurological deficits, highlighted benefits, such as prevention of falls, improved walking ability, support, a sense of security and greater independence.^{9,14,15} This information is novel for researchers working with a patient population using orthotic devices. Patient education, motivation,

and psychological support related to accepting the assistive device are some of the strategies mentioned in the papers reviewed that helped in improving adherence, especially at the beginning of the intervention.^{4,20} In some of these studies, patients expressed that wearing the AFO was especially difficult on uneven ground and doing activities around the house, such as walking up and down the stairs and doing yard work.^{11,21,23} Making sure the device fits well and feels comfortable seems very important to improve wear time.^{11-14,18,19,24} Given the low physical activity of many of the patients that are prescribed an orthotic device, ensuring that they can comfortably wear the device while performing activities of daily life is critical to increase adherence and possibly improve physical activity levels.²⁵⁻²⁸ The orthotist must work with the patient to provide an optimally fitting device. Future systematic investigations should propose, develop, and test methods that will improve compliance to assistive devices.

Future Directions

Overall, this review provides valuable data and direction on how to pursue improved compliance among non-users of orthotic and assistive devices but also on the goals we should pursue when developing and testing new devices. This valuable information is based on experience in every-day use coming directly from people with impaired movement that requires an assistive device.^{22,29-33} Incorporating the proposed suggestions into clinical research and product and service development can improve adherence and increase the beneficial impact of the device. Further investigations into how wear time impacts efficacy of orthotic devices would be useful in developing intervention and eventually providing guidance to patients.^{19,27,28,34,35} Our literature review indicates a need for research related to orthotic device compliance and for the development and evaluation of new devices with improved features and qualities that optimally accommodate patients' needs. In the near future, testing devices that fit well can be easily donned and/or doffed, can be used with the patients' own shoes and clothing, are esthetically pleasing, and that perform well during all types of activities (including walking on uneven terrain, golfing, driving, hiking uphill, squatting, and using stairs) would contribute to increased adherence.

Limitations

Most of the studies included in this scoping review were in the initial stages with small sample sizes; therefore, the findings are preliminary, and caution should be used with the conclusions. Adding diverse populations to assess cultural differences and inclusion of perspectives of different age groups may shed light into different needs within the demographics. There was limited knowledge regarding compliance differences between patients staying in a nursing home, rehabilitation center, or hospital and patients living at home and participating in social life. Specific published studies were not found on these topics. Follow-up studies with larger sample sizes that explore interventions to increase assistive device adherence are necessary and important.

CONCLUSION

Our findings indicate the existence of a broad range of compliance with orthotic and assistive devices. Patients embrace the assistive devices because they provide appreciable improvements in gait, balance and stability, and a sense of independence and safety. Optimal approach to improving adherence to orthotic devices requires a comprehensive strategy that increases interactions between the patients, patient families, health care providers, and health care systems throughout the treatment process. Appropriate follow-up should be arranged with the orthotist to adjust and for the team to reevaluate the treatment plan, identify barriers, address problems, and support adherence. As compliance in recent studies has not shown much improvement, it is important to improve and develop better devices that address unique functional deficits, pathologies, and anatomy of individual patients.

SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found in the online version at [doi:10.1016/j.jmpt.2022.04.003](https://doi.org/10.1016/j.jmpt.2022.04.003).

Practical Applications

- We performed a scoping review to identify information on compliance to wearing orthoses and other supportive devices, to discuss the barriers to adherence, and to suggest strategies for improvement based on these findings.
- From 12 studies, between 6% and 80% of patients were not using a prescribed device.
- Barriers to the use of the orthotic device included medical, functional, device properties, and lack of proper fit.
- Strategies for improved compliance included better communication between patient and clinician, patient education, and improved comfort and device esthetics.

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