CLINICAL PRACTICE GUIDELINES

A Clinical Practice Guideline for the Use of Ankle-Foot Orthoses and Functional Electrical Stimulation Post-Stroke

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ABSTRACT

Background: Level of ambulation following stroke is a long-term predictor of participation and disability. Decreased lower extremity motor control can impact ambulation and overall mobility. The purpose of this clinical practice guideline (CPG) is to provide evidence to guide clinical decision-making for the use of either ankle-foot orthosis (AFO) or functional electrical stimulation (FES) as an intervention to improve body function and structure, activity, and participation as defined by the International Classification of Functioning, Disability and Health (ICF) for individuals with poststroke hemiplegia with decreased lower extremity motor control.

Methods: A review of literature published through November 2019 was performed across 7 databases for all studies involving stroke and AFO or FES. Data extracted included time post-stroke, participant characteristics, device types, outcomes assessed, and intervention parameters. Outcomes were examined upon initial application and after training. Recommendations were determined on the basis of the strength of the evidence and the potential benefits, harm, risks, or costs of providing AFO or FES.

Results/Discussion: One-hundred twenty-two meta-analyses, systematic reviews, randomized controlled trials, and cohort studies were included. Strong evidence exists that AFO and FES can each increase gait speed, mobility, and dynamic balance. Moderate evidence exists that AFO and FES increase quality of life, walking endurance, and muscle activation, and weak evidence exists for improving gait kinematics. AFO or FES should not be used to decrease plantarflexor spasticity. Studies that directly compare AFO and FES do not indicate overall superiority of one over the other. But evidence suggests that AFO may lead to more compensatory effects while FES may lead to more therapeutic effects. Due to the potential for gains at any phase post-stroke, the most appropriate device for an individual may change, and reassessments should be completed to ensure the device is meeting the individual's needs.

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Limitations: This CPG cannot address the effects of one type of AFO over another for the majority of outcomes, as studies used a variety of AFO types and rarely differentiated effects. The recommendations also do not address the severity of hemiparesis, and most studies included participants with varied baseline ambulation ability.

Summary: This CPG suggests that AFO and FES both lead to improvements post-stroke. Future studies should examine timing of provision, device types, intervention duration and delivery, longer term follow-up, responders versus nonresponders, and individuals with greater impairments.

Disclaimer: These recommendations are intended as a guide for clinicians to optimize rehabilitation outcomes for people with poststroke hemiplegia who have decreased lower extremity motor control that impacts ambulation and overall mobility.

A Video Abstract is available as supplemental digital content from the authors (available at: http://links.lww.com/JNPT/A335).

Key words: *ankle-foot orthosis, clinical practice guidelines, functional electrical stimulation, hemiplegia, neuroprosthetics, stroke*

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The Evidence Based Documents Committee of the ANPT monitored and managed any perceived conflicts of interest identified among members of the Guideline Development Group and Advisory Board. Dr Johnston is currently employed by Ossur, but she was not an employee prior to acceptance of this CPG.

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LEVELS OF EVIDENCE AND GRADES OF RECOMMENDATIONS

This clinical practice guideline (CPG) is intended to provide recommendations to improve mobility, function, and quality-of-life (QOL) outcomes using an ankle-foot orthosis (AFO) or functional electrical stimulation (FES) for individuals with poststroke hemiplegia who have decreased lower extremity motor control that impacts body function and structure, activity, and participation. The intention is to provide evidence-based guidance to clinicians who evaluate and treat these individuals to assist in clinical decision-making. These recommendations should be interpreted based on the desired clinical outcomes, the patient presentation and goals, the potential risks and harms, and clinical practice needs. These guidelines were developed using accepted methodology[1,2] for critical appraisal and the assignment of levels of evidence and strength of recommendations (Tables 1 and 2) as defined in the *APTA Clinical Practice Guideline Process Manual*.[2] This CPG provides an introduction and description of the need for this CPG and clear recommendations through 8 action statements. For each action statement, a standardized profile is provided and supported by relevant evidence. Clinical interpretation and research recommendations follow to provide clinicians and researchers with guidance for each action statement. Each study included in this CPG was appraised by at least 2 trained appraisers, and assigned a level of evidence and strength of recommendation. The strength represents the overall strength of the available evidence to support that recommendation.

Table 1. Levels of Evidence[a,b]

LEVEL OF EVIDENCE	INTERVENTION
I. Evidence: high-quality systematic reviews, diagnostic or prospective studies, RCTs	Systematic review of high-quality RCTs High-quality RCT
II. Evidence from lesser-quality diagnostic studies, prospective studies, or weaker RCTs	Systematic review of high-quality cohort studies High-quality cohort study High-quality outcomes research High-quality quasi-experimental study High-quality single-subject design Lower-quality RCT
III. Case-controlled studies or retrospective studies	Systematic review of case-controlled studies High-quality case-controlled study Outcomes study or ecological study Lower-quality cohort study
IV. Case series	Case series
V. Expert opinion	Expert opinion

Abbreviation: RCT, randomized controlled trial.

[a]*APTA Clinical Practice Guideline Process Manual.*[2]

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Table 2. Grades of Recommendation[a,b]

LETTER GRADE	LEVEL OF OBLIGATION	DEFINITION
A	Strong	A high level of certainty of moderate to substantial benefit, harm, or cost, or a moderate level of certainty for substantial benefit, harm, or cost (based on a preponderance of level 1 or 2 evidence with at least 1 level 1 study).
B	Moderate	A high level of certainty of slight to moderate benefit, harm, or cost, or a moderate level of certainty for a moderate level of benefit, harm, or cost (based on a preponderance of level 2 evidence, or a single high-quality RCT).
C	Weak	A moderate level of certainty of slight benefit, harm, or cost, or a weak level of certainty for moderate to substantial benefit, harm, or cost (based on level 2-5 evidence).
D	Theoretical/ foundational	A preponderance of evidence from animal or cadaver studies, from conceptual/theoretical models/ principles, or from basic science/bench research, or published expert opinion in peer-reviewed journals that supports the recommendation.
P	Best practice	Recommended practice based on current clinical practice norms, exceptional situations in which validating studies have not or cannot be performed, yet there is a clear benefit, harm, or cost, expert opinion.
R	Research	An absence of research on the topic or disagreement among conclusions from higher-quality studies on the topic.

Abbreviation: RCT, randomized controlled trial.

[a]*APTA Clinical Practice Guideline Process Manual.*[2]

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SUMMARY OF ACTION STATEMENTS

The action statements are organized by outcome across the International Classification of Functioning, Disability and Health (ICF) domains of participation, activity, and body structure and function. The statements and recommendations are then further subdivided by phase of recovery and effect. A summary of these subdivisions is shown in Table 3, with further explanation provided within each action statement profile.

Participation Outcomes

Action Statement 1: ANKLE-FOOT ORTHOSIS (AFO) OR FUNCTIONAL ELECTRICAL STIMULATION (FES) TO IMPROVE QUALITY OF LIFE. Clinicians should provide an AFO or FES for individuals with foot drop due to chronic poststroke hemiplegia who have goals to improve QOL (evidence quality: II; recommendation strength: moderate).

Activity Outcomes

Action Statement 2: ANKLE-FOOT ORTHOSIS (AFO) OR FUNCTIONAL ELECTRICAL STIMULATION (FES) TO IMPROVE GAIT SPEED. Clinicians should provide an AFO or FES for individuals with decreased lower extremity motor control due to acute or chronic poststroke hemiplegia who have goals to improve gait speed (evidence quality: I; recommendation strength: strong).

Action Statement 3: ANKLE-FOOT ORTHOSIS (AFO) OR FUNCTIONAL ELECTRICAL STIMULATION (FES) TO IMPROVE OTHER MOBILITY. Clinicians should provide an AFO or FES for individuals with decreased lower extremity motor control due to acute or chronic poststroke hemiplegia who have goals to improve other mobility (evidence quality: I; recommendation strength: strong).

Action Statement 4: ANKLE-FOOT ORTHOSIS (AFO) OR FUNCTIONAL ELECTRICAL STIMULATION (FES) TO IMPROVE DYNAMIC BALANCE. Clinicians should provide an AFO or FES for individuals with decreased lower extremity motor control due to acute or chronic poststroke hemiplegia who have goals to improve dynamic balance (evidence quality: I; recommendation strength: strong).

Action Statement 5: ANKLE-FOOT ORTHOSIS (AFO) OR FUNCTIONAL ELECTRICAL STIMULATION (FES) TO IMPROVE WALKING ENDURANCE. Clinicians may provide an AFO or FES for individuals with decreased lower extremity motor control due to acute poststroke hemiplegia who have goals to improve walking endurance (evidence quality: II; recommendation strength: moderate).

Clinicians should provide an AFO or FES for individuals with decreased lower extremity motor control due to chronic poststroke hemiplegia who have goals to improve walking endurance (evidence quality: I; recommendation strength: strong).

Body Structure and Function Outcomes

Action Statement 6: ANKLE-FOOT ORTHOSIS (AFO) OR FUNCTIONAL ELECTRICAL STIMULATION (FES) TO IMPROVE PLANTARFLEXOR SPASTICITY. Clinicians should not provide an AFO or FES for individuals with decreased lower extremity motor control due to acute or chronic poststroke hemiplegia who have primary goals to improve plantarflexor spasticity (evidence quality: II; recommendation strength: moderate).

Action Statement 7: ANKLE-FOOT ORTHOSIS (AFO) OR FUNCTIONAL ELECTRICAL STIMULATION (FES) TO IMPACT MUSCLE ACTIVATION. Clinicians may provide an AFO with decreased stiffness for individuals with decreased lower extremity motor control due to acute or chronic poststroke hemiplegia who have goals to allow activation of the anterior tibialis and gastrocnemius/soleus muscles while walking with the AFO (evidence quality: II; recommendation strength: moderate).

Clinicians should provide FES for individuals with decreased lower extremity motor control due to chronic poststroke hemiplegia who have goals to improve activation of the anterior tibialis muscle while walking without FES (evidence quality: II; recommendation strength: moderate).

Action Statement 8: ANKLE-FOOT ORTHOSIS (AFO) OR FUNCTIONAL ELECTRICAL STIMULATION (FES) TO IMPROVE GAIT KINEMATICS. Clinicians may provide an AFO or FES for individuals with decreased lower extremity motor control due to acute or chronic poststroke hemiplegia who have goals to improve ankle dorsiflexion at initial contact and during loading response and swing (evidence quality: III; recommendation strength: weak).

Table 3. Action Statement Summary Based on Chronicity and Device

ACTION STATEMENT	AGGREGATE EVIDENCE QUALITY	PREPONDERANCE OF BENEFIT OR HARM	LEVEL OF OBLIGATION	PHASE AND DEVICE	INDIVIDUAL EVIDENCE QUALITY
1. Quality of life	II	Moderate	Should provide	Acute AFO Acute FES Chronic AFO Chronic FES	Best practice Best practice I II
2. Gait speed	I	Strong	Should provide	Acute AFO Acute FES Chronic AFO Chronic FES	I II I I
3. Other mobility	I	Strong	Should provide	Acute AFO Acute FES Chronic AFO Chronic FES	II I I I
4. Dynamic balance	I	Strong	Should provide	Acute AFO Acute FES Chronic AFO Chronic FES	II Best practice I I
5. Endurance	Acute II	Moderate	May provide	Acute AFO Acute FES	II III
	Chronic I	Strong	Should provide	Chronic AFO Chronic FES	I I
6. Spasticity	II	Moderate	Should not provide	Acute AFO Acute FES Chronic AFO Chronic FES	II II II II
7. Muscle activation	II	Moderate Best practice Moderate Moderate	May provide May provide May provide Should provide	Acute AFO Acute FES Chronic AFO Chronic FES	II Best practice III II
8. Gait kinematics	III	Weak	May provide	Acute AFO Acute FES Chronic AFO Chronic FES	III Best practice III III

Abbreviations: AFO, ankle-foot orthosis; FES, functional electrical stimulation.

INTRODUCTION

Purpose of Clinical Practice Guidelines

The Academy of Neurologic Physical Therapy (ANPT) of the APTA supports the development of CPGs to assist physical therapists in the decision-making process. Generally, the purpose of a CPG is to inform clinicians about who, what, how, and when to treat. The purpose of this CPG is to provide evidence to guide clinical decision-making for the use of either AFO or FES as an intervention to improve body function and structure, activity, and participation as defined by the ICF[3] for individuals with poststroke hemiplegia with decreased lower extremity motor control.

The objective of this CPG is to address the specific health question: "Is an AFO or FES effective at improving outcomes for individuals with decreased lower extremity motor control due to poststroke hemiplegia?". The scope of the CPG is intended to provide evidence on the effects of AFO or FES on important outcomes across the ICF, to define these effects based on the intended goal, which may include the use of the device as a compensatory strategy or as a means to promote recovery, and lastly this CPG will examine differences in outcomes and effects in the acute versus chronic period after stroke across any health care setting. The target population of the CPG includes adults (≥18 years) of both genders and all races and ethnicities.

Background and Need for a Clinical Practice Guideline on the Use of Ankle-Foot Orthoses or Functional Electrical Stimulation for Individuals With Poststroke Hemiplegia

Approximately 15 million individuals worldwide experience a stroke annually, with 795 000 of these occurring in the United States.[4] Stroke is currently the leading cause of serious long-term disability, with an estimated annual health care cost of $34 billion in the United States.[5] Following a stroke, damage to the motor cortex and corticospinal tract can lead to decreased motor control and lower extremity weakness, defined by the inability to generate sufficient force.[6] This decrease in motor control is a significant contributor to decreased gait speed and increased gait asymmetry.[7] Weakness or the inability to generate sufficient force of the dorsiflexor (DF) muscles can lead to an inability to lift the foot sufficiently for clearance during the swing phase of gait,[8] a condition commonly referred to as foot drop.[9] Weakness of the plantarflexors can lead to decreased stance-phase stability and decreased push-off.[10] These impairments can lead to compensations at other joints, decreased walking speed, falls, and decreased QOL.[8] Level of ambulation following stroke is a long-term predictor of participation and disability.[11,12]

The more traditional method to address foot drop and decreased stance-phase stability is an AFO, which better positions the foot for swing and can improve stance-phase ankle and knee stability.[13,14] Guidelines from the American Heart Association in 2016 recommended an AFO to compensate for foot drop to improve overall mobility and gait biomechanics post-stroke.[15] AFOs can improve gait deviations,[14] but they also have limitations. AFOs limit ankle excursion and can also decrease muscle activation and dynamic balance.[16,17] Tasks such as standing up from a chair can be made more difficult with an AFO[18] and many individuals find AFOs uncomfortable.[15]

There are many options for the design of an AFO.[19,20] Different materials can be used that vary in stiffness based on the material properties and the amount of material placed over the foot and shank. AFOs can be solid with motion only permitted by the flexibility of the material or can be articulating at the ankle to allow motion. The amount of motion allowed or restricted by AFO can also be manipulated. AFOs can also provide assistance or resistance to motion through springs, rods, straps, and stops that limit motion. AFO designs with increased stiffness and stops have additional biomechanical considerations, as they also impact stance-phase control. With so many options for design, there are various ways to approach AFO decision-making based on patient presentation. This situation also requires expertise in decision-making by the treating team that includes the physical therapist, orthotist, and physician when evaluating the needs of their patients with foot drop or stance-phase instability due to poststroke hemiplegia. While physical therapists learn the principles of different AFO types, there is variability in how these are applied. Chisholm and Perry[21] reported that increased knowledge translation is needed by physical therapists when choosing an AFO for a patient for measuring impairments and outcomes, identifying goals of an AFO including design features, and determining the influence of contextual factors. The role of the orthotist as part of the rehabilitation team is important in decision-making for planning, design, and provision due to their education and expertise.[22]

The 2016 guidelines from the American Heart Association state that FES of the DF and peroneal muscles during swing is a reasonable alternative to an AFO for foot drop for individuals with upper motor neuron involvement.[15] FES creates an orthotic effect when the FES is on,[8] and may also be used therapeutically for strengthening or retraining muscles so that it may later be withdrawn.[8] With FES, there are different decisions to be made than with AFO. Commercially available systems are commonly used clinically. The physical therapist's decision-making focuses on stimulation intensity and electrode placement based on the desired response of the muscles to achieve the effect.[23] Due to differences in how the FES is controlled or triggered by the different commercially available systems, the physical therapist also needs to decide which FES device works best for each patient.[23] FES has limitations. If ankle medial/lateral instability is a significant concern, FES may be less effective.[24] The sensory aspect of FES is not always tolerated, setup can be complex, and pain may limit the ability to achieve adequate DF in swing.[18] Many physical therapists do not recommend FES due to lack of knowledge of devices or of which individuals would most benefit.[23,25] Inconsistent reimbursement can also be a deterrent for choosing FES.[23,25]

There are no CPGs on the use of AFO or FES that address deficits in body function and structure, activity, and participation in individuals with poststroke hemiplegia who have lower extremity motor control deficits. Three related CPGs were published in 2006,[26] 2009,[22] and 2010.[27] Two[26,27] of these CPGs were on overall stroke rehabilitation that included AFO and FES as intervention options. One of these CPGs[27] concluded that there was fair evidence for using an AFO to prevent foot drop and increase knee stability and fair evidence for using FES as an adjunctive intervention for individuals with impaired muscle strength and impaired gait. The third CPG from 2009[22] was specific to AFO only and provides recommendations for assessment, fitting, and provision of AFO. These CPGs are at least 10 years old. More evidence is now available to develop a new CPG that takes outcomes into account across the ICF. In the past 5 years, 2 systematic reviews (SRs) on AFO and FES, 1 with a meta-analysis, have been conducted. In the SR, Dunning et al[8] examined the outcomes from 6 randomized controlled trials (RCTs), with a total of 820 participants and found that AFO and FES were effective and were equivalent for increasing gait speed.[8] In an SR with a meta-analysis, Prenton et al[9] included 7 RCTs also finding equivalent outcomes for AFO and FES but suggested that stronger studies are needed to link impairment to function. Additional SRs examine the effects of either AFO or FES.[20,21,28,29] Considering the current evidence available, a CPG is warranted. The health intent and expected benefit of this CPG are to inform and guide clinicians and consumers in choosing the best intervention using AFO or FES based on desired outcomes.

Statement of Intent

This guideline is intended for health care professionals, family members, educators, researchers, policy makers, and payers who have a role in the decision-making process for either AFO or FES. It is not intended to be construed or to serve as a legal standard of care. As rehabilitation knowledge expands, clinical guidelines are promoted as syntheses of current research and provisional proposals of recommended actions under specific conditions. Standards of care are determined on the basis of all clinical data available for an individual patient/client and are subject to change, as knowledge and technology advance, patterns of care evolve, and patient/family values are integrated. This CPG is a summary of practice recommendations that are supported with current published literature that has been reviewed by expert practitioners and other stakeholders. These parameters of practice should be considered guidelines only, not mandates. Adherence to them will not ensure a successful outcome in every patient, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate decision regarding a particular clinical procedure or treatment plan must be made using the clinical data presented by the patient/client/family, the diagnostic and treatment options available, the patient's values, expectations, and preferences, and the clinician's scope of practice and expertise.

METHODS

The broad topic of orthotics and neuroprosthetics was identified as being of importance by the Board of the ANPT following a member survey. A call for applicants to serve on the Guideline Development Group (GDG) was sent out to ANPT membership. In the fall of 2015, 5 GDG members were identified following an application process, creating a diverse team of neurologic physical therapists with backgrounds ranging from research, academia, service, and clinical practice in the area of orthotics and neuroprosthetics. Each GDG member signed a conflict of interest form, which was then approved by the Evidence Based Documents Committee of the ANPT. No competing conflicts of interest were identified. One GDG member resigned from the GDG early in the process and transitioned to the advisory board. The administrative, clinical content expert and co-chair (L.B.) is a faculty member within a physical therapy (PT) department at an R1 (high research activity) university with clinical and teaching expertise on the application of orthotics and neuroprosthetics. The research content expert and co-chair (T.J.) is a full professor in a PT department R2 (high research activity) university with research and clinical experience in the application of neuroprosthetics. The clinical content expert (S.K.) is a faculty member in a PT department with clinical and teaching expertise on the application of orthotics and neuroprosthetics, and the clinical content expert (C.D.-W.) is a clinician and administrator in a nationally ranked rehabilitation institution overseeing inpatient and outpatient clinical care. Three of the GDG members (L.B., SK, and C.D.-W.) are board-certified clinical specialists in neurologic PT, and 2 members (L.B. and S.K.) have experience as appraisal team members on prior CPGs. One member (T.J.) has experience conducting and reviewing SRs.

Three GDG members (T.J., S.K., and C.D.-W.) attended the APTA Workshop on Developing CPGs in August of 2016, and materials from this workshop and the subsequent *APTA Clinical Practice Guideline Process Manual*[2] were used to guide GDG development. The GDG received APTA funding for CPG development, specifically for travel for working meetings, a software license, and publication costs. Financial assistance was also provided by the ANPT to supplement travel and publication costs. The views or interests of the funding body have not influenced final recommendations or content of the guideline. Guidance on the CPG process was provided by the ANPT Evidence-Based Document Committee without impacting CPG content.

To gain important perspectives from diverse stakeholders, information was gathered from neurologic physical therapists, consumers of either AFOs or FES devices, and a multidisciplinary advisory board. Perspectives of neurologic physical therapists and consumers were gathered via web-based surveys using Qualtrics (Qualtrics, Seattle, Washington). The purpose of these surveys was to gain an understanding of the perceived knowledge gaps and needs of clinicians and consumers to guide the literature search and CPG development. The main needs that clinicians identified were considered when developing the CPG and included an improved understanding of the examination process and clinical decision-making related to timing, potential impact, and outcomes identified with AFO and FES interventions. Consumers identified a need for more extensive education about device selection, use, and expense along with increased training with devices prior to final selection. Both groups identified a need for better understanding of the effects of device application and the long-term impact on recovery. This information contributed to the development of the CPG in several ways including the organization of action statements by outcome along the ICF domain with the subdivision of statements and recommendations by effect.

A multidisciplinary advisory board was assembled by the GDG. This expert panel included 2 physical therapist researchers with experience with AFO and FES use post-stroke; a physician/researcher in the field of orthotics; a board-certified orthotist with experience in AFO, FES, reimbursement research, education, and industry; 2 consumers with a history of poststroke hemiplegia with experience in AFO or FES use; and an end-user advocate for technology for individuals with neurologic diagnosis. Advisory board members were solicited to gather a diverse group of stakeholders across health care providers, industry representatives, consumers, and advocates. Each advisory board member signed a conflict-of-interest form, which was then approved by the Evidence-Based Documents Committee of the ANPT. No competing conflicts of interest were identified. The advisory board provided guidance and feedback to the GDG at key points in the CPG development process. In addition to the advisory board, a methodologist with expertise in CPG development provided guidance with the CPG process.

External Review Process by Stakeholders

Throughout the development of the CPG, the advisory board and methodologist were invited to review and comment on drafts at various points via email and conference calls. The purpose of this phase was to gather feedback, assess the clarity, applicability, and feasibility of the action statements, recommendations, and supporting evidence as well as the overall organization of the information presented. Feedback was provided about important decisions to be made about CPG scope and format to best inform practice. The full draft of the guidelines underwent 3 formal reviews. The first review was completed by the advisory board. Following revisions, the second review was completed by the Evidence-Based Documents Committee of the ANPT and included completion of the Appraisal of Guidelines for Research and Evaluation II (AGREE II) tool. Following revisions, the draft was then distributed for public comment through the ANPT, the

American Academy of Geriatric Physical Therapy, and to the American Academy of Orthotists and Prosthetists to obtain the target population perspectives. Representatives from the American Academy of Orthotists and Prosthetists also completed the AGREE II.

Literature Search

A preliminary broad literature search was completed to identify and review all CPGs and SRs addressing the effects of either AFO or FES to improve outcomes across the ICF for individuals with poststroke hemiplegia. This search was completed to confirm that the topic of this CPG would not be replicating a previously published guideline, to ensure that there was sufficient high-quality evidence available to support the development of this CPG, and to refine the PICO (patient, intervention, control/comparison, and outcomes) question. A secondary review of the literature was then performed by the last author (L.B.), with specific inclusion and exclusion criteria and guidance on search terms and databases from an APTA librarian. Databases searched included PubMed, CINAHL, EMBASE, Pedro, Scopus, Web of Science, and Cochrane. The scope of the search was defined by the PICO question previously introduced, "Is AFO or FES effective at improving any outcome for individuals with foot drop or decreased stance-phase stability due to post-stroke hemiplegia?". Terms used across databases included stroke, hemiplegia, cerebrovascular accident, electrical stimulation, electric stimulation therapy, neuromuscular electrical stimulation, foot orthoses, FES, neuromuscular stimulation, neuromuscular electrical stimulation (NMES), orthoses, orthotic, foot drop, and peroneal nerve paralysis. As an example, the search string in PubMed was (Stroke[MeSH] OR Hemiplegia[Mesh] OR stroke*[tiab] OR hemiplegia*[tiab] OR foot drop[tiab]) AND (Electric Stimulation Therapy[Mesh] OR Foot Orthoses[Mesh] OR electrical stimulation[tiab] OR FES[tiab] OR neuromuscular stim*[tiab] OR NMES[tiab] OR orthoses[tiab] OR orthotic*[tiab]). Additional studies were located through reference lists within studies and SRs found through the literature search that were relevant to the clinical question.

Study types included were meta-analyses, SRs, RCTs, cohort studies, and case control studies. Inclusion criteria for all study types were human subjects, adults 18 years and older, stroke, AFO or FES, and measurement of an outcome related to the ICF categories. Excluded were case studies; studies written in a non-English language; and studies that included individuals with other neurologic diagnoses or children, electrical stimulation targeting the central nervous system or heart, and orthoses that only impacted the foot or crossed the knee or hip joints.

The Figure shows the PRISMA for the search results. The initial search was performed in May 2017 and 7726 potential articles were identified. All reference information was entered into Endnote (Clarivate Analytics, Philadelphia, Pennsylvania), where exact duplicates were removed yielding 6187 articles. Titles and abstracts were then uploaded into Covidence (Covidence, Melbourne, Australia), an SR management system, for review. In Covidence, the GDG first performed a title/abstract review where irrelevant articles and nonexact duplicates were identified and removed upon agreement of 2 GDG members. Full-text articles were uploaded into Covidence and then reviewed by 2 GDG members for further inclusion/exclusion. A third GDG member reviewed any disagreements. Articles were excluded that did not meet inclusion criteria, did not report outcomes relevant to the question, were solely about AFOs or FES development, or did not include an intervention or a 1-time test with AFOs or FES. The studies included were intervention studies, studies with a 1-time assessment of effects when wearing an AFO or FES, or an SR related to intervention or 1-time assessment. Thus, this CPG will focus on these areas.

Follow-up literature searches were performed every 4 months from May 2017 through November 2, 2019. Over this period, 9 articles were identified and appraised. Of these 9 articles, 5 were excluded and 4 were included in the CPG using the same consensus process by the GDG. Thus, this search process resulted in 288 studies that remained for critical appraisal, which included 272 primary studies and 16 SRs (Figure).

Critical Appraisal Process

Potential appraisers were recruited via 2 announcements in the ANPT Action Potential Newsletter. Following an application process, 30 physical therapists were selected. The appraisal team evaluated the quality of all intervention studies using the APTA Critical Appraisal Tool for Experimental Intervention Studies (CAT-EI).[2] The CAT-EI is a critical appraisal tool designed to evaluate research design and methodology, to appraise the risk of bias, and to inform the level of evidence by the rigor of the outcome measure(s) used. The CAT-EI includes 3 parts: Part A gathers information on the study question and content, Part B evaluates the research methods and quality of outcome measures, and Part C assesses the impact of the results. Items were scored with a "1" for yes and a "0" for no or not applicable.

Prior to appraising the intervention studies, the appraisers completed training on the CAT-EI using a web-based course taught by the methodologist. The training was completed in 3 phases. Phase 1 included individual review of a training manual, completion of an online module with a guided critical appraisal, and individual appraisal of 2 intervention studies chosen by the GDG. Appraisers were required to achieve more than 80% accuracy for the 2 intervention articles, with the gold standard being the mutually agreed-upon scores of the GDG team's keys. Following this process, less than 58% of the appraisers achieved more than 80% accuracy. Feedback on common errors was provided to the appraisal team prior to phase 2. In phase 2, appraisers were paired and asked to appraise a third intervention study, after which 83% of the appraisers achieved more than 80% accuracy. Discrepancies in scoring remained for items assessing reliability and validity of outcome measures. Further instructions were provided, and appraisers rescored these items for this third study, resulting in 100% of the appraisers achieving more than 80% accuracy.

Critical appraisals were then performed in rotating pairs for each intervention study included in the CPG. Each pair completed the appraisal individually and then compared scores, and conflicts in scoring were resolved prior

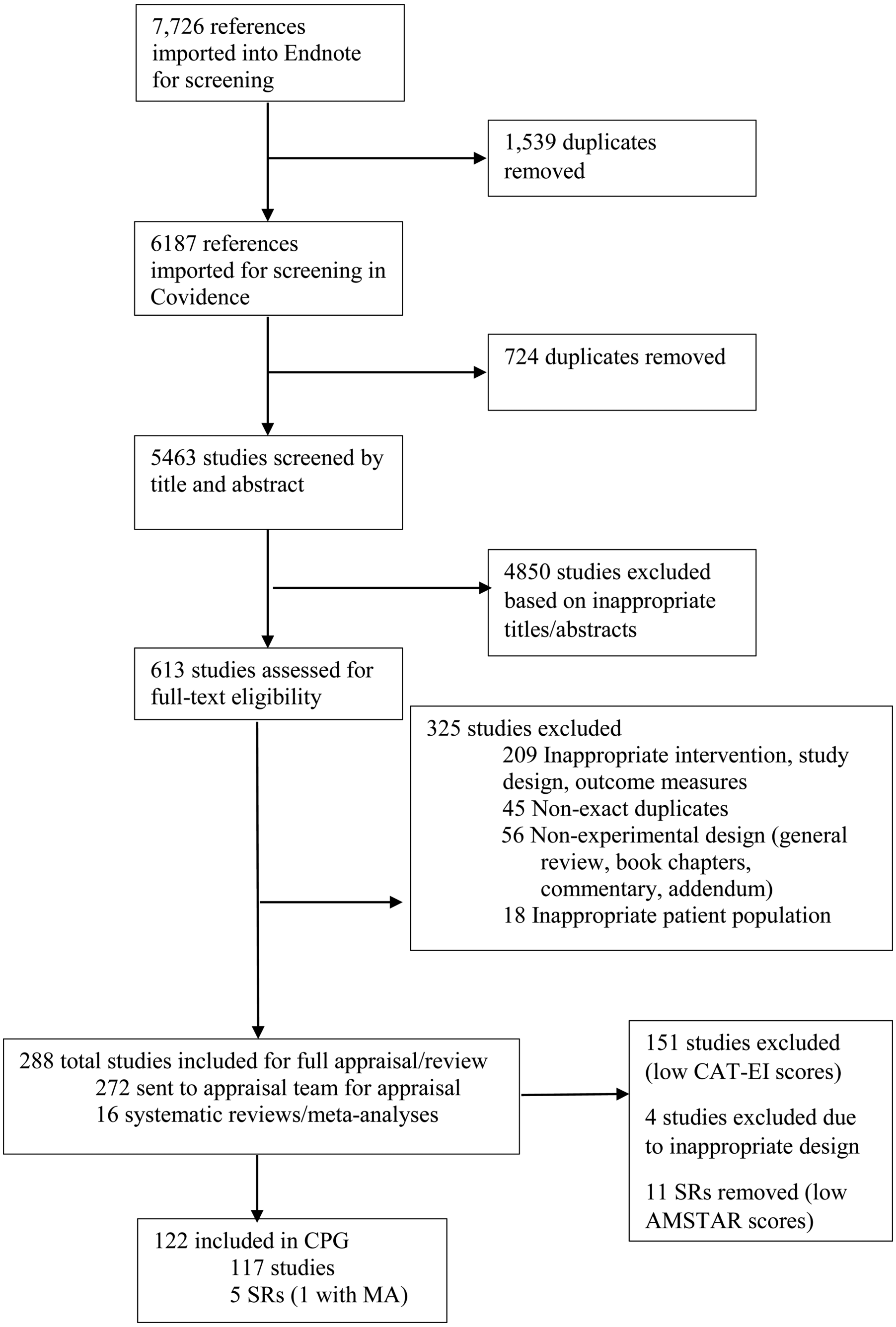

Figure. PRISMA.

to entering data into Qualtrics, a secure online database. In the event significant conflicts could not be resolved, a third appraiser was added to achieve consensus. In addition to completing the CAT-EI, appraisers extracted data from each study as identified by the GDG. Key information that was further extracted included device type, baseline mobility, and intervention dose parameters. Any SRs and meta-analyses were appraised by the GDG members using the measurement tool to assess systematic reviews (AMSTAR). Members of the GDG appraised all articles in pairs and resolved conflicts prior to entering data into Qualtrics. SRs were then rated as moderate, low, or critically low evidence based on the overall AMSTAR score.

After all critical appraisals and data extraction were completed by the appraisal team, the CAT-EI score for each article was tallied and the GDG reviewed all CAT-EI scores and extracted data. Each study was first assigned a level of evidence based on study type as defined in Table 1. If there was a discrepancy in CAT-EI score within the paired 2 appraisers, the lower score was taken. These CAT-EI scores were then used to determine the final level of evidence for each study. Studies were rated as high quality (CAT-EI

Table 4. Classification of Levels of Evidence Based on CAT-EI Scores[a]

CATEGORY	CAT-EI SCORE	FINAL LEVEL OF EVIDENCE CLASSIFICATION
High quality	≥50%	No change
Acceptable	>35% but <50%	Downgraded 1 level of evidence
"Other" low quality	20%-35%	Downgraded 2 levels of evidence
Unacceptable	<20%	Excluded from the CPG

Abbreviations: CAT-EI, Clinical Appraisal Tool for Experimental Intervention Studies; CPG, clinical practice guideline; GDG, Guideline Development Group.
[a]The score ranges were determined by the GDG. The criteria were chosen to categorize all study types included in the CPG.

score ≥50%), acceptable quality (CAT-EI score >35% but <50%), low quality (CAT-EI score 20%-35%), or unacceptable (CAT-EI scores <20%) as seen in Table 4. As defined in the *APTA Clinical Practice Guideline Process Manual*, studies rated as acceptable were downgraded by 1 level of evidence, those as low quality were downgraded by 2 levels, and those that were unacceptable were excluded from the CPG (Table 4).[2] The cut-off scores for studies that scored less than 50% were determined based on group consensus after reviewing all studies as a group due to clear distinctions in quality seen based on the score categories seen in Table 4. It is important to note that Part B items 13 to 20 of the CAT-EI provide a score for each individual outcome measure within a study. Depending on the strength of the outcome as scored in items 13 to 20, the overall study quality for each outcome measure added could differ. Therefore, studies were assigned final CAT-EI scores for each outcome by tallying scores for the overall study quality items, then adding in the score for the items assessing the outcome measure of interest. For example, a study with 10 different outcome measures could potentially have 10 different CAT-EI scores. This final CAT-EI score per outcome measure was then used to identify the final level of evidence for the study for the outcome of interest (Table 4). For example, an RCT may be assigned a level I for evidence for gait speed using the 10-meter walk test (10mWT) (final CAT-EI score ≥50%), but be downgraded to level II for a QOL measure that scored lower (final CAT-EI score >35% but <50%).

The appraisal process and the review of the AMSTAR and CAT-EI scores resulted in the following. Using the AMSTAR, 3 SRs were rated as critically low and were subsequently excluded from this CPG. An additional 8 SRs were also removed at this stage due to not being SRs (2), including FES to multiple muscles (3), including mixed populations (2), not including an outcome measure (1), and reporting synthesized results (1). Five SRs then remained for inclusion in this CPG.[8,20,28-30]

Following the appraisal process, an additional 151 studies were removed due to CAT-EI scores less than 20% indicating unacceptable quality of evidence or, regardless of CAT-EI scores, due to lack of data to use to determine change, outcome measures with little clinical application (ie, engineering/design outcomes), and any other issues that prevented study interpretation in relation to CPG goals. An additional 4 studies were removed due to study designs not meeting inclusion criteria for the CPG. Thus, a total of 117 studies and 5 SRs were included in the development of this CPG.

Device Definitions

In reviewing the extracted data, numerous types of AFOs were included within and among studies and device names often differed. When possible, AFOs were combined into 1 category if a description and/or photograph could adequately represent the AFO type. All AFO types included are identified in Table 5.[23,31-59] There was less variation with FES, as studies were only included if they only applied FES to 1 muscle or muscle group distal to the knee to have a primary effect on control of the ankle dorsiflexion. In studies that provided multichannel stimulation, data were extracted only if these results could be isolated and not influenced by the other muscles. FES applications included both surface and implanted systems (Table 5).

Outcome Measures

Key outcome measures spanning the ICF were identified across studies. Outcome measures were grouped by construct (Appendix Table 1).[60-71] When data were available within studies, minimal clinically important difference (MCID) and/or minimal detectable change (MDC) were used to identify the importance of any changes seen for that measure in the included studies[8] (Table 5 Appendix Table 1). Small meaningful change (SMC) was also included for gait speed, as this metric has been developed based on an effect size of 0.2 as compared to an effect size of 0.5 for the MCID used for gait speed.[62] An additional broad literature review was conducted to identify these properties for the included measures. Unless specified that only a subsection was performed, any outcome measure included was completed in its entirety. When data were presented in tables but not included in the text of the results or discussion sections, data were examined by the GDG to determine whether the MCID, the SMC or the MDC could be determined across the different effects. This approach has some limitations in that it examines mean change within a group rather than at an individual level. However, it does provide additional clinical interpretation beyond statistical significance. Both statistical significance as reported by each study and clinical significance were considered in developing this CPG.

All studies were reviewed to identify the conditions for evaluating the outcomes to determine how the device was used. As study participants could have been tested with and without the AFO or FES at different time points in a study, it was important to note all testing conditions to determine the device's effects. Table 6[8,9,72-76] identifies the different effects that were used in writing recommendations and

Table 5. Description of Devices[a]

AFO GENERAL TYPE	DESCRIPTION
Prefabricated[31]	An AFO made to general specifications and of various sizes but not custom-made.
Custom[31]	An AFO made and adapted specifically for an individual, made of any material, stiffness, articulating, or nonarticulating.
Dynamic[32]	An AFO made of composite, spring-like material (eg, carbon fiber and fiberglass) and AFOs with an ankle joint equipped with springs. Mechanisms of AFO enhance or resist a direction of ankle movement. Designed to allow for some movement and storage of energy to be returned during push-off and/or to lift the foot during swing. Specific types seen in studies in this CPG: carbon fiber[31]; dorsiflexion assist[31]; Chignon AFO[33]; oil damper[34,35]; Liberté elastic dynamic[36]; hybrid[37]; and DF stop with DF assist.[38]
Articulating[31]	An AFO made with a hinge between foot insert or shoe and lower leg upright; hinge provides varying levels of motion at the ankle with stops to limit motion depending on individual needs. Stops may be placed at any degree to limit DF or PF within the individual's available range of motion.
Ground reaction[31]	An AFO made with the addition of an anterior shell on the lower leg that provides a posteriorly directed force to the superior anterior tibia/patellar tendon to create an extension moment to stabilize the knee.
Solid, rigid, semirigid, or flexible[31]	An AFO made from continuous polypropylene or similar materials from the footplate to lower leg with a shell that contacts the posterior calf. A rigid AFO designed to prevent movement and stabilize the foot. Semirigid or flexible AFO designed to allow for some movement but also support the foot during swing. Specific types seen in studies in this CPG: flexible/posterior leaf[31]; anterior; Ytech[39]; solid plastic with inhibitor bar[40]; SWIFT cast[41]; heel cutout[42,53]
FES DEVICES	**DESCRIPTION**
Surface FES	
Bioness L300[23,43] (US)	Wireless surface FES unit composed of a cuff with electrodes for the lower leg to stimulate muscles that lift the foot. Uses a foot sensor on the shoe.
WalkAide (Innovative Neurotronics/ Hanger) [23,54] (US)	Wireless surface FES unit composed of a cuff with electrodes applied below the knee and an in-cuff accelerometer to detect tilt.
Odstock[23,44] (UK)	Surface FES unit with a cuff with electrodes applied below the knee, and a foot switch.
Surface FES brands less commonly reported	CyberMedic EMS (Korea)[55,56] Neurostimulator KDC 2000A[45] (Denmark) Respond II[46] Electronic dorsiflexion stimulator[47] Dorsiflex[48] (Brazil) CEFAR Step II[57] (US) Novastim CU-FS[58] (Korea) Power Assist (PAFES)[59] (Japan)
Implanted FES	
ActiGait[49,50]	Implanted 4-channel nerve stimulator with 12-contact electrode cuff, an external control unit, and a heel switch.
STIMuSTEP[51]	Implanted 2-channel peroneal nerve stimulator with an external transmitter with a built-in antenna, a foot switch.
Biotech (Japan)[52]	Three-channel stimulator (BIOTEC Ltd, Akita, Japan) with a heel sensor switch that triggers the stimulator and implanted intramuscular electrodes.

Abbreviations: AFO, ankle-foot orthosis; DF, dorsiflexors/dorsiflexion; FES, functional electrical stimulation; PF, plantarflexors/plantarflexion.

[a]For AFO general types, it should be noted that these categories are not mutually exclusive and that an AFO type may fit into more than 1 category.

evidence summaries for the CPG. Only one of these effects, the therapeutic effect, would suggest recovery as compared to compensation, as testing is done with the device off at baseline and off after using the device for a period of time. For the other effects, effects after first use and after a period of time are tested with the device on. The immediate effect identifies the effects when the device is on as compared to off at the same time point. Both the training and combined orthotic effects test with the device on after a period of time, but testing at baseline is done with the device to assess the training effect and the device off to assess the combined orthotic effect.

Table 6. Different Effects of Ankle-Foot Orthoses and Functional Electrical Stimulation

EFFECT	TESTING CONDITIONS	NOTATION[a]
Immediate orthotic effect[8,9,72,73]	With and without AFO/FES at the same point in time	On vs off at 1 time point
Therapeutic effect[8,9,72-75]	Without FES/AFO before and after using FES/AFO for a period of time	Off vs Off over time
Training effect[8,9,76]	With FES/AFO on before and after using FES/AFO for a period of time	On vs On over time
Combined orthotic effect[8,9,72]	Without FES/AFO before and with FES/AFO after using FES/AFO for a period of time	Off vs On over time

Abbreviations: AFO, ankle-foot orthosis; FES, functional electrical stimulation.

[a]The notation provides a shortened version of the testing conditions.

Diagnostic Considerations

For the purpose of this CPG, acute poststroke hemiplegia was defined as up to 3 months post-stroke and chronic post-stroke hemiplegia was defined as 3 months or greater post-stroke.[29] Definitions of the acute and chronic phases after stroke are not consistently defined in the literature, and thus the definitions earlier as defined by Tyson et al[29] were accepted by the GDG and agreed upon by the advisory board. For any study that included individuals with both acute and chronic stroke, the GDG used the average time post-stroke for the group from that study to determine chronicity. The GDG then reviewed participant details in that study to ensure agreement with the classification chosen based on the average time post-stroke. There were no studies in which agreement was unable to be achieved using this process.

The term accepted for use in this CPG was decreased lower extremity motor control. Many studies focused on addressing foot drop, which was not clearly defined across studies. Thus, a singular definition cannot be provided. The GDG accepts the definition of foot drop as the inability to achieve sufficient ankle DF during the swing phase of gait.[8] Studies were included if they used an AFO and/or FES to address foot drop, or decreased stance-phase stability, or used a device with a known goal to address outcomes across the ICF.

Treatment Effects

Included studies were those that tested the immediate effects of device use at one point in time as well as those that provided an intervention with a device over a period of time and examined the effects of the intervention (therapeutic, training, and combined orthotic effects) (Table 6). Some studies examined both the immediate effects and effects post-intervention. Included studies were limited in regard to examination details of study participants; thus, evidence-based recommendations based on patient/client examination cannot be developed to guide decision-making for device choice. Examination-based recommendations were developed using clinical expertise and evidence when available to support the recommendations.

Formation of Action Statements and Recommendations

Action statements were written based on each of the included outcomes. All studies that included that outcome were examined for both AFOs and FES, if applicable, to determine the aggregate level of evidence. Thus, an individual study with more than 1 measure of interest will appear in more than 1 supporting evidence section. If the evidence included an SR, the SR was examined to determine which of its included studies also met criteria for this CPG for that outcome. Those individual studies are then identified as being included in the SR. There were instances in which a lower-quality study included in an SR did not meet criteria for this CPG.

For each action statement, findings from relevant studies were examined based on AFOs and FES separately to determine the effects of each device. These results could be from studies only examining one device as compared to a baseline or from a comparative study that reported data separately for AFOs or FES. Studies that compared devices were then examined to determine possible benefits of one device compared to another.

Once the aggregate level of evidence was determined, the benefits and harms as well as the presence of a preponderance of evidence as defined in Table 2 across the different levels (I-IV) were identified. Then, a letter grade and level of obligation were assigned as per the criteria in Table 2. The word for the level of obligation in Table 2 was used to identify the strength of each action statement (strong, moderate, and weak). The strength for each statement was agreed upon by all 4 GDG members. When there were discrepancies between GDG members, concerns were discussed during in-person meetings with all GDG members present until consensus was met. Finally, the strength of the evidence was used to write each recommendation and assign a level of obligation to follow the recommendation. A strong or moderate recommendation for a certainty of benefit resulted in the use of "should," whereas a strong or moderate recommendation for lack of a benefit resulted in the use of "should not." A weak recommendation resulted in the use of "may" or "may not" due to lack of certainty of benefit. This process continued for each outcome. One recommendation was written to incorporate both AFOs/FES and acute/chronic stroke. This decision was made to create concise action statements to address each outcome based on the overall preponderance of evidence for that outcome, as defined in Table 2. For each action statement, the strength of each condition (acute AFO, acute FES, chronic AFO, and chronic FES) was then determined to further clarify the level of certainty of benefit based on chronicity and device.

Action statements and action statement profiles were written using the guidelines of BridgeWiz for APTA 3.0. BridgeWiz allows the generation of action statements that include clear and implementable recommendations, consistent with the Institute of Medicine recommendations for transparency.[77,78] Action statement profiles were further developed following the standards of BridgeWiz. For each statement, the following were written: (1) benefits, harms, and costs associated with clinical implementation of the recommendation, (2) assumptions or judgments made by the GDG in writing the recommendation, (3) reasons for intentional vagueness of the recommendation if applicable, and (4) a summary and clinical interpretation of the supporting evidence.[1]

As seen in Appendix Table 1, outcomes included in this CPG focused on body structure and function, activity, and participation. Action statements and recommendations were based on each outcome to provide appropriate recommendation strength in relation to individual goals. However, most studies included more than 1 outcome, with minimal attempt made to examine relationships between those outcomes. Therefore, this CPG is unable to make a statement about these relationships. For example, if ankle DF during swing showed a clinically meaningful increase, it cannot be stated that this increase will lead to gains in gait speed. Likewise, few studies examined relationships among common PT evaluation items for individuals post-stroke and outcomes, and few studies provided sufficient evaluation findings to guide decision-making for AFOs or FES in relation to outcomes. No differences in outcomes were seen between surface and implanted FES systems. Thus, all FES recommendations apply to both types.

Table 7. Key to Symbols in Supporting Evidence

PROPERTY	SYMBOL
MCID	++
SMC/MDC	+
Statistically significant	*
No change	0
Negative effect	–

Abbreviations: MCID, minimal clinically important difference; MDC, minimal detectable change; SMC, small meaningful change.

For each included study, pertinent details are included in the supporting evidence sections and associated supporting evidence tables for each action statement. For further details about each study, refer to the master tables (Appendix Table 2[13,16,18,32-40,42,45,46,48-53,55-59,72,73,76,79-165] and Appendix Table 3[8,20,21,28,29]). It is important to note that most studies often focused only on 1 or 2 effects and did not report data on the other effects. Thus, no conclusions can be reached about the other effects for those studies. Tables with supporting evidence are provided for each action statement as its evidence is presented. In these tables, the results are displayed based on effect. The symbols (Table 7) indicate the direction of change and whether statistical or clinical significance was achieved. Statistical significance was determined by study authors. Clinical significance was determined by either the study authors or the GDG who evaluated the data provided by each study.

ACTION STATEMENTS AND RESEARCH RECOMMENDATIONS

The action statements are organized by outcomes across the ICF domains of participation, activity, and body structure and function. Action statements within each ICF domain section are presented starting with the statements with the strongest level of evidence. The statements and recommendations are then further subdivided by phase of recovery and effect.

Participation Outcomes

The participation measures captured by the literature search included a variety of tools that could be classified as QOL (Appendix Table 1). No studies were found that included QOL outcomes in the acute phase since this can be challenging to measure in the initial stage of recovery, so this action statement will only address QOL in the chronic phase.

Action Statement 1: ANKLE-FOOT ORTHOSIS (AFO) OR FUNCTIONAL ELECTRICAL STIMULATION (FES) TO IMPROVE QUALITY OF LIFE. Clinicians should provide an AFO or FES for individuals with decreased lower extremity motor control due to chronic poststroke hemiplegia who have goals to improve QOL (evidence quality: II; recommendation strength: moderate).

- Acute AFO: evidence quality: not applicable; recommendation strength: best practice
- Acute FES: evidence quality: not applicable; recommendation strength: best practice
- Chronic AFO: evidence quality: II; recommendation strength: moderate
- Chronic FES: evidence quality: II; recommendation strength: moderate

Action Statement Profile

Aggregate Evidence Quality: Level II due to lack of moderate to substantial gains in QOL across studies, despite having 5 level I studies. Based on 1 level I SR, 4 level I RCTs, and 1 level II, 1 level II/III, 1 level III, and 1 level IV studies (Appendix Table 4).[8,76,85,146,148,159]

Benefits:

- QOL and participation may improve with AFO or FES use.

Risk, Harm, Cost:

- Costs may be high to the individual due to lack of sufficient insurance coverage or financial resources for AFOs or FES.
- Falls may increase with AFOs and FES by increasing mobility.
- Abandonment of AFOs may occur due to discomfort, difficulty donning/doffing, cosmesis, increased sweating, skin irritation, an uncomfortable stretching feeling when wearing, increased spasticity, and issues using with shoes.
- Abandonment of FES may occur due to intolerance to the sensation of the stimulation, insufficient DF achieved, general dissatisfaction, and skin irritation. With an implanted FES system, FES may not be successful due to system failure, infection, hematoma, lymphedema, nerve injury, and neurodermatitis.

Benefit-Harm Assessment:

- Preponderance of benefit.

Value Judgments:

- Outcome measures chosen influence benefits or lack of benefits.
- It is difficult to differentiate responsiveness of measures used and duration needed for benefits.

Intentional Vagueness:

- The differing effects on AFOs and FES on QOL are not included, as these cannot be determined due to the more global nature of QOL measures.
- The recommendations purposefully do not address the effects of one type of AFO over another, as studies used a variety of AFO types and rarely differentiated effects.
- The recommendations also do not address the severity of hemiparesis, as most studies included participants with the ability to ambulate independently or with minimal assistance often for at least 10 m.

Role of Patient Preferences:

- Individuals may prefer FES over AFO.

Exclusions:

- Individuals with acute poststroke hemiplegia, as QOL measures are not recommended in the acute phase.
- The recommendations may not apply to individuals with severe cognitive or communication deficits or neglect, history of multiple strokes, pacemakers, skin conditions, or severe spasticity [Modified Ashworth Scale (MAS) $\geq$ 3].

Quality Improvement:

- Patient-centered care and satisfaction may improve in clinical practice.

Implementation and Audit:

- QOL and patient preference should be measured and considered in decision-making when choosing FES or an AFO.
- AFOs or FES should be considered during any evaluation to improve outcomes and satisfaction in individuals in the acute or chronic phases of stroke.
- Physical therapists would benefit from education on the effects of AFOs and FES and on clinical decision-making for monitoring effects, making adjustments to AFOs or FES, changing devices as individuals' needs change, and on appropriate outcome measures across the ICF to assess the effects of the devices.
- Review of medical records can identify outcomes seen with AFOs and FES use across a larger group of individuals.
- Potential barriers to implementation of the recommendation include lack of education about appropriate devices, access to devices, or lack of funding.

Supporting Evidence and Clinical Interpretation

Supporting Evidence: The different effects (immediate, therapeutic, training, and combined orthotic) of AFOs and FES cannot be determined separately based on the nature of QOL measurement. Thus, the benefits are discussed as a whole (Appendix Table 4).

Acute Stroke AFOs and FES: Evidence is limited to 1 level II RCT in which Salisbury et al[144] (n = 16) found no changes within groups in Stroke Impact Scale (SIS) scores for the 14 participants randomized to using FES or a prefabricated AFO after 12 weeks. One potential reason for lack of change was the use of the SIS in more acute stroke, which is not recommended if the stroke occurred less than 2 months prior.[166] Due to this issue, acute stroke was not included in the recommendation for QOL.

Chronic Stroke AFOs and FES: One level I SR, 4 level I RCTs, and 1 level II/III, 1 level III, and 1 level IV studies examined the effects of AFOs and/or FES on QOL with mixed results. The level I SR by Dunning et al[8] included 3 RCTs that examined QOL after the use of various FES and AFO types, concluding that QOL was improved with AFOs or FES. Two of their included RCTs (Kluding et al[76] and Bethoux et al[85]) also met criteria for this CPG.

Studies comparing FES to AFOs or no device included 4 level I RCTs, 2[76,85] of which were in the SR by Dunning et al.[8] In Kottink et al,[118] 29 outdoor ambulators were randomized to an FES (n = 14) or usual care group using a plastic AFO, orthopedic shoes, or no device (n = 15). After training, participants used the device at home as desired for 26 weeks. After 26 weeks, participants using FES (n = 13) had significant increases in scores for the Short Form-36 (SF-36) (physical function, general health, and physical component summary domains) and Disability Impact Profile (DIP) (mobility, self-care, and psychological domains) compared to the usual care group (n = 12). Two level I RCTs also reported changes in QOL within both FES and AFO groups. Sheffler et al[148] found increases in Stroke-Specific Quality of Life (SSQOL) scores for 96 of the 110 participants who completed the study who used FES (n = 46) or a custom-molded articulating AFO with a plantarflexion (PF) block (n = 50). Participants received training for 1 hour 10 times over 5 weeks and then 1 hour 3 more times over 7 weeks and used the devices at home up to 8 hours per day. After the 12 weeks, SSQOL scores improved and were maintained 3 (n = 93) and 6 months (n = 84) later despite not using the devices. In a larger study (n = 197), Kluding et al[76] evaluated changes in QOL using the SIS for participants using FES (n = 99) or a molded AFO (n = 98) specific to each participant's needs. Participants received 8 training sessions over 6 weeks followed by 24 weeks of home use, and significant gains were seen in the SIS for both groups after the 30 weeks. In contrast to these studies that found within group changes, another large level I study (n = 495) by Bethoux et al[85] reported no changes within groups for SIS or SSQOL scores for participants using FES (n = 187) or a custom-molded AFO (n = 212) over a 6-month intervention. While 495 participants were randomized, 55 in the FES group and 41 in the AFO group did not complete the study. It is not clear why the results differed from the studies by Sheffler et al[148] or Kluding et al,[76] as study designs were similar. In addition to the level I studies, there was a level II study by Schiemanck et al[146] (n = 10) that reported no changes in SIS scores for the 8 participants with an FES system who also had an AFO to use as desired for up to 26 weeks. In a level IV qualitative study by Wilkie et al,[159] FES users reported that FES impacted important areas of life, with 4 themes reported that included improved walking, better control in life, improved sense of well-being, and FES being imperfect but of value.

Comparison of AFOs and FES: For acute stroke, 1 level II RCT by Salisbury et al[144] found no difference in SIS scores between AFO and FES users after 12 weeks. However, as the SIS is not advised to be used in acute stroke, this result is questionable. For chronic stroke, there is level I evidence based on 1 level I SR[8] and 3 level I RCTs[76,85,148] that found no differences between AFOs and FES in SSQOL[85,148] or SIS scores.[8,76,85] However, Kluding et al[76] reported that FES users reported higher scores on a user satisfaction survey compared to AFO users.

Clinical Interpretation: QOL may improve with FES and AFO use. One challenge with the included studies is variability of FES and AFO types, the length of time for device use, and the outcome measures chosen. The SIS, SSQOL, SF-36, and Euro-QOL are the most commonly recommended measures.[166] All except 1 study examined chronic as opposed to acute stroke. QOL is challenging to use as an outcome measure in acute stroke, as individuals have not experienced many of the tested activities at this early phase poststroke. Importantly, participants in 2 studies reported preferring FES over an AFO, and FES users feel that FES has a positive impact on their lives.[8,76] When comparing the effects of AFOs compared to FES for QOL, no differences were found in any measures of QOL; however, 1 study found that user satisfaction was higher in FES users compared to AFO users (Appendix Table 4).

Research Recommendations: More research is needed on the effects of AFOs and FES on QOL using measures with the best psychometric properties for stroke to obtain meaningful assessment. Further research is needed to determine what aspects of QOL improve with AFOs and FES to develop measures with improved responsiveness.

Activity Outcomes

The following section includes measures that can be categorized under the activity domain of the ICF. Many outcome measures capture more than 1 construct. Outcome measures were grouped within each action statement by the construct it primarily defined (Appendix Table 1).

Action Statement 2: ANKLE-FOOT ORTHOSIS (AFO) OR FUNCTIONAL ELECTRICAL STIMULATION (FES) TO IMPROVE GAIT SPEED. Clinicians should provide an AFO or FES for individuals with decreased lower extremity motor control due to acute or chronic poststroke hemiplegia who have goals to improve gait speed (evidence quality: I; recommendation strength: strong).

- Acute AFO: evidence quality: I; recommendation strength: moderate
- Acute FES: evidence quality: II; recommendation strength: moderate
- Chronic AFO: evidence quality: I; recommendation strength: strong
- Chronic FES: evidence quality: I; recommendation strength: strong

Measures that are included in the gait speed statement are those that only measured the construct speed of walking over a level surface.

Action Statement Profile

Aggregate Evidence Quality: Level I based on a preponderance of level I studies (1 SR, 1 SR/meta-analysis, and 13 RCTs).

- Acute AFO: Level I based on 3 level I, 2 level II, 3 level III, and 1 level IV studies (Appendix Table 5).[92,121,126,129-131,140,144,145]
- Acute FES: Level II based on 2 level I and 1 level II studies (Appendix Table 6).[126,144,160]
- Chronic AFO: Level I based on 1 SR, 1 level II SR/meta-analysis, 6 level I, 5 level II, 13 level III, and 11 level IV studies (Appendix Table 7).[8,13,29,32,34-36,38-40,42,72,76,79,83,85-87,98,101,103,104,106,107,116,123,124,133,134,136,138,140,156-158,162,163]
- Chronic FES: Level I based on 1 level I SR, 7 level I, 1 level II SR, 2 level II, 7 level III, and 15 level IV studies (Appendix Table 8).[8,72,85,86,108]

Benefits:

- Increases in gait speed may increase overall mobility, balance confidence, and overall health status[167] at any phase post-stroke.
- Provision of an AFO or FES early during acute rehabilitation may result in faster increases in gait speed, thus potentially impacting length of stay.
- Provision of FES as an intervention in the acute phase may lead to improved recovery of gait speed.

Risk, Harm, Cost:

- Costs may be high to the individual due to lack of sufficient insurance coverage or financial resources for AFOs or FES.
- Falls may increase with AFOs and FES by increasing mobility.
- Abandonment of AFOs may occur due to discomfort, difficulty donning/doffing, cosmesis, increased sweating, skin irritation, an uncomfortable stretching feeling when wearing, increased spasticity, and issues using with shoes.
- Abandonment of FES may occur due to intolerance to the sensation of the stimulation, insufficient DF achieved, general dissatisfaction, and skin irritation. With an implanted FES system, FES may not be successful due to system failure, infection, hematoma, lymphedema, nerve injury, and neurodermatitis.

Benefit-Harm Assessment:

- Preponderance of benefit.

Value Judgments:

- Gait speed is an important outcome for individuals with poststroke hemiplegia that may be addressed through an AFO or FES.

Intentional Vagueness:

- The recommendations purposefully do not address the effects of one type of AFO over another, as studies used a variety of AFO types and rarely differentiated effects.
- The recommendations also do not address the severity of hemiparesis, as most studies included participants with the ability to ambulate independently or with minimal assistance often for at least 10 m.

Role of Patient Preferences:

- Individuals may prefer FES over AFOs.

Exclusions:

- The recommendations may not apply to individuals with severe cognitive or communication deficits or neglect, history of multiple strokes, pacemakers, skin conditions, or severe spasticity (MAS $\geq$3).

Quality Improvement:

- Early use of an AFO or FES early in the recovery phase may allow for faster improvements in gait speed, which may allow for decreased length of stay.
- Provision of an AFO or FES in the chronic phase may improve both gait speed and overall satisfaction with care.
- Device type should be driven by individual goals and desired effects, as FES use over time may allow increased gait speed with the FES off, while AFO use over time may allow increased gait speed with the AFO on.
- PT intervention and sufficient practice must be performed when an AFO or FES is provided to achieve optimal effects.
- Evaluation for a device should include an assessment of desired outcomes using different AFO and FES types and settings before making a final decision.

Implementation and Audit:

- AFOs or FES should be considered in inpatient rehabilitation to increase outcomes and satisfaction.
- AFO provision needs to consider individual needs for AFO type to increase outcomes and satisfaction.
- AFOs or FES should be considered during any evaluation to improve outcomes and satisfaction in individuals in the acute or chronic phases of stroke.
- Physical therapists would benefit from education on the effects of AFOs and FES and on clinical decision-making for monitoring effects, making adjustments to AFOs or FES, changing devices as individuals' needs change, and on appropriate outcome measures across the ICF to assess the effects of the devices.
- Review of medical records can identify outcomes seen with AFOs and FES use across a larger group of individuals.
- Potential barriers to implementation of the recommendation include lack of education about appropriate devices, access to devices, or lack of funding.

Supporting Evidence and Clinical Interpretation

Supporting Evidence:

Acute Stroke AFO: Most studies that used AFOs for individuals with acute poststroke hemiplegia report strong evidence for immediate orthotic and combined orthotic effects for gait speed (Appendix Table 5).

- *Immediate Orthotic Effect*: One level I and 3 level III studies examined the immediate effect. A level I RCT by Nikamp et al[131] provided a custom AFO to 32 participants at week 1 or week 9 of inpatient rehabilitation. When gait speed was measured on a subset of 20 participants upon AFO provision, there was no immediate effect of the AFO.[131] In a level III study, Lairamore et al[121] found similar results using a posterior leaf spring (PLS) or a flexible AFO with a short footplate with 15 participants. Two additional level III studies, however, found a significant increase in gait speed with a custom solid AFO.[92,140] One of these studies, Carse et al,[92] reported that participants with a slower gait speed without an AFO increased gait speed from 0.22 to 0.36 m/s when wearing an AFO, thus exceeding the MCID. The faster group also showed significant increases in gait speed from 0.4 m/s without an AFO to 0.5 m/s with an AFO exceeding the SMC. These findings suggest a larger effect on slower ambulators.
- *Therapeutic Effect*: One level II and 1 level IV studies found therapeutic effects of AFOs when combined with usual care. The RCT by Morone et al[126] reported significant increases of 0.11 m/s (exceeding the SMC) after 10 participants walked with a nonspecified AFO for 40 minutes 5 days per week for 4 weeks. Sankaranarayan et al[145] also found significant increases in gait speed when an AFO was initiated within 5 days after admission to rehabilitation, but the change of 0.05 m/s did not meet the SMC. This study had 26 participants walk with the custom solid AFO for a minimum of 14 2-hour sessions during the inpatient rehabilitation admission. These results demonstrate that AFOs may promote recovery when included as part of gait training in the acute phase of stroke.
- *Training Effect*: There is limited evidence available for the training effect. A level II RCT study by Nikamp et al[130] reported a training effect when participants in the "early group" were assessed at week 3 and again at week 9 of the rehabilitation stay. Mean gains in gait speed of 0.33 m/s were reported over a 6-week period, which exceeds the MCID. Participants wore the AFO in therapy when on the hospital unit or when home on weekends.[130]
- *Combined Orthotic Effect*: Two level I, 1 level II, and 1 level IV studies assessed the effectiveness of AFOs combined with usual care. One level I and 1 level II RCT were conducted with the same participants.[129,130] In the first study (level II), Nikamp et al[130] provided a custom AFO to 16 participants in the first week of rehabilitation. Following approximately 6 weeks of inpatient rehabilitation, gait speed increased by a median of 0.23 m/s, which exceeded the MCID and was significantly greater than the control group (n = 17) receiving usual care only. At week 9, the AFO plus usual care group continued to outperform the control group with increases of 0.56 m/s compared to the control group (0.36 m/s).[130] At the 9-week point, the control group then received an AFO, and Nikamp et al[129] (level I) continued to follow up both the early and late provision groups for 6 months after admission. No significant differences in gait speed were reported between groups after 6 months.[129] This finding suggests that early provision of a custom AFO may allow a higher level of participation in rehabilitation and earlier functional gains, but that providing an AFO later in rehabilitation results in similar longer term outcomes.[129,130] Another level I RCT by Salisbury et al[144] included a prefabricated AFO during gait training for 20 minutes 5 days per week for 12 weeks and daily wear if participants were independent with AFO use. Gait speed increases exceeded the SMC, improving from 0.2 to 0.3 m/s. In a level IV study, Sankaranarayan et al[145] also found a significant combined orthotic effect for gait speed when an AFO was used in rehabilitation, with the change of 0.11 m/s exceeding the SMC. Their study had 26 participants walk with the custom solid AFO for a minimum of 14 2-hour sessions within 5 days of admission to rehabilitation. Overall, these findings suggest that adding AFOs to usual care can increase gait speed with an AFO on. Earlier provision can lead to more rapid functional gains, which may have implications for length of stay.

Acute Stroke FES: Studies that used FES for individuals with acute poststroke hemiplegia report strong evidence for therapeutic and combined orthotic effects for gait speed (Appendix Table 6).

- *Immediate Orthotic Effect*: No evidence.
- *Therapeutic Effect*: One level I and 1 level II studies reported therapeutic effects after FES was added to usual care. In the level I RCT, Wilkinson et al[160] reported a significant change of 0.17 m/s that exceeded the MCID for the 10 participants using FES as part of usual care for 1 hour 2 days per week for 6 weeks. However, gait speed did not increase more than participants receiving usual care alone (n = 10) despite baseline gait speeds being similar between groups (0.39-0.42 m/s). In a level II RCT, Morone et al[126] added FES to usual care for 10 participants who participated for 40 minutes 5 days per week for about 1 month. They reported a significant increase in walking speed compared to baseline (from 0.31 to 0.50 m/s) that exceeded the MCID. Dosing did differ between the studies of Wilkinson et al[160] and Morone et al.[126] Wilkinson et al[160] found no change after 12 sessions over 6 weeks while Morone et al[126] found gains following an intervention provided 40 to 60 minutes 5 days per week for 4 to 12 weeks, indicating that more intensive intervention may be needed to provide a meaningful effect.

- *Training Effect*: No evidence.
- *Combined Orthotic Effect*: Two level I RCTs reported significant combined orthotic effects that exceeded the SMC. Wilkinson et al,[160] as described previously for therapeutic effect, reported a combined orthotic effect for their 10 participants using FES, and Salisbury et al[144] for their 9 participants using FES in addition to usual care for 12 weeks. Participants in Wilkinson et al[160] increased their gait speed an average of 0.17 m/s (baseline 0.39 m/s) and in Salisbury et al[144] by 0.07 m/s (baseline 0.2 m/s), demonstrating gains at these differing baseline gait speeds.

Chronic Stroke AFO: Studies that used AFOs for individuals with chronic poststroke hemiplegia report strong evidence for all 4 effects for gait speed (Appendix Table 7).

- *Immediate Orthotic Effect*: Two level I, 5 level II, 12 level III, and 10 level IV studies report on immediate effects. The level II SR/meta-analysis by Tyson et al[29] reported the immediate effects of 11 studies on gait speed. Only 3[42,101,157,162] of the 11 studies met inclusion criteria for this CPG. When a meta-analysis was completed on the available data from the 11 studies, there was a significant immediate effect on gait speed that met the SMC. The 2 level I RCTs by Everaert et al[72] and Kluding et al[76] reported immediate effects. Everaert et al[72] provided a custom AFO to 69 of the 120 study participants. The mean immediate effect of AFOs on gait speed exceeded the SMC for the 55 participants whose data were included in the analysis. All groups provided with a custom AFO consistently demonstrated increased gait speed that exceeded the SMC.[72] Kluding et al[76] randomized participants with an initial gait speed of less than 0.8 m/s into 2 groups, standard AFOs or FES. Ninety-eight participants wearing a custom AFO demonstrated significant increases in both comfortable and fast gait speed averaging gains of 0.09 m/s, thus exceeding the SMC. Many level II to IV studies report similar immediate orthotic effects when various AFO types are used, including solid, PLS, articulating, prefabricated, carbon composite, dynamic, Chignon, and oil damper AFOs, with results exceeding criteria for the MCID, the SMC, and/or statistical significance.[34-36,38,39,42,79,87,98,101,103,104,106,107,116,124,133,136,138,140,158,162] Two level IV studies report no changes.[13,39] The solid AFO was the most consistently included type of AFO. Level II and III evidence demonstrated significant gains in gait speed, most of which exceeded the SMC or the MCID when a solid AFO was compared to no orthosis.[42,101,104,124,138,140,168] The use of a solid AFO was also found to decrease gait speed for participants with DF passive range of motion (PROM) to neutral compared to those with a 5- to 10-PF contracture. There was no effect for the 30 participants who used an AFO with a DF assist or an AFO with free DF with a PF stop.[38] A similar result was found by Lewallen et al[123] with 13 participants walking 0.07 m/s slower with a solid AFO, with no effect using a PLS or articulating AFO. The most clinical meaningful effect, demonstrated by a change exceeding the MCID for gait speed, appeared to occur when an AFO was custom designed to meet the needs of the participant.[87,116,138,168]
- *Therapeutic Effect*: A therapeutic effect was examined by 3 level I and 1 level IV studies. The level I SR by Dunning et al[8] included 5 studies that examined a therapeutic effect[72,76,90,148,169] of which 2 studies met the criteria for this CPG.[72,76] In both studies, participants had significant increases in gait speed that exceeded the SMC when the AFO was worn for 6, 12, or 30 weeks.[72,76] The RCT by Everaert et al[72] assessed 2 different cohorts after 6 weeks of AFO use and 1 cohort after 6 and 12 weeks of AFO use. Each group's gains exceeded the SMC after 6 weeks. While improvements continued beyond 6 weeks, the additional gains were not significant or clinically meaningful, indicating that benefits can be achieved following shorter-term use.[72] The RCT by Kluding et al[76] provided 8 sessions of PT following AFO allocation with a focus on education, gait training, and provision of an individualized home exercise program. The 10mWT was readministered at 30 weeks without the AFO, and comfortable gait speed increased by a mean of 0.09 m/s, exceeding the SMC, and fast gait improved by a mean of 0.05 m/s. The level IV cohort study found no change in gait speed when 8 subjects wore an oil damper AFOs for 3 weeks.[162]
- *Training Effect*: A training effect was evaluated in 2 level I and 1 level IV studies. The level I SR by Dunning et al[8] included 1 study[76] included in this CPG that reported a significant training effect. In the level I RCT, Kluding et al[76] reported a significant increase that exceeded the SMC for comfortable walking speed (0.06 m/s) and for fast walking speed (0.07 m/s) following 30 weeks of AFO use. The AFO type varied depending on the needs of the patient and characterized as articulating, nonarticulating, prefabricated, or "other." In contrast, the level I RCT by Beckerman et al[83] reported no effect when a solid AFO set in 5° of DF was worn for 12 weeks and a level IV study[162] reported no effect with an oil damper AFO. This conflict in results may further support the need for custom AFOs.
- *Combined Orthotic Effect*: A combined orthotic effect was found in 6 level I, 1 level II, 2 level III, and 2 level IV studies. The level I SR by Dunning et al[8] included 3 level I RCTs that reported significant changes, all of which exceeded the MCID and met the criteria for this CPG.[72,76,85] The RCTs by Everaert et al[72] and Kluding et al,[76] as described earlier for therapeutic effect, found statistically significant increases in gait speed that also exceeded the MCID after 6 and 30 weeks of AFO use, respectively. The third RCT by Bethoux et al[85] followed up 212 participants over 6 months and reported significant improvements that exceeded the MCID for gait speed

while using an AFO. A fourth RCT by Erel et al[32] enrolled 32 participants but compared 14 participants using a dynamic AFO with 14 participants wearing only athletic shoes following 3 months of use. The group using the dynamic AFO demonstrated significant improvements in gait speed (0.15 m/s), which exceeded the MCID. The fifth RCT by Bethoux et al[86] followed up 204 of the original study participants from Bethoux et al[85] who wore an AFO for an additional 6 months. After 12 months of use, gait speed improved significantly with AFO use by 0.17 m/s, exceeding the MCID. When the 6-month data from Bethoux et al[85] are compared to 12-month data,[86] there was a nonsignificant change from 0.68 to 0.66 m/s, suggesting that the effect of wearing an AFO for home use may plateau following the initial 6 months. One level II, 2 level III, and 2 level IV studies[34,40,156,162,163] reported significant combined effects in gait speed, with 1 level III study reporting results that exceeded the MCID[34] and 2 level IV studies exceeding the SMC.[40,162] One study[163] reported exceeding the MCID for 1 AFO (oil damper with PF resistance) and the SMC for another (PF stop).

Chronic Stroke FES: Studies that used FES for individuals with chronic poststroke hemiplegia report strong evidence for all 4 effects for gait speed (Appendix Table 8).

- *Immediate Orthotic Effect*: An immediate orthotic effect was examined by 4 level I, 13 level II, 4 level III, and 10 level IV studies. In a crossover RCT with 90 subjects using FES or a conventional AFO followed by FES, Everaert et al[72] found a statistically significant increase in gait speed using FES for the 69 participants analyzed. The RCT by Kluding et al[76] randomized 197 subjects to FES or an AFO individualized to participants' needs and found statistically significant increases in gait speed of 0.07 m/s that also exceeded criteria for the SMC for the 99 in the FES group. In a secondary analysis, O'Dell et al[135] reported no further increase in the immediate orthotic effect over time, with the greatest effect being seen at initial testing. Kottink et al[51] randomized 29 participants to an FES group or a control group who used their own AFO, orthopedic shoes, or no device. Participants using FES increased gait speed from approximately 0.66 to 0.79 m/s (SMC) when walking with FES. The level II SR by Kottink et al[28] included 8 studies that reported an immediate effect of FES. Six of the studies were excluded from this CPG, as they did not meet the inclusion criteria. Of the remaining 2 articles included in the following discussion, 1 found no effect[90] while the other found a significant effect that exceeded the SMC for gait speed.[105] In a level II RCT, Street et al[73] reported increased gait speed from 0.50 to 0.59 m/s in 104 participants of the initially enrolled 133 participants when using FES while the RCT by Burridge et al[90] found no effect for 16 of the 32 participants. Three[50,114,153] of the 4 level III[50,114,132,153] and 7[45,49,52,82,88,89,127] of the 9[45,49,52,82,88,89,105,127,141,170] level IV studies that examined an immediate orthotic effect had similar findings to the higher-level studies.
- *Therapeutic Effect*: A therapeutic effect was reported by 6 level I, 2 level II, 4 level III, and 7 level IV studies. The level I SR by Dunning et al[8] included 6 studies of which 1 exceeded the MCID, 3 exceeded the SMC, and 2 showed no changes, with all but 1 study showing significant changes. Three of these studies[72,76,90] are included in this CPG as individual RCTs. One study used Botox in combination and was therefore not included. In an RCT with 90 participants randomized to using FES or a conventional AFOs before receiving FES, Everaert et al[72] found a statistically significant increase in gait speed that also exceeded criteria for the SMC after 6 weeks of FES use for 69 participants completing data collection. Exact gains differed based on whether participants received the AFO or FES first with greater gains with FES first. The level I RCT by Kluding et al[76] randomized 197 subjects to FES or an AFO individualized to participants' needs and found statistically significant increases of 0.10 m/s in gait speed that also exceeded criteria for the SMC after 30 weeks for the 99 participants using FES. After 12 more weeks of training for 69 of these 99 participants, O'Dell et al[135] found gait speed increases from 0.42 m/s at baseline to 0.61 m/s, exceeding the MCID. Three additional level I studies support a therapeutic effect of FES. The RCT by Kottink et al[51] previously described reported participants (n = 14) using FES had no increases in gait speed when walking without FES for 26 weeks. In an RCT comparing treadmill training (TT) with and without FES for 32 participants, Hwang et al[108] reported gait speed increases from 0.36 to 0.49 m/s that exceeded the SMC for the FES group and that were greater than the treadmill-only group for 14 of the 16 participants who completed training and data collection. A level II RCT by Street et al[73] reported gait speed changes that did not meet the SMC but were statistically significant in 104 of the 133 participants who completed 20 weeks of home use of FES. The second level II RCT by Burridge et al,[90] also included in the SR, reported no change in gait speed following 12 weeks of FES use combined with 10, 1-hour PT sessions in the first 4 weeks. In addition, 3[55,80,153] of the 4[50,55,80,153] level III and 4[18,56,142,170] of the 7[18,56,82,105,142,151,170,171] level IV studies that examined therapeutic effects of FES had similar findings to the higher-level studies.
- *Training Effect*: A training effect was examined by 2 level I, 1 level II, and 2 level IV studies. The RCT by Kluding et al[76] randomized 197 subjects to FES or an AFO individualized to participants' needs and found statistically significant increases of 0.08 m/s in gait speed, with FES on that also exceeded criteria for the SMC after 30 weeks of FES training. The RCT by Kottink et al,[51] as described earlier for therapeutic effect, reported that gait speed

improved from approximately 0.79 to 0.88 m/s, thus exceeding the SMC. The level II RCT by Burridge et al[90] randomized 32 subjects to receive FES or no FES during 1-hour PT sessions for 10 sessions over 4 weeks followed by an additional 8 weeks of FES use. The 16 participants who received FES had gait speed increase of 0.09 m/s, which exceeds the SMC.

- *Combined Orthotic Effect*: A combined orthotic effect was reported by 6 level I, 2 level II, 2 level III, and 4 level IV studies. The level I SR by Dunning et al[8] included 6 studies with significant increases in gait speed, of which 3 exceeded the MCID and 3 exceeded the SMC. Four of those studies met criteria for this CPG.[72,76,85,90] The RCTs by Everaert et al[72] and Kluding et al,[76] as described earlier for therapeutic effect, found statistically significant increases in gait speed of 0.14 m/s that also exceeded the MCID after 6 weeks and 30 weeks of FES use, respectively. In Everaert et al,[72] gait speed changes again differed based on whether participants received the AFO or FES first, with greater gains with FES first. Two other studies, which included the same cohort of participants, also reported statistically significant combined orthotic effects: Bethoux et al after 6 months[85] and 12 months[86] of home FES use with gait speed increasing from 0.45 m/s at baseline to 0.64 and 0.65 m/s after 6 and 12 months, respectively. The RCT by Kottink et al,[51] as described earlier for therapeutic effect, reported that gait speed increased significantly from approximately 0.66 to 0.88 m/s, exceeding the MCID. The RCTs by Bethoux et al[85,86] allocated 242 participants across 30 sites to the FES group with 187 completing the 6-month follow-up and 80 completing the 12-month follow-up. The level II RCT by Burridge et al,[90] also included in the SR, reported a significant gait speed change of 0.13 m/s, exceeding the SMC following 12 weeks of use. Another level II RCT by Street et al,[73] as described earlier under immediate orthotic effect, reported a significant increase in gait speed from 0.50 to 0.64 m/s that exceeded the MCID after 20 weeks of home use. In addition, 2 level III studies reported combined significant orthotic effects[153,156] that exceeded the SMC in 1 study.[153] Two level IV studies[18,88] also reported increases that exceeded the SMC and 1 level IV study exceeded the MCID.[88]

Comparison of AFO and FES: For acute stroke, there is level I evidence based on 1 level I[144] and 1 level II studies.[126] The RCT by Salisbury et al[144] found no difference in a combined orthotic effect between AFOs and FES. However, an RCT by Morone et al[126] reported that the FES group had a significantly greater increase in walking speed of 0.08 m/s compared to usual care with AFOs.

For chronic stroke, there is level I evidence based on 4 level I studies.[8,72,76,85] The 3 RCTs were included in the SR by Dunning et al,[8] who reported that AFOs and FES were equivalent for increasing gait speed based on these 3 studies[72,76,85] for therapeutic and combined orthotic effects. For the level I RCTs, no differences were reported between AFOs and FES by Kluding et al[76] for any of the 4 effects, by Bethoux et al[85] for a combined effect, or by Everaert et al[72] for therapeutic and combined effects. But Everaert et al[72] did report that the AFO group had significant immediate orthotic effects on gait speed compared to the FES group.

Clinical Interpretation: The introduction of an AFO or FES to improve gait speed is a common clinical consideration following stroke. A prior CPG concluded that an AFO can have a positive effect on gait speed,[22] but did not differentiate benefits based on effects. The literature to support the clinical decision-making process in the acute phase post-stroke is limited (Appendix Tables 5 and 6). When considering an AFO in this acute phase, there is some evidence across all effects, with most studies reporting immediate or combined orthotic effects.[73] There is mixed evidence for immediate effects with higher-level evidence reporting no effect, but level III evidence suggests a larger effect may be seen in individuals with a slower initial gait speed. Inclusion of an AFO early in recovery may have a positive effect on gait speed indicating that it may promote recovery, especially when included as part of a more intense dosage of intervention. In addition, early provision during acute rehabilitation, especially for those who walk more slowly, may allow faster gains in gait speed when wearing the AFOs,[129-131] which has possible implications for length of stay and costs. Outcomes reported were similar with a custom or a prefabricated AFO suggesting that a less expensive temporary prefabricated AFO may be appropriate for initial use. A potentially less restrictive option can then be considered later in the rehabilitation process.

The evidence for using FES in the acute phase to enhance recovery and participation is stronger than for AFOs and suggests that FES may be better than AFOs to promote recovery as demonstrated by the reported therapeutic effects (Appendix Tables 5 and 6). In addition, dosing may be important for promoting recovery, as studies with greater intervention frequency and duration (5 days/week for 40-60 minutes for 4-12 weeks)[51,72,73,76,90,108,135] led to better therapeutic effects. For combined orthotic effects, gains were seen regardless of baseline gait speed, suggesting that FES may be a better choice than AFOs for individuals ambulating at a faster gait speed.[8,32,72,76,85,90]

While evidence for AFOs and FES is limited in the acute phase, there is a larger body of evidence supporting their use to increase gait speed in the chronic phase (Appendix Tables 7 and 8). While all 4 effects are reported for AFOs, the majority of studies reported an immediate effect when compared to no device. Immediate improvements seen in gait speed often exceeded the SMC and the MCID using the 10mWT. The most consistent improvements were seen when a custom AFO was used, regardless of AFO type (Appendix Table 7). However, no effect was noted when the participant had limited PF range of motion[38] or if the AFO allowed free DF with a PF stop.[13,103] Custom AFO use also led to other effects that appear to be dependent on the number of weeks of use. After 6 to 30 weeks of home use, gains were found that exceeded the SMC for a therapeutic effect and often exceeded the MCID for a combined orthotic effect.[72,76,85] One study with only 3 weeks of use showed no effect.[162] While gait speed appears to improve meaningfully with long-term wear, peak improvements occurred after 6 weeks,[72] which may indicate a critical point for reassessment. The training effects on gait speed were the least studied and results were mixed. The most significant improvements (Appendix Table 7) were seen with a custom AFO, while no effect was reported with solid AFOs set in 5° of DF, or an oil damper AFOs, supporting the need for a custom AFO designed to meet the needs of the individual.

For FES, gains are reported across all 4 effects, but unlike AFOs, the most significant effects reported were therapeutic and combined effects (Appendix Table 8). The immediate effects of FES are mixed, with most studies reporting gait speed gains that were significant or exceeded the SMC, while other studies reported no effect. While the evidence is strong for therapeutic and combined effects, studies suggest that individuals considering FES may need practice or skilled PT intervention/gait training to see a meaningful improvement in gait speed. Studies also indicate that a minimum of 18 treatment sessions[151] or use of FES over a period of 20 to 42 weeks may be important for these effects.[8,51,88,135] Thus, gait speed can continue to improve with FES use and individuals should be encouraged to use FES following discharge and educated on the benefits. The strongest predictors of responders to FES were younger age, faster baseline gait speed, faster Timed Up and Go (TUG) scores, and better balance. The ability to produce some level of motor activation of the key muscle group being stimulated appeared to distinguish responders from nonresponders,[151,172] especially in individuals with a slower baseline gait speed.[172] Training effects are also seen with FES and are studied more than for AFOs, with more consistent improvements seen in gait speed that were significant and often exceeded the SMC when used for 12 to 30 weeks. Effects were demonstrated earlier and were more meaningful when combined with skilled PT intervention with 6 to 15 sessions of 30 to 60 minutes over a 1- to 5-week period.[76,90]

There is some evidence against the use of FES over AFOs to produce an immediate orthotic effect.[72] However, it was noted by the authors that these results may also be flawed due to a significant difference in baseline gait speed between groups. In addition, more studies with FES alone show a therapeutic effect on gait speed than do studies with AFOs (Appendix Tables 5-8). Thus, clinical decision-making regarding potential for recovery versus the need for compensation should be considered in choosing AFOs or FES to make the best decision for an individual. These devices should also be considered at any point following the stroke.

The results of the included studies indicate that AFOs and FES improve gait speed in both the acute and chronic phases post-stroke. The effects desired, time post-stroke, and baseline gait speed may assist clinicians in choosing a device. Consideration needs to be given to adequate dosing for both AFOs and FES and to individual needs when choosing an AFO.

Research Recommendations: While there is strong evidence for AFOs and FES for increasing gait speed, further research is needed to better guide clinical decision-making. There is an imbalance in terms of the effects studied across AFOs and FES. Studies on AFOs tend to focus more on compensation-based effects, while most studies on FES also examine recovery-based (therapeutic) effects. Thus, research is needed to identify all effects of each device type to guide clinicians in device choice as well as the focus on recovery or compensation. Evidence is also limited on the comparison of different AFO types, optimal timing post-stroke to introduce FES or AFOs, and dosing needed to obtain optimal effects. More research with individuals with acute post-stroke hemiplegia is also needed with both AFOs and FES.

Action Statement 3: ANKLE-FOOT ORTHOSIS (AFO) OR FUNCTIONAL ELECTRICAL STIMULATION (FES) TO IMPROVE OTHER MOBILITY. Clinicians should provide an AFO or FES for individuals with decreased lower extremity motor control due to acute or chronic post-stroke hemiplegia who have goals to improve other mobility (evidence quality: I; recommendation strength: strong).

- Acute AFO: evidence quality: II; recommendation strength: moderate
- Acute FES: evidence quality: I; recommendation strength: strong
- Chronic AFO: evidence quality: I; recommendation strength: strong
- Chronic FES: evidence quality: I; recommendation strength: strong

The other mobility statement incorporates multi-item outcome measures that assess gait and mobility dysfunction through a variety of constructs including timed and untimed ambulation on varied surfaces, ambulation with assistance, transfers, and stairs.[67,85,173-180]

Action Statement Profile

Aggregate Evidence Quality: Level I based on 1 level I SR, 1 level II SR/meta-analysis, 7 level I RCTs, and 6 level II, 6 level III, and 3 level IV studies.

- Acute AFO: Level II based on 4 level II, 2 level III, and 2 level IV studies (Appendix Table 9).[46,102,122,125,126,129,130,145,154,160]
- Acute FES: Level I based on 2 level I and 1 level II studies (Appendix Table 9).[46,102,122,125,126,129,130,145,154,160]
- Chronic AFO: Level I based on 1 level I SR, 1 level II SR/meta-analysis, 4 level I, 2 level II, and 4 level III studies (Appendix Table 10).[8,29,42,72,79,85,86,106,113,147,148,155]
- Chronic FES: Level I based on 1 level I SR, 3 level I, and 1 level II studies (Appendix Table 11).[8,85,86,147,148]

Benefits:

- Early provision of an AFO or FES may increase mobility and safety with ambulation when introduced earlier in the rehabilitation process, allowing more independent exercise participation[130] and enhancing recovery and independence for safe discharge to home. Early provision of an AFO following acute stroke does not appear to interfere with recovery of mobility.[130]
- Early provision of an AFO or FES as an intervention in rehabilitation may avoid added costs of making a decision about a device too soon.[125]

- In the chronic phase post-stroke, AFOs and FES provide both compensation and recovery-based effects. Thus, individuals can make gains in mobility relative to their needs even years after the stroke, which may further increase QOL and participation.

Risk, Harm, Cost:
- Costs may be high to the individual due to lack of sufficient insurance coverage or financial resources for AFOs or FES.
- Falls may increase with AFOs and FES by increasing mobility.
- Abandonment of AFOs may occur due to discomfort, difficulty donning/doffing, cosmesis, increased sweating, skin irritation, an uncomfortable stretching feeling when wearing, increased spasticity, and issues using with shoes.
- Abandonment of FES may occur due to intolerance to the sensation of the stimulation, insufficient DF achieved, general dissatisfaction, and skin irritation. With an implanted FES system, FES may not be successful due to system failure, infection, hematoma, lymphedema, nerve injury, and neurodermatitis.

Benefit-Harm Assessment:
- Preponderance of benefit.

Value Judgments:
- Faster gains in mobility in the acute phase may decrease length of stay.

Intentional Vagueness:
- The recommendations purposefully do not address the effects of one type of AFO over another, as studies used a variety of AFO types and rarely differentiated effects.
- The recommendations also do not address the severity of hemiparesis, as most studies included participants with the ability to ambulate independently or with minimal assistance often for at least 10 m.

Role of Patient Preferences:
- Individuals with poststroke hemiplegia may prefer walking with an AFO earlier rather than delaying walking to learn a more "normative" gait pattern.[125,154]
- Individuals with poststroke hemiplegia may prefer FES to AFOs due to improved movement and safety with FES.[147]
- Individuals may prefer FES over AFOs.

Exclusions:
- The recommendations may not apply to individuals with severe cognitive or communication deficits or neglect, history of multiple strokes, pacemakers, skin conditions, or severe spasticity (MAS ≥3).

Quality Improvement:
- Early provision of an AFO or FES may improve patient mobility and safety, allowing improved confidence for the individual and physical therapist.
- AFOs do not have a negative effect on recovery of mobility, so an AFO is appropriate to use in acute rehabilitation based on individual goals and desired effects.
- PT intervention and sufficient practice must be performed when an AFO or FES is provided to achieve optimal effects.
- Evaluation for a device should include an assessment of desired outcomes using different AFO and FES types and settings before making a final decision.

Implementation and Audit:
- AFOs or FES should be incorporated early in rehabilitation to improve mobility immediately and over time to improve rehabilitation potential.
- AFOs or FES should be considered during any evaluation to improve outcomes and satisfaction in individuals in the acute or chronic phases of stroke.
- Physical therapists would benefit from education on the effects of AFOs and FES and on clinical decision-making for monitoring effects, making adjustments to AFOs or FES, changing devices as individuals' needs change, and on appropriate outcome measures across the ICF to assess the effects of the devices.
- Review of medical records can identify outcomes seen with AFOs and FES use across a larger group of individuals.
- Potential barriers to implementation of the recommendation include lack of education about appropriate devices, access to devices, or lack of funding.

Supporting Evidence and Clinical Interpretation

Acute Stroke AFO: Studies that used AFOs for individuals with acute poststroke hemiplegia demonstrate moderate evidence for immediate orthotic, therapeutic, and combined orthotic effects to improve mobility (Appendix Table 9).

- *Immediate Orthotic Effect*: An immediate effect was reported in 1 level II, 1 level III, and 1 level IV studies. The level II RCT by Tyson and Rogerson[154] fitted a PLS to 20 nonambulatory participants. Functional Ambulation Category (FAC) scores significantly improved compared to walking without the PLS. The level III and level IV cohort studies found similar effects using various AFOs.[102,122] Dogan et al[102] assessed 51 participants using the Stroke Rehabilitation Assessment of Movement (STREAM) with and without an articulating AFO with a 90° PF stop. Significant improvements were noted in the mobility subscale of the STREAM score when wearing the articulating AFOs compared to no AFO. Lan et al[122] had similar results in 20 individuals with significantly improved FAC scores using a custom solid AFO.
- *Therapeutic Effect:* A therapeutic effect was reported in 1 level II[126] and 1 level IV studies.[145] In the RCT by Morone et al,[126] 20 participants walked with an unknown AFO type for 40 minutes 5 days per week for 4 weeks. Significant improvements were noted in the FAC. Mobility, as measured by the Barthel Index (BI) and Rivermead Mobility Index (RMI), also improved, exceeding the MDC for both and the MCID for the BI. A level IV cohort study

reported significant improvements in the Functional Independence Measure (FIM) with 26 participants using a nonspecified AFO during inpatient rehabilitation.[145]

- *Training Effect*: No evidence.
- *Combined Orthotic Effect*: Three studies, including 2 level II and 1 level III studies, reported on the combined orthotic effect.[125,129,130] Two level II RCTs, which included the same cohort of study participants, by Nikamp et al[129,130] compared immediate versus delayed provision of an AFO and considered the short- and long-term effects. A total of 33 subjects were assigned to receive a prefabricated solid, semisolid, or PLS AFO either early in the rehab process (week 1) or delayed (at week 9) to compare recovery (delayed group without initial AFO provision) to recovery combined with an AFO. Data from 26 subjects were analyzed. Both the early group with an AFO and the delayed group made significant improvements in the first 1 to 3 weeks of rehabilitation in FAC, RMI, and BI scores.[130] Only the early provision group reported improvements in BI scores that exceeded the MCID. The delayed group was provided an AFO at week 9. Upon discharge at week 11, both groups achieved similar levels of functional improvement.[130] At the 26-week follow-up, there were no significant differences between groups, with all study participants achieving an FAC level greater than 3, indicating ambulation without the assist of another person.[129] These results suggest only marginal improvement in mobility when an AFO is provided early in rehabilitation versus later with no differences seen longer term.

A level III retrospective cohort study by Momosaki et al[125] found that 792 participants who used an AFO early in rehabilitation had significantly higher discharge FIM scores, FIM score gain, and FIM efficiency compared to participants matched on demographics who did not receive an AFO. In addition, discharge FIM scores were significantly higher for individuals with lower admission FIM scores (<63) who were provided an AFO early in rehabilitation. This finding suggests that an AFO may be most appropriate in individuals who present with more impaired mobility following acute stroke.[125]

Acute Stroke FES: Studies that used FES for individuals with acute poststroke hemiplegia demonstrate strong evidence for therapeutic effects to improve mobility (Appendix Table 9).

- *Immediate Orthotic Effect*: No evidence.
- *Therapeutic Effect*: Two level I and 1 level II studies reported therapeutic effects.[46,126,160] In 1 level I RCT, FES was delivered in an outpatient setting, while the other group was provided FES in an acute rehabilitation hospital. Both studies used FES during walking and to assist with exercise. In the level I RCT by MacDonell et al,[46] the FES (n = 20) and non-FES (n = 18) groups received an equivalent dose of PT for 8 weeks, but the FES group used FES during exercise and functional training. Both groups made significant improvements in FAC and BI at 4 and 8 weeks, with improvements that exceeded the MDC and the MCID for the BI. The FES group also had a significantly greater rate of mobility improvement compared to the non-FES group as measured by the FAC.[46] In the second level I RCT, Wilkinson et al[160] provided 20 participants with PT for 1 hour 2 days per week for 6 weeks. Ten participants randomized to a group received FES during gait training, along with exercise and daily home use. Both groups reported significant improvements in RMI scores that exceeded the MDC, with no differences seen between groups.[160]

A level II RCT by Morone et al[126] included 20 participants undergoing conventional rehabilitation with 10 participants randomized to a group using FES during the sessions, while the control group wore an AFO. The walking training included 40 minutes 5 days per week for 4 weeks. Both groups had improvements in mobility exceeding the MDC in the BI and RMI.[126]

- *Training Effect*: No evidence.
- *Combined Orthotic Effect*: No evidence.

Chronic Stroke AFO: Studies that used AFOs for individuals with chronic poststroke hemiplegia demonstrate strong evidence for immediate orthotic, therapeutic, and training effects to improve mobility. The evidence is stronger for therapeutic and training effects compared to immediate orthotic effects (Appendix Table 10).

- *Immediate Orthotic Effect*: Seven studies including 3 level II and 4 level III studies reported on the immediate orthotic effect.[29,42,79,106,113,147,155] The level II SR/meta-analysis by Tyson and Kent[29] reported the immediate effects of 3 studies using the FAC. Two[42,155] of the 3 studies were level III studies that included participants with chronic stroke and are included in this section of the CPG. In a level II retrospective study, Kesikburun et al[113] reported significant improvements in FAC in 28 participants when a custom solid AFO was provided. In Sheffler et al,[147] significant improvements were seen in the ambulation on floor, carpet, and TUG items on the Modified Emory Functional Ambulation Profile (mEFAP) when a custom AFO was worn compared to no device.[147] Level III evidence by Abe et al[79] reported improvements in FAC in 16 participants when a PLS or hinged AFO was provided. The number of participants who were able to achieve an FAC level of 5 (able to independently ambulate on level surfaces, nonlevel surfaces, stairs, and inclines) significantly improved from 0% when ambulating barefoot to 63% when ambulating with an AFO.[79]

Further level III evidence assessed mobility with the use of the participant's own or custom AFO compared to no AFO, and found significantly improved FAC or the mEFAP scores when walking with versus without AFO. AFO types used included solid, anterior shell and articulating.[42,106,155] Group differences were primarily in individuals who were independent ambulators, thus allowing them the ability to access more complex environments with an AFO.[42,106,155] Tyson and Thornton[155] also reported improved FAC scores from 2 to 4 for participants who required support to walk without AFOs (FAC level 2). Thus, the AFOs allowed them to become independent ambulators (FAC 4).

- *Therapeutic Effect*: Two level I studies reported therapeutic effects following training.[8,148] The level I SR by Dunning et al[8] reported improved mEFAP scores in 1 study by Sheffler et al,[148] which is included in this CPG. In the RCT by Sheffler et al, 110 participants received training for 1 hour 2 days per week for the first 5 weeks followed by 3 more 1-hour sessions over a 7-week period. They were also instructed to wear the AFOs for up to 8 hours per day. Significant differences were noted in mobility using the mEFAP. The MCID was exceeded after the 12-week intervention and gains were maintained 6 months later, despite AFO discontinuation after 12 weeks.[148]
- *Training Effect*: Four level I studies examining the same participants reported a training effect.[8,72,85,86] The level I SR by Dunning et al[8] included 1 RCT[85] that is also included in this CPG for a training effect. This RCT by Bethoux et al[85] included 495 participants whose walking speed was less than 0.08 m/s. Based on individual needs, 253 participants were provided with a custom solid or articulating AFO. Participants were instructed to wear the orthosis on a full-time basis after an initial 2-week progressive wearing schedule. Improvements exceeding the MDC on mEFAP were reported at 6 months for the 212 individuals who completed data collection. Participants (n = 204) were able to maintain gains when reassessed at 12 months, but no further improvements were noted.[86] In addition, a multicenter RCT by Everaert et al[72] reported improvement in the RMI for 24 participants who were provided a custom AFO. No changes were seen after 6 weeks, but improvements in the RMI exceeded the MDC after 12 weeks.[72]
- *Combined Orthotic Effect*: No evidence.

Chronic Stroke FES: Studies that used FES for individuals with chronic poststroke hemiplegia demonstrate strong evidence for immediate orthotic, therapeutic, and training effects to improve mobility. The evidence is stronger for therapeutic and training effects compared to immediate orthotic effects (Appendix Table 11).

- *Immediate Orthotic Effect*: One level II RCT by Sheffler et al[147] compared 5 elements of the mEFAP in 14 subjects. Significant improvements were seen in the item of ambulation on carpet when wearing FES compared to no device.[147]
- *Therapeutic Effect*: One level I RCT by Sheffler et al[148] is included in the level I SR by Dunning et al.[8,59] In the RCT by Sheffler et al,[148] 110 participants participated for 1 hour 2 days per week for the first 5 weeks followed by 3 more 1-hour sessions over a 7-week period and were instructed to use FES for up to 8 hours per day. Significant differences that exceeded the MDC were noted in mobility using the mEFAP after the 12-week intervention that were maintained after 6 months, despite discontinuation of FES at 12 weeks.
- *Training Effect*: Three level I studies reported on the training effect of AFOs on mobility. The level I SR by Dunning et al[8] included 1 RCT[85] reporting training effect that is also included in this CPG. In this RCT, Bethoux et al[85] included 495 participants of which 242 were provided FES for home use after 2 weeks of programming and training. Of these 242 participants, 187 completed the 6-month follow-up and 180 completed the 12-month follow-up. Gait Functional Ambulation Profile (FAP), total mEFAP, and mEFAP subtasks of floor time and obstacle course time improved significantly with use of FES from baseline to 6 months, with the changes in total mEFAP exceeding the MDC. In the absence of intervention beyond the initial 2 weeks, the authors theorized that the improvements may be due to the mechanism of foot drop correction provided by FES with improved clearance of obstacles and barriers.[85] Continued improvements exceeding the MDC were noted for the mEFAP total score between 6 and 12 months.[86]
- *Combined Orthotic Effect*: No evidence.

Comparison of AFO and FES: For acute stroke, there is level II evidence based on 2 level II RCTs that show conflicting results.[126,144] For a combined orthotic effect, a level II RCT by Salisbury et al[144] found no difference in a combined orthotic effect between use of an AFO and FES. However, a level II RCT by Morone et al[126] reported that the FES group had a significantly greater increase in mobility with an increase in FAC from 2 to 4 compared to an increase in FAC from 2 to 3 in the AFO group.

For chronic stroke, there is level I evidence based on 3 level 1[8,72,85] and 1 level II studies[86] that showed no difference in effects on mobility between AFOs and FES. A level I SR by Dunning et al[8] reported a change in mobility using the mEFAP and included 1 study also included in this CPG that compared effects between AFO and FES groups. This level I RCT by Bethoux et al[85] reported no difference in training effect between AFO and FES groups following 6 months of use. A level I RCT by Everaert et al[72] reported no difference in combined orthotic effect, and Bethoux et al[86] reported no difference in the training effect between AFOs and FES at the 12-month follow-up.

Clinical Interpretation: In the acute phase post-stroke, there is more evidence to support AFO use than FES use, with varied considerations for each device (Appendix Table 9). A combined orthotic effect for mobility was seen when a custom AFO was provided both early (at 1 week) and late (at 9 weeks).[129,130] The type of AFOs used in studies varies without a preference for one type over another. The key indication noted across many studies is just that the AFO meets the needs of the individual. Therapeutic effects were reported with unspecified types of AFO. The improvements appeared to be more meaningful when the device is applied over 20 PT sessions.[126] While the improvement in mobility were marginal, individuals with a lower admission FIM score (<63) may benefit from earlier AFO use to improve mobility.[125]

When considering FES, there is only evidence to support a therapeutic effect when FES is provided during rehabilitation process for at least 5 sessions per week over 4 weeks.[126] When considering the available evidence for either device, it may be beneficial to include FES as an intervention during inpatient rehabilitation to improve mobility and then reassess the need for either device based on the individuals.

For individuals with chronic poststroke hemiplegia, the evidence is strong for custom AFO use. In many studies, participants were already using an AFO, which further supports the need for assessment for revisions to meet the changing needs of the individual at this phase. Improvements were seen ranging from increased levels of independence to the ability to access more complex environments regardless of baseline mobility. Both therapeutic and training effects were noted following 12 weeks of AFO use.[72,148] Further therapeutic benefits continued to be made after the AFO was discontinued demonstrating the potential for recovery in the chronic phase. Thus, AFO use along with skilled PT may promote recovery and not necessarily dependence on the AFO during this chronic phase. For FES use in chronic stroke, immediate and combined effects are limited compared to therapeutic and training effects. Strong evidence supports FES use combined with skilled PT intervention and daily wear over 12 weeks.[8,148] These findings are consistent with other outcomes where there was a benefit following initial device training during PT intervention before significant results were reported. While there is little research on the use of FES to improve mobility in individuals with acute poststroke hemiplegia, best practice suggests that benefits are possible similar to what are seen with individuals with chronic poststroke hemiplegia.

Overall, both AFOs and FES can provide positive mobility benefits for individuals with acute or chronic poststroke hemiplegia. Combining AFO or FES use with other PT interventions may be important to promote mobility gains. There is some evidence for FES to have a greater therapeutic effect on mobility compared to AFOs in acute stroke.

Research Recommendations: More research is needed for the use of AFOs and FES in the acute and chronic population across effects to guide clinical decision-making regarding optimal timing of device introduction, to further understand the best responders, and to differentiate AFO types to improve mobility based on examination findings. For both AFOs and FES, more research is needed on dosing to achieve maximum effect.

Action Statement 4: ANKLE-FOOT ORTHOSIS (AFO) OR FUNCTIONAL ELECTRICAL STIMULATION (FES) TO IMPROVE DYNAMIC BALANCE. Clinicians should provide an AFO or FES for individuals with decreased lower extremity motor control due to acute or chronic poststroke hemiplegia who have goals to improve dynamic balance (evidence quality: I; recommendation strength: strong).

- Acute AFO evidence quality II; recommendation strength: weak
- Acute FES evidence quality: not applicable; recommendation strength: best practice
- Chronic AFO evidence quality I; recommendation strength: strong
- Chronic FES evidence quality I; recommendation strength: strong

Measures that are included under dynamic balance primarily assess stability, balance, balance confidence, or fall risk.

Action Statement Profile

Aggregate Evidence Quality: Level I based on 1 level II meta-analysis, 1 level I SR, 1 level II SR, 9 level I, 3 level II, 6 level III, 1 level III/IV, and 7 level IV studies.

- Acute AFO: Level I based on 1 level I RCT, 1 level II RCT, 1 level III study, and 2 level IV studies (Appendix Table 12).[102,122,129,130,137]
- Acute FES: No evidence.
- Chronic AFO: Level I based on 1 level II SR, 1 level II meta-analysis, 4 level I RCTs, 2 level II studies, 4 level III studies, 1 level III/IV study, and 3 level IV studies (Appendix Table 13).[21,29,32,39,42,72,76,85,91,93,101,106,136,138,157,165]
- Chronic FES: Level I based on 1 level I SR, 7 level I RCTs, 2 level III studies, and 2 level IV studies (Appendix Table 14).[8,49,59,72,76,81,85,95,108,115,141,151]

Benefits:

- AFOs can decrease the risk for falls and improve dynamic ambulation and balance confidence.
- FES can increase foot clearance in swing, decrease risks for falls, and increase gait symmetry, which can improve dynamic balance reactions.
- AFOs and FES can increase overall safety in the home and community.

Risk, Harm, Cost:

- AFOs may limit DF instance, thus limiting the ability to perform some dynamic balance tasks and reactions.
- Costs may be high to the individual due to lack of sufficient insurance coverage or financial resources for AFOs or FES.
- Falls may increase with AFOs and FES by increasing mobility.
- Abandonment of AFOs may occur due to discomfort, difficulty donning/doffing, cosmesis, increased sweating, skin irritation, an uncomfortable stretching feeling when wearing, increased spasticity, and issues using with shoes.
- Abandonment of FES may occur due to intolerance to the sensation of the stimulation, insufficient DF achieved, general dissatisfaction, and skin irritation. With an implanted FES system, FES may not be successful due to system failure, infection, hematoma, lymphedema, nerve injury, and neurodermatitis.

Benefit-Harm Assessment:

- Preponderance of benefit.

Value Judgments:

- Wearing a static AFO can limit ankle DF, which may cause compensation at more proximal joints and decrease dynamic balance.

Intentional Vagueness:

- The recommendations purposefully do not address the effects of one type of AFO over another, as

- studies used a variety of AFO types and rarely differentiated effects.
- The recommendations also do not address the severity of hemiparesis, as most studies included participants with the ability to ambulate independently or with minimal assistance often for at least 10 m.

Role of Patient Preference:
- Individuals may find that AFOs provide increased balance confidence in daily mobility tasks.
- Individuals may prefer FES over an AFO.

Exclusions:
- The recommendations may not apply to individuals with severe cognitive or communication deficits or neglect, history of multiple strokes, pacemakers, skin conditions, or severe spasticity (MAS $\geq$3).

Quality Improvement:
- Earlier AFO provision may allow earlier improvements in dynamic balance, so AFOs should be considered earlier post-stroke.
- AFO or FES provision in the chronic phase may improve dynamic balance and decrease the risk of falls.
- PT intervention and sufficient practice must be performed when an AFO or FES is provided to achieve optimal effects.
- Evaluation for a device should include an assessment of desired outcomes using different AFOs and FES types and settings before making a final decision.

Implementation and Audit:
- The Functional Gait Assessment (FGA), and not the Berg Balance Scale (BBS), should be used to assess effects of AFOs and FES for individuals with dynamic balance deficits.
- AFOs or FES should be considered during any evaluation to improve outcomes and satisfaction in individuals in the acute or chronic phases of stroke.
- Physical therapists would benefit from education on the effects of AFOs and FES and on clinical decision-making for monitoring effects, making adjustments to AFOs or FES, changing devices as individuals' needs change, and on appropriate outcome measures across the ICF to assess the effects of the devices.
- Review of medical records can identify outcomes seen with AFO and FES use across a larger group of individuals.
- Potential barriers to implementation of the recommendation include lack of education about appropriate devices, access to devices, or lack of funding.

Supporting Evidence and Clinical Interpretation

Supporting Evidence:

Acute Stroke AFO: Studies that used AFOs for individuals with acute poststroke hemiplegia demonstrate moderate evidence for immediate orthotic and combined orthotic effects to improve dynamic balance (Appendix Table 12).

- *Immediate Orthotic Effect*: Three studies, 1 level III and 2 level IV, assessed the immediate effect of AFOs on dynamic balance with mixed results.[102,122,137] One level III cohort study by Dogan et al[102] used an articulating AFO with posterior stop and 90° PF stop with 51 participants. They found significant improvements that exceeded the MDC in TUG scores and significant changes in BBS scores. Two level IV studies found no effects on BBS scores with use of an AFO. In these studies, Park et al[137] assessed 17 participants with a PLS AFO or anterior AFO, and Lan et al[122] assessed 20 participants with a plastic-molded AFO at 90° of DF.
- *Therapeutic Effect*: No evidence.
- *Training Effect*: No evidence
- *Combined Orthotic Effect*: One level II RCT by Nikamp et al[129,130] reported a combined orthotic effect following AFO use. Thirty-three participants were provided a flexible, semirigid, or rigid AFO at week 1 (early provision) or week 9 (delayed provision) of inpatient rehabilitation. Two weeks after receiving the AFO, the early provision group showed significant improvements that exceeded the MDC in the BBS and TUG and significant improvements in the Timed Up/Down Stairs (TUDS) compared to the group that received usual care without an AFO. The delayed provision group was provided with an AFO at week 9. After 2 weeks, they demonstrated significant improvements in the BBS, significant improvements in the TUG that exceeded the MDC, and no changes in the TUDS. Early provision of AFOs resulted in faster improvements in dynamic balance outcomes.[129,130]

Acute Stroke FES: There are no studies that use FES to improve dynamic balance for individuals with acute poststroke hemiplegia.

- *Immediate Orthotic Effect*: No evidence.
- *Therapeutic Effect*: No evidence.
- *Training Effect*: No evidence.
- *Combined Orthotic Effect*: No evidence.

Chronic Stroke AFO: Studies that used AFOs for individuals with chronic poststroke hemiplegia demonstrate strong evidence for all 4 effects to improve dynamic balance (Appendix Table 13).

- *Immediate Orthotic Effect*: Thirteen studies including 2 level I, 3 level II, 4 level III and 4 level IV, assessed the immediate orthotic effect with differing results using different outcome measures.[21,29,30,42,72,76,91,93,101,106,136,157,165] In a level I RCT, Kluding et al[76] enrolled 197 participants of which 98 received a custom AFO and 8 sessions of education and practice prior to baseline assessments. Significant improvements were seen with the BBS and TUG scores, with the TUG exceeding the MDC. There was no effect on Functional Reach Test (FRT) scores.[76] In a level I RCT, Everaert et al[72] found that the 93 participants who completed data collection were significantly faster during the figure-of-8 test when wearing an unspecified AFO.[72]

A level II cohort by de Wit et al[101] evaluated 20 participants who had worn a solid plastic AFO with various types of posterior steel supports for at least 6 months prior to testing. Significant improvements that exceeded the MDC for the TUG as well as significant changes in the TUDS were found.[101] Chisholm and Perry[21] conducted a level II SR that included studies with various unspecified AFO types and found overall trends in decreased TUG times with an AFO.[21] Tyson et al[29] completed a level II meta-analysis that found no patterns in BBS, TUG, and TUDS changes with varying types of AFOs.[29]

Seven out of the 8 level III and level IV studies that assessed the immediate orthotic effect also found positive impact on dynamic balance using the BBS, TUG, and/or TUDS.[39,42,91,93,106,136,165] The types of AFOs used in these studies ranged from solid plastic with varying types of posterior steel supports, anterior, prefabricated dynamic, custom, articulating, and PLS and they were compared to no AFO. One of the level III cohort studies, Pardo et al,[136] compared custom to prefabricated AFOs in 14 participants and found no difference between AFO types. The 1 of the 8 level III and level IV studies that found no difference in dynamic balance was by Wang et al.[157] They evaluated 103 participants on the BBS while using a prefabricated AFO.

There were 2 studies that assessed balance confidence with use of an AFO. Two level III cohort studies used either the Activities-Specific Balance Confidence Scale (ABC) or the Falls Efficacy Scale-International (FES-I). Zissimopoulos et al[165] assessed 15 participants with the ABC with use of a nonrigid custom AFO, and Hung et al[106] assessed 52 participants using an anterior plastic AFO with the FES-I. Both studies found significant improvements in balance confidence measures.[106,165]

- *Therapeutic Effect*: Two level I studies reported therapeutic effect of AFOs.[72,76] In Kluding et al,[76] a level I RCT, 98 of the 197 participants were provided with a custom AFO and instructed to wear it daily for 30 weeks. Significant improvements were found in BBS scores, yet there was no effect with the TUG. Everaert et al,[72] a level I RCT with 93 participants, assessed 3 groups in their study who used an unspecified AFO. Group 1 used an AFO for 6 weeks followed by 6 weeks of FES, group 2 used FES for 6 weeks followed by 6 weeks of AFO use, and group 3 used an AFO for 12 weeks. Significant improvements were found in figure-of-8 gait speed with AFOs at either 6 or 12 weeks of use.
- *Training Effect*: Two level I studies evaluated the training effect with differing results using different outcome measures.[76,85] In Kluding et al,[76] a level I RCT as described earlier, significant improvements in BBS scores were found after 30 weeks, yet there was no effect on the TUG. A level I RCT by Bethoux et al[85] reported that 212 of the 253 participants who completed 6 months of home use of a custom AFO had no changes in TUG or BBS scores.
- *Combined Orthotic Effect*: Five studies, 3 level I, 1 level II, and 1 level III, reported combined orthotic effects.[32,39,72,76,138] Across studies, some outcome measures included were responsive to the AFO use and some were not. Kluding et al,[76] a level I RCT as described earlier, found significant changes that exceeded the MDC for the TUG and significant changes on the BBS. Erel et al,[32] a level I RCT, had 14 of their 28 participants use a dynamic AFO daily for 3 months. They found significant improvements in the Timed Up Stairs (TUS), but no change in the Timed Down Stairs (TDS), TUG, or FRT. Participants had no prior AFO use and had to have a MAS score of less than 3. Another level I RCT by Everaert et al[72] assessed 93 participants 6 or 12 weeks after AFO use and found significant improvements in figure-of-8 gait speed.

A level II cohort study by Pavlik[138] that used a solid or articulating AFO with 4 participants for 6 months of daily use found significant changes that exceeded the MDC for the TUG. Bouchalova et al,[39] a level III cohort, used a dynamic Maramed AFO or prefabricated AFO in 15 participants for 1 month of daily wear. They found changes in the TUG that exceeded the MDC. There was no effect using the Four Square Step Test (FSST).

Chronic Stroke FES: Studies that used FES for individuals with chronic poststroke hemiplegia demonstrate strong evidence for all 4 effects to improve dynamic balance (Appendix Table 14).

- *Immediate Orthotic Effect*: Four studies, 2 level I, 1 level III, and 1 level IV, assessed immediate orthotic effects with differing results using different outcome measures.[49,72,76,141] A level I RCT by Kluding et al[76] used FES with 99 out of 197 enrolled participants and found significant improvements in the BBS and TUG, exceeding the MDC for the TUG. There was no effect on Functional Reach Test (FRT) scores. Everaert et al.[72] a level I RCT, assessed 69 out of 93 enrolled participants using FES and found significant improvements in figure-of-8 gait speed. A level III cohort by Robertson et al[141] assessed 15 participants and found no effect on the TUG, BBS, or ABC. In addition, a level IV cohort study by Martin et al[49] that included 27 participants with implantable FES found significant improvements that exceeded the MDC for the TUG.
- *Therapeutic Effect*: Seven studies, 5 level I, 1 level III, and 1 level IV, reported a therapeutic effect.[59,72,76,81,108,115,151] A level I RCT by Kluding et al[76] assessed FES use in 99 out of 197 enrolled participants after 30 weeks of daily use and found changes in the BBS and TUG that reached the MDC. The FRT showed no significant changes. Another level I RCT by Hwang et al[108] combined use of FES with TT for 30 minutes 7 days per week for 4 weeks for 15 out of 30 enrolled participants. The authors found significant changes that exceeded the MDC in BBS and TUG scores, and the FES group had greater changes than the 15 participants in the control group doing TT only. Lee et al,[59] a level I RCT

with 30 participants, used FES in combination with body-weight support treadmill training (BWSTT) for 1 hour 5 days per week for 4 weeks, and demonstrated significant changes that exceeded the MDC in the BBS and TUG. These improvements were significantly better than those of the control group, who received BWSTT only. In another level I RCT, Bae et al[81] had participants perform FES with robot-assisted gait training for 30 minutes 3 days per week for 5 weeks plus an additional 30 minutes of unspecified usual care with 10 out of the 20 enrolled participants. The control group performed robot-assisted gait training without FES. They found significant improvements in the BBS and TUG in both groups, with the TUG exceeding the MDC; however, there were no differences between groups. Everaert et al,[72] a level I RCT described earlier, assessed balance following FES use in 2 groups: group 1 received FES for 6 weeks followed by an AFO for 6 weeks and group 2 received an AFO for 6 weeks followed by FES for 6 weeks. They found significant increases in figure-of-8 gait speed following 6 weeks of daily FES use.

In a level III retrospective study by Sota et al,[151] 101 participants used FES for 26.6 ± 19.6 sessions for a total of 19.4 ± 18.2 hours. When analyzed together, all participants significantly decreased TUG times and met the MDC. For further analysis, participants were divided into responders (>0.1 m/s gait speed change, n = 58) and nonresponders (<0.1 m/s gait speed change, n = 43). The responders had significant decreases in TUG times of 3.6 ± 3.9 seconds, and the nonresponders decreased significantly by 1.6 ± 3.9 seconds, which was significantly different between groups. However, the responders exceeded the MDC while the nonresponders did not. In a level IV study with 28 participants, Kim et al[72] combined FES with treadmill and virtual reality (VR) training for 20 minutes 3 days per week for 8 weeks. Participants were assigned to 3 TT groups, with group 1 receiving FES and VR, group 2 receiving FES, and group 3 receiving TT only. They found significant improvements for the BBS and TUG for all groups. The MDC was exceeded for the BBS for the 2 groups using FES and for the TUG for the VR plus FES group only.

- *Training Effect*: There were 3 level I studies that assessed training effect with overall mixed results.[76,85,95] Kluding et al,[76] a level I RCT with 197 participants, found significant changes in BBS and TUG scores for the 99 participants using FES after 30 weeks. There was no effect on FRT scores. Bethoux et al,[85] a level I RCT with 399 participants completing the study, had 187 of the participants use FES daily for 6 months and found no effect on TUG and BBS scores. Cho et al,[95] a level I RCT, had 11 of the 34 enrolled participants use FES combined with TT for 30 minutes 5 days per week for 4 weeks. They found no effect on BBS scores for the FES group or the control group receiving TT without FES.
- *Combined Orthotic Effect*: There were 2 level I studies that assessed combined orthotic effects with differing results using different outcome measures.[72,76] The level I RCT with by Kluding et al[76] previously described used FES for 30 weeks and found significant changes in TUG and BBS scores, with the TUG exceeding the MDC. There was no effect on FRT scores. Another level I RCT by Everaert et al[72] used FES for 6 weeks in 93 participants and found significant increases in figure-of-8 gait speed.

Comparison of AFO and FES: While there is no evidence that compares the effects of AFOs and FES on dynamic balance in the acute phase, there is some level I evidence for AFOs to have greater immediate orthotic effects and for FES to have greater therapeutic effects on dynamic balance in the chronic phase based on 1 level I SR[8] and 3 level I RCTs.[72,76,85] Using the BBS and TUG, the SR by Dunning et al[8] reported no differences in balance between AFOs and FES for therapeutic and training effects. For a combined orthotic effect, AFOs were reported to be better than FES using the BBS but not the TUG, even though no statistical or clinical significance was reported. Two of the level I RCTs in this CPG were included in the SR by Dunning et al.[8] Kluding et al[76] found no difference between AFOs and FES groups in immediate, therapeutic, training, or combined orthotic effects using the BBS, TUG, and FRT,[76] and Bethoux et al[85] found no difference in training effects using the BBS. However, Everaert et al[72] found that the AFO group had a significantly larger immediate orthotic effect in dynamic balance compared to the FES group when using the figure-of-8 test. For the therapeutic effect, the FES group had significantly larger improvements in dynamic balance compared to the AFO group.

Clinical Interpretation: Dynamic balance can be defined as the ability to maintain the center of mass over the base of support during motion.[6] For individuals with decreased lower extremity motor control due to acute poststroke hemiplegia, the evidence is varied on the impact of AFOs on dynamic balance, and there is currently no evidence on FES use. A significant improvement in dynamic balance across effects was reported when the AFO was custom-made to meet the needs of the individual. In contrast, no effect was reported when the same type of AFO was required for all participants regardless of the individual needs. When an AFO was provided early in rehabilitation, participants demonstrated significantly improved dynamic balance compared to those not using an AFO, which may indicate a decreased fall risk and improved ability to participate in rehabilitation. Long-term outcomes in dynamic balance were similar regardless of the timing of AFO provision, which may indicate the need for individualized assessment of fall risk early to determine need. The lack of change in dynamic balance after long-term use may be related to the measure included. Improvements in the BBS were reported in the initial stages of rehabilitation and AFO use, but a ceiling effect may limit the ability of the BBS to capture improvements later in the rehabilitation stages.

The literature for AFO use in individuals with chronic poststroke hemiplegia is strong for immediate orthotic and combined orthotic effects. An immediate effect is reported with different AFO types, and improvements may be greater when a custom AFO is provided. A variety of outcome measures were used across studies, with the improvements noted more consistently with the TUG than with the BBS and FRT, suggesting that outcome measure choice should also be considered. For combined orthotic effects, a significant and often clinically meaningful improvement was seen across studies. Stronger results were reported when the participant was able to ambulate at a slower baseline speed, and when the AFO was worn for greater than 12 weeks.[32,76,85] There is a limited evidence supporting therapeutic or training effects of an AFO on dynamic balance after 6 weeks to 6 months of use.[72,76,85] Lack of skilled PT interventions may contribute to limited outcomes.

For FES use for chronic poststroke hemiplegia, strong immediate, therapeutic, and combined effects were reported. The therapeutic and combined improvements may be more clinically meaningful when combined with skilled PT provided for at least 30 minutes 3 days per week for 4 weeks or for at least 18 sessions.[59,76,81,108,151] Studies with longer duration interventions had stronger results supporting the inclusion of skilled PT following FES provision to enhance the potential for recovery. The results of studies examining training effects were inconclusive as to effects of skilled PT. Most studies considering this effect did not include intensive intervention, which may be a limiting factor in the results considering the level of improvements in other effects when intensive skilled PT was applied. While there is little research on the use of FES to improve dynamic balance in individuals with acute poststroke hemiplegia, best practice suggests that benefits are possible similar to what are seen with individuals with chronic poststroke hemiplegia.

An important aspect of the assessment of dynamic balance is related to the outcome measure chosen. The BBS and the TUG were the most commonly used outcome measures for dynamic balance across the included studies, yet different results were often seen across these measures. While the BBS is included in the core set of outcome measures recommended for individuals with neurologic conditions, adding the FGA as recommended as a core measure may be beneficial to assess dynamic balance during more challenging tasks, especially for individuals with less balance difficulties.[181]

Strong evidence exists for the use of AFOs to increase dynamic balance in individuals with decreased lower extremity motor control due to acute and chronic poststroke hemiplegia and for the use of FES in those with chronic poststroke hemiplegia. Outcomes may be improved when the AFO is designed to meet the needs of the individual. A period of skilled intervention upon AFO or FES provision can lead to more meaningful outcomes. The BBS and the FGA are recommended measures to assess dynamic balance in this population. There is also some evidence for greater therapeutic effects with FES compared to AFOs and for greater immediate orthotic effects with AFO compared to FES.

Research Recommendations: More research is needed on the effects of AFOs and FES on dynamic balance for individuals with acute poststroke hemiplegia. There is some evidence that longer use is needed to show effects, but more studies are needed on dosing for those with both acute and chronic poststroke hemiplegia. Studies should also examine the effects of different AFO types, as the current literature is insufficient to recommend specific types of AFO. Other outcome measures of dynamic balance that may be more responsive to AFOs or FES, such as the FGA, should be included as measures in these studies.

Action Statement 5: ANKLE-FOOT ORTHOSIS (AFO) OR FUNCTIONAL ELECTRICAL STIMULATION (FES) TO IMPROVE WALKING ENDURANCE. Clinicians may provide an AFO or FES for individuals with decreased lower extremity motor control due to acute poststroke hemiplegia who have goals to improve walking endurance (evidence quality: II; recommendation strength: moderate). Clinicians should provide an AFO or FES for individuals with decreased lower extremity motor control due to chronic poststroke hemiplegia who have goals to improve walking endurance (evidence quality: I; recommendation strength: strong).

- Acute AFO: evidence quality: II; recommendation strength: moderate
- Acute FES: evidence quality: III; recommendation strength: weak
- Chronic AFO: evidence quality: I; recommendation strength: strong
- Chronic FES: evidence quality: I; recommendation strength: strong

Outcome measures captured under the statement on walking endurance include those that primarily consider energy expenditure and endurance.

Action Statement Profile

Aggregate Evidence Quality: Acute: level II based on 2 level I RCTs, 1 level II, and 1 level III studies. Despite having 2 level I studies, a moderate to substantial change in endurance was not seen in these studies, resulting in an overall level II for evidence. Chronic: level I based on 1 level I SR, 6 level I, 1 level II SR, 3 level II, 6 level III, and 3 level IV studies.

- Acute AFO: Level II based on 1 level I, 1 level II, and 1 level III studies (Appendix Table 15).[109,129,130,160]
- Acute FES: Level II based on 1 level I study (Appendix Table 15).[109,129,130,160]
- Chronic AFO: Level I based on 1 level I SR, 5 level I, 1 level II, and 3 level III studies (Appendix Table 16).[8,32,72,76,85,86,98,99,133]
- Chronic FES: Level I based on 1 level I SR, 6 level I, 1 level II SR, 2 level II, 4 level III, and 3 level IV studies (Appendix Table 17).[8,28,50,51,55,56,72,76,85,86,89,90,95,142,146,151,153]

Benefits:

- Walking endurance may improve with the use of an AFO or FES, potentially increasing the ability to participate in the community.

- AFOs may improve walking endurance in a compensatory manner while FES may improve it in a recovery-based manner with acute stroke. Thus, FES may allow future walking without a device, decreasing costs and minimizing equipment needed.
- Greater walking endurance with an AFO or FES may promote increased steps per session, steps per day, cardiovascular health, and community engagement.

Risk, Harm, Costs:

- Costs may be high to the individual due to lack of sufficient insurance coverage or financial resources for AFOs or FES.
- Falls may increase with AFOs and FES by increasing mobility.
- Abandonment of AFOs may occur due to discomfort, difficulty donning/doffing, cosmesis, increased sweating, skin irritation, an uncomfortable stretching feeling when wearing, increased spasticity, and issues using with shoes.
- Abandonment of FES may occur due to intolerance to the sensation of the stimulation, insufficient DF achieved, general dissatisfaction, and skin irritation. With an implanted FES system, FES may not be successful due to system failure, infection, hematoma, lymphedema, nerve injury, and neurodermatitis.

Benefit-Harm Assessment:

- Preponderance of benefit.

Value Judgments:

- Walking endurance is important to allow improved activity tolerance, a return to life roles, increased community engagement, and return to work.

Intentional Vagueness:

- The recommendations purposefully do not address the effects of one type of AFO over another, as studies used a variety of AFO types and rarely differentiated effects.
- The recommendations also do not address the severity of hemiparesis, as most studies included participants with the ability to ambulate independently or with minimal assistance often for at least 10 m.

Role of Patient Preferences:

- Individuals may prefer FES over AFOs.

Exclusions:

- The recommendations may not apply to individuals with severe cognitive or communication deficits or neglect, history of multiple strokes, pacemakers, skin conditions, or severe spasticity (MAS $\geq$3).

Quality Improvement:

- Earlier AFO provision may allow earlier improvements in endurance, so AFOs should be considered earlier poststroke.
- PT intervention and sufficient practice must be performed when an AFO or FES is provided to achieve optimal effects.
- Evaluation for a device should include an assessment of desired outcomes using different AFOs and FES types and settings before making a final decision.

Implementation and Audit:

- The 6-minute walk test (6MWT) is recommended to measure endurance, as it is more readily replicated in the clinic and has strong psychometric properties.
- AFOs or FES should be considered during any evaluation to improve outcomes and satisfaction in individuals in the acute or chronic phases of stroke.
- Physical therapists would benefit from education on the effects of AFOs and FES and on clinical decision-making for monitoring effects, making adjustments to AFOs or FES, changing devices as individuals' needs change, and on appropriate outcome measures across the ICF to assess the effects of the devices.
- Review of medical records can identify outcomes seen with AFO and FES use across a larger group of individuals.
- Potential barriers to implementation of the recommendation include lack of education about appropriate devices, access to devices, or lack of funding.

Supporting Evidence and Clinical Interpretation

Supporting Evidence:

Acute Stroke AFO: Studies that used AFOs for individuals with acute poststroke hemiplegia demonstrate moderate evidence for immediate orthotic and combined orthotic effects to improve walking endurance. The evidence is strongest for a combined orthotic effect (Appendix Table 15).

- *Immediate Orthotic Effect*: One level III cohort study by Hyun et al[109] evaluated the aerobic capacity of 15 participants with and without solid plastic AFOs and found significant improvements in the 6MWT.[109]
- *Therapeutic Effect*: No evidence.
- *Training Effect*: No evidence.
- *Combined Orthotic Effect*: In 2 RCTs, 1 level I and 1 level II, with the same 33 participants, Nikamp et al[129,130] provided a flexible, semirigid, or rigid AFO at week 1 or week 9 of inpatient rehabilitation. Participants were provided with a prefabricated, PLS, or plastic AFO (flexible, semirigid, or rigid). AFOs were provided during either week 1 (early group) or week 9 (delayed group) of inpatient rehabilitation. In the level I RCT, there were no differences between the early and delayed groups in the 6MWT after 26 weeks.[129] However, when evaluating patterns of improvement, the early group had improvements significantly earlier than the delayed group.[129] The level II RCT by Nikamp et al[130] reported on the same study but with the 12-week results. The early group had a significantly greater improvement in the 6MWT that exceeded the MCID in weeks 1 to 3 compared to the delayed group. By week 12, the 6MWT results were not significantly different between groups.[130]

Acute Stroke FES: There is only 1 study that used FES for individuals with acute poststroke hemiplegia in which a therapeutic response was reported for walking endurance. However, the improvement was not greater than PT alone (Appendix Table 15).

- *Immediate Orthotic Effect*: No evidence.
- *Therapeutic Effect*: One level I RCT by Wilkinson et al[160] randomized 20 participants to an FES group or a PT only group. The FES group received FES for walking and cyclical exercise to the DF. All participants received PT focusing on gait specific to individual needs for 1 hour for 12 sessions over 6 weeks, but the FES group had FES for walking and cyclical exercise to the DF integrated into sessions and available for home use. After 8 weeks, therapy was discontinued and follow-up was performed after 20 weeks. Both groups demonstrated a significant improvement that exceeded the MCID in the first 8 weeks. No significant differences were seen between groups and there were no further improvements at follow-up.[160]
- *Training Effect*: No evidence.
- *Combined Orthotic*: No evidence.

Chronic Stroke AFO: Studies that used AFOs for individuals with chronic poststroke hemiplegia demonstrate strong evidence for all 4 effects to improve walking endurance. The evidence is strongest for a combined orthotic effect (Appendix Table 16).

- *Immediate Orthotic Effect*: Five studies, 2 level I, 1 level II, and 2 level III, reported immediate orthotic effects.[72,76,98,99,133,138] In a level I RCT by Kluding et al,[76] 98 of the 197 participants were randomized to the custom AFO group, with a significant improvement seen in the 6MWT upon provision. In a level I RCT by Everaert et al,[72] the Physiologic Cost Index (PCI) for 77 of the 93 subjects was assessed, with significant effects seen when wearing the AFO. In a level II cohort study by Nolan et al,[133] 18 participants walked significantly greater distances during the 6MWT with versus without their own AFO. When results were separated by walking speed, participants who walked slower had a greater response to AFO use compared to those who walked faster.

In comparison, 2 level III studies by Danielsson and Sunnerhagen[98] and Danielsson et al[99] found less impact of the AFO on energy cost and endurance measures. In Danielsson et al,[99] 20 participants walked on a treadmill for 5 minutes with and without an AFO. When comparing walking with and without an AFO, the PCI did not differ, while the energy cost of walking was lower with AFOs. Similar results were found in Danielsson and Sunnerhagen[98] in which 10 participants walked on a treadmill with and without a carbon composite. Energy cost was found to be significantly lower with AFOs.

- *Therapeutic Effect*: One level I and 1 level II studies reported the therapeutic effects of an AFO on endurance.[8,72,76] The level I SR by Dunning et al[8] included 2 studies that were also included in this CPG. In the previously described level I RCT by Kluding et al,[76] there was a significant effect for the 6MWT following 30 weeks of AFO use that included 8 sessions of PT and an individualized home program. The second level I RCT, also described previously, by Everaert et al[72] reported a significant effect for the PCI with AFOs.
- *Training Effect*: Four level I studies reported on the training effects.[8,76,85,86] In the previously described level I SR by Dunning et al,[8] a significant improvement in the 6MWT was found across the included studies. Two of the 3 level I studies that reported training effects for AFOs were part of the SR by Dunning et al.[8,76,85] One of these studies[85] had an additional follow-up report.[86] Bethoux et al[85] enrolled 495 participants of which 253 were assigned to the group receiving a custom-articulated or solid plastic AFO. After a 2-week period of progressive wear, participants were asked to use the device at all times. After 6 months, distance walked during the 6MWT significantly increased but did not meet the MCID.[85] At the 12-month follow-up with 212 participants still wearing AFOs, no difference in the 6MWT was found compared to baseline.[86] In the level I RCT by Kluding et al,[76] as described earlier, the AFO groups received 8 PT sessions over 6 weeks with the expectation of using the AFOs for mobility for the study duration of 30 weeks. A significant change in the 6MWT was reported that did not meet the MDC.[76]
- *Combined Orthotic Effect*: One level I SR and 3 level I studies reported on the combined orthotic effect of AFOs during the chronic phase of stroke.[8,32,72,76] The level I SR by Dunning et al[8] included 2 RCTs that are also included in this CPG. The first study by Kluding et al[76] reported a significant change in the 6MWT that met the MDC. In the second level I RCT by Everaert et al,[72] there was a statistically significant difference found for the PCI. In another level I RCT by Erel et al,[32] 14 of the 28 received a dynamic AFO. A significant improvement in the PCI was reported following 12 weeks of wear.[32]

Chronic Stroke FES: Studies that used FES for individuals with chronic poststroke hemiplegia demonstrate strong evidence for all 4 effects to improve walking endurance (Appendix Table 17).

- *Immediate Effect*: 2 level I, 1 level II, 1 level III, and 1 level IV studies reported immediate orthotic effects.[72,76,89,90,153] In a level I RCT by Kluding et al,[76] 99 of the 197 participants were randomized to the FES group, with a significant improvement seen in the 6MWT upon provision. In a level I RCT by Everaert et al,[72] the PCI for 38 of the 93 subjects was assessed, with no significant immediate effects seen when wearing FES. In a level II RCT by Burridge et al,[90] 16 of the 32 participants were assigned to the FES group. Results at the initial assessment showed that the PCI was significantly lower with FES compared to without FES. In a level III retrospective study by Taylor et al,[153] 111 participants were assessed with and without the use of FES at baseline. The participants demonstrated a significant decrease in the PCI when walking with FES compared to without FES. These improvements were further supported by a level IV study by Burridge and McLellan.[89]

- *Therapeutic Effect*: 3 level I, 1 level II, 3 level III, and 1 level IV cohort studies reported on the therapeutic effects.[8,50,72,76,89,90,151,153] The level I SR by Dunning et al[8] included 2 studies that reported on the therapeutic effect of FES use on endurance, both of which are included in this CPG. The first study included is the level I RCT by Kluding et al,[76] which reported significant improvements in endurance measured by the 6MWT after 30 weeks of use for 99 participants using FES. The second study is a level II RCT by Burridge et al,[90] described in the previous section, found no significant change in the PCI following 60-minute PT sessions provided 10 times over 4 to 5 weeks combined with daily use. The RCT by Everaert et al[72] measured endurance using the PCI and reported a significant decrease in 33 participants following 6 weeks of use. A level III retrospective study by Taylor et al[153] reported results in 111 participants, with a significant decrease in the PCI following FES use for 4.5 months. In contrast, a small level III study by Ernst et al[50] with 5 participants showed no improvements in the 6MWT following 6 weeks and 3 months of FES use. In a level III retrospective study by Sota et al,[151] 101 participants used FES for 26.6 ± 19.6 sessions for a total of 19.4 ± 18.2 hours and significantly increased 6MWT distance, exceeding the MDC but not the MCID. For further analysis, participants were divided into responders (>0.1 m/s gait speed change, n = 58) and nonresponders (<0.1 m/s gait speed change, n = 43). Significant differences were found between groups, and the responders exceeded the MDC/MCID while the nonresponders did not.[151] In addition, a level IV study by Burridge and McLellan[89] showed a significant decrease in the PCI with FES after 3 months of use.
- *Training Effect*: Six studies, 4 level I, 1 level II, and 1 level III cohort, reported training effects.[8,76,85,86,90,153] In the previously described level I SR by Dunning et al,[8] a significant improvement in the 6MWT and the PCI was found across the included studies. Two of the 3 level I studies that reported training effects for FES were part of the SR by Dunning et al.[8,76,85] One of these studies[85] had an additional follow-up report.[86] Bethoux et al[85] enrolled 495 participants of which 242 were assigned to the group receiving FES. After a 2-week period of progressive wear, participants were asked to use the device at all times. After 6 months, distance walked during the 6MWT significantly increased but did not meet the MCID for the 187 participants who completed 6 months of the study.[85] At the 12-month follow-up with 180 participants still wearing FES, no additional gains were made in the 6MWT between 6 and 12 months.[86] The level I study by Kluding et al[76] reported a significant training effect on endurance, measured by the 6MWT, in 74 participants who completed 30 weeks of FES use. The level III retrospective study by Taylor et al[153] reported significant improvements in the PCI for their 111 participants who used FES for 4.5 months.
- *Combined Orthotic Effect*: Fourteen studies, including 5 level I, 3 level II, 3 level III, and 3 level IV, reported combined orthotic effects.[8,28,50,51,55,56,72,76,89,90,95,142,146,153] In the previously described level I SR by Dunning et al,[8] 3 studies considered the combined effect of FES on endurance and reported significant improvements using the 6MWT and the PCI and are included in this CPG. The level I RCTs by Kluding et al[76] and Everaert et al[72] included in the SR reported significant improvements in the 6MWT[76] following 30 weeks of use, and the PCI [72] following 6 weeks of FES use. A level I RCT by Kottink et al[51] reported similar outcomes. In their study, 14 of the 27 participants used an FES system and were acclimated to FES over 2 weeks. They were then instructed to use the system daily. After 26 weeks, 13 participants who completed the study reported significant improvements in the 6MWT compared to the control group.[51] A level I RCT by Cho et al[95] studied the effects of TT combined with FES. Thirty-one participants were randomized into 3 groups: TT only, TT plus FES to the anterior tibialis, and TT plus FES to the anterior tibialis and gluteus medius. Each group received training for 30 minutes 5 times per week for 4 weeks, but no gains were found when FES to the anterior tibialis was added to TT.[95]

In a level II SR by Kottink et al,[28] 2 of the 8 studies reviewed considered the combined orthotic effect of FES on endurance as reported by the PCI and found a significant improvement with use of FES.[28] One of the studies in the SR is included in this CPG.[90,182] A level II RCT by Burridge et al[90] randomized 16 of the 32 participants to the FES group. All participants received 1 hour of PT 10 times during the first month, and then continued to use FES at home. After 12 weeks of FES use, the PCI was significantly improved.[90] In a level II RCT by Sabut et al,[55] a total of 30 participants received a conventional stroke rehabilitation program for 60 minutes, 5 days per week, while 16 participants received an additional 30 minutes of FES. After 12 weeks, there were significant improvements in the PCI for the FES users compared to the control group.[55] Two level II studies further supported the earlier findings. Ernst et al[50] reported improvements in the 6MWT for 5 participants after 6 weeks of FES use, but no further improvement between 6 and 12 weeks. A retrospective study by Taylor et al[153] reported significant improvements in the PCI for the 111 FES users. In addition, 3 level IV studies[56,89,142] found significant improvements in the PCI and 1 study[142] reported significant results in energy cost.

One additional level III study by Schiemanck et al[146] examined the effects of an implantable FES system in 10 participants. Once participants could tolerate at least 6 hours of FES use per day, they were instructed to use FES or their AFOs as tolerated. Data from 8 participants showed that energy expenditure and 6MWT distance with FES use did not change after FES use when tested after 8 and 26 weeks.[146] Daily use of the FES system varied between participants from 1 to 7 days per week.

Comparison of AFO and FES: There is level I evidence based on 1 level I SR[8] and 4 level I RCTs.[72,76,85,86] Using the 6MWT, Dunning et al[8] found no difference for therapeutic, training, or combined orthotic effects in an SR. In the 2 RCTs in the SR by Dunning et al,[8] Bethoux et al[85,86] found no difference for training effects and Kluding et al[76] found no difference between devices for any effect. Using the PCI, Dunning et al[8] found that FES users had a significant improvement compared to AFO users for a therapeutic effect; however, Everaert et al,[72] 1 study in the SR, found no difference for this effect. In addition, Everaert et al[72] also found no difference when examining a combined orthotic effect, but found that AFO users had significantly greater improvements compared to FES users for an immediate orthotic effect.

Clinical Interpretation: The evidence supports the use of AFOs or FES to improve endurance as measured by the 6MWT and the PCI. The PCI may be inaccurate in individuals taking cardiac medications that impact heart rate response to activity.[99] The evidence for the effects of AFOs or FES on endurance is stronger for individuals with chronic compared to acute poststroke hemiplegia. In the acute phase, the inclusion of a custom AFO, regardless of type, provided combined orthotic effects when applied in weeks 1 to 3 of rehabilitation compared in weeks 9 to 11.[130] This earlier ability to ambulate more efficiently may lead to improved participation in rehabilitation at a higher intensity, leading to faster progress toward rehabilitation goals. While individuals provided with an AFO early may achieve higher levels of endurance sooner, the long-term outcomes did not differ based on the timing of provision.[129]

In the chronic phase post-stroke, all 4 effects of AFOs are supported in the literature. An immediate effect is more likely when using a custom AFO while walking overground compared to on a treadmill.[76,99] Individuals who walk more slowly may have greater gains in endurance when using an AFO. Therapeutic and training effects are reported following 30 weeks of AFO use following 8 PT sessions and a home program, and a training effect was seen after 6 months.[85] When reassessed after 12 months, there was no difference in endurance as compared to baseline suggesting the need for a follow-up assessment or skilled PT 6 months after AFO provision to progress the home program or adjust the AFO to maximize benefits.[86] A combined effect was found following 12 to 30 weeks of AFO use.[32,72,76] Thus, these results across outcomes suggest that individuals may need skilled PT, longer use, and reassessment to maximize benefits.

While there is a lack of evidence for FES to improve endurance in the acute phase, there is strong evidence to support its use in the chronic phase across all effects. An immediate effect was consistently demonstrated through significant improvements in the 6MWT and the PCI.[76,89,90,153] A therapeutic effect was reported following daily use over 3 to 7 months when combined with PT intervention. As 1 small study reported no effect after 4 to 5 weeks, longer use may be needed to promote recovery.[50] A training effect with continued FES use was also noted, with longer duration daily use ranging from 4.5 to 7 months. The benefits of wear appear to peak at 6 to 7 months, which may indicate the need for reassessment after 6 months to determine the need for further intervention or FES adjustments. Finally, combined effects were reported with daily use over 5 to 30 weeks.[8,51,72,76] As noted in other effects, improvements in endurance were more clinically meaningful when combined with skilled PT. No effect was reported when FES was combined with BWSTT, but daily wear was not combined with the intervention, so the total dose was less than other studies that reported an effect.[95] While there is little research on the use of FES to improve walking endurance in individuals with acute poststroke hemiplegia, best practice suggests that benefits are possible similar to what are seen with individuals with chronic poststroke hemiplegia.

The use of AFOs and FES may improve endurance for individuals in the acute or chronic phase post-stroke. Improvements may be greater and more meaningful when combined with skilled PT, provided over a longer period, combined with daily use, and reassessed at least every 6 months. The 6MWT should be used to assess endurance outcomes. There is some evidence for greater therapeutic effects with FES compared to AFOs and for greater immediate orthotic effects with AFOs compared to FES

Research Recommendations: More research is needed for the effects of AFO or FES use on walking endurance for individuals with acute poststroke hemiplegia, as studies with this population are limited. As research is primarily with individuals who walk independently or with very little assistance, further studies are needed with individuals at lower ambulation levels. Research is also needed on dosing and decision-making regarding AFO type.

Body Structure and Function Outcomes

The following section includes key body structure and function outcomes that were captured in the literature search. While these outcomes are currently only supported by lower levels of evidence, the topics were identified as important to the clinical decision-making process of either AFO or FES selection in the clinician and consumer surveys. Device effects on plantarflexor spasticity, muscle activation, and gait kinematics are presented. For gait kinematics, the evidence only supported developing an action statement for effects at the ankle. While evidence exists and is presented at the hip and knee in the clinical interpretation section, there was inconclusive evidence for benefits or harms at these joints to support the development of an additional action statement.

Action Statement 6: ANKLE-FOOT ORTHOSIS (AFO) OR FUNCTIONAL ELECTRICAL STIMULATION

(FES) TO IMPROVE PLANTARFLEXOR SPASTICITY. Clinicians should not provide an AFO or FES for individuals with decreased lower extremity motor control due to acute or chronic poststroke hemiplegia who have goals to improve plantarflexor spasticity (evidence quality: II; recommendation strength: moderate).

- Acute AFO: evidence quality: II; recommendation strength: moderate
- Acute FES: evidence quality: II; recommendation strength: moderate
- Chronic AFO: evidence quality: II; recommendation strength: moderate
- Chronic FES: evidence quality: II; recommendation strength: moderate

Action Statement Profile

Aggregate Evidence Quality: Level II. Based on 1 level I, 3 level II, and 2 level IV studies.

- Acute AFO: Level II based on 1 level I and 1 level II studies (Appendix Table 18).[33,126]
- Acute FES: Level II based on 1 level II study (Appendix Table 18).[33,126]
- Chronic AFO: Level II based on 1 level II and 1 level IV studies (Appendix Table 19).[55,56,84,143,145,151]
- Chronic FES: Level II based on 1 level II, 2 level III, and 1 level IV studies (Appendix Table 19). [55,56,84,143,145,151]

Benefits:

- By not providing an AFO or FES to decrease spasticity, the harms of an AFO or FES are avoided.

Risk, Harm, Costs:

- Costs may be high to the individual due to lack of sufficient insurance coverage or financial resources for AFOs or FES.
- Falls may increase with AFOs and FES by increasing mobility.
- Abandonment of AFOs may occur due to discomfort, difficulty donning/doffing, cosmesis, increased sweating, skin irritation, an uncomfortable stretching feeling.
- FES may occur due to intolerance to the sensation of the stimulation, insufficient DF achieved when wearing, increased spasticity and issues using with shoes.
- Abandonment of FES may occur due to intolerance to the sensation of the stimulation, insufficient DF achieved, general dissatisfaction, and skin irritation. With an implanted FES system, FES may not be successful due to system failure, infection, hematoma, lymphedema, nerve injury, and neurodermatitis.

Benefit-Harm Assessment:

- Preponderance of harm due to device cost without measurable improvements in PF spasticity.
- There is no evidence that the inclusion of an AFO or FES will increase PF spasticity.

Value Judgments:

- AFOs or FES may be used to address other outcomes even if PF spasticity improvement is unlikely.

Intentional Vagueness:

- None.

Role of Patient Preferences:

- None.

Exclusions:

- None.

Quality Improvement:

- AFOs or FES should not be used as an intervention with the only goal of decreasing PF spasticity.

Implementation and Audit:

- Physical therapists require education on the lack of effects so that AFOs and FES will not be used to decrease PF spasticity.

Supporting Evidence and Clinical Interpretation

Supporting Evidence: The MAS is the main measure to evaluate PF spasticity clinically. As PF spasticity is assessed without an AFO or FES, all studies regarding the effectiveness of an AFO or FES on PF spasticity would be demonstrating therapeutic effects.

Acute AFO: Studies that used AFOs for individuals with acute poststroke hemiplegia demonstrate moderate evidence for the lack of a therapeutic effect on PF spasticity (Appendix Table 18).

- *Immediate Orthotic Effect*: No evidence.
- *Therapeutic Effect*: Two studies, 1 level I and 1 level II, reported on the impact of AFOs on PF spasticity. One level I RCT by de Sèze et al[33] evaluated the impact of a standard AFO as compared to a Chignon AFO in 28 participants to wear as desired. After 30 and 90 days of use, there was no change in PF spasticity as measured by the MAS between or within groups. In a level II RCT, Morone et al[126] provided walking training using different AFO types with 10 participants for 40 minutes 5 days per week for 4 weeks. No significant changes in PF spasticity using the MAS were found after 1 month.
- *Training Effect*: No evidence.
- *Combined Orthotic Effect*: No evidence.

Acute FES: Studies that used FES for individuals with acute poststroke hemiplegia demonstrate moderate evidence for the lack of a therapeutic effect on PF spasticity (Appendix Table 18).

- *Immediate Orthotic Effect*: Not applicable.
- *Therapeutic Effect*: One level II study reported on the impact of FES on PF spasticity. In a level II RCT by Morone et al,[126] FES was provided walking training with 10 participants for 40 minutes 5 days per week for 4 weeks. No significant changes in PF MAS were found after 1 month.
- *Training Effect*: Not applicable.
- *Combined Orthotic Effect*: Not applicable.

Chronic AFO: Studies that used AFOs for individuals with chronic poststroke hemiplegia demonstrate moderate evidence for the lack of a therapeutic effect on PF spasticity (Appendix Table 19).

- *Immediate Orthotic Effect*: Not applicable.

- *Therapeutic Effect*: Two studies, 1 level II and 1 level IV, found no changes in PF spasticity after AFO use. In a level II RCT, Beckerman et al[84] included 16 participants who used a custom AFO set in 5° of DF and 13 participants who used an AFO without restrictions on DF and PF. After 6 and 15 weeks of daily use, there were no changes in PF spasticity using the MAS. In a level IV study by Sankaranarayan et al,[145] there were no changes in PF spasticity using the MAS for 26 participants who used a custom solid AFO combined with therapy for 2 hours per day 6 days per week for at least 2 weeks.
- *Training Effect*: Not applicable.
- *Combined Orthotic Effect*: Not applicable.

Chronic FES: Studies that used FES for individuals with chronic poststroke hemiplegia demonstrate moderate evidence for the lack of a therapeutic effect on spasticity (Appendix Table 19).

- *Immediate Orthotic Effects*: Not applicable.
- *Therapeutic Effect*: Two studies, 1 level II and 1 level IV, showed no effect of FES on PF spasticity, while 2 level III studies demonstrated a significant change. In a level II RCT with 30 participants by Sabut et al,[55] FES was compared to no device. All participants received undefined usual care 60 minutes 5 days per week for 12 weeks. The FES group used FES for 15 minutes progressing up to 45 minutes per day. The FES group demonstrated a change in PF spasticity using the MAS of 0.8 over the 12 weeks. As a change of 0.8 is less than what can be measured using the MAS, this change was interpreted as no change. For the upper extremity, the MDC for the MAS post-stroke is 1,[183] thus supporting this interpretation. In a level IV study with 20 participants by Sabut et al,[56] FES was used for 15 to 30 minutes per day along with an undefined usual care therapy program for 1 hour 5 days per week for 12 weeks. They reported changes of 0.5 to 0.8 in PF spasticity as measured by the MAS. Two additional studies did perform statistical analyses of MAS changes. In a level III study with 51 participants, Sabut et al[143] compared FES to no device. All participants received usual care consisting of 60 minutes 5 days per week for 12 weeks. The FES group also received 20 to 30 minutes of FES. While the authors reported a significant decrease in PF spasticity, their statistical analysis was inappropriate, bringing their results into question. In a level III retrospective study by Sota et al,[151] 101 participants used FES for 26.6 ± 19.6 sessions for a total of 19.4 ± 18.2 hours. The median change in the MAS for the PF was reported as 0 but significant, as the range for change was -2 to 0.5.
- *Training Effect*: Not applicable.
- *Combined Orthotic Effect*: Not applicable.

Comparison of AFO and FES: In a level II RCT, Morone et al[126] found no differences in changes in spasticity when FES was compared to usual care that included an AFO.

Clinical Interpretation: The evidence does not support the use of an AFO or FES to decrease PF spasticity in the acute or chronic phase post-stroke. Therefore, AFOs or FES should not be a primary intervention for decreasing PF spasticity. AFO or FES use to mediate the impact of PF spasticity on mobility, gait speed, balance, or endurance is beyond the scope of this statement. It can be noted that both AFO and FES have demonstrated the ability to improve outcomes, as stated in prior action statements, despite the lack of impact on spasticity. As many studies excluded individuals with higher MAS scores, it is not known whether those individuals would have similar outcomes for PF spasticity or other measures. AFOs and FES are not contraindicated for individuals with some PF spasticity following a stroke, but there is no evidence that they change PF spasticity.

Research Recommendations: Research needs to address the poor reliability of measures of spasticity and how PF spasticity impacts mobility to better understand the effects of an AFO or FES. An accepted operational definition of spasticity in relation to functional mobility is also needed. Comparison of different types of AFOs or inclusion of spasticity measures related to functional mobility outcomes in higher-level, large population RCTs would be beneficial.

Action Statement 7: ANKLE-FOOT ORTHOSIS (AFO) OR FUNCTIONAL ELECTRICAL STIMULATION (FES) TO IMPACT MUSCLE ACTIVATION. Clinicians may provide an AFO with decreased stiffness for individuals with decreased lower extremity motor control due to acute or chronic poststroke hemiplegia who have goals to allow activation of the anterior tibialis and gastrocnemius/soleus muscles while walking with the AFO (evidence quality: II; recommendation strength: moderate).

- Acute AFO: evidence quality: II; recommendation strength: moderate
- Chronic AFO: evidence quality: III; recommendation strength: weak

Clinicians should provide FES for individuals with decreased lower extremity motor control due chronic poststroke hemiplegia who have goals to improve activation of the anterior tibialis muscle while walking without FES (evidence quality: II; recommendation strength: moderate).

- Acute FES: no evidence
- Chronic FES: evidence quality: II; recommendation strength: moderate

Action Statement Profile

Aggregate Evidence Quality: Level III due to lower-level evidence.

- Acute AFO: Level II based on 1 level I, 1 level II, 1 level III, and 1 level IV studies (Appendix Table 20).[121,128,152,184]
- Acute FES: No evidence.

- Chronic AFO: Level III based on 1 level III and 3 level IV studies (Appendix Table 21).[16,35,36,38]
- Chronic FES: Level II based on 1 level I, 1 level II, 1 level III, and 3 level IV studies (Appendix Table 22).[55,57,110,119,139,142]

Benefits:

- Provision of an AFO with decreased stiffness may allow individuals to use any volitional activity while walking. Less muscle atrophy may then be seen, especially in the gastrocnemius, which may then allow for increased walking speed.[185]
- Provision of a walking intervention using FES may increase the ability to activate the muscle while walking without FES. This recovery of activation may save future costs of devices and avoid the harms of an AFO.

Risk, Harm, Cost:

- Costs may be high to the individual due to lack of sufficient insurance coverage or financial resources for AFOs or FES.
- Falls may increase with AFOs and FES by increasing mobility.
- Abandonment of AFOs may occur due to discomfort, difficulty donning/doffing, cosmesis, increased sweating, skin irritation, an uncomfortable stretching feeling when wearing, increased spasticity, and issues using with shoes.
- Abandonment of FES may occur due to intolerance to the sensation of the stimulation, insufficient DF achieved, general dissatisfaction, and skin irritation. With an implanted FES system, FES may not be successful due to system failure, infection, hematoma, lymphedema, nerve injury, and neurodermatitis.

Benefit-Harm Assessment:

- Preponderance of benefit.

Value Judgments:

- Increases in muscle activation may or may not lead to increases in other measures such as gait speed, balance, and mobility.

Intentional Vagueness:

- The recommendations also do not address the severity of hemiparesis, as most studies included participants with the ability to ambulate independently or with minimal assistance often for at least 10 m.

Role of Patient Preferences:

- Individuals may prefer FES over an AFO.

Exclusions:

- There is a lack of evidence with acute stroke with FES.
- The recommendations may not apply to individuals with severe cognitive or communication deficits or neglect, history of multiple strokes, pacemakers, skin conditions, or severe spasticity (MAS ≥3).

Quality Improvement:

- Individuals with poststroke hemiplegia may increase their muscle activation by walking with an AFO that has decreased stiffness or by using FES as a therapeutic intervention once in the chronic phase. These may increase satisfaction with the device and overall care.
- PT intervention and sufficient practice must be performed when an AFO or FES is provided to achieve optimal effects.
- Evaluation for a device should include an assessment of desired outcomes using different AFOs and FES types and settings before making a final decision.

Implementation and Audit:

- Physical therapists need more education on choosing a design with decreased stiffness that allows muscle activation if present and also adequately addresses the activity-based goals of the individual.
- AFOs or FES should be considered during any evaluation to improve outcomes and satisfaction in individuals in the acute or chronic phases of stroke.
- Physical therapists would benefit from education on the effects of AFOs and FES and on clinical decision-making for monitoring effects, making adjustments to AFOs or FES, changing devices as individuals' needs change, and on appropriate outcome measures across the ICF to assess the effects of the devices.
- Review of medical records can identify outcomes seen with an AFO or FES use across a larger group of individuals.
- Potential barriers to implementation of the recommendation include lack of education about appropriate devices, access to devices, or lack of funding.

Supporting Evidence and Clinical Interpretation

Supporting Evidence:

Acute AFO: Studies that used AFOs for individuals with acute poststroke hemiplegia demonstrate moderate evidence for immediate orthotic and therapeutic effects for increased muscle activation with an AFO with decreased stiffness as compared to an AFO with greater stiffness (Appendix Table 20).

- *Immediate Orthotic Effect*: One level I, 1 level III, and 1 level IV studies reported an immediate orthotic effect. The level I RCT by Nikamp et al[128] found that anterior tibialis activity in swing did not decrease with a PLS, semisolid or solid AFO compared to walking without an AFO either upon provision of the AFO at week 1 or week 26 for 26 participants. As muscle activation was not compared across devices, it is unknown whether results differed based on device stiffness. The authors concluded that swing-phase anterior tibialis activation was not hindered by the AFO. In a level III study by Lairamore et al,[121] 15 participants walked barefoot and while wearing a PLS and a dynamic AFO. Anterior tibialis activity was greatest in the barefoot condition and significantly reduced only when wearing the dynamic AFO. The authors hypothesized that muscle activity would be greater with the dynamic AFO, but felt that the sagittal plane stability it provided may have had the opposite effect. In a level IV study, Tang et al[152] compared a more rigid versus a more flexible short elastic AFO (Ober AFO), finding that the more flexible AFO led to increased activation of the anterior tibialis and the gastrocnemius for 20 participants.

- *Therapeutic Effect*: Only 1 level II study reported a therapeutic effect. In this study by Kim et al,[184] 25 participants who required an assistive device (AD) walked on a treadmill wearing a nonspecified solid AFO (n = 12) or with kinesiotape (n = 13) to the anterior tibialis, gastrocnemius, and ankle joint using the figure-of-8 for 30 minutes 3 times per week for 4 weeks. Following training, only the kinesiotape group had an increase in anterior tibialis and gastrocnemius activation. Both groups showed increased activity in the gluteus maximus, rectus femoris, and biceps femoris when walking without a device, but only rectus femoris activation was greater for the kinesiotape group than for the AFO group. The authors theorized that the more restrictive design of the AFO likely led to decreased muscle activation around the ankle.
- *Training Effect*: No evidence.
- *Combined Orthotic Effect*: No evidence.

Acute FES: There is no evidence for the use of FES to increase muscle activation for individuals with decreased lower extremity motor control due to acute poststroke hemiplegia.

- *Immediate Orthotic Effect*: Not relevant since volitional and electrical stimulated contractions cannot be separated.
- *Therapeutic Effect*: No evidence.
- *Training Effect*: Not relevant since volitional and electrical stimulated contractions cannot be separated.
- *Combined Orthotic Effect*: Not relevant since volitional and electrical stimulated contractions cannot be separated.

Chronic AFO: Studies that used AFOs for individuals with chronic poststroke hemiplegia demonstrate weak evidence for an immediate orthotic effect for increased muscle activation with an AFO with decreased stiffness as compared to an AFO with greater stiffness (Appendix Table 21).

- *Immediate Orthotic Effect*: One level III and 3 level IV studies reported immediate orthotic effects. In the level III study, Mulroy et al[38] compared an AFO with a 0° PF stop with free DF, an AFO with a DF assist with DF stop at 5°, a solid AFO and shoes only in 30 participants. In comparing the 2 articulating AFOs, they found that anterior tibialis activity was decreased with the AFO with a PF stop with free DF but that soleus activity was increased. The 3 level IV studies also showed some effects. Boudarham et al[36] studied the effects of an elastic Liberté AFO set to position the ankle in neutral DF and found increased anterior tibialis and gastrocnemius activation but no change in soleus activation compared to barefoot in 12 participants. Hesse et al[16] reported that an AFO with DF assist that only allowed range of motion between neutral and 10° of PF decreased anterior tibialis and increased quadriceps activity in 21 participants. Finally, Ohata et al[35] compared the effects on an oil damper AFO that changed PF resistance to an AFO with a PF stop. The added resistance provided by the oil damper decreased gastrocnemius activity in loading response, allowing improved heel rocker function.
- *Therapeutic Effect*: No evidence.
- *Training Effect*: No evidence.
- *Combined Orthotic Effect*: No evidence.

Chronic FES: One level 1, 1 level II, 1 level III, and 3 level IV studies reported therapeutic effects of increasing muscle activation. The other effects are not relevant since volitional and electrical stimulated contractions cannot be separated (Appendix Table 22).

- *Immediate Orthotic Effect*: Not relevant since volitional and electrical stimulated contractions cannot be separated.
- *Therapeutic Effect*: All 6 studies (levels I-IV) reported increased activation of the anterior tibialis muscle after 4 to 24 weeks of training. The only level I RCT by Kottink et al[119] found that 6 months of home use of FES in 14 of the 15 participants completing training led to increased anterior tibialis activation during swing and increased gastrocnemius activation. A level II RCT by Sabut et al[55] reported that the 16 participants using FES had improved anterior tibialis muscle activation after 12 weeks of FES delivered as part of PT. In a similar level III study with 17 participants, Shendkar et al[57] reported the same outcome in the 14 participants who completed training. Three level IV studies also reported increased activation of the anterior tibialis following 4 to 12 weeks of surface stimulation. Sabut et al[142] and Pilkar et al[139] found increased activation compared to a control group in 15 and 4 subjects, respectively. Jung et al[110] found that the use of electromyography (EMG)-driven FES led to improved outcomes over FES alone (n = 5 per group).
- *Training Effect*: Not relevant since volitional and electrical stimulated contractions cannot be separated.
- *Combined Orthotic Effect*: Not relevant since volitional and electrical stimulated contractions cannot be separated.

Comparison of AFO and FES: No included studies compared AFOs and FES use for muscle activation.

Clinical Interpretation: The choice of AFO type can impact the ability to increase muscle activity with the AFO on, which may be important for individuals post-stroke who have some ability to volitionally activate their muscles. An AFO with decreased stiffness may encourage muscle activation while wearing the AFO. However, clinicians need to weigh the balance between stance-phase stability of a more restrictive AFO and allowing motion within the AFO. FES may lead to a therapeutic effect, improving individuals' ability to activate their own muscles without a device, thus promoting recovery. Therefore, clinical decision-making and individual goals are important in device choice.

Research Recommendations: As the evidence for AFO is weaker, resulting in an overall weak recommendation, further study is needed on the effects of different AFO types on muscle activation. While the evidence for FES is moderate, stronger studies are needed to better understand how factors such as stimulation parameters and intervention protocols (frequency, duration) impact outcomes for therapeutic effects. Research is needed for therapeutic effects for FES with acute stroke.

Action Statement 8: ANKLE-FOOT ORTHOSIS (AFO) OR FUNCTIONAL ELECTRICAL STIMULATION (FES) TO IMPROVE GAIT KINEMATICS. Clinicians may provide an AFO or FES for individuals with decreased lower extremity motor control due to acute or chronic post-stroke hemiplegia who have goals to improve ankle dorsiflexion at initial contact and during loading response and swing (evidence quality: III; recommendation strength: weak).

- Acute AFO: evidence quality: III; recommendation strength: weak
- Acute FES: evidence quality: not applicable; recommendation strength: best practice
- Chronic AFO: evidence quality: III; recommendation strength: weak
- Chronic FES: evidence quality: III; recommendation strength: weak

Action Statement Profile

Aggregate Evidence Quality: Level III due to 3 level I, 2 level II, 15 level III, and 14 level IV studies with mixed outcomes.

- Acute AFO: Level III based on 2 level II, 1 level II SR, and 1 level IV study (Appendix Table 23).[20,41,131,137]
- Acute FES: No evidence.
- Chronic AFO: Level III based on 1 level I, 1 level II SR, 1 level II, 7 level III, and 10 level IV studies (Appendix Table 24).[13,20,33–38,87,94,97,103,113,117,150,161-164]
- Chronic FES: Level III based on 2 level I, 1 level II, 6 level III, and 3 level IV studies (Appendix Table 25).[45,48,50,58,81,96,100,111,112,120,149,150]

Benefits:

- Improved ankle DF at initial contact and during swing can decrease falls by increasing ground clearance and better positioning the foot to accept weight.

Risk, Harm, Cost:

- While ankle DF at initial contact and during swing will likely improve with AFOs, effects at the knee may be problematic for individuals without sufficient quadriceps strength to overcome possible increased knee flexion at initial contact and into loading response. The inability to control the knee may lead to increased falls.
- FES may decrease swing-phase knee flexion leading to compensatory patterns to achieve clearance. These patterns may decrease safety and walking endurance.
- Costs may be high to the individual due to lack of sufficient insurance coverage or financial resources for AFOs or FES.
- Falls may increase with AFOs and FES by increasing mobility.
- Abandonment of AFOs may occur due to discomfort, difficulty donning/doffing, cosmesis, increased sweating, skin irritation, an uncomfortable stretching feeling when wearing, increased spasticity, and issues using with shoes.
- Abandonment of FES may occur due to intolerance to the sensation of the stimulation, insufficient DF achieved, general dissatisfaction, and skin irritation. With an implanted FES system, FES may not be successful due to system failure, infection, hematoma, lymphedema, nerve injury, and neurodermatitis.

Benefit-Harm Assessment:

- Preponderance of benefit, but clinicians need to consider quadriceps strength for AFOs and swing-phase knee flexion when choosing a specific device.

Value Judgments:

- Kinematics are an important part of the effects of an AFO or FES, as positioning the foot in more DF may impact other outcomes.

Intentional Vagueness:

- There is limited evidence for effects other than immediate orthotic effects.
- The recommendations purposefully do not address the effects of one type of AFO over another, as studies used a variety of AFO types and rarely differentiated effects.
- The recommendations also do not address the severity of hemiparesis, as most studies included participants with the ability to ambulate independently or with minimal assistance often for at least 10 m.

Role of Patient Preferences:

- Individuals may prefer FES over an AFO.

Exclusions:

- The recommendations may not apply to individuals with severe cognitive or communication deficits or neglect, history of multiple strokes, pacemakers, skin conditions, or severe spasticity (MAS ≥3).

Quality Improvement:

- Evaluation for a device based on kinematic effects should include an assessment of gait with different AFO types and settings and with FES to determine the effects at the ankle and knee before making a final decision.
- PT intervention and sufficient practice must be performed when an AFO or FES is provided to achieve optimal effects.
- Evaluation for a device should include an assessment of desired outcomes using different AFO and FES types and settings before making a final decision.

Implementation and Audit:

- Both desired and unwanted effects should be considered when choosing FES or an AFO.

- AFOs or FES should be considered during any evaluation to improve outcomes and satisfaction in individuals in the acute or chronic phases of stroke.
- Physical therapists would benefit from education on the effects of AFOs and FES and on clinical decision-making for monitoring effects, making adjustments to AFOs or FES, changing devices as individuals' needs change, and on appropriate outcome measures across the ICF to assess the effects of the devices.
- Review of medical records can identify outcomes seen with an AFO or FES use across a larger group of individuals.
- Potential barriers to implementation of the recommendation include lack of education about appropriate devices, access to devices, or lack of funding.

Supporting Evidence and Clinical Interpretation

Supporting Evidence:

Acute AFO: Studies that used AFOs for individuals with acute poststroke hemiplegia demonstrate weak evidence for an immediate orthotic effect to improve gait kinematics for ankle DF, and no therapeutic effect (Appendix Table 23).

- *Immediate Orthotic Effect*: Two level II and 1 level IV studies report on the immediate effects of AFOs on kinematics. A level II SR by Daryabor et al[20] reported immediate effects of AFOs with significant positive effects seen on ankle kinematics in loading response and during swing, but not on knee kinematics. Three of the 27 studies included in their SR assessed participants with acute poststroke hemiplegia. A positive effect was reported when statistical rather than clinical significance was obtained in each study. In reviewing those 3 studies included in Daryabor et al[20] for this CPG, 1 did not provide kinematic data to evaluate,[121] 1 was rated as level IV,[137] and 1 was excluded due to a mixed population.[186] Thus, the results of Daryabor et al[20] are less applicable despite good SR methodology. Two studies included in this CPG (levels II and IV)[131,137] reported immediate orthotic effects for ankle DF, and 1 of these studies (level II)[131] reported this effect for knee flexion (Appendix Table 26).[20,131,137] In the level II study, Nikamp et al (n = 20) reported significantly increased ankle DF at initial contact, toe-off, and swing that exceeded the MDC using an AFO specific to participants' needs (PLS; polyethylene or polypropylene flexible, semirigid, or rigid). At the knee, they found significantly increased hip and knee flexion at initial contact, which could be problematic for stability for individuals with weak quadriceps muscles. In the level IV study that was included in the SR by Daryabor et al,[20] Park et al[137] (n = 17) reported significantly increased ankle DF in swing that exceeded the MDC when using a PLS AFO compared to no AFO, but not when using an anterior leaf AFO compared to no AFO. No significant difference was seen in swing-phase DF when comparing the 2 AFOs. There was no immediate orthotic effect at the knee.
- *Therapeutic Effect*: One level II study[41] reported no therapeutic effect on ankle DF during gait for 46 of the 51 participants completing a 6-week intervention using a SWIFT cast as part of usual care. Usual care (n = 54) that included a nonspecified AFO for 35% of the participants also resulted in no therapeutic effect.
- *Training Effect*: No evidence.
- *Combined Orthotic Effect*: No evidence.

Acute FES: There is no evidence for FES to improve ankle, knee, or hip gait kinematics.

Chronic AFO: Studies that used AFOs for individuals with chronic poststroke hemiplegia demonstrate weak evidence for immediate orthotic, therapeutic, and combined orthotic effects to improve gait kinematics at the ankle, knee, and/or hip. Most studies report immediate orthotic effects (Appendix Table 24).

- *Immediate Orthotic Effect*: One level I, 1 level II, 7 level III, and 10 level IV studies evaluated immediate orthotic effects at the ankle[13,20,33–38,87,94,97,103,113,117,150,161,164,187] and/or the knee or hip.[10,13,37,38,53,87,104,164] A level II SR by Daryabor et al[20] reported immediate effects of AFOs with significant positive effects seen for ankle DF in loading response and during swing, but not on knee kinematics. Twenty-four of the 27 studies included in their SR included participants with chronic poststroke hemiplegia. A positive effect was noted by Daryabor et al[20] when statistical, but not clinical significance was obtained in each study. Of these 24 studies from Daryabor et al,[20] 16 are also included in this CPG (1 level I, 6 level III, and 9 level IV studies), with the remaining 8 being excluded due to low quality, mixed populations, or lack of numerical kinematic data. In this CPG and the SR, the only level I study by de Sèze et al[33] reported significantly improved correction of foot drop during gait that exceeded the MDC when wearing the Chignon AFO (n = 13) versus a prefabricated polypropylene AFO (n = 15). While de Sèze et al[33] reported better correction with the Chignon AFO, the specific phases of gait impacted were not described and no rationale was provided to explain the difference between the 2 AFO types. The 7 level III studies included in this CPG (6 studies from the SR by Daryabor et al[20]) reported changes based on phases of gait. Four of these studies each compared at least 2 types of AFOs or AFO settings. Cruz and Dhaher[97] (n = 9) reported significantly increased DF during toe-off and swing that exceeded the MDC for both a solid and articulating AFO. Kobayashi et al[117] compared 4 different fixed settings for DF at 0°, 2°, 4°, and 6°, finding significant differences in DF at initial contact between settings. But this difference did not exceed the MDC. Mulroy et al[38] (n = 30) reported that 3 different AFO types (solid, DF assist/

DF-stop, and PF stop/free DF) led to significantly increased DF at initial contact and during swing that exceeded the MDC. The 2 AFOs that restricted PF led to decreased PF during stance. Ohata et al[35] (n = 11) compared an oil damper AFO that provided resistance to PF to an AFO with a posterior stop, finding that both AFOs significantly increased DF at initial contact that exceeded the MDC, but that the effect with the oil damper AFO was better. Sheffler et al[150] showed increased DF that exceeded the MDC at initial contact but not during swing for 12 participants using a custom-molded AFO. While overall DF at initial contact was increased, participants with active DF exceeded the MDC for DF at initial contact with the AFO, while those without active DF did not. The final level III study[34] found significantly increased DF at initial contact, preswing, and swing using an oil damper AFO, with the increase exceeding the MDC. The level IV studies[13,36,37,87,94,113,161,162,164] support the findings of the level III studies, with improved DF seen at initial contact, during swing, and/or at toe-off with various AFO types.

At the knee (Appendix Table 27),[13,20,34,37,38,53,87,104,117,150,162-164] 4 level III studies showed significant immediate orthotic effects without meeting the MDC, while 1 level III and 4 level IV studies showed no effect. Gatti et al[104] (n = 10) found significant increases in swing-phase knee flexion with the use of a custom polypropylene AFO set in neutral alignment. Mulroy et al[38] (n = 30) compared 3 different AFO types (solid, DF-assist/DF-stop, and PF stop/free DF) and found that all 3 AFOs led to increased knee flexion at initial contact and loading response. The PF stop/free DF and the solid AFO provided increased knee flexion in loading response compared to the DF-assist/DF-stop AFO. Finally, Kobayashi et al[117] found significantly decreased peak knee extension, as the DF angle increased from 0° to 6° in 2° increments. One level III[150] and 4 level IV studies[13,37,87,164] reported no effect at the knee across a variety of AFO designs. At the hip, a level III study[53] (n = 15) reported a significant increase in hip external rotation with a solid AFO compared to a solid AFO with a heel cutout, and a level III study[150] showed no effect at the hip using a custom-molded articulated AFO.

- *Therapeutic Effect*: One level I study[33] reported no therapeutic effect and 1 level IV study[162] reported an effect. The RCT by de Sèze et al[33] reported no therapeutic effect after wearing a Chignon AFO (n = 13) or a standard AFO (n = 13 of 15 completing training) for 30 days. Yamamoto et al[162] (n = 8) found increased DF at initial contact that exceeded the MDC after wearing an oil damper AFO for 3 weeks. But they found no effect for knee kinematics.
- *Training Effect*: No evidence.
- *Combined Orthotic Effect*: One level II,[163] 1 level III,[34] and 1 level IV studies,[162] all by the same authors reported combined orthotic effects. In the level II study,[163] there was a significant change in DF at initial contact that did not meet the MDC, and there was no effect during swing for 40 of the 42 participants who completed the study. In this study, participants were randomized to a metal upright AFO with a PF stop or to an oil damper AFO with PF resistance, with no differences found between AFO types. At the knee, both AFOs significantly increased knee flexion in swing but did not exceed the MDC. While there was no effect at the hip, they did report that the trunk was significantly more upright when wearing the oil damper AFO compared to the AFO with the PF stop. In the level III[34] and IV[162] studies by the same author, there was an increase in DF that exceeded the MDC at initial contact and during swing for 8 participants in each study. The 2011 study[34] also reported effects that exceeded the MDC in preswing and neither study[34,162] found effects for knee kinematics.

Chronic FES: Studies that used FES for individuals with chronic poststroke hemiplegia demonstrate weak evidence for immediate orthotic, therapeutic, and combined orthotic effects to improve gait kinematics at the ankle, knee, and/or hip. Most studies report immediate orthotic effects (Appendix Table 25).

- *Immediate Orthotic Effect*: Four level III and 3 level IV studies reported significantly increased DF at initial contact, toe-off, and/or during swing with FES. These increases exceeded the MDC in all except 1 study.[150] For the level III studies, Ernst et al[50] reported increased DF at initial contact and during swing that exceeded the MDC when 5 participants used FES. Lee et al[58] reported the same results for 14 participants using FES. Sheffler et al[150] reported fewer improvements finding significantly increased DF that did not meet the MDC at initial contact but no increases during swing in 12 participants. The last level III study by Kesar et al[112] compared different stimulation frequency patterns for 13 participants and reported that DF at initial contact and during swing were significantly greater when a variable frequency was used rather than the typical constant frequency. This difference exceeded the MDC. The 3 level IV studies[45,100,111] support the findings of the level III studies. One of these studies[111] reported that stimulating the ankle DF had a significant negative effect of decreasing PF at toe-off in their 12 participants.

At the knee (Appendix Table 28),[45,81,96,111,112,120,150] 2 level III and 1 level IV studies reported significant changes in knee flexion in various phases of gait. An additional level IV study reported no effect. Sheffler et al[150] reported no change in knee flexion during swing. Kesar et al[111] reported that stimulating the ankle DF had a significant negative effect of decreasing knee flexion during swing in their 12 participants. In a later study, Kesar et al[112] reported that while swing-phase knee flexion was reduced with FES in the 12 participants, it was less reduced when variable frequency was used rather than the typical constant frequency.

- *Therapeutic Effect*: One level I, 1 level II, and 2 level III studies examined therapeutic effects at the ankle and/or knee. Only 1 of these studies[81] showed an effect. In a level II RCT, Bae et al[81] randomized 20 participants (10 per group) to robotic-assisted gait training plus FES or to robotic-assisted gait training alone. After 15 training sessions over 5 weeks, participants using FES had increased DF that exceeded the MDC but was not statistically significant. Phases of gait impacted were not reported. Significant improvements were also seen for maximal knee flexion and extension. No changes were seen around the hip. However, participants using the robotic-assisted gait training alone had similar gains except for DF and the only significant difference between groups was in maximal knee flexion. Sheffler et al[149] (level I, n = 12), Cozean et al[96] (level III, n = 18, with 16 completing training), and Prado-Medeiros et al[48] (level III, n = 12) reported no effect at the ankle following 12, 6, and 6 weeks of training, respectively. Cozean et al[96] (level III) also reported no change in knee flexion after 6 weeks.
- *Training Effect*: No evidence.
- *Combined Orthotic Effect*: Only 1 level I RCT by Kottink et al[120] examined this effect and found no effect at the ankle for the 9 participants randomized to the FES group after 26 weeks.

Comparison of AFO and FES: There is no evidence to compare the effects of AFOs and FES on gait kinematics in acute stroke. For chronic stroke, there is level III evidence indicating a lack of difference between AFOs and FES for an immediate effect based on 2 level III studies.[146,150] Sheffler et al[150] compared ankle, knee, and hip kinematics and found no differences between walking with AFOs compared to FES. Schiemanck et al[146] found significantly less ankle PF in late stance with an AFO compared to FES, but the difference did not exceed the MDC.

Clinical Interpretation: Both AFOs and FES provide immediate orthotic effects at the ankle that position the foot and ankle in a better position at initial contact and during swing. Thus, these devices should be considered for individuals with foot drop due to poststroke hemiplegia. A prior CPG concluded that an AFO can positively impact the alignment of the foot and ankle in both swing and stance,[22] but did not differentiate the benefits based on effect. Overall, there is minimal evidence for effects other than an immediate orthotic effect for both AFOs and FES for kinematic variables. Gait patterns with AFOs and FES need to be assessed prior to final device provision to ensure the device provides the effect but also does not negatively influence stance-phase stability or swing-phase knee flexion. Decreased quadriceps strength may lead to decreased stance-phase stability when using an AFO set in DF that also limits or prevents PF. FES may decrease knee flexion during swing,[111,112] resulting in unwanted compensations such as hip hiking. Significant ankle medial/lateral instability may lead to decreased effectiveness of FES during the stance phase.[24] Thus, careful evaluation is needed for clinical decision-making.

Research Recommendations: As studies that examine the effects of AFOs and FES are of lower-quality evidence, stronger study designs are needed. Most studies examined immediate orthotic effects, with few studies examining other effects. Thus, studies of longer-term effects with and without an AFO or FES are needed. More research is needed on AFO types and settings in relation to body structures and function measures to guide decision-making.

OVERALL CPG CLINICAL RECOMMENDATIONS

The recommendations made in this CPG are based on overall strong evidence for benefits of AFOs and FES on important outcomes for individuals with decreased lower extremity motor control due to acute or chronic poststroke hemiplegia (refer to Table 3 for a summary of the overall evidence based on chronicity and device). The amount of evidence is stronger for those with chronic versus acute poststroke hemiplegia. The chronic phase of stroke is typically considered to be a static phase with limited potential for spontaneous or natural recovery. At this point, many individuals who continue to use an AFO use the AFO provided to them in the acute phase of recovery, often without reassessment of its continued appropriateness. While improvements in mobility and function may slow in the chronic phase of stroke, reconsideration of needs for an AFO or FES remains important to allow for continued improvements or even a higher level of mobility and function. The evidence presented in this CPG supports that AFOs and FES can both lead to many improvements for those with chronic poststroke hemiplegia. For individuals with acute poststroke hemiplegia, evidence is more limited for using AFOs and FES to improve ambulation and overall mobility. In addition, the evidence for those with chronic poststroke hemiplegia can be used to guide decision-making with the acute population. Thus, consideration of AFOs and FES should be incorporated into more acute settings and along the continuum of care throughout the individual's lifetime. Due to the changes possible at any phase post-stroke, decisions about device choice may be made too soon in the process and individuals would benefit from rehabilitation before decision-making. However, as safety is often a concern, delaying a decision may not be possible. Thus, physical therapists should advocate for reimbursement sources to consider payment for a different device later if the individual's needs change.

Both AFOs and FES provide immediate orthotic effects at the ankle that position the foot and ankle in a better position at initial contact and during swing and increase gait speed, dynamic balance, mobility, and walking endurance. The other effects of AFOs and FES are seen after a period of practice and suggest that AFOs may lead to more compensatory effects while FES may lead to more therapeutic effects. Thus, this finding has different implications for recovery versus compensation. It should be noted that study design likely has some impact on these findings, as more studies examine the therapeutic effects of FES than they do for AFOs, yet some studies with AFOs do show a therapeutic effect. As FES activates the individual's muscles during gait, motor learning and muscle strengthening may occur leading to some recovery. Not all AFO designs block all motion and thus can allow for muscle activity as seen in the section on muscle activation in this CPG. While weak, the evidence does suggest that an AFO with decreased stiffness leads to greater activation of muscles within the AFO. Different settings for PF stops and for DF assists can also impact muscle activity. Thus, recovery-based approaches may be incorporated into AFO use and AFO design should incorporate motion if the individual has muscle activity and does not require extensive stability within the AFO. A more compensation-based approach may be needed for individuals with poor stability and absent volitional activation once recovery-based approaches have been exhausted. There is consistent and strong evidence to support the need for an AFO designed to meet the needs of the individual; therefore, an orthotist should be consulted as part of the health care team and the clinical decision-making process.[22] A certified and/or licensed orthotist can advise on the various material and design considerations when manufacturing an AFO to meet the needs of the individual. As neurologic rehabilitation focuses on recovery, FES and AFO designs with decreased stiffness should be considered first prior to making a long-term decision about an AFO that significantly blocks motion and alters gait kinematics.

There is some evidence that an AFO provides more orthotic effects while FES provides more therapeutic effects. Thus, clinical decision-making is important based on the PT evaluation, desired effects, potential outcomes, and individual goals. The evidence also indicates that outcomes are best when skilled PT intervention and long-term practice are included as part of AFO or FES provision. Providing a device without intervention or practice may thus limit the ability to fully achieve potential gains, showing the importance of the physical therapist's role. A CPG by Bowers and Ross[22] made the same recommendation. Evidence also suggests that custom AFOs may have greater benefits than prefabricated AFOs.[22] As reimbursement can be a barrier to implementation, physical therapists should advocate for reimbursement for treatment sessions to maximize outcomes and provide appropriate devices. Physical therapists should also use outcome measures that are most responsive to the benefits of AFO or FES use for appropriate assessment of baseline mobility and of long-term outcomes. Periodic reassessments are important, as needs may change over time and the initial device provided may not best meet the individual's needs in the future. A barrier to implementation may be decreased knowledge of appropriate outcome measures and device choices. This barrier can be addressed through advanced education and knowledge translation.

SUMMARY OF RESEARCH RECOMMENDATIONS

There are several areas needed for research to provide clinicians with increased evidence about the application of AFOs and FES across the outcomes included in this CPG. Thus, the following recommendations are made that apply to all outcomes.

Research Recommendation 1: Researchers should examine intervention duration and delivery. More evidence is needed regarding the duration of intervention and the type of interventions paired with AFOs or FES that are best to achieve outcomes. While the evidence indicates a longer period of intervention and practice is needed to achieve favorable outcomes, more research is needed to identify dosing criteria for the various devices based on the presentation of the individual. Research should also consider the intervention delivery, such as overground or TT or home-based training.

Research Recommendation 2: Researchers should perform studies on the effects of the timing of introduction of AFOs or FES. While there are a small number of studies with individuals with acute poststroke hemiplegia, these studies show benefits. In addition, individuals with foot drop due to chronic poststroke hemiplegia can improve in many outcomes years after the stroke. Thus, research needs to focus on appropriate timing for introduction and reassessment of AFOs or FES at all points in time post-stroke.

Research Recommendation 3: Researchers should examine the effects of different AFO types and FES parameters. As the evidence is insufficient to allow effects of specific AFO types to be differentiated, more research is needed on AFO types and stiffness, their specific benefits, potential harms, and how they impact outcomes using objective measures. To increase the ability to examine these aspects, all future research studies that include AFOs should report a detailed description of the AFO type used, including the following attributes: prefabricated or custom; solid, semisolid, or flexible; articulated or nonarticulated; ankle and shank angles; AFO trim lines including footplate length; and material type and stiffness. Stronger studies are also needed to better understand how factors such as electrical stimulation parameters and the strength of the muscle contraction impact outcomes for FES use.

Research Recommendations 4: Researchers should examine the ability to differentiate responders from nonresponders to various types of AFOs and FES. The current evidence is insufficient to understand the potential relationship between key impairments in body structure and function and their potential impact on activity levels to best inform the clinical decision-making when determining the most effective device choice.

Research Recommendation 5: Research is needed to better assess the risk of device abandonment. The ability to better understand why individuals stop using devices may better guide clinical device development and technical design.

Research Recommendation 6: Researchers should study all 4 effects with both AFOs and FES. Studies with AFOs tend to focus more on compensation-based effects, while most studies on FES also examine recovery-based therapeutic effects. Thus, research is needed to identify all effects of each device type to guide clinicians in device choice and potential use for recovery or compensation.

Research Recommendation 7: Researchers need to include individuals who have greater limitations in body structure/function and activity levels of the ICF in their research studies. Few studies include these individuals that physical therapists routinely treat. While the recommendations and principles from this CPG can be applied to this population, the evidence is lacking as to whether the effects would be the same or different from the population with fewer deficits.

Research Recommendation 8: Researchers should conduct longitudinal studies to identify the changes that occur over time and identify reassessment needs for long-term AFO or FES users. This research is important to allow individuals the opportunity to try new devices that may further increase functional mobility and QOL.

Research Recommendation 9: Researchers need to include a core set of outcome measures that have strong psychometric properties and are responsive to the use of AFOs and FES across the ICF. Further research is needed to determine what aspects of QOL improve with AFOs and FES to develop measures with improved responsiveness.

Research Recommendation 10: Researchers need to examine how findings from the patient evaluation can guide clinical decision-making for AFOs and FES. Research is needed on how to best use these findings in choosing an AFO or FES and for choosing specific types of each that may lead to optimal outcomes.

LIMITATIONS

There are several limitations of this CPG. There is a considerable difference in the quantity and quality of the literature that includes individuals in the acute poststroke phase compared to the chronic poststroke phase. Often, the initial determination for the need for a device and the type of device is made in the acute phase. Thus, there needs to be stronger and more consistent research performed with individuals in this phase of recovery. Another limitation in the acute phase is the inability to differentiate the effects of rehabilitation or natural recovery from the device for studies that did not compare devices or have a control group. In addition, it was not always possible to determine the specific health care setting in each study beyond the acute phase. This GDG also chose to consider the impact of an AFO or FES by the outcome that it may be impacting. A consistent weakness in the literature is the lack of documentation of standardized outcome measure training and implementation methods used by researchers. This potential inconsistency in measuring and reporting outcomes may have an impact on the validity of the outcome results reported. For each action statement, outcome measures used across studies vary in their psychometric properties. In some instances, outcomes are included that only partially measure the specific construct that the researchers were attempting to capture. This could limit the responsiveness of the outcome to the intervention and limits comparisons across the literature. Another limitation is the inability of this CPG to provide evidence-based recommendations for device type or device design features, including stiffness, to address specific activity limitations or impairments of body structure and function, except for AFO for muscle activation. Few studies addressed the impact of AFO design on stance-phase stability, which is an important consideration when choosing an AFO. The limitations in the literature thus limit the ability to provide evidence-based recommendations specific to AFO design or based on impairments. Finally, there are promising studies that add FES for PF, hip abduction, and a combination of joint motions that also show benefits, but these were beyond the scope of the CPG. It may be appropriate to consider use of FES beyond the single muscle activation included in this CPG. As the majority of the literature focused on DF only, this CPG was limited to those studies.

GUIDELINE IMPLEMENTATION RECOMMENDATIONS

The ANPT has formed a Knowledge Translation (KT) task force for the explicit purpose of promoting effective multi-faceted implementation strategies targeting both individuals and health care systems to disseminate the recommendations of this CPG. The Orthotics and Neuroprosthetics KT task force members were selected to represent a broad range of stakeholders with experience in the field of orthotics and neuroprosthetics and an expertise in knowledge translation.

The following strategies may be useful when implementing the action statements in this CPG. More details and resources will be provided by the KT team assembled by the ANPT.[188]

- Educational training:
  - Develop educational tools such as quick reference guides and clinical decision-making tools to promote the importance and relevance of the CPG to clinicians and consumers.
  - Develop a standardized screening tool or assessment form to support the application of the action statements in the clinical decision-making process.
  - Develop a standard set of outcomes to perform both with and without various devices to more effectively and reliably determine which AFO or FES will best address the goals of each individual.
  - Provide training sessions including all team members to maximize the understanding of the variety of AFOs or FES options that are available.
  - Develop case-based application modules that can be offered in various platforms to a diverse audience.
  - Identify any additional barriers to implementation of the CPG recommendations.
- Clinician CPG user supports:
  - Place a copy of the CPG and any resources provided by the KT team in an easily accessible location in the clinic.
  - Build relationships with several local vendors to diversify device options, obtain equipment for demonstration.
  - Develop relationships with several local certified and/or licensed orthotists to build a multidisciplinary team for the purpose of orthoses AFO and FES evaluation and development.
  - Obtain a variety of device options to include as training tools during interventions or as a temporary trial device to evaluate with individuals post-stroke.
  - Build relationships with referral sources to ensure continuity and consistent follow-up care.
  - Incorporate reminder and clinical decision-making algorithms into electronic medical records or support systems.

Update and Revision of Guidelines

This guideline will be updated and revised within 5 years of its publication, as new evidence becomes available. The procedures for updating the guideline will be similar to those used here, using procedures based on recommended standards, and sponsored by the APTA/ANPT.

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REFERENCES

1. Kaplan SL, Coulter C, Fetters L. Developing evidence-based physical therapy clinical practice guidelines. *Pediatr Phys Ther*. 2013;25(3):257-270. doi:10.1097/PEP.0b013e31829491c5.
2. APTA. *APTA Clinical Practice Guideline Process Manual*. Alexandria, VA: APTA; 2018.
3. Jette AM. Toward a common language for function, disability, and health. *Phys Ther*. 2006;86(5):726-734. doi:10.1093/ptj/86.5.726.
4. Benjamin EJ, Blaha MJ, Chiuve SE, et al. Heart disease and stroke statistics—2017 update: a report from the American Heart Association. *Circulation*. 2017;135(10):e146-e603. doi:10.1161/CIR.0000000000000485.
5. Centers for Disease Control and Prevention. Stroke Facts. https://www.cdc.gov/stroke/facts.htm. Accessed December 24, 2019.
6. O'Sullivan SB, Portney LG. Examination of motor function: motor control and learning. In: O'Sullivan SB, Schmitz TJ, Fulk GD, eds. Physical Rehabilitation. 7th ed. Philadelphia, PA: F.A. Davis; 2019:135-187.
7. Lin PY, Yang YR, Cheng SJ, Wang RY. The relation between ankle impairments and gait velocity and symmetry in people with stroke. *Arch Phys Med Rehabil*. 2006;87(4):562-568. doi:10.1016/j.apmr.2005.12.042.
8. Dunning K, O'Dell MW, Kluding P, McBride K. Peroneal stimulation for foot drop after stroke: a systematic review. *Am J Phys Med Rehabil*. 2015;94(8):649-664. doi:10.1097/PHM.0000000000000308.
9. Prenton S, Hollands KL, Kenney LPJ. Functional electrical stimulation versus ankle foot orthoses for foot-drop: a meta-analysis of orthotic effects. *J Rehabil Med*. 2016;48(8):646-656. doi:10.2340/16501977-2136.
10. Silver-Thorn B, Herrmann A, Current T, McGuire J. Effect of ankle orientation on heel loading and knee stability for post-stroke individuals wearing ankle-foot orthoses. *Prosthet Orthot Int*. 2011;35(2):150-162. doi:10.1177/0309364611399146.
11. Andrenelli E, Ippoliti E, Coccia M, et al. Features and predictors of activity limitations and participation restriction 2 years after intensive rehabilitation following first-ever stroke. *Eur J Phys Rehabil Med*. 2015;51(5):575-585.
12. Rinere O'Brien S. Trends in inpatient rehabilitation stroke outcomes before and after advent of the prospective payment system: a systematic review. *J Neurol Phys Ther*. 2010;34(1):17-23. doi:10.1097/NPT.0b013e3181cfd3ac.
13. Fatone S, Gard SA, Malas BS. Effect of ankle-foot orthosis alignment and foot-plate length on the gait of adults with post-stroke hemiplegia. *Arch Phys Med Rehabil*. 2009;90(5):810-818. doi:10.1016/j.apmr.2008.11.012.
14. Franceschini M, Massucci M, Ferrari L, Agosti M, Paroli C. Effects of an ankle-foot orthosis on spatiotemporal parameters and energy cost of hemiparetic gait. *Clin Rehabil*. 2003;17(4):368-372. doi:10.1191/0269215503cr622oa.
15. Winstein CJ, Stein J, Arena R, et al. Guidelines for adult stroke rehabilitation and recovery: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*. 2016;47(6):e98-e169. doi:10.1161/STR.0000000000000098.
16. Hesse S, Werner C, Matthias K, Stephen K, Berteanu M. Non-velocity-related effects of a rigid double-stopped ankle-foot orthosis on gait and lower limb muscle activity of hemiparetic subjects with an equinovarus deformity. *Stroke*. 1999;30(9):1855-1861.
17. Vistamehr A, Kautz SA, Neptune RR. The influence of solid ankle-foot-orthoses on forward propulsion and dynamic balance in healthy adults during walking. *Clin Biomech (Bristol, Avon)*. 2014;29(5):583-589. doi:10.1016/j.clinbiomech.2014.02.007.
18. Taylor P, Humphreys L, Swain I. The long-term cost-effectiveness of the use of functional electrical stimulation for the correction of dropped foot due to upper motor neuron lesion. *J Rehabil Med*. 2013;45(2):154-160. doi:10.2340/16501977-1090.
19. Alam M, Choudhury IA, Bin Mamat A. Mechanism and design analysis of articulated ankle foot orthoses for drop-foot. *ScientificWorldJournal*. 2014;2014:867869. doi:10.1155/2014/867869.
20. Daryabor A, Arazpour M, Aminian G. Effect of different designs of ankle-foot orthoses on gait in patients with stroke: a systematic review. *Gait Posture*. 2018;62:268-279. doi:10.1016/j.gaitpost.2018.03.026.

21. Chisholm AE, Perry SD. Ankle-foot orthotic management in neuromuscular disorders: recommendations for future research. *Disabil Rehabil Assist Technol*. 2012;7(6):437-449. doi:10.3109/17483107.2012.680940.
22. Bowers R, Ross K. Development of a best practice statement on the use of ankle-foot orthoses following stroke in Scotland. *Prosthet Orthot Int*. 2010;34(3):245-253. doi:10.3109/03093646.2010.486392.
23. Bosch PR, Harris JE, Wing K; American Congress of Rehabilitation Medicine (ACRM) Stroke Movement Interventions Subcommittee. Review of therapeutic electrical stimulation for dorsiflexion assist and orthotic substitution from the American Congress of Rehabilitation Medicine stroke movement interventions subcommittee. *Arch Phys Med Rehabil*. 2014;95(2):390-396. doi:10.1016/j.apmr.2013.10.017.
24. Dapul GP, Mellen Center for Multiple Sclerosis Treatment and Research, Neurological Institute, Cleveland Clinic, Cleveland, Ohio, US, Bethoux F, Mellen Center for Multiple Sclerosis Treatment and Research, Neurological Institute, Cleveland Clinic, Cleveland, Ohio, US. Functional electrical stimulation for foot drop in multiple sclerosis. *US Neurol*. 2015;11(1):10. doi:10.17925/USN.2015.11.01.10.
25. Auchstaetter N, Luc J, Lukye S, et al. Physical therapists' use of functional electrical stimulation for clients with stroke: frequency, barriers, and facilitators. *Phys Ther*. 2016;96(7):995-1005. doi:10.2522/ptj.20150464.
26. Ottawa Panel; Khadilkar A, Phillips K, et al.Ottawa panel evidence-based clinical practice guidelines for post-stroke rehabilitation. *Top Stroke Rehabil*. 2006;13(2):1-269. doi:10.1310/3TKX-7XEC-2DTG-XQKH.
27. Management of Stroke Rehabilitation Working Group. VA/DoD clinical practice guideline for the management of stroke rehabilitation. *J Rehabil Res Dev*. 2010;47(9):1-43.
28. Kottink AI, Oostendorp LJ, Buurke JH, Nene AV, Hermens HJ, IJzerman MJ. The orthotic effect of functional electrical stimulation on the improvement of walking in stroke patients with a dropped foot: a systematic review. *Artif Organs*. 2004;28(6):577-586. doi:10.1111/j.1525-1594.2004.07310.x.
29. Tyson SF, Kent RM. Effects of an ankle-foot orthosis on balance and walking after stroke: a systematic review and pooled meta-analysis. *Arch Phys Med Rehabil*. 2013;94(7):1377-1385. doi:10.1016/j.apmr.2012.12.025.
30. Tyson SF, Sadeghi-Demneh E, Nester CJ. A systematic review and meta-analysis of the effect of an ankle-foot orthosis on gait biomechanics after stroke. *Clin Rehabil*. 2013;27(10):879-891. doi:10.1177/0269215513486497.
31. May BJ, Lockard M. *Prosthetics & Orthotics in Clinical Practice: A Case Study Approach*. 1st ed. Philadelphia, PA: F.A. Davis Company; 2011.
32. Erel S, Uygur F, Engin SI, Yakut Y. The effects of dynamic ankle-foot orthoses in chronic stroke patients at three-month follow-up: a randomized controlled trial [with consumer summary]. *Clin Rehabil*. 2011;25(6):515-523.
33. de Sèze MP, Bonhomme C, Daviet JC, et al. Effect of early compensation of distal motor deficiency by the Chignon ankle-foot orthosis on gait in hemiplegic patients: a randomized pilot study. *Clin Rehabil*. 2011;25(11):989-998. doi:10.1177/0269215511410730.
34. Yamamoto S, Fuchi M, Yasui T. Change of rocker function in the gait of stroke patients using an ankle foot orthosis with an oil damper: immediate changes and the short-term effects. *Prosthet Orthot Int*. 2011;35(4):350-359. doi:10.1177/0309364611420200.
35. Ohata K, Yasui T, Tsuboyama T, Ichihashi N. Effects of an ankle-foot orthosis with oil damper on muscle activity in adults after stroke. *Gait Posture*. 2011;33(1):102-107. doi:10.1016/j.gaitpost.2010.10.083.
36. Boudarham J, Pradon D, Roche N, Bensmail D, Zory R. Effects of a dynamic-ankle-foot orthosis (Liberté®) on kinematics and electromyographic activity during gait in hemiplegic patients with spastic foot equinus. *NeuroRehabilitation*. 2014;35(3):369-379. doi:10.3233/NRE-141128.
37. Do KH, Song J, Kim JH, et al. Effect of a hybrid ankle foot orthosis made of polypropylene and fabric in chronic hemiparetic stroke patients. *Am J Phys Med Rehabil*. 2014;93(2):130-137. doi:10.1097/PHM.0b013e3182a92f85.
38. Mulroy SJ, Eberly VJ, Gronely JK, Weiss W, Newsam CJ. Effect of AFO design on walking after stroke: impact of ankle plantar flexion contracture. *Prosthet Orthot Int*. 2010;34(3):277-292. doi:10.3109/03093646.2010.501512.
39. Bouchalová V, Houben E, Tancsik D, Schaekers L, Meuws L, Feys P. The influence of an ankle-foot orthosis on the spatiotemporal gait parameters and functional balance in chronic stroke patients. *J Phys Ther Sci*. 2016;28(5):1621-1628. doi:10.1589/jpts.28.1621.
40. Iwata M, Kondo I, Sato Y, Satoh K, Soma M, Tsushima E. An ankle-foot orthosis with inhibitor bar: effect on hemiplegic gait. *Arch Phys Med Rehabil*. 2003;84(6):924-927. doi:10.1016/s0003-9993(03)00012-1.
41. Pomeroy VM, Rowe P, Clark A, et al. A randomized controlled evaluation of the efficacy of an ankle-foot cast on walking recovery early after stroke: SWIFT cast trial. *Neurorehabil Neural Repair*. 2016;30(1):40-48. doi:10.1177/1545968315583724.
42. Simons CD, van Asseldonk EH, van der Kooij H, Geurts AC, Buurke JH. Ankle-foot orthoses in stroke: effects on functional balance, weight-bearing asymmetry and the contribution of each lower limb to balance control. *Clin Biomech(Bristol, Avon)*. 2009;24(9):769-775. doi:10.1016/j.clinbiomech.2009.07.006.
43. Bioness. How the L300 Foot Drop System Works. http://www.bioness.com/Healthcare_Professionals/Exoskeletal_Products/L300_for_Foot_Drop/How_Does_It_Work.php. Accessed December 27, 2019.
44. Odstock Medical Ltd. What is FES? https://www.odstockmedical.com/about-fes. Accessed December 27, 2019.
45. Voigt M, Sinkjaer T. Kinematic and kinetic analysis of the walking pattern in hemiplegic patients with foot-drop using a peroneal nerve stimulator. *Clin Biomech (Bristol, Avon)*. 2000;15(5):340-51.
46. Macdonell RA, Triggs WJ, Leikauskas J, et al. Functional electrical stimulation to the affected lower limb and recovery after cerebral infarction. *J Stroke Cerebrovasc Dis*. 1994;4(3):155-160. doi:10.1016/S1052-3057(10)80178-8.
47. Lindquist AR, Prado CL, Barros RM, Mattioli R, da Costa PH, Salvini TF. Gait training combining partial body-weight support, a treadmill, and functional electrical stimulation: effects on poststroke gait. *Phys Ther*. 2007;87(9):1144-1154. doi:10.2522/ptj.20050384.
48. Prado-Medeiros CL, Sousa CO, Souza AS, Soares MR, Barela AM, Salvini TF. Effects of the addition of functional electrical stimulation to ground level gait training with body weight support after chronic stroke. *Rev Bras Fisioter*. 2011;15(6):436-444.
49. Martin KD, Polanski WH, Schulz A-K, et al. Restoration of ankle movements with the ActiGait implantable drop foot stimulator: a safe and reliable treatment option for permanent central leg palsy. *J Neurosurg*. 2016;124(1):70-76. doi:10.3171/2014.12.JNS142110.
50. Ernst J, Grundey J, Hewitt M, et al.Towards physiological ankle movements with the ActiGait implantable drop foot stimulator in chronic stroke. *Restor Neurol Neurosci*. 2013;31(5):557-569. doi:10.3233/RNN-120283.
51. Kottink AI, Hermens HJ, Nene AV, et al. A randomized controlled trial of an implantable 2-channel peroneal nerve stimulator on walking speed and activity in poststroke hemiplegia. *Arch Phys Med Rehabil*. 2007;88(8):971-978. doi:10.1016/j.apmr.2007.05.002.
52. Shimada Y, Matsunaga T, Misawa A, Ando S, Itoi E, Konishi N. Clinical application of peroneal nerve stimulator system using percutaneous intramuscular electrodes for correction of foot drop in hemiplegic patients. *Neuromodulation*. 2006;9(4):320-327. doi:10.1111/j.1525-1403.2006.00074.x.

53. Kim HJ, Chun MH, Kim HM, Kim BR. Effects on foot external rotation of the modified ankle-foot orthosis on post-stroke hemiparetic gait. *Ann Rehabil Med*. 2013;37(4):516-522. doi:10.5535/arm.2013.37.4.516.
54. Acclerated Care Plus. Dynamic FES for Neuro Rehabilitation. https://acplus.com/walkaide. Accessed December 27, 2019.
55. Sabut SK, Sikdar C, Mondal R, Kumar R, Mahadevappa M. Restoration of gait and motor recovery by functional electrical stimulation therapy in persons with stroke. *Disabil Rehabil*. 2010;32(19):1594-1603. doi:10.3109/09638281003599596.
56. Sabut SK, Sikdar C, Kumar R, Mahadevappa M. Clinical use of functional electrical stimulation for correction of foot drop: a comparison between subacute and chronic stroke patients. *J Mech Med Biol*. 2011;11(05):1165-1177. doi:10.1142/S0219519411004253.
57. Shendkar CV, Lenka PK, Biswas A, Kumar R, Mahadevappa M. Therapeutic effects of functional electrical stimulation on gait, motor recovery, and motor cortex in stroke survivors. *Hong Kong Physiother J*. 2015;33(1):10-20. doi:10.1016/j.hkpj.2014.10.003.
58. Lee YH, Yong SY, Kim SH, et al. Functional electrical stimulation to ankle dorsiflexor and plantarflexor using single foot switch in patients with hemiplegia from hemorrhagic stroke. *Ann Rehabil Med*. 2014;38(3):310-316. doi:10.5535/arm.2014.38.3.310.
59. Lee HJ, Cho KH, Lee WH. The effects of body weight support treadmill training with power-assisted functional electrical stimulation on functional movement and gait in stroke patients. *Am J Phys Med Rehabil*. 2013;92(12):1051-1059. doi:10.1097/PHM.0000000000000040.
60. Lin KC, Fu T, Wu CY, et al. Minimal detectable change and clinically important difference of the Stroke Impact Scale in stroke patients. *Neurorehabil Neural Repair*. 2010;24(5):486-492. doi:10.1177/1545968309356295.
61. Lin K, Fu T, Wu C, Hsieh C. Assessing the Stroke-Specific Quality of Life for outcome measurement in stroke rehabilitation: minimal detectable change and clinically important difference. *Health Qual Life Outcomes*. 2011;9:5. doi:10.1186/1477-7525-9-5.
62. Perera S, Mody SH, Woodman RC, Studenski SA. Meaningful change and responsiveness in common physical performance measures in older adults. *J Am Geriatr Soc*. 2006;54(5):743-749. doi:10.1111/j.1532-5415.2006.00701.x.
63. Mehrholz J, Wagner K, Rutte K, Meissner D, Pohl M. Predictive validity and responsiveness of the Functional Ambulation Category in hemiparetic patients after stroke. *Arch Phys Med Rehabil*. 2007;88(10):1314-1319. doi:10.1016/j.apmr.2007.06.764.
64. Beninato M, Gill-Body KM, Salles S, Stark PC, Black-Schaffer RM, Stein J. Determination of the minimal clinically important difference in the FIM instrument in patients with stroke. *Arch Phys Med Rehabil*. 2006;87(1):32-39. doi:10.1016/j.apmr.2005.08.130.
65. Baer HR, Wolf SL. Modified Emory Functional Ambulation Profile: an outcome measure for the rehabilitation of poststroke gait dysfunction. *Stroke*. 2001;32(4):973-979. doi:10.1161/01.str.32.4.973.
66. Hsieh YW, Wang CH, Wu SC, Chen PC, Sheu CF, Hsieh CL. Establishing the minimal clinically important difference of the Barthel Index in stroke patients. *Neurorehabil Neural Repair*. 2007;21(3):233-238. doi:10.1177/1545968306294729.
67. Chen HM, Hsieh CL, Sing Kai Lo, Liaw LJ, Chen SM, Lin JH. The test-retest reliability of 2 mobility performance tests in patients with chronic stroke. *Neurorehabil Neural Repair*. 2007;21(4):347-352. doi:10.1177/1545968306297864.
68. Hsieh YW, Wang CH, Sheu CF, Hsueh IP, Hsieh CL. Estimating the minimal clinically important difference of the Stroke Rehabilitation Assessment of Movement measure. *Neurorehabil Neural Repair*. 2008;22(6):723-727. doi:10.1177/1545968308316385.
69. Stevenson TJ. Detecting change in patients with stroke using the Berg Balance Scale. *Aust J Physiother*. 2001;47(1):29-38. doi:10.1016/S0004-9514(14)60296-8.
70. Flansbjer UB, Holmbäck AM, Downham D, Patten C, Lexell J. Reliability of gait performance tests in men and women with hemiparesis after stroke. *J Rehabil Med*. 2005;37(2):75-82. doi:10.1080/16501970410017215.
71. Kesar TM, Binder-Macleod SA, Hicks GE, Reisman DS. Minimal detectable change for gait variables collected during treadmill walking in individuals post-stroke. *Gait Posture*. 2011;33(2):314-317. doi:10.1016/j.gaitpost.2010.11.024.
72. Everaert DG, Stein RB, Abrams GM, et al. Effect of a foot-drop stimulator and ankle-foot orthosis on walking performance after stroke: a multicenter randomized controlled trial. *Neurorehabil Neural Repair*. 2013;27(7):579-591. doi:10.1177/1545968313481278.
73. Street T, Swain I, Taylor P. Training and orthotic effects related to functional electrical stimulation of the peroneal nerve in stroke. *J Rehabil Med*. 2017;49(2):113-119. doi:10.2340/16501977-2181.
74. Robbins SM, Houghton PE, Woodbury MG, Brown JL. The therapeutic effect of functional and transcutaneous electric stimulation on improving gait speed in stroke patients: a meta-analysis. *Arch Phys Med Rehabil*. 2006;87(6):853-859. doi:10.1016/j.apmr.2006.02.026.
75. Roche A, Laighin, G Ó, Coote S. Surface-applied functional electrical stimulation for orthotic and therapeutic treatment of drop-foot after stroke—a systematic review. *Phys Ther Rev*. 2009;14(2):63-80. doi:10.1179/174328809X405946.
76. Kluding PM, Dunning K, O'Dell MW, et al.Foot drop stimulation versus ankle foot orthosis after stroke: 30-week outcomes. *Stroke*. 2013;44(6):1660-1669. doi:10.1161/STROKEAHA.111.000334.
77. BridgeWiz for APTA 3.0. Guideline Elements Model. http:// Guideline Elements Model. Published 2001. Accessed December 12, 2019.
78. Graham R, Mancher M, Miller Wolman D, Greenfield S, Steinberg E, eds. *Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines*. Washington, DC: National Academies Press; 2001.
79. Abe H, Michimata A, Sugawara K, Sugaya N, Izumi SI. Improving gait stability in stroke hemiplegic patients with a plastic ankle-foot orthosis. *Tohoku J Exp Med*. 2009;218(3):193-199. doi:10.1620/tjem.218.193.
80. Alon G, Ring H. Gait and hand function enhancement following training with a multi-segment hybrid-orthosis stimulation system in stroke patients. *J Stroke Cerebrovasc Dis*. 2003;12(5):209-216. doi:10.1016/S1052-3057(03)00076-4.
81. Bae YH, Ko YJ, Chang WH, et al.Effects of robot-assisted gait training combined with functional electrical stimulation on recovery of locomotor mobility in chronic stroke patients: a randomized controlled trial. *J Phys Ther Sci*. 2014;26(12):1949-1953. doi:10.1589/jpts.26.1949.
82. Barrett C, Taylor P. The effects of the Odstock drop foot stimulator on perceived quality of life for people with stroke and multiple sclerosis. *Neuromodulation*. 2010;13(1):58-64. doi:10.1111/j.1525-1403.2009.00250.x.
83. Beckerman H, Becher J, Lankhorst GJ, Verbeek AL. Walking ability of stroke patients: efficacy of tibial nerve blocking and a polypropylene ankle-foot orthosis. *Arch Phys Med Rehabil*. 1996;77(11):1144-1151. doi:10.1016/s0003-9993(96)90138-0.
84. Beckerman H, Becher J, Lankhorst G, Verbeek A, Vogelaar T. The efficacy of thermocoagulation of the tibial nerve and a polypropylene ankle-foot orthosis on spasticity of the leg in stroke patients: results of a randomized clinical trial. *Clin Rehabil*. 1996;10:112-120.
85. Bethoux F, Rogers HL, Nolan KJ, et al.The effects of peroneal nerve functional electrical stimulation versus ankle-foot orthosis in patients with chronic stroke: a randomized controlled trial. *Neurorehabil Neural Repair*. 2014;28(7):688-697. doi:10.1177/1545968314521007.
86. Bethoux F, Rogers HL, Nolan KJ, et al. Long-term follow-up to a randomized controlled trial comparing peroneal nerve functional electrical stimulation to an ankle foot orthosis for patients with chronic stroke. *Neurorehabil Neural Repair*. 2015;29(10):911-922. doi:10.1177/1545968315570325.
87. Bleyenheuft C, Caty G, Lejeune T, Detrembleur C. Assessment of the Chignon dynamic ankle-foot orthosis using instrumented gait analysis in hemiparetic adults. *Ann Readapt Med Phys*. 2008;51(3):154-160. doi:10.1016/j.annrmp.2007.12.005.

88. Burridge JH, Haugland M, Larsen B, et al. Phase II trial to evaluate the ActiGait implanted drop-foot stimulator in established hemiplegia. *J Rehabil Med*. 2007;39(3):212-218. doi:10.2340/16501977-0039.
89. Burridge JH, McLellan DL. Relation between abnormal patterns of muscle activation and response to common peroneal nerve stimulation in hemiplegia. *J Neurol Neurosurg Psychiatry*. 2000;69(3):353-361. doi:10.1136/jnnp.69.3.353.
90. Burridge JH, Taylor PN, Hagan SA, Wood DE, Swain ID. The effects of common peroneal stimulation on the effort and speed of walking: a randomized controlled trial with chronic hemiplegic patients. *Clin Rehabil*. 1997;11(3):201-210. doi:10.1177/026921559701100303.
91. Cakar E, Durmus O, Tekin L, Dincer U, Kiralp MZ. The ankle-foot orthosis improves balance and reduces fall risk of chronic spastic hemiparetic patients. *Eur J Phys Rehabil Med*. 2010;46(3):363-368.
92. Carse B, Bowers R, Meadows BC, Rowe P. The immediate effects of fitting and tuning solid ankle-foot orthoses in early stroke rehabilitation. *Prosthet Orthot Int*. 2015;39(6):454-462. doi:10.1177/0309364614538090.
93. Chen CL, Teng YL, Lou SZ, Chang HY, Chen FF, Yeung KT. Effects of an anterior ankle-foot orthosis on walking mobility in stroke patients: get up and go and stair walking. *Arch Phys Med Rehabil*. 2014;95(11):2167-2171. doi:10.1016/j.apmr.2014.07.408.
94. Chen CC, Hong WH, Wang CM, et al. Kinematic features of rear-foot motion using anterior and posterior ankle-foot orthoses in stroke patients with hemiplegic gait. *Arch Phys Med Rehabil*. 2010;91(12):1862-1868. doi:10.1016/j.apmr.2010.09.013.
95. Cho MK, Kim JH, Chung Y, Hwang S. Treadmill gait training combined with functional electrical stimulation on hip abductor and ankle dorsiflexor muscles for chronic hemiparesis. *Gait Posture*. 2015;42(1):73-78. doi:10.1016/j.gaitpost.2015.04.009.
96. Cozean CD, Pease WS, Hubbell SL. Biofeedback and functional electric stimulation in stroke rehabilitation. *Arch Phys Med Rehabil*. 1988;69(6):401-405.
97. Cruz TH, Dhaher YY. Impact of ankle-foot-orthosis on frontal plane behaviors post-stroke. *Gait Posture*. 2009;30(3):312-316. doi:10.1016/j.gaitpost.2009.05.018.
98. Danielsson A, Sunnerhagen K. Energy expenditure in stroke subjects walking with a carbon composite ankle foot orthosis. *J Rehabil Med*. 2004;36(4):165-168.
99. Danielsson A, Willén C, Sunnerhagen KS. Measurement of energy cost by the physiological cost index in walking after stroke. *Arch Phys Med Rehabil*. 2007;88(10):1298-1303. doi:10.1016/j.apmr.2007.06.760.
100. Daniilidis K, Jakubowitz E, Thomann A, Ettinger S, Stukenborg-Colsman C, Yao D. Does a foot-drop implant improve kinetic and kinematic parameters in the foot and ankle? *Arch Orthop Trauma Surg*. 2017;137(4):499-506. doi:10.1007/s00402-017-2652-8.
101. de Wit DCM, Buurke JH, Nijlant JM, Ijzerman MJ, Hermens HJ. The effect of an ankle-foot orthosis on walking ability in chronic stroke patients: a randomized controlled trial. *Clin Rehabil*. 2004;18(5):550-557.
102. Doğan A, Mengüllüoğlu M, Özgirgin N. Evaluation of the effect of ankle-foot orthosis use on balance and mobility in hemiparetic stroke patients. *Disabil Rehabil*. 2011;33(15/16):1433-1439. doi:10.3109/09638288.2010.533243.
103. Fatone S, Hansen AH. Effect of ankle-foot orthosis on roll-over shape in adults with hemiplegia. *J Rehabil Res Dev*. 2007;44(1):11-20. doi:10.1682/JRRD.2006.08.0090.
104. Gatti MA, Freixes O, Fernández SA, et al. Effects of ankle foot orthosis in stiff knee gait in adults with hemiplegia. *J Biomech*. 2012;45(15):2658-2661. doi:10.1016/j.jbiomech.2012.08.015.
105. Granat MH, Maxwell DJ, Ferguson AC, Lees KR, Barbenel JC. Peroneal stimulator; evaluation for the correction of spastic drop foot in hemiplegia. *Arch Phys Med Rehabil*. 1996;77(1):19-24. doi:10.1016/s0003-9993(96)90214-2.
106. Hung JW, Chen PC, Yu MY, Hsieh YW. Long-term effect of an anterior ankle-foot orthosis on functional walking ability of chronic stroke patients. *Am J Phys Med Rehabil*. 2011;90(1):8-16. doi:10.1097/PHM.0b013e3181fc7d27.
107. Hwang YI, An DH, Yoo WG. Effects of the Dual AFO on gait parameters in stroke patients. *NeuroRehabilitation*. 2012;31(4):387-393.
108. Hwang DY, Lee HJ, Lee GC, Lee SM. Treadmill training with tilt sensor functional electrical stimulation for improving balance, gait, and muscle architecture of tibialis anterior of survivors with chronic stroke: a randomized controlled trial. *Technol Health Care*. 2015;23(4):443-452. doi:10.3233/THC-150903.
109. Hyun CW, Kim BR, Han EY, Kim SM. Use of an ankle-foot orthosis improves aerobic capacity in subacute hemiparetic stroke patients. *PM R*. 2015;7(3):264-269. doi:10.1016/j.pmrj.2014.08.944.
110. Jung GU, Moon TH, Park GW, Lee JY, Lee BH. Use of augmented reality-based training with EMG-triggered functional electric stimulation in stroke rehabilitation. *J Phys Ther Sci*. 2013;25:147-151.
111. Kesar TM, Perumal R, Reisman DS, et al. Functional electrical stimulation of ankle plantarflexor and dorsiflexor muscles: effects on poststroke gait. *Stroke*. 2009;40(12):3821-3827. doi:10.1161/STROKEAHA.109.560375.
112. Kesar TM, Perumal R, Jancosko A, et al. Novel patterns of functional electrical stimulation have an immediate effect on dorsiflexor muscle function during gait for people poststroke. *Phys Ther*. 2010;90(1):55-66. doi:10.2522/ptj.20090140.
113. Kesikburun S, Yavuz F, Güzelküçük Ü, Yaşar E, Balaban B. Effect of ankle foot orthosis on gait parameters and functional ambulation in patients with stroke. *Turk J Phys Med Rehabil*. 2017;63(2):143-148. doi:10.5606/tftrd.2017.129.
114. Kim JH, Chung Y, Kim Y, Hwang S. Functional electrical stimulation applied to gluteus medius and tibialis anterior corresponding gait cycle for stroke. *Gait Posture*. 2012;36(1):65-67. doi:10.1016/j.gaitpost.2012.01.006.
115. Kim IC, Lee BH. Effects of augmented reality with functional electric stimulation on muscle strength, balance and gait of stroke patients. *J Phys Ther Sci*. 2012;24(8):755-762.
116. Kobayashi T, Leung AK, Akazawa Y, Hutchins SW. Effect of ankle-foot orthoses on the sagittal plane displacement of the center of mass in patients with stroke hemiplegia: a pilot study. *Top Stroke Rehabil*. 2012;19(4):338-344. doi:10.1310/tsr1904-338.
117. Kobayashi T, Orendurff MS, Hunt G, et al. The effects of alignment of an articulated ankle-foot orthosis on lower limb joint kinematics and kinetics during gait in individuals post-stroke. *J Biomech*. 2019;83:57-64. doi:10.1016/j.jbiomech.2018.11.019.
118. Kottink AI, Ijzerman MJ, Groothuis-Oudshoorn CG, Hermens HJ. Measuring quality of life in stroke subjects receiving an implanted neural prosthesis for drop foot. *Artif Organs*. 2010;34(5):366-376. doi:10.1111/j.1525-1594.2009.00879.x.
119. Kottink AIR, Hermens HJ, Nene AV, Tenniglo MJ, Groothuis-Oudshoorn CG, IJzerman MJ. Therapeutic effect of an implantable peroneal nerve stimulator in subjects with chronic stroke and foot-drop: a randomized controlled trial. *Phys Ther*. 2008;88(4):437-448. doi:10.2522/ptj.20070035.
120. Kottink AI, Tenniglo MJ, de Vries WH, Hermens HJ, Buurke JH. Effects of an implantable two-channel peroneal nerve stimulator versus conventional walking device on spatiotemporal parameters and kinematics of hemiparetic gait. *J Rehabil Med*. 2012;44(1):51-57. doi:10.2340/16501977-0909.
121. Lairamore C, Garrison MK, Bandy W, Zabel R. Comparison of tibialis anterior muscle electromyography, ankle angle, and velocity when individuals post stroke walk with different orthoses. *Prosthet Orthot Int*. 2011;35(4):402-410. doi:10.1177/0309364611417040.
122. Lan Y, Xu GQ, Huang DF, et al.Association between improved trunk stability and walking capacity using ankle-foot orthosis in hemiparetic patients with stroke: evidence from three-dimensional gait analysis. *Chin Med J (Engl)*. 2013;126(20):3869-3873.
123. Lewallen J, Miedaner J, Amyx S, Sherman J. Effect of three styles of custom ankle foot orthoses on the gait of stroke patients while walking on level and inclined surfaces. *JPO J Prosthet Orthotics*. 2010;22(2):78-83. doi:10.1097/JPO.0b013e3181d84767.

124. Mojica JA, Nakamura R, Kobayashi T, Handa T, Morohashi I, Watanabe S. Effect of ankle-foot orthosis (AFO) on body sway and walking capacity of hemiparetic stroke patients. *Tohoku J Exp Med*. 1988;156(4):395-401.
125. Momosaki R, Abo M, Watanabe S, Kakuda W, Yamada N, Kinoshita S. Effects of ankle-foot orthoses on functional recovery after stroke: a propensity score analysis based on Japan rehabilitation database. *PLoS One*. 2015;10(4):e0122688. doi:10.1371/journal.pone.0122688.
126. Morone G, Fusco A, Di Capua P, Coiro P, Pratesi L. Walking training with foot drop stimulator controlled by a tilt sensor to improve walking outcomes: a randomized controlled pilot study in patients with stroke in subacute phase. *Stroke Res Treat*. 2012;2012:523564. doi:10.1155/2012/523564.
127. Mun BM, Kim TH, Lee JH, Lim JY, Seo DK, Lee DJ. Comparison of gait aspects according to FES stimulation position applied to stroke patients. *J Phys Ther Sci*. 2014;26(4):563-566. doi:10.1589/jpts.26.563.
128. Nikamp C, Buurke J, Schaake L, van der Palen J, Rietman J, Hermens H. Effect of long-term use of ankle-foot orthoses on tibialis anterior muscle electromyography in patients with sub-acute stroke: a randomized controlled trial. *J Rehabil Med*. 2019;51(1):11-17. doi:10.2340/16501977-2498.
129. Nikamp CD, Buurke JH, van der Palen J, Hermens HJ, Rietman JS. Six-month effects of early or delayed provision of an ankle-foot orthosis in patients with (sub)acute stroke: a randomized controlled trial. *Clin Rehabil*. 2017;31(12):1616-1624. doi:10.1177/0269215517709052.
130. Nikamp CD, Buurke JH, van der Palen J, Hermens HJ, Rietman JS. Early or delayed provision of an ankle-foot orthosis in patients with acute and subacute stroke: a randomized controlled trial. *Clin Rehabil*. 2017;31(6):798-808. doi:10.1177/0269215516658337.
131. Nikamp CDM, Hobbelink MSH, van der Palen J, Hermens HJ, Rietman JS, Buurke JH. A randomized controlled trial on providing ankle-foot orthoses in patients with (sub-)acute stroke: short-term kinematic and spatiotemporal effects and effects of timing. *Gait Posture*. 2017;55:15-22. doi:10.1016/j.gaitpost.2017.03.028.
132. Nolan KJ, Yarossi M, Mclaughlin P. Changes in center of pressure displacement with the use of a foot drop stimulator in individuals with stroke. *Clin Biomech (Bristol, Avon)*. 2015;30(7):755-761. doi:10.1016/j.clinbiomech.2015.03.016.
133. Nolan KJ, Savalia KK, Lequerica AH, Elovic EP. Objective assessment of functional ambulation in adults with hemiplegia using ankle foot orthotics after stroke. *PM R*. 2009;1(6):524-529. doi:10.1016/j.pmrj.2009.04.011.
134. Nolan KJ, Yarossi M. Preservation of the first rocker is related to increases in gait speed in individuals with hemiplegia and AFO. *Clin Biomech (Bristol, Avon)*. 2011;26(6):655-660. doi:10.1016/j.clinbiomech.2011.03.011.
135. O'Dell MW, Dunning K, Kluding P, et al. Response and prediction of improvement in gait speed from functional electrical stimulation in persons with poststroke drop foot. *PM R*. 2014;6(7):587-601; quiz 601. doi:10.1016/j.pmrj.2014.01.001.
136. Pardo V, Galen S, Gahimer JE, Goldberg A. Effects of custom-molded and prefabricated hinged ankle-foot orthoses on gait parameters and functional mobility in adults with hemiplegia: a preliminary report. *J Prosthet Orthotics*. 2015;27(1):33-38.
137. Park JH, Chun MH, Ahn JS, Yu JY, Kang SH. Comparison of gait analysis between anterior and posterior ankle foot orthosis in hemiplegic patients. *Am J Phys Med Rehabil*. 2009;88(8):630-634. doi:10.1097/PHM.0b013e3181a9f30d.
138. Pavlik AJ. The effect of long-term ankle-foot orthosis use on gait in the poststroke population. *JPO J Prosthet Orthotics*. 2008;20(2):49-52. doi:10.1097/JPO.0b013e3181695630.
139. Pilkar R, Yarossi M, Nolan KJ. EMG of the tibialis anterior demonstrates a training effect after utilization of a foot drop stimulator. *NeuroRehabilitation*. 2014;35(2):299-305. doi:10.3233/NRE-141126.
140. Rao N, Chaudhuri G, Hasso D, et al. Gait assessment during the initial fitting of an ankle foot orthosis in individuals with stroke. *Disabil Rehabil Assist Technol*. 2008;3(4):201-207. doi:10.1080/17483100801973023.
141. Robertson JA, Eng JJ, Hung C. The effect of functional electrical stimulation on balance function and balance confidence in community-dwelling individuals with stroke. *Physiother Can*. 2010;62(2):114-119. doi:10.3138/physio.62.2.114.
142. Sabut SK, Lenka PK, Kumar R, Mahadevappa M. Effect of functional electrical stimulation on the effort and walking speed, surface electromyography activity, and metabolic responses in stroke subjects. *J Electromyogr Kinesiol*. 2010;20(6):1170-1177. doi:10.1016/j.jelekin.2010.07.003.
143. Sabut SK, Sikdar C, Kumar R, Mahadevappa M. Functional electrical stimulation of dorsiflexor muscle: effects on dorsiflexor strength, plantarflexor spasticity, and motor recovery in stroke patients. *NeuroRehabilitation*. 2011;29(4):393-400. doi:10.3233/NRE-2011-0717.
144. Salisbury L, Shiels J, Todd I, Dennis M. A feasibility study to investigate the clinical application of functional electrical stimulation (FES), for dropped foot, during the sub-acute phase of stroke—a randomized controlled trial. *Physiother Theory Pract*. 2013;29(1):31-40. doi:10.3109/09593985.2012.674087.
145. Sankaranarayan H, Gupta A, Khanna M, Taly AB, Thennarasu K. Role of ankle foot orthosis in improving locomotion and functional recovery in patients with stroke: a prospective rehabilitation study. *J Neurosci Rural Pract*. 2016;7(4):544-549. doi:10.4103/0976-3147.185507.
146. Schiemanck S, Berenpas F, van Swigchem R, et al. Effects of implantable peroneal nerve stimulation on gait quality, energy expenditure, participation and user satisfaction in patients with post-stroke drop foot using an ankle-foot orthosis. *Restor Neurol Neurosci*. 2015;33(6):795-807. doi:10.3233/RNN-150501.
147. Sheffler LR, Hennessey MT, Naples GG, Chae J. Peroneal nerve stimulation versus an ankle foot orthosis for correction of footdrop in stroke: impact on functional ambulation. *Neurorehabil Neural Repair*. 2006;20(3):355-360. doi:10.1177/1545968306287925.
148. Sheffler LR, Taylor PN, Gunzler DD, Buurke JH, Ijzerman MJ, Chae J. Randomized controlled trial of surface peroneal nerve stimulation for motor relearning in lower limb hemiparesis. *Arch Phys Med Rehabil*. 2013;94(6):1007-1014. doi:10.1016/j.apmr.2013.01.024.
149. Sheffler LR, Taylor PN, Bailey SN, et al. Surface peroneal nerve stimulation in lower limb hemiparesis: effect on quantitative gait parameters. *Am J Phys Med Rehabil*. 2015;94(5):341-357. doi:10.1097/PHM.0000000000000269.
150. Sheffler LR, Bailey SN, Wilson RD, Chae J. Spatiotemporal, kinematic, and kinetic effects of a peroneal nerve stimulator versus an ankle foot orthosis in hemiparetic gait. *Neurorehabil Neural Repair*. 2013;27(5):403-410. doi:10.1177/1545968312465897.
151. Sota K, Uchiyama Y, Ochi M, Matsumoto S, Hachisuka K, Domen K. Examination of factors related to the effect of improving gait speed with functional electrical stimulation intervention for stroke patients. *PM R*. 2018;10(8):798-805. doi:10.1016/j.pmrj.2018.02.012.
152. Tang Z, Liu L, Wang S, et al. Impact of fixed and non-fixed foot orthoses on fatigue of lower limb muscles. *Int J Simulation Systems Sci Technol*. 2016;17(29):30.1-30.8.
153. Taylor PN, Burridge JH, Dunkerley AL, et al. Clinical use of the Odstock dropped foot stimulator: its effect on the speed and effort of walking. *Arch Phys Med Rehabil*. 1999;80(12):1577-1583. doi:10.1016/s0003-9993(99)90333-7.
154. Tyson SF, Rogerson L. Assistive walking devices in nonambulant patients undergoing rehabilitation after stroke: the effects on functional mobility, walking impairments, and patients' opinion. *Arch Phys Med Rehabil*. 2009;90(3):475-479. doi:10.1016/j.apmr.2008.09.563.
155. Tyson SF, Thornton HA. The effect of a hinged ankle foot orthosis on hemiplegic gait: objective measures and users' opinions. *Clin Rehabil*. 2001;15(1):53-58.

156. van Swigchem R, Vloothuis J, den Boer J, Weerdesteyn V, Geurts ACH. Is transcutaneous peroneal stimulation beneficial to patients with chronic stroke using an ankle-foot orthosis? A within-subjects study of patients' satisfaction, walking speed and physical activity level. *J Rehabil Med*. 2010;42(2):117-121. doi:10.2340/16501977-0489.
157. Wang RY, Yen, LU, Lee CC, Lin PY, Wang MF, Yang YR. Effects of an ankle-foot orthosis on balance performance in patients with hemiparesis of different durations. *Clin Rehabil*. 2005;19(1):37-44. doi:10.1191/0269215505cr797oa.
158. Wang RY, Lin PY, Lee CC, Yang YR. Gait and balance performance improvements attributable to ankle-foot orthosis in subjects with hemiparesis. *Am J Phys Med Rehabil*. 2007;86(7):556-562. doi:10.1097/PHM.0b013e31806dd0d3.
159. Wilkie KM, Shiels JE, Bulley C, Salisbury LG. Functional electrical stimulation (FES) impacted on important aspects of my life: "a qualitative exploration of chronic stroke patients" and carers' perceptions of FES in the management of dropped foot. *Physiother Theory Pract*. 2012;28(1):1-9. doi:10.3109/09593985.2011.563775.
160. Wilkinson IA, Burridge J, Strike P, Taylor P. A randomised controlled trial of integrated electrical stimulation and physiotherapy to improve mobility for people less than 6 months post stroke. *Disabil Rehabil Assist Technol*. 2015;10(6):468-474. doi:10.3109/17483107.2014.917125.
161. Yamamoto S, Tomokiyo N, Yasui T, Kawaguchi T. Effects of plantar flexion resistive moment generated by an ankle-foot orthosis with an oil damper on the gait of stroke patients: a pilot study. *Prosthet Orthot Int*. 2013;37(3):212-221. doi:10.1177/0309364612460266.
162. Yamamoto S, Ibayashi S, Fuchi M, Yasui T. Immediate-term effects of use of an ankle-foot orthosis with an oil damper on the gait of stroke patients when walking without the device. *Prosthet Orthot Int*. 2015;39(2):140-149. doi:10.1177/0309364613518340.
163. Yamamoto S, Tanaka S, Motojima N. Comparison of ankle-foot orthoses with plantar flexion stop and plantar flexion resistance in the gait of stroke patients: a randomized controlled trial. *Prosthet Orthot Int*. 2018;42(5):544-553. doi:10.1177/0309364618774055.
164. Zissimopoulos A, Fatone S, Gard S. Effects of ankle-foot orthoses on mediolateral foot-placement ability during post-stroke gait. *Prosthet Orthot Int*. 2015;39(5):372-379. doi:10.1177/0309364614534294.
165. Zissimopoulos A, Fatone S, Gard S. The effect of ankle-foot orthoses on self-reported balance confidence in persons with chronic poststroke hemiplegia. *Prosthet Orthot Int*. 2014;38(2):148-154. doi:10.1177/0309364613490445.
166. Academy of Neurologic Physical Therapy. StrokEDGE-II Recommendations. http://neuropt.org/docs/default-source/edge-documents/inal-strokeedge-ii-recommendations-spread-sheet.pdf?sfvrsn=ffc5443_2. Published 2015. Accessed December 11, 2019.
167. Fritz S, Lusardi M. White paper: "walking speed: the sixth vital sign." *J Geriatr Phys Ther*. 2009;32(2):46-49. doi:10.1519/00139143-200932020-00002.
168. Nolan KJ, Yarossi M. Weight transfer analysis in adults with hemiplegia using ankle foot orthosis. *Prosthet Orthot Int*. 2011;35(1):45-53. doi:10.1177/0309364610393061.
169. Johnson CA, Burridge JH, Strike PW, Wood DE, Swain ID. The effect of combined use of botulinum toxin type A and functional electric stimulation in the treatment of spastic drop foot after stroke: a preliminary investigation. *Arch Phys Med Rehabil*. 2004;85(6):902-909. doi:10.1016/j.apmr.2003.08.081.
170. Ignat B, Duca A, Bohotin V, Poboroniuc M, Popescu CD. The effect of a short functional electrical stimulation training programme on gait parameters in chronic stroke survivors. *Romanian J Neurol*. 2009;9(1):21-27.
171. Israel S, Kotowski S, Talbott N, Fisher K, Dunning K. The therapeutic effect of outpatient use of a peroneal nerve functional electrical stimulation neuroprosthesis in people with stroke: a case series. *Top Stroke Rehabil*. 2011;18(6):738-745. doi:10.1310/tsr1806-738.
172. Awad LN, Reisman DS, Pohlig RT, Binder-Macleod SA. Identifying candidates for targeted gait rehabilitation after stroke: better prediction through biomechanics-informed characterization. *J Neuroeng Rehabil*. 2016;13(1):84. doi:10.1186/s12984-016-0188-8.
173. Holden MK, Gill KM, Magliozzi MR, Nathan J, Piehl-Baker L. Clinical gait assessment in the neurologically impaired. Reliability and meaningfulness. *Phys Ther*. 1984;64(1):35-40. doi:10.1093/ptj/64.1.35.
174. Antonucci G, Aprile T, Paolucci S. Rasch analysis of the Rivermead Mobility Index: a study using mobility measures of first-stroke inpatients. *Arch Phys Med Rehabil*. 2002;83(10):1442-1449. doi:10.1053/apmr.2002.34618.
175. Hsueh IP, Wang CH, Sheu CF, Hsieh CL. Comparison of psychometric properties of three mobility measures for patients with stroke. *Stroke*. 2003;34(7):1741-1745. doi:10.1161/01.STR.0000075295.45185.D4.
176. Mahoney FI, Barthel DW. Functional evaluation: the Barthel Index. *Md State Med J*. 1965;14:61-65.
177. Kelly-Hayes M, Robertson JT, Broderick JP, et al. The American Heart Association stroke outcome classification. *Stroke*. 1998;29(6):1274-1280. doi:10.1161/01.str.29.6.1274.
178. Brosseau L, Wolfson C. The inter-rater reliability and construct validity of the Functional Independence Measure for multiple sclerosis subjects. *Clin Rehabil*. 1994;8(2):107-115. doi:10.1177/026921559400800203.
179. Liaw LJ, Hsieh CL, Lo SK, Lee S, Huang MH, Lin JH. Psychometric properties of the modified Emory Functional Ambulation Profile in stroke patients. *Clin Rehabil*. 2006;20(5):429-437. doi:10.1191/0269215506cr950oa.
180. Wolf SL, Catlin PA, Gage K, Gurucharri K, Robertson R, Stephen K. Establishing the reliability and validity of measurements of walking time using the Emory Functional Ambulation Profile. *Phys Ther*. 1999;79(12):1122-1133.
181. Moore JL, Potter K, Blankshain K, Kaplan SL, O'Dwyer LC, Sullivan JE. A core set of outcome measures for adults with neurologic conditions undergoing rehabilitation: a clinical practice guideline. *J Neurol Phys Ther*. 2018;42(3):174-220. doi:10.1097/NPT.0000000000000229.
182. Burridge J, Taylor P, Hagan S, Swain I. Experience of clinical use of the Odstock dropped foot stimulator. *Artif Organs*. 1997;21(3):254-60.
183. Shaw L, Rodgers H, Price C, et al.BoTULS: a multicentre randomised controlled trial to evaluate the clinical effectiveness and cost-effectiveness of treating upper limb spasticity due to stroke with botulinum toxin type A. *Health Technol Assess*. 2010;14(26):1-113, iii-iv. doi:10.3310/hta14260.
184. Kim WI, Park YH, Sung YB, Nam CW, Lee JH. Influence of Kinesio taping for stroke's ankle joint versus ankle-foot orthosis on muscle stimulation and gait ability in stroke's foot drop. *IJBSBT*. 2016;8(1):263-274. doi:10.14257/ijbsbt.2016.8.1.23.
185. Ramsay JW, Barrance PJ, Buchanan TS, Higginson JS. Paretic muscle atrophy and non-contractile tissue content in individual muscles of the post-stroke lower extremity. *J Biomech*. 2011;44(16):2741-2746. doi:10.1016/j.jbiomech.2011.09.001.
186. Pohl M, Mehrholz J. Immediate effects of an individually designed functional ankle-foot orthosis on stance and gait in hemiparetic patients [with consumer summary]. *Clin Rehabil*. 2006;20(4):324-330.
187. Singer ML, Kobayashi T, Lincoln LS, Orendurff MS, Foreman KB. The effect of ankle-foot orthosis plantarflexion stiffness on ankle and knee joint kinematics and kinetics during first and second rockers of gait in individuals with stroke. *Clin Biomech (Bristol, Avon)*. 2014;29(9):1077-1080. doi:10.1016/j.clinbiomech.2014.09.001.
188. Graham R, Mancher M, Miller Wolman D, Greenfield S, Steinberg E, eds. Institute of Medicine (US) Committee on Standards for Developing Trustworthy Clinical Practice Guidelines. *Clinical Practice Guidelines We Can Trust*. Washington, DC: National Academies Press (US); 2011. doi:10.17226/13058.

APPENDIX: TABLES

Appendix Table 1. Outcome Measures[a]

FUNCTIONAL AREA OR IMPAIRMENT	PRIMARY OUTCOME MEASURES	MCID/MDC	SECONDARY OUTCOME MEASURES	MCID/MDC
Quality of life	Stroke Impact Scale (SIS)[60]	MCID: strength 9.2, ADL/ IADL: 5.9, mobility 4.5, MDC: strength 24, ADL/ IADL 17.3, mobility 15.1	Short Form-36 (SF-36)	
	Stroke-Specific Quality of Life (SSQOL)[61]	Mobility subscale: MCID: 1.5-2.4 points MDC: 5.9 points	European Quality of Life (Euro-QOL)	
	Sickness Impact Profile (SIP)		Disability Impact Profile (DIP)	
Gait speed	*10-m walk test (10mWT)*[62]	MCID: ≥ 0.14 m/s SMC: ≥ 0.06 m/s	20-m walk test (20mWT) 11-m walk test (11mWT) 5-m walk test (5mWT) 6-m walk test (6mWT) 6-m walk test (6MWT) 25-ft walk test "Gait speed"	
Other mobility	Functional Ambulation Category (FAC)[63]		Functional Independence Measure (FIM)[64]	MCID: 22 points
	Modified Emory Functional Ambulation Profile (mEFAP)[65]	MDC: 8.81 points	Barthel Index (BI)[66]	MCID: 1.85 points MDC: 4.02 points
			Stroke Rehabilitation Assessment of Movement (STREAM) mobility subscale[67,68]	MCID: mobility subscale 4.8 points MDC: 4.2 points
Dynamic balance	*Berg Balance Scale (BBS)*[69]	MDC: 6.9 points	Figure-of-8 test	
	Timed Up and Go (TUG)[70]	MDC: 2.9 s		
	Timed Up and Down Stairs (TUDS)		*Activities Balance Confidence Scale (ABC)* Functional Reach Test (FRT) Falls Efficacy Scale-International (FES-I)	
Endurance	*6-min walk test (6MWT)*[62,70]	MCID: 50 m MDC: 36.6 m		
	Physiologic Cost Index (PCI)			
Spasticity	Modified Ashworth Scale (MAS)			
Muscle activation	Electromyography (EMG)			
Gait kinematics	Kinematics[71]	Ankle DF: 4.9° Knee flexion: 5.7°		

Abbreviations: ADL, activities of daily living; DF, dorsiflexors/dorsiflexion; IADL, instrumental activities of daily living; MCID, minimal clinically important difference; MDC, minimal detectable change; SMC, small meaningful change.

[a]Measures in *italics* are recommended as part of the core set of outcome measures for adults with neurologic conditions.[181]

Appendix Table 2. Master Study Details

AUTHORS	YEAR	STUDY TYPE	ACUTE/ CHRONIC	MOBILITY	BASELINE GAIT SPEED*	SESSION DURATION	SESSION FREQUENCY	INTERVENTION DURATION	COMBINED INTERVENTIONS	COMPARISON INTERVENTIONS	AFO TYPE	FES TYPE	SAMPLE SIZE	QOL	GAIT SPEED	FUNCTION	BALANCE	ENDURANCE	SPASTICITY	MUSCLE ACTIVATION	KINEMATICS
Abe et al[79]	2009	Cohort	C	I; 8 m with or without cane	0.3 ± 0.14 m/s	N/A	N/A	N/A	N/A	N/A	PLS or articulating plastic	N/A	16		X	X					
Alon and Ring[80]	2003	Cohort	C	I; 5 m without AD or AFO	FES: 0.88 ± 0.23 m/s Control: 0.76 ± 0.22 m/s	20-120 min	7x/wk	8 wk	Functional exercise program Robot-assisted gait	Functional exercise program Robot-assisted	N/A	Bioness	19		X						
Bae et al[81]	2014	RCT	C	I; 10 m with or without AD	Control: 0.43 m/s	60 min	3x/wk	5 wk	training with FES and NDT/PT	Gait training without FES and	N/A	Walk Aide	20				X				X
Barrett and Taylor[82]	2010	Cohort	C	Not specified	0.59 m/s (median)	N/A	N/A	18 wk	N/A	N/A	N/A	Odstock	21		X						
Beckerman et al[84]	1996	RCT	C	I	4 groups: 0.45, 0.44, 0.42, 0.32 m/s (median)	N/A	1x/wk	12 wk	Thermocoagulation	N/A	Articulating plastic, solid plastic	N/A	60		X						
Beckerman et al[84]	1996	RCT	C	I	4 groups: 0.45, 0.44, 0.42, 0.32 m/s (median)	N/A	N/A	N/A	Thermocoagulation	N/A	plastic, solid plastic	N/A	60						X		
Bethoux et al[86]	2015	RCT	C	I; 10m with or without AD	AFO: 0.49 ± 0.21 m/s FES: 0.45 ± 0.22 m/s	N/A	Daily home use	12 mo	N/A	N/A	Custom solid or articulating	WalkAide	384		X	X		X			
Bethoux et al[85]	2014	RCT	C	I; 10 m with or without AD	AFO: 0.49 ± 0.21 m/s FES: 0.45 ± 0.22 m/s	N/A	Daily home use	24 wk	N/A	N/A	Custom solid or articulating	WalkAide	399	X	X	X	X	X			
Bleyenheuft et al[87]	2008	Cohort	C	I; on treadmill	0.64 ± 0.25 m/s	N/A	N/A	N/A	N/A	N/A	Chignon, PLS	N/A	10		X						X
Bouchalova et al[39]	2016	Cohort	C	without AFO, no bilateral AD	With AD: 0.4 ± 0.2 m/s No AD: 1.0 ± 0.2 m/s	N/A	N/A	N/A	N/A	N/A	Prefab plastic, custom Y-tech	N/A	15		X		X				

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Appendix Table 2. Master Study Details (*Continued*)

AUTHORS	YEAR	STUDY TYPE	ACUTE/ CHRONIC	MOBILITY	BASELINE GAIT SPEED*	SESSION DURATION	SESSION FREQUENCY	INTERVENTION DURATION	COMBINED INTERVENTIONS	COMPARISON INTERVENTIONS	AFO TYPE	FES TYPE	SAMPLE SIZE	QOL	GAIT SPEED	FUNCTION	BALANCE	ENDURANCE	SPASTICITY	MUSCLE ACTIVATION	KINEMATICS
Boudarham et al[36]	2014	Cohort	C	Not specified	0.42 ± 0.16 m/s	N/A	N/A	N/A	N/A	N/A	Liberté elastic dynamic	N/A	12		X					X	X
Burridge and McLellan[89]	2000	Cohort	C	I; 10 m	0.63 m/s	N/A	Daily home use	3 mo	N/A	N/A	N/A	Odstock	18		X			X			
Burridge et al[88]	2007	Cohort	C	I; 100 m continuously	0.50 ± 0.20 m/s	N/A	Daily home use	Up to 15 mo	NO/overground gait	N/A	N/A	ActiGait	15		X						
Burridge et al[90]	1997	RCT	C	I; 10 m with or without AD	FES: 0.64 m/s Control 0.48 m/s	60 min	2-3x/wk	4-5 wk	training; Bobath focused PT	Bobath PT	N/A	Odstock	32		X			X			
Cakar et al[91]	2010	Cohort	C	I; without AD	Not stated	N/A	Daily home use	1 wk	N/A	N/A	PLS	N/A	25				X				
Carse et al[92]	2015	Cohort	A	I or assistance	0.22 ± 0.2 m/s	N/A	N/A	N/A	N/A	N/A	Custom solid	N/A	8		X						
Chen et al[93]	2014	Cohort	C	I or assistance; without AFO	Not stated	N/A	N/A	N/A	N/A	N/A	Anterior	N/A	21				X				
Chen et al[94]	2010	Cohort	C		Not stated	N/A	N/A	N/A	N/A	N/A	Anterior, posterior	N/A	14								X
Cho et al[95]	2015	RCT	C	I; 10 m	0.40 ± 0.15 m/s	30 min	5x/wk	4 wk	Treadmill training	N/A	N/A	Cyber-Medic EMS	36				X	X			
Cozean et al[96]	1988	RCT	C	With assistance of no >1 person	Not stated	30 min	3x/wk	6 wk	Biofeedback	N/A	sNo/lAid or	Medtronic Respond II	36								X
Cruz and Dhaher[97]	2009	Cohort	C	I; 10 m	0.39 ± 0.08 m/s	N/A	N/A	N/A	N/A	N/A	Articulating plastic	N/A	9								X
Danielsson and Sunnerhagen[98]	2004	Cohort	C	I; 5 min with or AD	0.27 ± 0.03 m/s	N/A	N/A	N/A	N/A	N/A	Carbon composite	N/A	10		X			X			
Danielsson et al[99]	2007	Cohort	C	I; 150 m 0 min	0.48 ± 0.28 m/s	N/A	N/A	N/A	N/A	N/A	Unspecified	N/A	20					X			
Daniilidis et al[100]	2017	Cohort	C	Without AD or AFO	0.62 ± 0.27 m/s	N/A	N/A	N/A	N/A	N/A	N/A	ActiGait	18								X

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Appendix Table 2. Master Study Details (*Continued*)

AUTHORS	YEAR	STUDY TYPE	ACUTE/ CHRONIC	MOBILITY	BASELINE GAIT SPEED*	SESSION DURATION	SESSION FREQUENCY	INTERVENTION DURATION	COMBINED INTERVENTIONS	COMPARISON INTERVENTIONS	AFO TYPE	FES TYPE	SAMPLE SIZE	QOL	GAIT SPEED	FUNCTION	BALANCE	ENDURANCE	SPASTICITY	MUSCLE ACTIVATION	KINEMATICS
de Sèze et al[33]	2011	RCT	A	Not specified	Chignon: 0.11 ± 0.11 m/s Standard: 0.13 ± 0.14 m/s	N/A	Daily home use	90 d	N/A	N/A	Standard versus Chignon	N/A	28						X		X
de Wit et al[101]	2004	Cohort	C	I; with and without AFO	0.45 ± 0.24 m/s	N/A	N/A	N/A	N/A	N/A	Polid plastic	N/A	20		X		X				
Do et al[37]	2014	Cohort	C	I; 10 m	0.41 ± 0.14 m/s	180 min	7x/wk	2 wk	N/A	N/A	PF stop/free DF vs hybrid	N/A	17								X
Dogan et al[102]	2011	Cohort	A	I or assistance	0.29 m/s	N/A	N/A	N/A	N/A	N/A	with 90° PF stop	N/A	59			X	X				
Erel et al.	2011	RCT	C	I	AFO: 0.84 ± 0.40 m/s Control: 0.65 ± 0.19 m/s	N/A	Daily home use	12 wk	N/A	N/A	Dynamic	N/A	32		X		X	X			
Ernst et al[32]	2013	Cohort	C	I; 20 m in <2 min	0.62 ± 0.07 m/s	N/A	Daily home use	12 wk	N/A	N/A	N/A	ActiGait	5		X			X			X
Everaert et al[72]	2013	RCT	C	I; 10 m with or without AD	FES/AFO: 0.46 ± 0.25 m/s AFO/FES: 0.42 ± 0.22 m/s AFO/AFO: 0.36 ± 0.26 m/s	N/A	Daily home use	12 wk	N/A	N/A	Custom	WalkAide	121		X	X	X	X			
Fatone and Hansen[103]	2007	Cohort	C	Not specified	0.57 m/s	N/A	N/A	N/A	N/A	N/A	90° PF stop, free DF, full footplate	N/A	13		X						X
Fatone et al[13]	2009	Cohort	C	Not specified	0.31 m/s	N/A	N/A	N/A	N/A	N/A	90° PF stop, free DF, full	N/A	22								X
Gatti et al[104]	2012	Cohort	C	I; 10 m	0.48 ± 0.14 m/s	N/A	N/A	N/A	N/A	N/A	Custom solid set at 90°	N/A	10		X						X
Granat et al[105]	1996	Cohort	C	I	0.89 ± 0.56 m/s	N/A	Daily home use	3 wk	N/A	N/A	ANr/tAiculating	Single channel	16		X						

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Appendix Table 2. Master Study Details (*Continued*)

AUTHORS	YEAR	STUDY TYPE	ACUTE/ CHRONIC	MOBILITY	BASELINE GAIT SPEED*	SESSION DURATION	SESSION FREQUENCY	INTERVENTION DURATION	COMBINED INTERVENTIONS	COMPARISON INTERVENTIONS	AFO TYPE	FES TYPE	SAMPLE SIZE	QOL	GAIT SPEED	FUNCTION	BALANCE	ENDURANCE	SPASTICITY	MUSCLE ACTIVATION	KINEMATICS
Hesse et al[16]	1999	Cohort	C	I; 20 m barefoot	0.32 ± 0.17 m/s	N/A	N/A	N/A	N/A	N/A	with 10 to 0° DF stops and	N/A	21							X	
Hung et al[106]	2011	Cohort	C	I; 10 m	Not stated	N/A	N/A	N/A	N/A	N/A	Anterior	N/A	52		X	X	X				
Hwang et al[107]	2012	Cohort	C	I; with or without AD	0.21 ± 0.13 m/s	N/A	N/A	N/A	N/A	N/A	Articulating	N/A	15		X						
Hwang et al[108]	2015	RCT	C	I; 15 m without AD	Tilt sensor: 0.36 m/s Placebo: 0.32 m/s	30 min	7x/wk	4 wk	Treadmill training	N/A	N/A	WalkAide	32		X		X				
Hyun et al[109]	2015	Cohort	A	I; 3 min with or without AD	Not stated	N/A	N/A	N/A	N/A	N/A	${}_{s}P_{o}LS_{lid\ plastic}$	N/A	15					X			
Iwata et al[40]	2003	Cohort	C	I	0.50 ± 0.27 m/s	N/A	Daily home use	2 wk	N/A	N/A	With inhibi-tor bar	N/A	18		X						
Jung et al[110]	2013	Cohort	C	I; 10 m	Not stated	20 min	5x/wk	4 wk	Virtual reality	N/A	N/A	Cyber-Medic EMS	10							X	
Kesar et al[111]	2009	Cohort	C	I; 5 min	0.7 ± 0.1 m/s	N/A	N/A	N/A	N/A	N/A	N/A	Custom	13								X
Kesar et al[112]	2010	Cohort	C	I; 5 min	0.7 ± 0.3 m/s	N/A	N/A	N/A	N/A	N/A	N/A	Custom	13								X
Kesikburun et al[113]	2017	Cohort	C	I; with or without AD	0.32 m/s (median)	N/A	N/A	N/A	N/A	N/A	Custom solid plastic	N/A	28			X					X
Kim and Lee[115]	2012	RCT	C	I	Not stated	20 min	3x/wk	8 wk	Treadmill training	Virtual reality	N/A	Cyber Medic EMS	38				X				
Kim et al[114]	2012	Cohort	C	I; 10 m	0.27 ± 0.09 m/s	N/A	N/A	N/A	N/A	N/A	N/A	Cyber Medic EMS	36		X						
Kim et al[53]	2013	Cohort	A	I; with or without cane	0.34 m/s	N/A	N/A	N/A	N/A	N/A	Heel cut out vs solid	N/A	15								X
Kluding et al[76]	2013	RCT	C	I or as-sistance; 10 m	Not stated	N/A	Daily home use	30 wk	N/A	N/A	Custom	Bioness	197	X	X		X	X			
Kobayashi et al[117]	2019	Cohort	C	Unspeci-fied	Not stated	N/A	N/A	N/A	N/A	N/A	Plastic with custom DF/ OF resistance, set a	N/A	10								X

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Appendix Table 2. Master Study Details (*Continued*)

AUTHORS	YEAR	STUDY TYPE	ACUTE/ CHRONIC	MOBILITY	BASELINE GAIT SPEED*	SESSION DURATION	SESSION FREQUENCY	INTERVENTION DURATION	COMBINED INTERVENTIONS	COMPARISON INTERVENTIONS	AFO TYPE	FES TYPE	SAMPLE SIZE	QOL	GAIT SPEED	FUNCTION	BALANCE	ENDURANCE	SPASTICITY	MUSCLE ACTIVATION	KINEMATICS
Kobayashi et al[116]	2012	Cohort	C	I; with and without AFO	0.57 ± 0.30 m/s	N/A	N/A	N/A	N/A	N/A	Custom plastic articulated or nonarticu-lated	N/A	5		X						
Kottink et al[51]	2007	RCT	C	I; outdoor ambu-lator	Not stated	N/A	Daily home use	26 wk	N/A	Control group used previ-ous AFO	Solid plastic; orthopedic shoes	STIMuS-TEP	29		X			X			
Kottink et al[118]	2010	RCT	C	I; outdoor ambu-lator	Not stated	N/A	Daily home use	26 wk	N/A	Control group used previous AFO	Custom	STIMuS-TEP	29	X							
Kottink et al[119]	2008	RCT	C	I; outdoor ambu-lator	Not stated	N/A	Daily home use	26 wk	N/A	Control group used previous AFO Control group	Solid plastic; orthopedic shoes	STIMuS-TEP	29							X	
Kottink et al[120]	2012	RCT	C	I; outdoor ambu-lator	Control: 0.75 ± 0.21 m/s	N/A	N/A	26 wk	N/A	used previ-ous AFO	Custom	STIMuS-TEP	23								X
Lairamore et al[121]	2011	Cohort	A	I; 20 m without AFO	0.42 ± 0.29 m/s	N/A	N/A	N/A	N/A	N/A	Dynamic, PLS	N/A	15		X					X	
Lan et al[122]	2013	Cohort	A	I; 10 m	0.60 ± 0.21 m/s	N/A	N/A	N/A	N/A	N/A	Custom molded at 90° DF	N/A	20			X	X				
Lee et al[58]	2014	Cohort	C	I; 5 min no AD	0.49 ± 0.26 m/s	N/A	N/A	N/A	N/A	N/A	N/A	Novastim CU-FS1	14								X
Lee et al[59]	2013	RCT	C	I; 10 m with or without AD	PAFES: 0.36 ± 0.20 m/s BWSTT: 0.38 ± 0.20 m/s	60 min	5x/wk	4 wk	Treadmill training	N/A	N/A	Power-as-sist	30			X	X				
Lewallen et al[123]	2010	Cohort	C	I; 500 ft indoors and outdoors, no AD	0.63 m/s	N/A	N/A	N/A	N/A Functional	N/A	Rigid solid, articulated with 90° PF stop	N/A	13		X						
Macdonell et al[46]	1994	RCT	A	Not spec-ified	Not stated	20 min	3x/wk	4 wk	Activities or exercise	N/A	N/A	Respond II	38			X					
Martin et al[49]	2016	Cohort	C	Not spec-ified	0.59 m/s	N/A	N/A	N/A	N/A	N/A	N/A	ActiGait	27		X		X				
Mojica et al[124]	1988	Cohort	C	Not spec-ified	0.55 ± 0.42 m/s	N/A	N/A	N/A	N/A	N/A	Solid plastic	N/A	8		X						

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Appendix Table 2. Master Study Details (*Continued*)

AUTHORS	YEAR	STUDY TYPE	ACUTE/ CHRONIC	MOBILITY	BASELINE GAIT SPEED*	SESSION DURATION	SESSION FREQUENCY	INTERVENTION DURATION	COMBINED INTERVENTIONS	COMPARISON INTERVENTIONS	AFO TYPE	FES TYPE	SAMPLE SIZE	QOL	GAIT SPEED	FUNCTION	BALANCE	ENDURANCE	SPASTICITY	MUSCLE ACTIVATION	KINEMATICS
Momosaki et al[125]	2015	Cohort	A	Not specified	Not stated	40 min	5-7x/wk	average 15.2 wk	Overground gait training-standard PT	N/A	Unspecified	N/A	792			X					
Morone et al[126]	2012	RCT	A	I or assistance; 10 m with or without AD	AFO: 0.38 ± 0.20 m/s FES: 0.31 ± 0.15 m/s	40 min	5x/wk	4 wk	Overground gait training	N/A	Unspecified	WalkAide	20		X	X			X		
Mulroy et al[38]	2010	Cohort	C	I	Neutral: 0.60 ± 0.28 m/s Contracture: 0.35 ± 0.22 m/s	N/A	N/A	N/A	N/A	N/A	Solid, PF stop with free DF, DF assist with	N/A	30		X					X	X
Mun et al[127]	2014	Cohort	C	I	0.47 ± 0.13 m/s	N/A	N/A	N/A	N/A	N/A	N/A	Cyber Medic EMS	10		X						
Nikamp et al[129]	2017	RCT	A	Not specified	Not stated	N/A	N/A	11 wk	Usual care	Delayed AFO provision	PLS, semi-solid, solid	N/A	33		X	X	X				
Nikamp et al[130]	2017	RCT	A	Not specified	Not stated	N/A	N/A	26 wk	Usual care	Delayed AFO provision	PLS, semi-solid, solid	N/A	33		X	X	X				
Nikamp et al[131]	2017	RCT	A	Not specified	0.44 ± 0.22 m/s	N/A	N/A	N/A	Overground gait training	N/A	PLS, semi-solid, solid	N/A	20		X						X
Nikamp et al[128]	2019	RCT	A	Not specified	Early: 0.37 ± 0.19 m/s Delayed: 0.40 ± 0.25 m/s	N/A	N/A	N/A	Conventional PT	Delayed AFO provision	PLS, semi-solid, solid	N/A	26							X	
Nolan and Yarossi[134]	2011	Cohort	C	25 ft with or without AFO	0.57 ± 0.24 m/s	N/A	N/A	N/A	N/A	N/A	Custom rigid plastic	N/A	15		X						
Nolan et al[133]	2009	Cohort	C	I or assistance; 25ft with and without AFO	0.60 m/s	N/A	N/A	N/A	N/A	N/A	Dynamic, solid, articulating	N/A	18		X			X			
Nolan et al[132]	2015	Cohort	C	I; 10 m	0.62 ± 0.28 m/s	N/A	N/A	N/A	N/A	N/A	N/A	WalkAide	11		X						

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Appendix Table 2. Master Study Details (*Continued*)

AUTHORS	YEAR	STUDY TYPE	ACUTE/ CHRONIC	MOBILITY	BASELINE GAIT SPEED*	SESSION DURATION	SESSION FREQUENCY	INTERVENTION DURATION	COMBINED INTERVENTIONS	COMPARISON INTERVENTIONS	AFO TYPE	FES TYPE	SAMPLE SIZE	QOL	GAIT SPEED	FUNCTION	BALANCE	ENDURANCE	SPASTICITY	MUSCLE ACTIVATION	KINEMATICS
O'Dell et al[135]	2014	Cohort	C	10 m < max assistance of 1, with or without AD	0.42 ± 0.21 m/s	225-285 min	2x/wk 2 wk + 1x/wk 4 wk	6 wk	Device fitting, cyclic stimulation at home	N/A	N/A	Bioness	99		X						
Ohata et al[35]	2011	Cohort	C	I or assistance; with or without cane and AFO	0.47 ± 0.18 m/s	N/A	N/A	N/A	N/A	N/A	Oil damper, conventional with PF stop	N/A	11		X					X	X
Pardo et al[136]	2015	Cohort	C	I; no AD	0.53 ± 0.07 m/s	N/A	N/A	N/A	N/A	N/A	Custom, prefabricated articulating	N/A	14		X		X				
Park et al[137]	2009	Cohort	A	I; 10 m	0.34 ± 0.29 m/s	N/A	N/A	N/A	N/A	N/A	Anterior versus posterior	N/A	17				X				X
Pavlik[138]	2008	Cohort	C	I; with and without AFO	0.34 m/s	N/A	N/A	N/A	N/A	N/A	articulating with DF assist and PF stop	N/A	4		X		X	X			
Pilkar et al[139]	2014	Cohort	C	I; 10 m no AD	Not stated	N/A	Daily home use	4 wk	N/A	N/A	N/A	WalkAide	4							X	
Prado-Medeiros et al[48]	2011	Cohort	C	I or assistance; FAC > level 1	0.39 ± 0.2 m/s	45 min	3x/wk	18 wk	Overground gait training using BWS	N/A	N/A	Dorsiflex	12								X
Rao et al[140]	2008	Cohort	A/C	I; 10 m with or without AD	Acute: 0.41 ± 0.09 m/s Chronic: 0.50 ± 0.06 m/s	N/A	N/A	N/A	FNu/nAction and	N/A	Custom molded polypropylene	N/A	40		X						
Robertson et al[141]	2010	Cohort	C	I; 10 m with or without AD	0.65 ± 0.21 m/s	120 min	1x/wk	4 wk	Balance-based activities	N/A	Custom	WalkAIde	15		X		X				
Sabut et al[142]	2010	Cohort	C	I; 10 m	0.39 ± 0.17 m/s	90 min	5x/wk	12 wk	Overground gait training; conventional PT	N/A	N/A	Cyber Medic EMS	15		X			X		X	
Sabut et al[143]	2011	Cohort	C	I; 10 m	<6 mo: 0.32 ± 0.17 m/s >6 mo: 0.42 ± 0.17 m/s	75-90 min	5x/wk	12 wk	Overground gait training; conventional PT	N/A	N/A	Cyber Medic EMS	20		X			X	X		

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Appendix Table 2. Master Study Details (*Continued*)

AUTHORS	YEAR	STUDY TYPE	ACUTE/ CHRONIC	MOBILITY	BASELINE GAIT SPEED*	SESSION DURATION	SESSION FREQUENCY	INTERVENTION DURATION	COMBINED INTERVENTIONS	COMPARISON INTERVENTIONS	AFO TYPE	FES TYPE	SAMPLE SIZE	QOL	GAIT SPEED	FUNCTION	BALANCE	ENDURANCE	SPASTICITY	MUSCLE ACTIVATION	KINEMATICS
Sabut et al[143]	2011	Cohort	C	I; 10 m	Not stated	60 min	5x/wk	12 wk	Convention-al PT	Conventional PT	N/A	Cyber Medic EMS	51						X		
Sabut et al[142]	2010	RCT	C	I; 10 m continu-ously	FES: 0.36 ± 0.21 m/s Control: 0.36 ± 0.16 m/s	60 min	5x/wk	12 wk	Convention-al PT	Conventional PT	N/A	Cyber Medic EMS	30		X			X	X	X	
Salisbury et al[144]	2013	RCT	A	I or up to mod assistance of 2; 5 m	0.2 m/s (median)	20 min	5x/wk	12 wk	Reeducation: gait, balance, LE control/ strength	N/A	Prefabri-cated	Odstock	16	X	X						
Sankarana-rayan et al[145]	2016	Cohort	A	Not spec-ified	0.4 m/s	120 min	6x/wk	2+ wk	Conventional rehab	N/A	Custom solid plastic	N/A	26		X	X			X		
Schiemanck et al[146]	2015	Cohort	C	I; 10 min no AD	Not stated	N/A	Daily home use	26 wk	N/A	N/A	Hinged custom molded	ActiGait	10	X				X			X
Sheffler et al[147]	2006	Cohort	C	I or as-sistance; 30 ft, no AFO	0.33 m/s	N/A	N/A	N/A	N/A	N/A	Custom solid, hinged, or prefabri-cated	Odstock	14			X					
Sheffler et al[148]	2013	Cohort	C	I or < mod assis-tance; 10m	0.70 ± 0.25 m/s	N/A	N/A	N/A	N/A	N/A	Custom molded hinged	Odstock	12								X
Sheffler et al[150]	2013	RCT	C	I; 30 ft without AFO	Not stated	60 min	2x/wk for 5 Wk + 3x/wk over 7 wks	12 wk	Functional training; convention-al PT	N/A conventional PT	Custom articulating with PF block	Odstock	110	X		X					
Sheffler et al[149]	2015	RCT	C	I; 30 ft without AFO	FES: 0.35 ± 0.20 m/s Control: 0.40 ± 0.24 m/s	60 min	wk + 3x over7 weeks	12 wk	Convention-al PT	With or without AFO	Unspeci-fied or none	Odstock	110								X
Shendkar et al[57]	2015	Cohort	C	I; 10 m	FES: 0.52 ± 0.05 m/s Control: 0.51 ± 0.04 m/s	30 m i n	5x/wk	12 wk	30-min convention-al PT	60-min conventional PT	N/A	CEFAR Step II	34							X	
Shimada et al[52]	2006	Cohort	C	I; with AFO	0.50 ± 0.26 m/s	N/A	N/A	N/A	N/A	N/A	N/A	Biotech	8		X						

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Appendix Table 2. Master Study Details (*Continued*)

AUTHORS	YEAR	STUDY TYPE	ACUTE/ CHRONIC	MOBILITY	BASELINE GAIT SPEED*	SESSION DURATION	SESSION FREQUENCY	INTERVENTION DURATION	COMBINED INTERVENTIONS	COMPARISON INTERVENTIONS	AFO TYPE	FES TYPE	SAMPLE SIZE	QOL	GAIT SPEED	FUNCTION	BALANCE	ENDURANCE	SPASTICITY	MUSCLE ACTIVATION	KINEMATICS
Simons et al[42]	2009	Cohort	C	I; 10 m with or without AFO	0.46 ± 0.21 m/s	N/A	N/A	N/A	N/A	N/A	And double metal upright	N/A	20		X	X	X				
Sota et al[151]	2018	Cohort	C	Not specified	0.78 ± 0.28 m/s	>20 min	Variable	Variable	N/A	N/A	N/A	WalkAide	101		X		X	X	X		
Street et al[73]	2017	Cohort	C	I; 10 m with or without AD	0.50 m/s	N/A	Daily home use	20 wk	N/A	N/A	N/A	Odstock	133		X						
Tang et al[152]	2016	Cohort	A	I; 15 min	Not stated	N/A	N/A	N/A	N/A	N/A	Flexible vs rigid wrap	N/A	20							X	
Taylor et al[153]	1999	Cohort	C	I; 10 m with or without AD	Not stated	N/A	Daily home use	6 mo	Overground gait training	N/A	N/A	Odstock	129		X			X			
Taylor et al[18]	2013	Cohort	C	Not specified	0.49 ± 0.31 m/s	N/A	N/A	N/A	N/A	N/A	N/A	Odstock	126		X						
Tyson and Rogerson[154]	2009	Cohort	A	Assistance	0.3 ± 0.14 m/s	N/A	N/A	N/A	N/A	N/A	A,efabricated	N/A	20			X					
Tyson and Thornton[155]	2001	Cohort	C	Not specified	0.18 ± 0.1 m/s	N/A	N/A	N/A	N/A	N/A	Plastic with PF stop	N/A	25			X					
van Swigchem et al[156]	2010	Cohort	C	I; 10 min no AD	1.02 ± 0.05 m/s	N/A	Daily home use	8 wk	N/A	N/A	Plastic	Bioness	26		X						
Voigt and Sinkjaer[45]	2000	Cohort	C	I; without AD or stimulator	0.77 ± 0.83 m/s	N/A	N/A	N/A	N/A	N/A	N/A	KDC 2000A	8		X						X
Wang et al[157]	2005	Cohort	C	I; 10 m with or without AD	0.58 ± 0.29 m/s	N/A	N/A	N/A	N/A	N/A	Prefabricated solid	N/A	103		X		X				
Wang et al[158]	2007	Cohort	C	I; 10 m without AD	0.63 ± 0.27 m/s	N/A	N/A	N/A	N/A	N/A	PLS	N/A	58		X						
Wilkie et al[159]	2012	Cohort	C	I; 10 m	Not stated	N/A	Home use	2.4 ± 1 y	N/A	N/A	N/A	Odstock	19	X							
Wilkinson et al[160]	2014	RCT	A	I; 10 m with or without AD	FES: 0.39 m/s Control: 0.42 m/s	60 min	2x/wk	6 wk	PT	N/A	N/A	Odstock	20		X	X		X			
Yamamoto et al[34]	2011	Cohort	C	Not specified	0.40 ± 0.18 m/s	20 min	1-3x/wk	3 wk	N/A	N/A	Oil damper	N/A	8		X						X

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Appendix Table 2. Master Study Details (*Continued*)

AUTHORS	YEAR	STUDY TYPE	ACUTE/ CHRONIC	MOBILITY	BASELINE GAIT SPEED*	SESSION DURATION	SESSION FREQUENCY	INTERVENTION DURATION	COMBINED INTERVENTIONS	COMPARISON INTERVENTIONS	AFO TYPE	FES TYPE	SAMPLE SIZE	QOL	GAIT SPEED	FUNCTION	BALANCE	ENDURANCE	SPASTICITY	MUSCLE ACTIVATION	KINEMATICS
Yamamoto et al[161]	2013	Cohort	C	I	0.32 ± 0.28 m/s	N/A	N/A	N/A	N/A	N/A	Oil damper with various resistances	N/A	4								X
Yamamoto et al[162]	2015	Cohort	C	Not specified	0.39 m/s (median)	20 min	3x/wk + daily home use	3 wk	Overground gait training	N/A	Oil damper	N/A	8		X						X
Yamamoto et al[163]	2018	RCT	A	I or <min assistance; 10 m, with or without cane	PS: 0.27 ± 0.19 m/s OD: 0.25 ± 0.12 m/s	60 min	7x/wk	2 wk	Overground gait training	N/A	Articulating with PF stop or PF resistance oil damper	N/A	42		X						X
Zissimopoulos et al[164]	2015	Cohort	C	I; 12 m without AD	Not stated	N/A	N/A	N/A	N/A	N/A	Various non-rigid	N/A	15								X
Zissimopoulos et al[165]	2014	Cohort	C	I; with or without AD	Not stated	N/A	N/A	N/A	N/A	N/A	Various non-rigid	N/A	15				X				

Abbreviations: AD, assistive device; AFO, ankle-foot orthosis; BWS, body weight support; BWSTT, body-weight support treadmill training; DF, dorsiflexion/dorsiflexors; FAC, Functional Ambulation Category; FES, functional electrical stimulation; PAFES, power-assist functional electrical stimulation; PF, plantarflexion/plantarflexors; PLS, posterior leaf spring; pre-fab, prefabricated; PT, Physical therapy/physical therapist; QOL, quality of life; RCT, randomized controlled trial.

Appendix Table 3. Master Details for Systematic Reviews and Meta-Analyses

AUTHORS	YEAR	STUDY TYPE	ACUTE OR CHRONIC	AFO	FES	QOL	GAIT SPEED	FUNCTION	DYNAMIC BALANCE	ENDURANCE	SPASTICITY	MUSCLE ACTIVATION	KINEMATICS
Chisholm and Perry[21]	2012	SR	C	X					X				
Daryabor et al[20]	2018	SR	A/C	X									X
Dunning et al[8]	2015	SR	C	X	X	X	X	X	X	X			
Kottink et al[28]	2004	SR	C		X					X			
Tyson and Kent[29]	2013	SR/MA	C	X					X				

Abbreviations: A, acute; AFO, ankle-foot orthosis; C, chronic; FES, functional electrical stimulation; MA, meta-analysis; QOL, quality of life; SR, systematic review.

Appendix Table 4. Quality-of-Life Acute and Chronic Ankle-Foot Orthoses and Functional Electrical Stimulation

AUTHOR	YEAR	LEVEL OF EVIDENCE	DEVICE	MEASURE[a] SIS	SSQOL	SF-36	OTHER
Acute							
Salisbury et al[144]	2013	II	Odstock, prefabricated AFO	0 for AFO and FES			
Chronic							
Dunning et al[8]	2015	I (SR)	Various	++/+/* for AFO & FES across studies, 0 between AFO & FES	0		↑ satisfaction with FES
Bethoux et al[85]	2014	I	WalkAide, custom solid or articulating AFO	0 between or within	0 between or within		
Kluding et al[76]	2013	I	Bioness, custom AFO	*within groups, 0 between			↑ satisfaction with FES
Kottink et al[118]	2010	I	STIMuSTEP implanted			* FES	DIP/Euro-QOL: * FES
Sheffler et al[148]	2013	I	Odstock, custom articulating AFO with PF stop		* both groups, 0 between		
Schiemanck et al[146]	2015	II/III	ActiGait implanted, hinged custom-molded AFO	0			↑ satisfaction
Wilkie et al[159]	2012	IV	Odstock				↑ via qualitative interviews

Abbreviations: AFO, ankle-foot orthosis; DIP, Disability Impact Profile; FES, functional electrical stimulation; SF-36, Short From 36; SIS, Stroke Impact Scale; SR, systematic review; SSQOL, Stroke-Specific Quality of Life.

[a]Symbols: * = statistically significant, ++ = MCID (minimal clinically important difference), + = MDC (minimal detectable change), 0 = no change.

Appendix Table 5. Gait Speed Acute Ankle-Foot Orthoses[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	AFO TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
NiKamp et al[129]	2017	I	PLS, semi-solid, solid				++/0 between early and delayed groups
Nikamp et al[131]	2017	I	PLS, semi-solid, solid	0			
Salisbury et al[144]	2013	I	Prefabricated				+
Morone et al[126]	2012	II	Unspecified		+/*		
NiKamp et al[130]	2017	II	PLS, semi-solid, solid			++	++/*
Carse et al[92]	2015	III	Custom solid	++/*			
Rao et al[140]	2008	III	Custom molded	+/*			
Lairamore et al[121]	2011	III	PLS, dynamic	0			
Sankaranarayan et al[145]	2016	IV	Custom solid		0/*		+/*

Abbreviations: AFO, ankle-foot orthosis; PLS, posterior leaf spring.

[a]Symbols: * = statistically significant, ++ = MCID (minimal clinically important difference), + = SMC/MDC (small meaningful change/minimal detectable change), 0 = no change.

Appendix Table 6. Gait Speed Acute Functional Electrical Stimulation[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	FES TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Salisbury et al[144]	2013	I	Odstock				+
Wilkinson et al[160]	2014	I	Odstock		++/*		+/*
Morone et al[126]	2012	II	WalkAide		+/*		

Abbreviation: FES, Functional Electrical Stimulation.

[a]Symbols: * = statistically significant, ++ = MCID (minimal clinically important difference), + = SMC/MDC (small meaningful change/minimal detectable change).

Appendix Table 7. Gait Speed Chronic Ankle-Foot Orthoses[a]

AUTHOR & YEAR	YEAR	LEVEL OF EVIDENCE	AFO TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Dunning et al[8]	2015	I (SR)	Various		++/+/0/* across studies	+/0/* across studies	++/* across studies
Beckerman et al[83]	1996	I	Solid w/ 5° DF vs articulating			0	
Bethoux et al[85]	2014	I	Custom solid or articulating				++/*
Bethoux et al[86]	2015	I	Custom solid or articulating				++/*
Erel et al[32]	2011	I	Dynamic				++/*
Everaert et al[72]	2013	I	Custom	+/*	+/*		++/*
Kluding et al[76]	2013	I	Custom	+/*	+/*	+/*	++/*
Tyson and Kent[29]	2013	II (SR/MA)	Solid/articulating	+/* across studies			
Abe et al[79]	2009	II	PLS, articulating	+/*			
de Wit et al[101]	2004	II	Solid	0/*			
Mulroy et al[38]	2010	II	Solid, PF stop with free DF, DF assist with DF stop	0, except + for decline with solid for those with greater DF PROM			
Nolan et al[133]	2009	II	Dynamic, solid, articulating	+/*			
Yamamoto et al[163]	2018	II	Metal upright with oil damper or PF stop				++/* oil damper, +/*PF stop
Pavlik[138]	2008	III	Custom solid, articulating	++/*			
Simons et al[42]	2009	III	3 types of solid, DMU	+/*			
Lewallen et al[123]	2010	III	Solid, articulating, PLS	0 PLS/articulating, * decline with solid			
Gatti et al[104]	2012	III	Custom solid set to neutral	++/*			
Danielsson and Sunnerhagen[98]	2004	III	Carbon composite	+/*			
Mojica et al[124]	1988	III	Solid plastic	++/*			
Yamamoto et al[34]	2011	III	Oil damper	0/*			++/*
Nolan and Yarossi[134]	2011	III	Custom rigid plastic	+/*			
Hwang et al[107]	2012	III	Articulating	0/*			

(*continues*)

Appendix Table 7. Gait Speed Chronic Ankle-Foot Orthoses[a] (*Continued*)

AUTHOR & YEAR	YEAR	LEVEL OF EVIDENCE	AFO TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Rao et al[140]	2008	III	Custom molded	+/*			
Pardo et al[136]	2015	III	Custom, prefabricated articulating	+/* (both)			
van Swigchem et al[156]	2010	III	Plastic				0/*
Wang et al[158]	2007	III	PLS	+/*			
Hung et al[106]	2011	IV	Anterior	0/*			
Fatone et al[13]	2009	IV	3 conditions: (1) PF stop at 0°, full footplate; (2) PF stop at 5°-7° PF, full footplate; (3) PF stop at 0°, ¾ footplate	0			
Fatone and Hansen[103]	2007	IV	90° PF stop with free DF and full footplate	+			
Bouchalova et al[39]	2016	IV	Prefabricated plastic, individualized Y-tech, shoes	0 prefabricated, 0/* Y-tech for those who walked without AD only			
Ohata et al[35]	2010	IV	Oil damper, conventional with PF stop	++/*			
Iwata et al[40]	2003	IV	Solid plastic with inhibitor bar				+/*
Bleyenheuft et al[87]	2008	IV	Chignon, PLS	++/* Chignon, + PLS			
Kobayashi et al[116]	2012	IV	Custom plastic articulated or nonarticulated	++/*			
Boudarham et al[36]	2014	IV	Liberté elastic dynamic	++/*			
Wang et al[157]	2005	IV	Prefabricated solid	+/*			
Yamamoto et al[162]	2015	IV	Oil damper	0/*	0		+/*

Abbreviations: AFO, ankle-foot orthosis; DF, dorsiflexors/dorsiflexion; M, meta-analysis; PF, plantarflexors/plantarflexion; PLS, posterior leaf spring; PROM, passive range of motion; SR, systematic review.

[a]Symbols: * = statistically significant, ++ = MCID (minimal clinically important difference), + = SMC/MDC (small meaningful change/minimal detectable change), 0 = no change.

Appendix Table 8. Gait Speed Chronic Functional Electrical Stimulation[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	FES TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Dunning et al[8]	2015	I (SR)	Surface: various types		++/+/0/* across studies		++/+/* across studies
Bethoux et al[85]	2014	I	WalkAide				++/*
Bethoux et al[86]	2015	I	WalkAide				++/*
Everaert et al[72]	2013	I	WalkAide	0/*	+/*		++/*
Hwang et al[108]	2015	I	WalkAide		+/*		
Kluding et al[76]	2013	I	Bioness	+/*	+/*	+/*	++/*
Kottink et al[51]	2007	I	STIMuSTEP Implanted	+	0	+	++/*
O'Dell et al[135]	2014	I	Bioness	0	++/*		
Kottink et al[28]	2004	II (SR)	Various surface and implanted	0/+/* across studies			
Burridge et al[90]	1997	II	Odstock	0	0	+	+/*
Street et al[73]	2017	II	Odstock	+/*	0/*		++/*
Alon and Ring[80]	2003	III	Bioness		++		
Ernst et al[50]	2013	III	ActiGait implanted	++/*	0		
Kim et al[114]	2012	III	CyberMedic EMS	*			
Nolan et al[132]	2015	III	WalkAide	0			
Sabut et al[55]	2010	III	CyberMedic EMS		+		
Taylor et al[153]	1999	III	Odstock	+/*	+/*		+/*
van Swigchem et al[156]	2010	III	Bioness				*
Barrett and Taylor[82]	2010	IV	Odstock	+	0	0	+
Burridge and McLellan[89]	2000	IV	Odstock	+			++/*
Burridge et al [88]	2007	IV	Odstock	+			+
Granat et al[105]	1996	IV	Single channel	0			
Martin et al[49]	2016	IV	ActiGait implanted	++			
Mun et al[127]	2014	IV	CyberMedic EMS	+			
Robertson et al[141]	2010	IV	WalkAide	0	0		
Sabut et al[142]	2010	IV	CyberMedic EMS		++		
Sabut et al[56]	2011	IV	CyberMedic EMS		+		
Shimada et al[52]	2006	IV	Biotech implanted	+			
Sota et al[151]	2018	IV	WalkAide		+/*		
Taylor et al[18]	2013	IV	Odstock				+
Voigt and Sinkjaer[45]	2000	IV	KDC 2000A	+			

Abbreviation: FES, functional electrical stimulation; SR, systematic review.

[a]Symbols: * = statistically significant, ++ = MCID (minimal clinically important difference), + = SMC/MDC (small meaningful change/minimal detectable change), 0 = no change.

Appendix Table 9. Other Mobility Acute Ankle-Foot Orthoses and Functional Electrical Stimulation[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	DEVICE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
FES							
MacDonell et al[46]	1994	I	Respond II		* FAC and BI, +/++ BI		
Wilkinson et al[160]	2014	I	Odstock		*/+ RMI, 0 compared to usual care		
Morone et al[126]	2012	II	WalkAide		*/+ RMI and BI, ++ BI		
AFO							
NiKamp et al[130]	2017	II	PLS, semisolid, solid				* BI, RMI, and FAC; ++ BI
NiKamp et al[129]	2017	II	PLS, semisolid, solid				* FAC
Morone et al[126]	2012	II	Unspecified		*/+ RMI and BI, ++ BI		
Tyson and Rogerson[154]	2009	II	Prefabricated	* FAC			
Dogan et al[102]	2011	III	Articulating with 90° PF stop	* STREAM (mobility subscale)			
Momosaki et al[125]	2015	III	Unspecified				*/++ FIM
Lan et al[122]	2013	IV	Custom with neutral DF	* FAC			
Sankaranarayan et al[145]	2016	IV	Custom sold		* FIM		

Abbreviations: AFO, ankle-foot orthosis; BI, Barthel Index; DF, dorsiflexors/dorsiflexion; FAC, Functional Ambulation Category; FES, functional electrical stimulation; FIM, Functional Independence Measure; PF, plantarflexors/plantarflexion; PLS, posterior leaf spring; RMI, Rivermead Mobility Index; STREAM, Stroke Rehabilitation Assessment of Movement.

[a]Symbols: * = statistically significant, ++ = MCID (minimal clinically important difference), + = MDC (minimal detectable change), 0 = no change.

Appendix Table 10. Other Mobility Chronic Ankle-Foot Orthoses[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	AFO TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Dunning et al[8]	2015	I (SR)	Various AFO		* mEFAP across studies	*/+ mEFAP across studies	
Bethoux et al[85]	2014	I	Custom solid or articulating			*/+ mEFAP	
Bethoux et al[86]	2015	I	Custom solid or articulating			0 mEFAP	
Everaert et al[72]	2013	I	Custom			*/+ RMI	
Sheffler et al[148]	2013	I	Custom articulating AFO with PF stop		* mEFAP		
Tyson and Kent[29]	2013	II (SR/MA)	PLS, solid, DMU, articulating	* FAC across studies			
Kesikburun et al[113]	2017	II	Custom solid	* FAC			
Sheffler et al[147]	2006	II	Custom	* FAC			
Abe et al[79]	2009	III	PLS, articulating	* FAC			
Hung et al[106]	2011	III	Anterior	* FAC			
Simons et al[42]	2009	III	3 types of solid, DMU	* FAC			
Tyson and Thornton[155]	2001	III	Articulating	* FAC			

Abbreviations: AFO, ankle-foot orthosis; DMU, double metal upright; FAC, Functional Ambulation Category; MA, meta-analysis; mEFAP, Modified Emory Functional Ambulation Profile; PF, plantarflexors/plantarflexion; PLS, posterior leaf spring; RMI, Rivermead Mobility Index; SR, systematic review.

[a]Symbols: * = statistically significant, + = MDC (minimal detectable change), 0 = no change.

Appendix Table 11. Other Mobility Chronic Functional Electrical Stimulation[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	FES TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Dunning et al[8]	2015	I (SR)	Various		*/+ mEFAP across studies	*/+ mEFAP across studies	
Bethoux et al[85]	2014	I	WalkAide			*/+ mEFAP	
Bethoux et al[86]	2015	I	WalkAide			+ mEFAP	
Sheffler et al[148]	2013	I	Odstock		*/+ mEFAP		
Sheffler et al[147]	2006	II	Odstock	* mEFAP			

Abbreviations: FES, functional electrical stimulation; mEFAP, Modified Emory Functional Ambulation Profile; SR, systematic review.

[a]Symbols: * = statistically significant, + = MDC (minimal detectable change), 0 = no change.

Appendix Table 12. Dynamic Balance Acute Ankle-Foot Orthoses[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	AFO TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Nikamp et al[129]	2017	I	PLS, semisolid, solid				
Nikamp et al[130]	2017	II	PLS, semisolid, solid				+/* TUG, * TUDS, +/* BBS
Dogan et al[102]	2011	III	Articulating with 90° PF stop	++/* TUG, 0/* BBS			
Lan et al[122]	2013	IV	Custom with neutral DF	0/0 BBS			
Park et al[137]	2009	IV	Anterior, posterior	0/0 BBS			

Abbreviations: AFO, ankle-foot orthosis; BBS, Berg Balance Scale; DF, dorsiflexors/dorsiflexion; PF, plantarflexors/plantarflexion; PLS, posterior leaf spring; TUDS, Timed Up and Down Stairs; TUG, Timed Up and Go.

[a]Symbols: * = statistically significant, ++ = MCID (minimal clinically important difference), + = MDC (minimal detectable change), 0 = no change.

Appendix Table 13. Dynamic Balance Chronic Ankle-Foot Orthoses[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	AFO TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Tyson and Kent[29]	2013	II (MA)	Various	0 BBS, 0 TUG, 0 TUDS across studies			
Chisholm and Perry[21]	2012	II (SR)	Various	Decreased TUG score with AFO across studies			
Bethoux et al[85]	2014	I	Custom solid or articulating			0/0 TUG, 0/0 BBS	
Erel et al[32]	2011	I	Dynamic				0/0 TUG, 0 TDS, * TUS, 0 FR
Everaert et al[72]	2013	I	Custom	* Figure-of-8 test	* Figure-of-8 test		* Figure-of-8 test
Kluding et al[76]	2013	I	Custom	++/* TUG, 0/* BBS, 0 FR	0/0 TUG, 0/* BBS, 0 FR	0/0 TUG, 0/* BBS, 0 FR	++/* TUG, 0/* BBS, 0 FR
de Wit et al[101]	2004	II	Solid	++/* TUG, 0/* TUDS			
Pavlik[138]	2008	II	Custom solid, articulating				++/* TUG
Bouchalova et al[39]	2016	III	Individual-ized Y-tech vs prefabricated				++/0 TUG, 0 FSST
Chen et al[93]	2014	III	Anterior	++/* TUG			
Pardo et al[136]	2015	III	Custom, prefabricated articulating	++/* TUG			
Simons et al[42]	2009	III	3 types of solid, DMU	++/* TUG, 0/* BBS			
Wang et al[157]	2005	III	Prefabricated	0/0 BBS			
Cakar et al[91]	2010	IV	PLS	0/* BBS, * FR			
Chen et al[93]	2014	IV	Anterior	* TUDS			
Hung et al[106]	2011	IV	Anterior	* FES-I			
Zissimopou-los et al[165]	2014	IV	Nonrigid (various)	* ABC			

Abbreviations: ABC, Activities-Specific Balance Confidence Scale; AFO, ankle-foot orthosis; BBS, Berg Balance Scale; DMU, double metal upright; FES-I, Falls Efficacy Scale-International; FR, Functional Reach; FSST, Four Square Step Test; MA, meta-analysis; PLS, posterior leaf spring; SR, systematic review; TUDS, Timed Up/Down Stairs; TUG, Timed Up and Go; TUS, Timed Up Stairs.

[a]Symbols: * = statistically significant, ++ = MCID (minimal clinically important difference), 0 = no change.

Appendix Table 14. Dynamic Balance Chronic Functional Electrical Stimulation[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	FES TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Dunning et al[8]	2015	I (SR)	Various	* TUG, * BBS across studies			
Bae et al[81]	2014	I	WalkAide with robotic gait training		++/* TUG, 0/* BBS		
Bethoux et al[85]	2014	I	WalkAide			0/0 TUG, 0/0 BBS	
Cho et al[95]	2015	I	CyberMedic EMS with BWSTT			0/0 BBS	
Everaert et al[72]	2013	I	WalkAide	* Figure-of-8 test	* Figure-of-8 test		* Figure-of-8 test
Hwang et al[108]	2015	I	WalkAide		++/* TUG, ++/* BBS		
Kluding et al[76]	2013	I	Bioness	++/* TUG, 0/* BBS, 0 FR	0/* TUG, 0/* BBS, 0 FR	0/* TUG, 0/* BBS, 0 FR	++/* TUG, 0/* BBS, 0 FR
Lee et al[59]	2013	I	Power-assist with BWSTT		++/* TUG, ++/* BBS		
Robertson et al[141]	2010	III	WalkAide	0/0 TUG, 0/0 BBS			
Sota et al[151]	2018	III	WalkAide		+/* TUG		
Kim and Lee[115]	2012	IV	CyberMedic EMS with VR		++/* TUG, ++/0 BBS		
Martin et al[49]	2016	IV	ActiGait implanted	++/* TUG			

Abbreviations: FES, functional electrical stimulation; BBS, Berg Balance Scale; BWSTT, body-weight support treadmill training; FR, Functional Reach; SR, systematic review; TUG, Timed Up and Go; VR, virtual reality.

[a]Symbols: * = statistically significant, ++ = MCID (minimal clinically important difference), + = MDC (minimal detectable change), 0 = no change.

Appendix Table 15. Walking Endurance Acute Ankle-Foot Orthoses and Functional Electrical Stimulation[a]

AUTHOR/	YEAR	LEVEL OF EVIDENCE	DEVICE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
AFO							
Nikamp et al[129]	2017	I	PLS, semi-rigid, or solid				* 6MWT
Nikamp et al[130]	2017	II	PLS, semi-rigid, or solid				++/* 6MWT
Hyun et al[109]	2015	III	PLS	* 6MWT			
FES							
Wilkinson et al[160]	2014	I	Odstock		++/* 6MWT		

Abbreviations: AFO, ankle-foot orthosis; FES, functional electrical stimulation; PLS, posterior leaf spring; 6MWT, 6-minute walk test.
[a]Symbols: * = statistically significant, ++ = MCID (minimal clinically important difference), 0 = no change.

Appendix Table 16. Walking Endurance Chronic Ankle-Foot Orthoses[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	AFO TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Dunning et al[8]	2015	I (SR)	Variable		* 6MWT, *PCI across studies	* 6MWT across studies	*/+ 6MWT across studies
Bethoux et al[85]	2014	I	Custom solid or articulating			* 6MWT	
Bethoux et al[86]	2015	I	Custom solid or articulating			0 6MWT	
Erel et al[32]	2011	I	Dynamic				* PCI
Everaert et al[72]	2013	I	Custom	* PCI	*PCI		* PCI
Kluding et al[76]	2013	I	Custom	* 6MWT	* 6MWT	* 6MWT	*/+ 6MWT
Nolan et al[133]	2009	II	Dynamic, solid, articulating	* 6MWT			
Danielsson and Sunnerhagen[98]	2004	III	Carbon composite	* Energy cost			
Danielsson et al[99]	2007	III	Various	0 PCI; * $\dot{V}O_2$			

Abbreviations: AFO, ankle-foot orthosis; PCI, Physiologic Cost Index; PLS, posterior leaf spring; 6MWT, 6-minute walk; SR, systematic review.
[a]Symbols: * = statistically significant, + = MDC (minimal detectable change), 0 = no change.

Appendix Table 17. Walking Endurance Chronic Functional Electrical Stimulation[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	FES TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Dunning et al[8]	2015	I (SR)	Variable		* 6MWT; *PCI across studies	*6MWT across studies	*/+ 6MWT; *PCI across studies
Bethoux et al[85]	2014	I	WalkAide			* 6MWT	
Bethoux et al[86]	2015	I	WalkAide			* 6MWT	
Cho et al[95]	2015	I	CyberMedic EMS with BWSTT				0 6MWT
Everaert et al[72]	2013	I	WalkAide	0 PCI	* PCI		* PCI
Kluding et al[76]	2013	I	Bioness	* 6MWT	* 6MWT	* 6MWT	*/+ 6MWT
Kottink et al[51]	2007	I	STIMuSTEP implanted				* 6MWT
Kottink et al[28]	2004	II	Variable				*PCI
Burridge et al[90]	1997	II	Odstock	* PCI	*PCI	0 PCI	* PCI
Sabut et al[55]	2010	II	CyberMedic EMS				*PCI
Ernst et al[50]	2013	III	ActiGait implanted		0 6MWT		*/+ 6MWT (6 wk); 0 (12 wk)
Schiemanck et al[146]	2015	III	ActiGait implanted				0 6MWT
Sota et al[151]	2018	III	WalkAide		+/* 6MWT		
Taylor et al[153]	1999	III	Odstock	* PCI	* PCI	* PCI	* PCI
Burridge and McLellan[89]	2000	IV	Odstock	* PCI	* PCI		* PCI
Sabut et al[142]	2010	IV	CyberMedic EMS				* PCI, * EC
Sabut et al[56]	2011	IV	CyberMedic EMS				* PCI

Abbreviations: BWSTT, body-weight support treadmill training; EC, energy cost; FES, functional electrical stimulation; PCI, Physiologic Cost Index; 6MWT, 6-minute walk test; SR, systematic review.

[a]Symbols: * = statistically significant, + = MDC (minimal detectable change), 0 = no change.

Appendix Table 18. Spasticity Acute Ankle-Foot Orthoses and Functional Electrical Stimulation[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	DEVICE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
AFO							
de Sèze et al[33]	2011	I	Prefabricated vs Chignon (articulated, double stop AFO, DF assist)		0 MAS—Chignon and AFO; 0 MAS between		
Morone et al[126]	2012	II	Unspecified		0 MAS		
FES							
Morone et al[126]	2012	II	WalkAide		0 MAS		

Abbreviations: AFO, ankle-foot orthosis; DF, dorsiflexors/dorsiflexion; FES, functional electrical stimulation; MAS, Modified Ashworth Scale.

[a]Symbol: 0 = no change.

Appendix Table 19. Spasticity Chronic Ankle-Foot Orthoses and Functional Electrical Stimulation[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	AFO TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
AFO							
Beckerman et al[84]	1996	II	Custom in 5° DF		0 MAS		
Sankaranarayan et al[145]	2016	IV	Custom solid		0 MAS		
FES							
Sabut et al[55]	2010	II	CyberMedic EMS		0 MAS		
Sabut et al[143]	2011	III	CyberMedic EMS		* MAS		
Sota et al[151]	2018	III	WalkAide		* MAS		
Sabut et al[56] ”	2011	IV	CyberMedic EMS		0 MAS		

Abbreviations: AFO, ankle-foot orthosis; DF, dorsiflexors/dorsiflexion; MAS, Modified Ashworth Scale.

[a]Symbols: * = statistically significant, 0 = no change.

Appendix Table 20. Muscle Activation Acute Ankle-Foot Orthoses[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	AFO TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Nikamp et al[128]	2019	I	PLS, semisolid, solid	0			
Kim et al[184]	2016	II	Solid vs kinesiotape		* ↑ GA, GM, RF, more ↑ with taping		
Lairamore et al[121]	2011	III	PLS vs dynamic	*↓ TA with dynamic vs PLS or no AFO			
Tang et al[152]	2016	IV	Flexible vs rigid wrap	*↑ TA and GA with flexible, 0 for RF and BF			

Abbreviations: AFO, ankle-foot orthosis; BF, barefoot; GA, gastrocnemius; GM, gluteus medius; PLS, posterior leaf spring; RF, rectus femoris; TA, tibialis anterior.

[a]Symbols: * = statistically significant, 0 = no change.

Appendix Table 21. Muscle Activation Chronic Ankle-Foot Orthoses[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	AFO TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Mulroy et al[38]	2010	III	Solid, PF stop with free DF, DF assist with DF stop	* ↑ SOL with PF stop over DF assist; most TA with shoes only			
Boudarham et al[36]	2014	IV	Liberté dynamic elastic	* ↑ TA and GA with AFO, 0 for SOL			
Hesse et al[16]	1999	IV	−10° to 0° DF stops and DF assist	* ↓ TA, ↑ quads over no AFO			
Ohata et al[35]	2011	IV	Oil damper, conventional with PF stop	* ↓ GA in LR w/oil damper (↑ heel rocker)			

Abbreviations: AFO, ankle-foot orthosis; DF, dorsiflexor/dorsiflexion; GA, gastrocnemius; LR, loading response; PF, plantarflexors/plantarflexion; PL, peroneus longus; SOL, soleus; TA, tibialis anterior.

[a]Symbols: * = statistically significant, 0 = no change, − = negative effect.

Appendix Table 22. Muscle Activation Chronic Functional Electrical Stimulation[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	FES TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Kottink et al[119]	2008	I	STIMuSTEP implanted		* ↑ TA and GA, 0 PL and SOL after 24 wk		
Sabut et al[55]	2010	II	CyberMedic EMS		* ↑ TA conduction velocity after 12 wk		
Shendkar et al[57]	2015	III	CEFAR Step II		* ↑ TA amp and conduction velocity after 12 wk		
Jung et al[110]	2013	IV	CyberMedic EMS		* ↑ TA with EMG-triggered FES vs non-triggered after 4 wk		
Pilkar et al[139]	2014	IV	WalkAide		* ↑ TA post 4 wk		
Sabut et al[142]	2010	IV	CyberMedic EMS		* ↑ TA post 12 wk		

Abbreviations: EMG, electromyography; FES, functional electrical stimulation; GA, gastrocnemius; PL, peroneus longus; SOL, soleus; TA, tibialis anterior.

[a]Symbols: * = statistically significant, 0 = no change.

Appendix Table 23. Ankle Kinematics Acute Ankle-Foot Orthoses[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	AFO TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Daryabor et al[20]	2018	II (SR)	Various	+ ↑ DF at LR and SW			
Nikamp et al[131]	2017	II	PLS, semi-solid, solid	+/* ↑ DF at IC, TO, SW (all AFO)			
Pomeroy et al[41]	2016	II	SWIFT cast, standard care		0		
Park et al[137]	2009	IV	Anterior, posterior	+/* ↑ DF with PLS vs none, 0 anterior vs none, 0 between anterior and PLS			

Abbreviations: AFO, ankle-foot orthosis; DF, dorsiflexors/dorsiflexion; IC, initial contact; LR, loading response; PLS, posterior leaf spring; SR, systematic review; SW, swing; TO, toe-off.

[a]Symbols: * = statistically significant, + = MDC (minimal detectable change), 0 = no change.

Appendix Table 24. Ankle Kinematics Chronic Ankle-Foot Orthoses[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	AFO TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
de Sèze et al[33]	2011	I	Chignon, standard	+/* ↑ DF Chignon > Standard	0		
Daryabor et al[20]	2018	II (SR)	Various	+ ↑ DF at LR and SW			
Yamamoto et al[163]	2018	II	Metal upright with oil damper or posterior stop				0/* ↑ DF IC, 0 DF swing
Cruz and Dhaher[97]	2009	III	Solid, articulating	+/* ↑ DF peak SW, TO with AFO			
Kobayashi et al[117]	2019	III	Articulating set at 0°, 2°, 4°, and 6° DF	* DF at IC between settings			
Mulroy et al[38]	2010	III	Solid, PF stop with free DF, DF assist with DF stop	+/*↑ DF IC, SW all AFO, AFO with PF stops led to ↓ PF in stance			
Ohata et al[35]	2011	III	Oil damper, conventional with PF stop	*↑ DF at IC with posterior stop, better timing w/oil damper			
Sheffler et al[150]	2013	III	Custom-molded hinged	+ DF at IC, 0 SW			
Yamamoto et al[34]	2011	III	Oil damper	+/* ↑ DF at IC, pre-SW, SW			+/* ↑ DF at IC, pre-SW, SW
Bleyenheuft et al[87]	2008	IV	Chignon, PLS	+/* DF HS & SW Chignon vs none. No difference with PLS			
Boudarham et al[36]	2014	IV	Liberté dynamic elastic	+/* HS, SW, TO with Liberté			
Chen et al[94]	2010	IV	Posterior, anterior	* DF at IC with posterior compared to anterior and none			
Do et al[37]	2014	IV	Plastic (0 PF stop, free DF); hybrid (same but some fabric)	+/* DF IC and SW with plastic and hybrid vs none			
Fatone et al[13]	2009	IV	3 settings	*all AFOs increased DF at IC and SW			
Fatone and Hansen[103]	2007	IV	90° PF stop with free DF and full footplate	+/* DF at IC and SW			
Kesikburun et al[113]	2017	IV	Custom solid	+/* DF at IC and SW			
Yamamoto et al[161]	2013	IV	Oil damper at 3 settings	+/* DF at IC and SW all oil damper settings vs none			
Yamamoto et al[162]	2015	IV	Oil damper		+ DF at IC		+/* DF at IC and SW
Zissimopoulos et al[164]	2015	IV	Nonrigid (various)	* DF SW			

Abbreviations: AFO, ankle-foot orthosis; DF, dorsiflexors/dorsiflexion; HS, heel strike; IC, initial contact; PF, plantarflexors/plantarflexion; PLS, posterior leaf spring; SR, systematic review; SW, swing; TO, toe-off.

[a]Symbols: * = statistically significant, + = MDC (minimal detectable change), 0 = no change.

Appendix Table 25. Ankle Kinematics Chronic Functional Electrical Stimulation[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	FES TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Kottink et al[120]	2012	I	STIMuSTEP implanted				0
Sheffler et al[149]	2015	I	Odstock		0		
Bae et al[81]	2014	II	WalkAide with robotic gait training		+		
Cozean et al[96]	1988	III	Respond-II		0		
Ernst et al[50]	2013	III	ActiGait implanted	+/* ↑ DF IC, SW			
Kesar et al[112]	2010	III	Custom system	+/* ↑ DF during SW with VFTs			
Lee et al[58]	2014	III	Novastim CU-FS1	+/* ↑ DF SW, IC			
Prado-Medeiros et al[48]	2011	III	Dorsiflex		0		
Sheffler et al[150]	2013	III	Odstock	+↑ DF at IC, 0 SW			
Daniilidis et al[100]	2017	IV	ActiGait implanted	+/* DF in SW and at IC			
Kesar et al[111]	2009	IV	Custom system	+/* DF during SW with doublets *PF at PO			
Voigt and Sinkjaer[45]	2000	IV	KDC 2000A	+/* DF at TO and SW			

Abbreviations: FES, functional electrical stimulation; DF, dorsiflexors/dorsiflexion; IC, initial contact; PF, plantarflexors/plantarflexion; PO, push-off; SW, swing; TO, toe-off; VFT, variable frequency train.

[a]Symbols: * = statistically significant, + = MDC (minimal detectable change), 0 = no change.

Appendix Table 26. Hip and Knee Kinematics Acute Ankle-Foot Orthoses[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	AFO TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Daryabor et al[20]	2018	II (SR)	Various	0			
Nikamp et al[131]	2017	II	PLS, semisolid, solid	*↑ Knee flexion, hip flexion at IC			
Park et al[137]	2009	IV	Anterior, posterior	Knee flex: no difference between AFOs or none			

Abbreviations: AFO, ankle-foot orthosis; IC, initial contact; PLS, posterior leaf spring; SR, systematic review.

[a]Symbols: * = statistically significant, 0 = no change.

Appendix Table 27. Hip and Knee Kinematics Chronic Ankle-Foot Orthoses[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	AFO TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Daryabor et al[20]	2018	II (SR)	Various	0			
Yamamoto et al[163]	2018	II	Metal upright with oil damper or posterior stop				0/* ↑ Knee flexion swing, 0 hip
Gatti et al[104]	2012	III	Custom solid set at neutral	*↑ Knee flexion in SW			
Kim et al[53]	2013	III	Heel cutout, solid	* Solid ↑ hip/foot ER >heel cutout			
Kobayashi et al[117]	2019	III	Articulating set at 0°, 2°, 4°, and 6° DF	* Peak knee extension between settings			
Mulroy et al[38]	2010	III	Solid, PF stop with free DF, DF assist with DF stop	*↑ Knee flexion at IC, LR all AFO			
Sheffler et al[150]	2013	III	Custom-molded hinged	0 Peak hip or knee flexion SW, 0 knee extension in stance			
Yamamoto et al[34]	2011	III	Oil damper	0			0
Bleyenheuft et al[87]	2008	IV	Chignon, PLS	0			
Do et al[37]	2014	IV	Plastic with 0 PF stop, free DF: hybrid (same but some fabric)	0			
Fatone et al[13]	2009	IV	3 settings	0			
Yamamoto et al[162]	2015	IV	Oil damper		0		0
Zissimopoulos et al[164]	2015	IV	Nonrigid (various)	0			

Abbreviations: AFO, ankle-foot orthosis; DF, dorsiflexors/dorsiflexion; ER, external rotation; IC, initial contact; LR, loading response; PF, plantarflexors/plantarflexion; PLS, posterior leaf spring; SR, systematic review; SW, swing.

[a]Symbols: * = statistically significant, 0 = no change.

Appendix Table 28. Hip and Knee Kinematics Chronic Functional Electrical Stimulation[a]

AUTHOR	YEAR	LEVEL OF EVIDENCE	FES TYPE	IMMEDIATE ORTHOTIC EFFECT	THERAPEUTIC EFFECT	TRAINING EFFECT	COMBINED ORTHOTIC EFFECT
Kottink et al[120]	2012	I	STIMuSTEP implanted				0 Knee flexion
Bae et al[81]	2014	II	WalkAide with robotic gait training		*↑ Knee flexion, 0 hip		
Cozean et al[96]	1988	III	Respond-II		0 Change knee flexion		
Kesar et al[112]	2010	III	Custom system	*↑ SW knee flexion with VFTs			
Sheffler et al[150]	2013	III	Odstock	0 Knee flexion SW			
Kesar et al[111]	2009	IV	Custom system	*/− Peak SW knee flexion			
Voigt and Sinkjaer[45]	2000	IV	KDC 2000A	0			

Abbreviations: FES, functional electrical stimulation; SW, swing; VFT, variable frequency train.

[a]Symbols: * = statistically significant, 0 = no change, − = negative effect.