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*Prosthet Orthot Int*. Author manuscript; available in PMC 2025 August 13.

Published in final edited form as:

*Prosthet Orthot Int*. 2023 October 01; 47(5): 457–465. doi:10.1097/PXR.0000000000000217.

# Carbon fiber ankle-foot orthoses in impaired populations: A systematic review

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## Abstract

**Background:** Carbon fiber is increasingly being used in ankle-foot orthoses (AFOs). Orthotic devices and carbon fiber-containing devices have been shown to reduce pain and improve function in multiple patient populations. Although the number of publications and interest in carbon fiber AFOs is growing, a systematic evaluation of their effects is lacking.

**Objectives:** To characterize the effects of carbon fiber AFOs in impaired individuals.

**Study design:** Qualitative systematic review.

**Methods:** Systematic searches in PubMed, Embase, CINAHL, and Cochrane Library were completed in July 2020. The results were deduplicated, screened, and assessed for quality by independent reviewers. Articles were excluded if they had nonhuman subjects, only healthy subjects, or included active control systems, motors, or other power sources.

**Results:** Seventy-eight articles were included in the qualitative synthesis. Most articles were of low to moderate methodological quality. Five commonly used devices were identified: the Intrepid Dynamic Exoskeletal Orthosis, ToeOff, WalkOn, Neuro Swing, and Chignon. The devices have unique designs and are associated with specific populations. The Intrepid Dynamic Exoskeletal Orthosis was used in individuals with lower-limb trauma, the Neuro Swing and ToeOff in individuals with neurological disorders, the Chignon in individuals with hemiplegia and stroke, and the WalkOn in people with hemiplegia and cerebral palsy. Each device produced favorable outcomes in their respective populations of interest, such as increased walking speed, reduced pain, or improved balance.

**Conclusions:** The mechanical characteristics and designs of carbon fiber AFOs improve outcomes in the populations in which they are most studied. Future literature should diligently report patient population, device used, and fitting procedures.

### Keywords

ankle-foot orthosis; dynamic; carbon fiber; impairment; outcomes

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Declaration of conflicting interest

The authors disclosed no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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## Introduction

Ankle-foot orthoses (AFOs) are commonly used to restore function and mobility, improve limb alignment, and reduce pain in people with lower-limb impairments associated with injury or disease. AFOs are the most prescribed orthotic device (26%), with an estimated 4 million people in the United States using them.[1–3] Carbon fiber is increasingly being used in AFOs because of the many advantages of the material, recent successes in treating individuals with traumatic lower-limb injuries, and greater commercial availability.[4–6] A strong, lightweight material, carbon fiber is made from long chains of carbon atoms that are grouped and woven together.[6] In AFOs, carbon fiber is typically embedded in a resin matrix that holds the fibers together, forming a layered composite material. Carbon fiber is commonly used as the primary structural material for the AFO cuff and foot plate and/or as a posterior strut (spring) element allowing energy storage and return. Carbon fiber orthoses take on many forms. These devices can range from thin, lightweight designs intended to prevent foot drop due to dorsiflexor weakness to robust designs to support the limb during stance, maintaining the joint in a functional and pain-free position or replacing weak or absent plantarflexor muscles. These devices, like AFOs in general, have a wide range of stiffnesses that complement their design and intended population.[7]

Carbon fiber dynamic orthoses are relatively new, with the first article specifically describing a carbon fiber orthosis published in 1990.[8] Publications including carbon fiber AFOs remained limited until 2014 when regular US military use of carbon fiber orthoses for service members and European studies evaluating various designs led to frequent publications. Previous literature reviews have summarized articles that include carbon fiber AFOs, including the systematic review by Highsmith et al[5] which found that an orthosis with a posterior carbon fiber spring element (the Intrepid Dynamic Exoskeletal Orthosis [IDEO]) can decrease pain and allow return to exercise when coupled with the Return to Running rehabilitation program.

One of the goals of systematic reviews is to assist in the translation of evidence into clinical care. This is made easier with an abundance of high-quality evidence. Although the Center for Evidence-Based Medicine has since updated their hierarchy of evidence levels, it is still held that randomized controlled trials present strong, dependable evidence on the effectiveness of the intervention.[9] Systematic reviews with a mix of study designs, but primarily including randomized controlled trials, have an opportunity to draw conclusions based on the evidence with a high level of confidence.

Despite the growing interest and body of literature related to carbon fiber orthoses, a systematic evaluation of the effects of these devices is lacking. The purpose of this review was to summarize the effects of carbon fiber AFOs in impaired individuals.

### PICO question

The PICO (population [P], intervention [I], comparator [C], and outcome [O]) question guiding this review was (P) in individuals with impaired ankle and/or foot function or pain, (I) do carbon fiber AFOs (O) significantly change patient reported outcomes, physical

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performance, activity level, and/or gait biomechanics (C) when compared with no orthosis or other orthosis types?

## Methods

### Search strategy

After development of the PICO question, a strategy for searching databases was established with the assistance of a medical librarian. The searches were conducted on July 27, 2020 (PROSPERO: CRD #42020191630), in the PubMed, Embase, CINAHL, and Cochrane Library databases and were based on the following primary terms (see Appendix A, Supplemental Digital Content 1, https://links.lww.com/POI/A131, for full listing):

(ankle-foot orthosis OR orthosis OR brace) AND (Carbon fiber OR composite OR dynamic) AND (ankle OR foot OR lower limb)

The resulting references from each database were exported into an EndNote library (vX9, Clarivate Analytics LLC, Philadelphia, PA) and deduplicated using the Bramer deduplication method.[10] A protocol was not prepared for this review.

### Screening

The deduplicated references were exported into Rayyan (Rayyan QCI, Doha, Qatar), an online cloud-based software designed to streamline the process of completing systematic reviews.[11] Each citation was independently reviewed by at least 2 team members, who were unable to see responses from others, using the inclusion and exclusion criteria listed in Table 1. Articles were not excluded based on quality.

Conflicts regarding whether to include or exclude an article were resolved by the senior author (J.M.W.). The included articles were then classified into study types using the American Academy of Orthotists and Prosthetists State-of-the-Science Evidence Report Classification Definitions.[12] The categories of study designs include structured reviews (S1-S2), (quasi)experimental trials (E1-E5), observational studies (O1-O6), and expert opinions (X1-X2).

### Quality assessment

The American Academy of Orthotists and Prosthetists State-of-the-Science Evidence Report Quality Assessment Form was used to rate the methodological quality of each included article.[12] The form includes 18 potential threats to internal validity and 8 potential threats to external validity. Some threats to internal validity were not applicable to certain study designs; IV-5 was not applicable to group designs (E1-E2), IV-1–IV-4 to within-subject designs (E3-E5), and IV-1–IV-4 to observational studies (O1-O6). Two reviewers (M.M.G. and R.C.W.) independently rated each article as “high,” “moderate,” or “low” quality based on the number of threats and their assessment of the weight of each threat. Conflicts between quality ratings were resolved by discussion between the 2 reviewers and re-review of the article in question.

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### Study data

Key data including study purpose, AFOs used, outcomes, and population demographics were extracted from each article by 2 independent reviewers and entered into an Excel database (Microsoft Corporation, Redmond, WA). Articles were then grouped by AFO type and results were analyzed. Articles that were clearly from the same population and study were grouped together and their findings are presented as the same product, and study authors were consulted as needed. Only the most comprehensive article was cited.[13,14] See Supplemental Digital Content 5 and 6 (SDC1, https://links.lww.com/POI/A135 and SDC2, https://links.lww.com/POI/A136) for comparison to the Equator PRISMA guidelines.[15]

## Results

In total, 6,889 articles were identified in the search (Figure 1). The 4,322 articles remaining after deduplication were then screened by title and abstract and 102 articles met the inclusion and exclusion criteria. The full texts of these articles were assessed for eligibility; 8 were excluded, and 16 articles were identified as including the same cohort of participants as another already included study (see Appendix B, Supplemental Digital Content 2, https://links.lww.com/POI/A132 for products and associated articles). A final total of 78 articles were included in the qualitative synthesis. These articles were primarily experimental study designs, followed by observational case series and case studies (Table 2). Articles were published in a large range of journal types, from Prosthetics and Orthotics International to IEEE Transactions on Neural Systems and Rehabilitation Engineering (Table 3).

Most of the studies identified in the search were of low to moderate overall quality. Most (40/78) articles had moderate internal validity and (57/78) high external validity (see Appendix C, Supplemental Digital Content 3, https://links.lww.com/POI/A133 for internal validity and Appendix D, Supplemental Digital Content 4, https://links.lww.com/POI/A134 for external validity of each included article). The most common threat to internal validity was blinding of the intervention, followed by reporting appropriate exclusion criteria and adequate statistical power. Common threats to external validity included placing findings in the context of existing literature and having clinically significant or relevant findings.

Four primary types of carbon fiber orthoses account for a majority of the reviewed articles. These were the IDEO,[5,16–38] dorsiflexion-assist AFOs (ToeOff and WalkOn),[28,39–55] the Neuro Swing,[56–60] and the Chignon.[61–64] The IDEO consists of a carbon fiber footplate and cuff along with a strut-like posterior spring (Figure 2(a)). The dorsiflexion-assist devices include the ToeOff, BlueRocker, and KiddieGait as well as the WalkOn. The ToeOff design (including BlueRocker and KiddieGait) has a carbon fiber footplate and anterior shin plate, which are connected by a lateral carbon fiber strut (Figure 2(b)). The WalkOn has a carbon fiber footplate and strut that extends medially to posteriorly, connecting to a posterior cuff below the knee (Figure 2(c)). The Neuro Swing has a carbon fiber footplate and anterior shin plate, which are connected by a lateral spring-hinged metal ankle joint (Figure 2(d)). The Chignon orthosis has a carbon fiber cuff above the ankle and below the knee, which are joined together by steel articulations (Figure 2(e)). The cuff above the ankle is linked to the footplate with elastic elements that assist dorsiflexion and limit plantarflexion. These carbon fiber orthoses have several overlapping similarities, as shown in Figure 2.

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The 4 primary device types use different approaches to managing or controlling ankle stiffness. The IDEO and dorsiflexion-assist devices all have a carbon fiber posterior strut or linkage between the cuff and footplate that acts as a spring-like component. By contrast, the Neuro Swing and Chignon use carbon fiber as structural elements and other materials (e.g., metal springs) to control motion of the ankle. These devices also span a wide range of stiffnesses, with IDEO spring bending stiffness of approximately 785 N/mm,[25] and the ToeOff and WalkOn devices at 2.02 and 2.88 Nm/deg, respectively.[4] The spring-hinged Neuro Swing ranged from 0.05 to 2.2 Nm/deg.[56] Although the IDEO device stiffness was assessed using a 3-point bending test and rotational stiffness was assessed for the other devices, it is apparent that the IDEO is much stiffer than the other devices. The devices have limited overlap in the populations studied, with generally positive outcomes demonstrated for each device, as shown in Table 4.

The IDEO was primarily used in patients with lower-extremity weakness or trauma. These patients were predominantly male US military service members. Most (17/24) of the IDEO articles used an experimental study design, followed by (6/24) observational, and one systematic review. The IDEO is commonly described as a custom, energy-storing device, as the posterior strut can bend to store and return energy.[5,17,20,65] Four of 24 IDEO-specific articles investigated stiffness using mechanical 3-point bending tests and gait analysis.[25,26,35,36] Each concluded that varying stiffnesses had a limited effect on gait mechanics in these very stiff devices.[25,26,35,36] Two articles investigated the effect of varying posterior spring bending axis by using selective laser sintering to decrease the cross-sectional area 30% higher or 30% lower than the center of the bolt hole-to-bolt hole distance.[24,37] Bending axis position produced small but significant changes in sagittal plane ankle range of motion, power absorption, and power generation[37] but did not result in large, consistent changes in walking performance.[24] The IDEO was often coupled with the Return to Running clinical pathway, a high-intensity rehabilitation program designed for military service members, resulting in significant improvements in performance measures such as the Four Square Step Test, timed stair ascent, and Sit to Stand 5×, and allowing return to high-energy activities.[5,20,22,23,31,33] Outcomes were generally improved with the IDEO, including significantly increased walking speed and significantly reduced pain (on a visual analog scale, numerical scale, or as “no pain”/“controlled”/“uncontrolled”[21]),[5,21,29,32–34] although 1 article with a small sample size reported no improvement in average pain, measured using a Numeric Pain Rating Scale.[30]

Dorsiflexion-assist AFOs are commonly used to prevent excessive plantarflexion during swing for individuals with a wide range of health conditions. The WalkOn orthosis was used in adults with hemiplegia[55] or children with cerebral palsy (Gross Motor Function Classification System [GMFCS] GMFCS levels 1 and 2).[54] Both articles used experimental study designs. One study in patients with hemiplegia with moderate methodological quality reported that botulinum toxin A coupled with the WalkOn was not more effective than the botulinum toxin alone at improving spatiotemporal gait parameters, but application of the AFO significantly increased peak dorsiflexion in swing and peak plantarflexion moment. The article concluded that the botulinum toxin A and AFO were more effective than the botulinum toxin A alone.[55] The second study was of low methodological quality and used

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gait analysis to determine that the efficacy of AFOs in children with cerebral palsy (GMFCS levels 1 and 2) is dependent on the mechanical qualities of the device.[54]

Outcomes and limb mechanics with the ToeOff AFO have been reported in more diverse patient groups than other devices. Study participants include individuals with cerebral palsy,[39,42,46,50,53] stroke,[44,45,52] peripheral neuropathy,[40,41,43] hemiplegia,[44,45,51,52] muscular dystrophy,[40,48] lower-limb reconstruction,[28] and traumatic brain injury.[47] Nine of these articles were experimental study designs, and seven were observational. In participants with cerebral palsy, the ToeOff improved foot drop (GMFCS levels 1 and 2).[46,50] These 2 studies used gait analysis and compared shoes + AFO after lower-limb surgery with barefoot postoperation and barefoot preoperation,[50] or compared shoes + AFO with barefoot and shoes-only.[46] However, using temperature sensors placed in the orthoses over 3 months, Schwarze et al[39] reported that only 1 of 6 participants (cerebral palsy, GMFCS levels 1–3) wore their prescribed orthosis the recommended amount of time. One study aimed to determine whether the ToeOff produced additional improvements in gait after multilevel surgery in 20 children with cerebral palsy (GMFCS levels 1–3). The ToeOff produced an additional significant improvement in a gait scoring method that relies on spatiotemporal measures (Gillette Gait Index) but did not produce an additional improvement in gait scoring methods that rely on joint angles (Gait Deviation Index and Gait Profile Score). This indicated that the ToeOff produced an additional improvement in walking ability rather than gait pattern after multilevel surgery.[53] However, subgroup analysis was not performed in the study. In patients with hemiplegia, the ToeOff significantly reduced energy cost (measured using breath-by-breath analysis and electrocardiography)[45] and increased speed[44,45] when compared with no AFO, but differences in energy cost[52] (as measured by the Physiological Cost Index[52]) and speed[51] were small when compared with a plastic hinged AFO and spring AFO.[51,52] The ToeOff also had high ratings for satisfaction[40,41] (1 article did not report the satisfaction measure used[40] and the other used a 6-point Likert scale[41]), improved balance[43,47] (using the School Function Assessment[47] and Mini Balance Evaluation Systems Test[43]), and pain relief (using an 11-point Numerical Pain Rating Scale).[49] The use of the ToeOff in boys with Duchenne muscular dystrophy is not supported by the findings in 1 product.[48]

The Neuro Swing has been evaluated in multiple patient populations including individuals with cerebral palsy,[57–59] neurological disorders,[60] and unilateral calf muscle weakness due to polio.[56] Three articles were experimental and 2 were observational study designs. Results regarding changes in walking speed are conflicting. The Neuro Swing resulted in improved walking speed in children with cerebral palsy in 2 articles (GMFCS level 2[58] and GMFCS level not reported[57]),[57,58] but 2 other articles about children with cerebral palsy[59] (GMFCS levels 1–3) and individuals with calf muscle weakness due to polio did not demonstrate consistent changes.[56,59] Net energy cost was improved with AFO application in 18 total participants compared with shoes-only,[56,59] measured using a telemetric gas analysis device to measure oxygen reuptake and respiratory exchange ratios[56] or a breath gas analysis system to assess breath-by-breath oxygen uptake and carbon dioxide production.[59] Conversely, 1 article reported no change in energy cost (measured using a spiroergometer during a rest and 6-minute walk test) between shoes-only and AFO conditions, but this was only in 1 participant.[58] One article examined outcomes from gait analysis on the day of

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device delivery and at 3-month follow-up in 1 participant with cerebral palsy and found all temporal-spatial parameters were improved and ankle plantarflexion decreased on the day of device delivery. Improvements in step length, velocity, and cadence persisted at 3 months, as well as decreased hip flexion both with and without the AFO.[57] Maximum plantarflexion moment increased and the minimum knee angle in terminal stance decreased compared with barefoot walking in 8 participants with neurological disorders using the Neuro Swing during 3D gait analysis, but actual kinematic values were not reported.[60]

An experimental study design was used in all Chignon-related publications, with the exception of one systematic review.[62] In individuals with stroke or hemiplegia, the device significantly improved walking speed[63,64] on the 10-m walk test compared with a prefabricated AFO and shoes-only[64] or compared with no-AFO and an off-the-shelf polypropylene AFO.[63] In the same population, the Chignon significantly decreased mechanical work[61,64] when compared with shoes-only. The Chignon had improved ankle position at heel strike and dorsiflexion at toe-off in 10 hemiplegic patients when compared with shoes-only.[64] Knee recurvatum and foot varus were corrected with the orthosis in 13 patients with hemiplegia after stroke, and there were no difference in spasticity scores on the Ashworth scale with the Chignon orthosis compared with a control polypropylene orthosis.[63]

The remaining 28 articles[66–93] did not include the brand name of the carbon fiber AFO used, did not include a picture of the device, were the only included publication using a highly specific device, or were vague in their description of the AFO. Most of these articles (14/28) were of moderate methodological quality, followed by low (9/28) and high (5/28). These articles covered a range of populations from hemiplegia and postpolio to Charcot–Marie–Tooth disease. Sixteen articles had experimental study designs, 11 were observational, and 1 systematic review. In the articles where the device was adequately described, most of the devices used seem to be low-profile, compliant devices analogous to the dorsiflexion-assist devices. Common comparator conditions included shoes-only, thermoplastic AFOs, or barefoot. Most articles demonstrate increased walking speed with the orthoses,[69–73,75–78,81,86,90,93] 2 found no change,[67,92] and 1 had decreased walking speed.[80] Walking energy cost was decreased[69,71,86,92] and stride length was increased.[70,78,80,81,84,90]

## Discussion

The publications identified in this review were a mix of experimental and observational study designs; however, a more favorable body of work would include more randomized controlled trials to increase the strength of the evidence. A strength of the included articles is the external validity. A majority of the articles had high external validity, indicating that most results are generalizable—there is a high likelihood of the same results in different patients, at a different location, or at a different time. Most of the articles were of moderate internal validity, indicating a moderate probability that the observed results were the product of the experimental intervention. Internal and external validity could be strengthened by making small changes. Many articles reported either inclusion criteria or exclusion criteria, few reported both. Reporting both inclusion and exclusion criteria increases clarity and abides by reporting guidelines.[12] In addition, clearly comparing study findings to other

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literature improves the ability to generalize the findings and also gives readers context regarding the results.

As a material, carbon fiber has many advantages, including being lightweight, strong, and fatigue resistant.[6] Therefore, it is used in many forms in the devices included in this review. Because of its high strength to weight ratio and energy storage and return properties, it is used as both a spring element to offload the limb and control ankle motion, as well as a structural element in the cuff and footplate. These devices take on different forms and designs and incorporate carbon fiber in unique ways to address the needs of specific patient populations. The 4 included device types represent different uses of carbon fiber; the IDEO and dorsiflexion-assist devices use carbon fiber as a primary component for energy storage and return, where the Neuro Swing and Chignon use carbon fiber as a lightweight structural component. However, some of the included articles did not include enough detail in their description of the AFO studied. This lack of sufficient information regarding AFOs in research publications has been noted in other reviews and articles.[7,94–96] In the articles that adequately described device design, the advantages of carbon fiber in each AFO are typically highlighted.

The IDEO is a very stiff, robust device designed to withstand high forces during demanding activities, controlling motion, and storing and returning energy.[22] It was developed specifically for lower-extremity trauma patients[22,65] and intended to support the limb to "act in lieu of the impaired torque-producing capability of the musculature."[20] The stiffness of the IDEO is much higher[25,35,36] than the stiffnesses of many other commercially available devices[4] and allows for the return to many high-intensity activities.[97] Although the clinical presentation for limb trauma patients may vary widely, the limited motion allowed by the device keeps the foot and ankle in pain-free optimal alignment.[32] The posterior spring element allows for energy storage and return to offload the limb, enabling high-energy and impact activities.

The ToeOff, WalkOn, and Neuro Swing were predominantly used in patients with lower-limb muscle weakness or spasticity due to neurologic conditions, including individuals with cerebral palsy, polio, and hemiplegia. The ToeOff was designed for people with an "impaired ability to actively dorsiflex" the foot,[98] the WalkOn for people with moderate to severe foot drop,[99] and the Neuro Swing for individuals with central nervous system disorders.[100] The ToeOff and WalkOn have carbon fiber struts that keep the foot from dropping during the swing phase of gait. The strut elements have fixed stiffnesses of 2.02 Nm/deg for the ToeOff and 2.88 Nm/deg for the WalkOn,[4] and resist both plantarflexion and dorsiflexion. The Neuro Swing has springs on the anterior and posterior sides of the ankle axis, allowing dorsiflexion and plantarflexion stiffness adjustments ranging from 0.05 to 2.2 Nm/deg.[56] Although the ToeOff and WalkOn have the same, fixed stiffnesses in dorsiflexion and plantarflexion, the Neuro Swing allows adjustable resistance to limit foot drop or support plantarflexor muscles simultaneously. The inability to directly compare stiffnesses between these devices and the IDEO due to the differences in measurement approach is due in part to the lack of a standardized procedure or commercially available tool for measuring stiffness.[7,95,96] Limited information regarding the mechanical characteristics or intended population is available for the Chignon orthosis.

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The body of literature is continually growing; therefore, a limitation of this study is the inability to capture relevant articles after conducting the search.[101–103] Furthermore, despite the purposeful language in the inclusion criteria, studies using devices primarily made of plastic with carbon fiber components may have been missed.[104] Additional limitations include the identification of articles exclusively in the databases evaluated. In aggregating the data, limitations within each individual study (e.g., lack of stratification by patient impairment, subset analysis, or varied device stiffness) cannot be fully accounted for. Although publication bias exists, there were no measures taken to assess that bias in this review.

## Conclusion

Carbon fiber in ankle-foot orthoses can be used as a spring-like component or as a structural element. Outcomes with the ToeOff, WalkOn, and Neuro Swing include improved foot drop and balance and decreased energy cost. IDEO outcomes include increased walking speed, decreased pain, and return to high-energy activities. There is clear alignment between the type of device and the patient population with which it is used. The ToeOff, WalkOn, and Neuro Swing are most commonly used in neurological conditions for the prevention of foot drop and to provide modest support at the ankle. By contrast, stiff IDEO-like devices are used to provide greater levels of support about the ankle joint and are well suited for use in individuals with significant weakness or who have sustained limb trauma. Future studies should provide detailed descriptions of the patient population, device used, and fitting procedures.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Acknowledgments

The authors would like to acknowledge Medical Librarian Matt Regan for his assistance in developing search terms and DPT students Taylor Quandt, Sarah Rohloff, Katie Riedell, Tyler Rogers, and Anthony Kollasch for their contributions to article reviews.

### Funding

Supported by the Iowa Center for Research by Undergraduates Research Fellowship Program and the National Institutes of Health under Award Number UL1TR002537. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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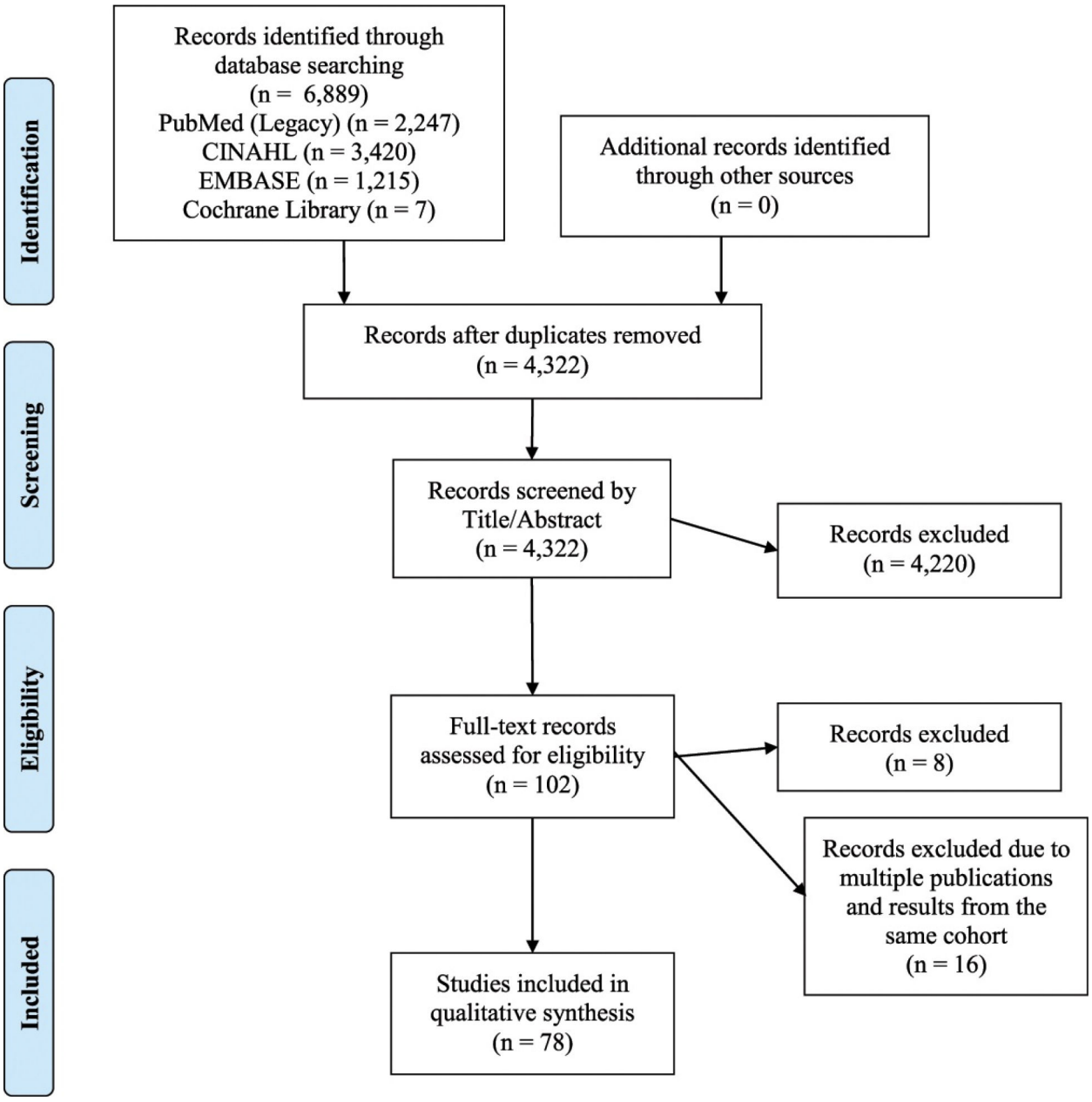



**Figure 1.**
PRISMA flow diagram

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**Figure 2.**
Identified carbon fiber ankle-foot orthoses. (a) IDEO, (b) dorsiflexion-assist ToeOff, (c) dorsiflexion-assist WalkOn, (d) Neuro Swing, (e) Chignon.

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**Table 1. -**

Inclusion and exclusion criteria.

| Inclusion | Exclusion |
|---|---|
| Published any time before July 27, 2020 | Language other than English |
| Published in a peer-reviewed journal and indexed in the selected databases | Nonhuman subject studies |
| Makes a comparison between a carbon fiber passive AFO to no orthosis or other orthosis types or configurations | Internal joint prosthesis/joint replacement including hip, knee, or ankle arthroplasty |
| Includes human subjects with impaired/painful ankle or foot using an external ankle–foot orthosis | Only healthy population used |
| All ages of ambulatory subjects | Orthosis at or above the knee or an in-shoe orthotic |
| Purpose is to identify changes in patient-reported outcomes, physical performance measures, activity level, and/or gait biomechanics | Lacks main topic of passive carbon fiber AFO |
| | Uses only robotic AFOs |
| | Does not compare with other orthosis or no orthosis conditions |

Abbreviation: AFO, ankle-foot orthosis.

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**Table 2. -**

Study design distribution.

| **Classification Type of study** | | |
|---|---|---|
| S1 | Meta-analysis | 0 |
| S2 | Systematic review | 3 |
| E1 | Randomized controlled trial | 1 |
| E2 | Controlled trial | 5 |
| E3 | Interrupted time series trial | 3 |
| E4 | Single subject trial | 3 |
| E5 | Controlled before and after trial | 37 |
| O1 | Cohort study | 0 |
| O2 | Case-control study | 0 |
| O3 | Cross-sectional study | 2 |
| O4 | Qualitative study | 2 |
| O5 | Case series | 13 |
| O6 | Case study | 9 |
| X1 | Group consensus | 0 |
| X2 | Expert opinion | 0 |
| | Total | 78 |

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**Table 3. -**

Journal distribution.

| Journal | No. of publications |
|---|---|
| Annals of Physical and Rehabilitation Medicine | 5 |
| Brain Injury | 1 |
| Clinical Biomechanics | 4 |
| Clinical Orthopedics and Related Research | 3 |
| Clinical Rehabilitation | 1 |
| Developmental Medicine and Child Neurology | 3 |
| Disability and Rehabilitation | 2 |
| European Journal of Physical and Rehabilitation Medicine | 1 |
| Gait and Posture | 15 |
| Haemophilia | 2 |
| IEEE Transactions on Neural Systems and Rehabilitation Engineering | 1 |
| Journal of Biomechanics | 1 |
| Journal of Biomechanical Engineering | 1 |
| Journal of Bone and Joint Surgery | 2 |
| Journal of Children's Orthopaedics | 1 |
| Journal of Foot and Ankle Research | 1 |
| Journal of NeuroEngineering and Rehabilitation | 2 |
| Journal of Orthopaedic Trauma | 2 |
| Journal of Pediatric Rehabilitation Medicine | 1 |
| Journal of Physical Therapy Science | 1 |
| Journal of the Royal Army Medical Corps | 1 |
| Journal of Rehabilitation Medicine | 2 |
| Journal of Prosthetics and Orthotics | 6 |
| Military Medicine | 3 |
| Muscle and Nerve | 1 |
| Neurology | 1 |
| NeuroRehabilitation | 2 |
| Pediatric Physical Therapy | 1 |
| PLoS One | 1 |
| Prosthetics and Orthotics International | 6 |
| Rehabilitation Research and Practice | 3 |
| Theoretical Issues in Ergonomics Science | 1 |
| Total | 78 |

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**Table 4. -**

Summary of results.

| Device | Population | Results |
|---|---|---|
| IDEO (Figure 2(a)) | Lower-extremity trauma | Decreased pain, increased mobility |
| Dorsiflexion assist: ToeOff Design (Figure 2(b)) | Cerebral palsy | Increased stride length, walk speed, and foot clearance<br>AFO produced additional improvements in spatiotemporal measures after multilevel surgery |
| | Peripheral neuropathy | High satisfaction |
| | Hemophilia | Reduced energy cost and increased speed, but these were small changes compared with plastic AFO and spring AFO |
| Dorsiflexion assist: Walk On (Figure 2(c)) | Hemiplegia | No difference between AFO + Botox injections and Botox injection alone in spatiotemporal measures. AFO improved kinematic parameters, so Botox + AFO more effective than Botox only |
| | Cerebral palsy | Foot drop improved, efficacy of AFO dependent on mechanical properties |
| Neuro Swing (Figure 2(d)) | Cerebral palsy | Conflicting results regarding walking speed Improved energy cost |
| | Neurological disorders | Ankle and knee kinematics improved |
| Chignon (Figure 2(e)) | Hemiplegia | Speed increased<br>Gait kinematics and foot drop improved |

Abbreviations: AFO, ankle-foot orthosis; IDEO, Intrepid Dynamic Exoskeletal Orthosis.