Descriptive Articles Relative to Gait and Mobility Impairment in Multiple Sclerosis	
Title/Author/Year	**Gait impairment and optimizing mobility in multiple sclerosis** **Stevens et al. (2013)[1]**
Main Points:	MS commonly leads to impairment in the function of muscles and sensation which are innervated by the most caudal nerves (feet, legs, and bladder). Gait abnormalities present often and include decreased step length, cadence, joint movement, and increase in variability of gait parameters. These deficits may even be observed in individuals with lower disability (i.e. EDSS ≤ 3.5) Limitations in mobility can present in the stance and/or swing phase of gait, depending on which muscles/joints are affected. The most common form of ankle-foot weakness consists of two characteristics: 1. Weakness of dorsiflexion 2. Motor fatigue caused by conduction block over a period of extended activation and may be associated with increased body temperature or other causes. It has been reported that up to 77% of persons with MS (pwMS) cite fatigue as a significant problematic symptom. This article includes a brief description of several common assessments used by physical therapists in the measurement of gait and balance in pwMS. Treatments for gait-related impairment discussed: 1. Locomotor Training: Body Weight Supported Treadmill Training (BWSTT), Robotic-assisted Gait Training (RAGT) are discussed and compared to conventional over-ground walking training (COGWT). There is limited evidence to support that BWSTT has a positive effect on gait speed, endurance, and QoL in pwMS. There is not enough evidence to support that either BWSTT or RAGT has a clear advantage over COGWT, but the severity of patient disability should be considered. There is limited evidence to support immediate effects of BWSTT and RAGT, but limited carry-over. 2. Functional Electrical Stimulation (FES) There is evidence to support the use of FES in pwMS to treat foot drop secondary to dorsiflexor weakness. A strengthening program may be more beneficial for improving unassisted walking performance than the use of FES alone. FES has been shown to have an immediate and ongoing orthotic effect in short distance and endurance walking tests, but may not be beneficial for individuals with lower walking disability in increasing speed on short walking tests. Contraindications to FES use include patients with a pacemaker, lower motor neuron injury, and skin sensitivity. Compared to AFOs, FES does not provide medial-lateral stability, is costly, takes more effort to use, and does not work for every patient. 3. Medications: - 4AP (narrow therapeutic window) - Ampyra (only ~40% are responders) 4. Orthotics: AFOs are commonly used to address deficits in gait and improve safe ambulation. They are effective in compensating for weakness, restoring energy, and ankle/knee control. Type and design of AFOs and other orthotics depends on the impairments of the individual patient and stiffness and energy storage of the AFO may reduce energy cost of walking in pwMS. **TABLE 2** in the review provides a great resource to guide appropriate prescription of AFOs and other orthotic devices depending on patient deficits and observed gait impairments. Assistive devices and Wheelchair mobility generally discussed in relation to patient appropriateness and recommendations.

Clinical Implications:	This article is a comprehensive review of gait impairment in MS and reports on evidence to support various treatment options for primary deficits that commonly contribute to walking difficulty in MS. It also discusses many useful outcome measures that may help in the quantification or assessment of walking, gait parameters, and balance in patients with MS. Finally, it includes a very helpful table that organizes common deficits seen at the body structure/function level and links these directly with observed gait impairments and then recommended orthotics.
Title/Author/Year	**Ambulatory rehabilitation in multiple sclerosis** **Kelleher et al. (2009)[2]**
Main Points:	Up to 50% of individuals will require assistance with walking within 15 years from diagnosis, and 10% are restricted to a wheelchair. There is a close relationship with walking ability and quality of life in pwMS. This article provides a summary of literature on impairments associated with MS, specifically regarding effects on ambulation, and an overview of treatment techniques and assistive technology that can address ambulation needs in MS. Pathophysiology of MS: Fatigue: - Generally worsens as the day progresses, but not necessarily related to functionality. - Likely to be worse in warmer environments - Addressed with medications, optimizing hydration, nutrition, body weight and aerobic fitness, and keeping a cool body temperature. Spasticity: - Spasticity can be a significant contributor to increased disability - Medications such as baclofen and tizanidine can be beneficial - Cost and benefits of spasticity must be considered in treating or relieving spasticity Ataxia: - Can interfere with truncal balance, extremity dexterity, and transfer and ambulation activities - Balance, coordination, and neuromuscular rehabilitation exercises can be beneficial for sensation, anterior balance, gait parameters, and disability. Balance: - Balance in MS may be affected by deficits in any or all of the systems involved in balance: visual, vestibular, and somatosensory. - Can be further complicated by spasticity and/or weakness Gait in MS: - pwMS typically walk slower with shorter stride length and prolonged double-support time compared to healthy controls. This may indicate a “protective” gait pattern - See more initial contact with midfoot with higher EDSS scores compared to lower scores - Ataxia, weakness, and spasticity can increase the energy consumption of walking. Rehabilitation in MS: Weakness and Exercise: - Resistance and endurance training can result in improvement in muscular strength and aerobic fitness for pwMS, respectively Rehabilitative Technology for MS: Orthosis: - Intended to prevent misalignments and deformities, modify moments at joints, and result in safer and more comfortable ambulation - The primary goal is to provide appropriate external support for stability in stance and enough clearance for swing phase of gait - Coordination, sensation, reflexes, skin and subcutaneous tissue condition should be evaluated prior to prescription - Hand function and vision should also be considered - Other factors are size/weight of orthosis and aesthetics - AFOs are the standard treatment for footdrop in MS FES:

	- Benefits for neurological patients include reduced tone and spasticity, reduced energy cost, and increased fatigue resistance, independence in daily living, and gait improvement Carry-over may be limited in pwMS
Clinical Implications:	This article highlights several contributing factors to gait impairment in pwMS. This stresses the importance of a holistic and comprehensive approach to treatments of gait and balance disturbances in MS based on appropriate evaluation at an individual level. As there has been shown to be a correlation between walking ability and quality of life in pwMS, this is an important dimension to address.
Title/Author/Year	**Orthotics and FES for maintenance of walking in patients with MS** **Wening et al. (2013)[3]**
Main Points:	Drop foot occurring in the swing phase and absence of heel strike at initial contact can significantly alter the gait pattern. Orthotics and FES are two classes of assistive devices that can mitigate deficits in lower extremity and thus decrease walking impairment: 1. Orthotics: - AFOs are most common – designed to compensate for various specific functional limitations of the foot, ankle, and to some extent, the knee. - Always consist of a foot plate and a shin section - Ground reaction AFO – most rigid – no PF or DF and designed to prevent tibial progression in stance to prevent buckling at knee (knee kept in extension) - Resistance to DF and PF decrease with stiffness of design as follows: solid, rigid, semi-rigid, and flexible (posterior leaf spring). - Discusses limited evidence focused on the effects of AFOs on gait speed and functional ambulation, and that in general, benefits may be greater for individuals with more significant gait impairment at baseline. - Suggest that a low-profile dorsiflexion-assist, free plantarflexion AFO , although unconventional, may be well suited for many pwMS. 2. FES: Benefits: light weight, low profile, unrestrictive, potential slowing of atrophy, continued activation of cortical motor areas associated with walking - Orthotic effect: “the difference in walking ability at any given time between the with FES and without FES conditions. - Therapeutic Effect = “The improvement, caused by FES use, over time in the function measured without the FES device” - Indications: upper motor nerve lesions, able to achieve neutral DF, skin tolerance to electrodes, cognitive ability to manage technology, realistic expectations - Contraindications: “lower motor neuron injury, localized malignancy, plantar flexion contracture, and internal fixation around the knee of the affected limb. Patients with cardiac pacemaker, deep brain stimulator, or who are pregnant, or experience seizures should seek physician approval prior to an evaluation for FES technology.”
Clinical Implications:	This is a great resource to generally compare and contrast the use of AFOs and FES to address foot drop in multiple sclerosis. General indications and contraindications are reviewed for each assistive device category. AFO choices vary primarily based on individual impairments, but generally should also consider issues related to weight, heat dissipation, and stiffness in prescription practices. FES is an alternative treatment that could be appropriate for certain, but not all patients. In general, the authors conclude that FES may have a greater potential for pwMS to regain and/or maintain walking function than an AFO. They also caution that FES is considerably more expensive, requires more cognitive energy, and places additional burden in follow-up maintenance. Furthermore, there is limited evidence to support that FES has a therapeutic effect for patients with MS.
Synthesis:	These three descriptive review articles were found to be great general resources for broad coverage of gait impairment in multiple sclerosis. The Steven et al. and Kelleher et al. articles offer a more comprehensive coverage of prevalence, significance, assessment and treatment of gait impairments in pwMS, while the Wening et al. article focuses primarily on the use of AFOs and FES to address foot drop. In particular, the Stevens et al. review offers a very helpful table (Table 2)(PAGE) that is a great clinical resource to understand commonly observed gait impairments due to specific body structure/function level impairments with basic recommendations for specific orthotic designs.

	The literature supports that pwMS commonly report walking difficulty due to a variety of reasons, often lower extremity weakness, and that this may be observable in persons with lower disability according to EDSS scores. This underscores the importance of determining early and effective rehabilitative interventions. Given the neurodegenerative nature of MS, emphasis is placed on avoiding the limitation of available functions when choosing orthotics. For example, not blacking active plantarflexion in a patient that displays isolated dorsiflexion weakness. From available evidence, both AFO and FES are supported in their benefits in orthotic effects for pwMS that may lead to increased walking ability (speed, distance, energy cost). Some evidence suggests exercise to strengthen lower extremities may be more beneficial than FES alone in therapeutic effects for walking, as FES has not been shown to have significant carry-over in patients with MS. It may be inferred from this general information that FES, given its mechanism of action, only provides this orthotic effect in the swing phase of gait (during stimulation). Given the immense heterogeneity in patient clinical presentation in MS, one must consider the entire clinical picture on an individual basis and benefits and disadvantages of orthotics and FES in addressing foot drop, a swing phase impairment, in MS. Fatigue is another common symptom reported in MS, and must be considered when choosing foot drop treatment options.

Outcome Measures Used to Assess Walking in Multiple Sclerosis:

Title/Author/Year	Evaluating walking in patients with multiple sclerosis: which assessment tools are useful in clinical practice? Bethoux and Bennett. (2011)[4]		
Design:	**Outcomes Assessed/Discussed:**	**Results:**	**Conclusions/Clinical Implications:**
Literature Review	• EDSS • Hauser Ambulation Index • Dynamic Gait Index (DGI) • Rivermead Visual Gait Assessment (RVGA) Timed Walking Tests: • 10-meter Walk Test (10mWT) • Timed 25-ft Walk (T25FW) • 6-minute Walk Test (6MWT) • 2MWT • Timed Up and Go (TUG) • Six Spot Step Test (SSST) Quantitative Gait Analysis Physiologic Cost Index (PCI) Patient Report Outcomes: • Multiple Sclerosis Walking Scale (MSWS-12)	The EDSS and HAI may not be clinically useful to assess walking performance on a routine basis in MS due to suboptimal responsiveness, cumbersome administrations, and relatively low sensitivity and reliability. The T25FW test has been extensively validated in MS and is a useful assessment of walking performance over a short distance. As such, it may not be ideal for individuals with lower disability levels. It has been deemed responsive, with a 20% MCID as measured compared to clinically observable changes in walking and patients' perception of change. Additionally, the T25FW has high practical value since it requires little time and space. The 6MWT correlates strongly with the EDSS, MSFC, and MSWS-12. It also correlates strongly with the T25FW but is a better measure of walking endurance. It may be overly burdensome for some pwMS, and so the 2MWT is a shorter alternative that may be more feasible but remains to be properly validated in MS. Practical limitations for longer distance tests are primarily space related. The SSST includes more coordination and balance and may be viewed as a more comprehensive walking assessment. It has shown high correlation with the EDSS and T25FW, but less so with the MSWS-12. Its psychometrics and specific use has not yet been defined.	This narrative review summarizes several outcome measures that are commonly used to assess walking ability in pwMS. Recommendations to choose valid, reliable, responsive, and clinically practical measures should be noted. Timed walking tests, particularly the T25FW, can be quick objective measures, that have been shown to have favorable responsiveness to change. Additionally, the use of a longer walking test such as the 6MWT or 2MWT should be incorporated to assess walking endurance, along with a measure of energy cost such as the PCI, given the prevalence of fatigue as a confounding impairment in MS. The authors recommend short walking tests be performed from a static start at the fastest and safest pace. Of final importance, the self-report MSWS-12 should be included in the assessment of walking as a uselful measure of a patient's perception of theor walking ability. The T25FW and MSWS-12 are recommended to be regularly implemented in clinical practice to assess walking ability in MS.

		The MSWS-12 has been extensively validated with high internal consistency, reliability and validity, responsiveness, and generalizability. It is less prone to floor and ceiling effects	
Title/Author/Year	**Walking measures to evaluate assistive technology for foot drop in multiple sclerosis: A systematic review of psychometric properties.** **Andreopoulou et al. (2018)[5]**		
Design:	**Outcomes Assessed:**	**Results:**	**Conclusions/Clinical Implications:**
Systematic Review: Search involved a two-step process in which the first (preliminary) search was used to identify studies assessing FES or AFO used in pwMS and to extract data regarding outcome measures used in identified studies. The second search (principle) was conducted to identify studies that evaluated the psychometric properties of the outcome measures identified in the first study, restricted to those concerned with walking performance, effort of walking, and lower limb function in pwMS.	The principal search yielded reporting of psychometric properties of 10 outcome measures: - MSFC - MSWS-12 - spatiotemporal parameters - 10mWT - T25FW - 2 min Walk Test (2MWT) - 6MWT - Rate of Perceived Exertion (RPE) - peak oxygen uptake (VO2peak) - reaction time/movement time (RT/MT)	Of the 10 outcome measures: MSWS-12: found to have strong evidence for internal consistency and test-retest reliability T25FW: strong evidence for construct validity 6MWT: moderate evidence for test-retest reliability and responsiveness 10mWT: moderate evidence for responsiveness Shorter distance walking tests (i.e. 10mWT and T25FW) may be classified as reliable but may not be able to assess benefits of FES for pwMS with lower levels of disability	Of the 10 outcome measures included in the analysis of this systematic review, the psychometric properties of the MSWS-12, T25FW, and to a lesser degree, the 6MWT, indicate their utility as favorable walking ability assessments for pwMS. Methodological limitations in the included studies should be considered. For example, “analysis and reporting of the psychometric properties of outcome measures is often innapropriate.” Furthermore, many studies used the EDSS as a “gold standard” to evaluate outcome measures. The EDSS has become increasingly criticized and its reliability and validity questioned. Limitations in the current review were reported including use of the COSMIN checklist which was developed to be used to assess patient-report outcome measures, not performance based measures, publication bias by language criteria, and the inclusion of studies which mostly had participants with higher EDSS scores which may have affected the reliability and responsiveness of walking performance measures used.
Synthesis	The above articles summarize several of the same and most common outcome measures that are used in clinical practice to assess the walking ability of a person with MS. The Bethoux and Bennett article, a narrative review concerned more with clinical utility, makes a poignant recommendation that measures should be reliable, valid, and responsive, but also have feasibility and practicality to be used		

	regularly in a clinical setting. Ideally, more than one measure should be used in order to more comprehensively assess walking ability. Objective, short and long walking performance tests, and subjective self-report measures should be chosen. The systematic review by Andreopoulou et al. was focused on assessing the psychometric properties of many of the same assessment tools. Ultimately, both articles support the same clinical conclusion and measures: use of the T25FW, 6MWT (or possibly 2MWT), and the MSWS-12 are most highly recommended and practical in clinical use while also having favorable psychometric properties. While Quantitative Gait Analysis (QGA) using motion sensor analysis is referred to as the "gold standard" in walking assessment, this technology carries high cost, equipment, and training burden This makes it an impractical assessment tool in the clinical environment, mostly suited for the research setting at this time. The systematic review notes that most studies did not properly report standard error of measurement or responsiveness such that values like the MCID were not reliably determined or reported at all. This does not disqualify these measures from clinical use, but indicates that higher quality psychometric studies should be performed in order to better guide clinical implementation of these measures.

INTERVENTION STUDIES: AFOs, FES, and Exercise for foot drop in MS

Title/Autor/Year	**Six-Minute Walk Test Performance in Persons With Multiple Sclerosis While Using Passive or Powered Ankle-Foot Orthoses** **Boes et al. 2018[6]**		
Purpose/Design/Subjects	**Interventions/Outcomes**	**Results:**	**Conclusions**
Purpose: "To determine whether a powered ankle-foot orthosis (AFO) that provides dorsiflexor and plantar flexor assistance at the ankle can improve walking endurance of persons with multiple sclerosis (MS)." Design: quasi-experimental intervention Subjects: 16 pwMS with daily use of a prescribed custom passive AFO 12 women, 4 men Mean age: 54.6±5.3 years Median EDSS score: 5.75 (interquartile range 4-6) Type of MS: PPMS (n=4), RRMS (n=7), SPMS (n=5) AD use: single-point cane (n=4), 2-wheeled walker (n=1), 4-wheeled walker (n=3), walls and arms of caregivers (n=2), and none (n=6).	Methods: Each subject performed the 6MWT under three conditions 1. shoes only 2. patient-prescribed passive AFO 3. PPAFO Procedure: 20 minute training session with PPAFO for accommodation and programing of device 6MWT was completed under each condition with a minimum 10 minute rest between conditions Shoe only was performed first as a baseline Other two conditions (AFO, PPAFO) were randomized and counter-balanced across participants Outcomes Measured: 1. 6MWT distance 2. metabolic cost of transport (CoT) during the 6MWT (used VO2net and VCO2net values from portable metabolic unit in a modified Brockway equation)	The PPAFO resulted in significantly less distance walked in the 6MWT compared to AFO and shoes only. The prescribed AFO condition resulted in the furthest distance walked and less CoT than other two conditions. There was no significant difference in CoT between conditions.	Most AFOs are designed to limit the foot drop such that they impede plantar flexion needed for adequate propulsion during walking. The investigators used a portable powered AFO (PPAFO) with bidirectional (plantarflexion and dorsiflexion) assistance capabilities. The modified Brockway equation used to calculate CoT accounts for additional mass of PPAFO and controller unit (worn on participant's chest). This study failed to demonstrate an increased benefit in walking and energy expenditure with the use of a PPAFO, and indicated that conditions favored the use of a patient-prescribed AFO. Confounders may have contributed to the obtained results such as lack of extended training with new device, additional weight of PPAFO device and controller, amount of baseline daily use of each prescribed AFO, and higher disability of participants limiting gait adaptation or improvement. The average outcomes for 6MWT distance in this study cohort were well below normative data for geriatric and chronic stroke populations, which should be considered.
Title/Autor/Year	**Polypropylene ankle foot orthoses to overcome drop-foot gait in central neurological patients: A mechanical and functional evaluation.** **Bregman et al. 2010[7]**		
Purpose/Design/Subjects	**Interventions/Outcomes**	**Results:**	**Conclusions**

Purpose: to assess the functional effects and mechanical contribution of Ankle Foot Orthoses (AFO) prescribed to overcome drop-foot gait. Design: Cross-sectional, quasi-experimental Subjects: N=7 (MS=3, Stroke=4) Inclusion criteria: chronic stroke or MS, prescribed a Dynafo or Orteam AFO within the last 3 years for assistance with swing phase impairment. Required to be able to walk faster than 0.5 m/s	Methods/Procedure: Participants walked with shoes only and with shoes and AFO for 6 min each condition with a 10 min rest period between. Order of conditions was randomized. Mechanical characteristics of AFOs were assessed using the BRUCE device. Each participant underwent Berg Balance Scale (BBS) screening and spasticity assessment (SPAsticity Test – SPAT) for soleus and gastrocnemius muscles. 3-D gait analysis was also performed with shoes only and with AFO on 10-m walkway, 3 trails each condition. Outcomes Measured: 1. Energy cost of walking 2. AFO mechanical characteristics 3. Gait kinematics and kinetics	AFOs resulted in a significant (12.1%) reduced energy cost of walking and a significantly higher walking speed (0.10 $\pm$ 0.12 m/s greater) In subjects that benefited from AFO, they were observed to have altered ankle kinematics, moments, and torque as a result of the AFO compared to the non-benefit group. There was not a significant effect of the AFO on knee or hip kinematics in the benefit group.	Those participants who already walked with the ankle in a neutral position during swing phase with no AFO did not benefit functionally from AFO use in terms of reduced energy cost. Furthermore, those individuals with less disability, benefited the least from AFO use. The average stiffness of AFOs in this study was relatively small, and could have influenced the lack of observed contribution to ankle joint kinematics. The small and heterogeneous sample makes this study limited in generalization. Overall, this study found that the mechanical contributions of the AFOs used (low-stiffness) were low, but adequate to prevent foot drop in swing phase. However, there was a clear link between the mechanical effect and cost of energy in walking which indicates the importance of proper AFO prescription based on individual patient characteristics. It should be noted that only 3 of the participants had MS, and those with lower walking speed without an AFO benefited the most in terms of speed and cost of energy when using the AFO. Larger studies with stronger design are desired to further support the matching of AFO mechanical characteristic with patient mechanical deficits to strengthen orthotic prescription practices. This study does support the use of AFOs for patients experiencing foot drop due to mechanical impairments causing foot drop to increase walking speed and decrease energy cost, especially

			those with lower walking speed at baseline. This study neglects the potential contribution of fatigue on walking and joint kinematics that may occur in pwMS, potentially missing the important and increasing contribution of an AFO with more prolonged activity. Since gait analysis was performed on a shorter track and not during the 6-minute walking trials, this was likely not captured in the participants with MS.
Title/Autor/Year	**Perceived Exertion Is Lower When Using a Functional Electrical Stimulation Neuroprosthesis Compared With an Ankle-Foot Orthosis in Persons With Multiple Sclerosis** **Khurana et al. 2017[8]**		
Purpose/Design/Subjects	**Interventions/Outcomes**	**Results**	**Conclusions**
Purpose: to compare the energy cost, efficiency, and perceived exertion of walking with FES and an AFO in patients with MS and foot drop Design: cross-over counterbalanced quasi-experimental Subjects: n=22, 20 participants with foot drop due to MS completed the study and were included in the analysis Mean age: 54.6 (32-74) years • EDSS: 5.5 (4.0 – 6.0) • Fatigue Severity Scale: 5.4 (1.8 – 7.0) • Falls Efficacy Scale: 46.5 (13 – 91) • 11 females	Methods/Procedures: Testing was completed on 2 separate visits 1-4 weeks apart. Each visit participants performed 2 walking trails (3-10min), one with an AFO and one with FES. There was a 1-hour rest break between trials. The order of the trial conditions was randowized on the first visit and counter-balanced on visit 2. Participants either used their personal AFO or an off-the-shelf AFO was provided. In the FES condition, a physical therapist walked with each participant and manually delivered stimulation at the proper phase of the gait cycle. Outcomes measured: Primary: 1. Borg RPE 2. Caloric expenditure (“energy”) 3. Metabolic efficiency (“efficiency”) Secondary: - Walking time, distance and speed - Heart rate elevation, VO2, and pulmonary ventilation	15/20 participants consistently reported less perceived exertion when using FES compared to AFO (mean difference =1.63; CI, 0.49 – 2.76). Energy and efficiency measures were not found to differ significantly between conditions. • Mean Duration showed a trend towards significantly increased time walked while using FES: ○ Within-Subjects Difference Mean = 36.25s (-2.26 to 74.76), P=0.06 • Mean Distance and speed were higher in FES but not significant: ○ Within Subjects Difference Mean - Distance: 28.57m (-11.79 to 68.92), P=0.16 ○ Within Subjects Difference Mean - Speed: 0.03m/s (-0.03 to 0.08), P=0.29 There was also an association demonstrating that individuals with higher Falls Efficacy Scale scores and longer time since diagnosis were more likely to report lower RPE with FES use.	The authors concluded that the use of FES was effective in leading to statistically and clinically significant less perceived effort (RPE) compared to the AFO, and that this effect was not dependent on device order as more patients consistently reported lower RPE scores for the FES across trials and visits. They conclude that the association of the Falls Efficacy Scale and time since diagnosis may suggest that patients with a longer diagnosis and higher fear of falling may benefit from FES more than AFO for improving activity levels secondary to fatigue and foot drop. They warrant caution with interpreting results in light of study limitations, suggesting need for future longitudinal trials to compare effects of these different devices. Comments:

• MS subtypes: 14 relapse-remitting, 2 primary progressive, 4 secondary progressive • Time since diagnosis, years: 8.8 (0.17 – 22) • 6 patients had their own AFO previously, which was used in the study • 2 patients owned and used a FES device previously			Although this is a small convenience sample study with some methodological limitations, it does reveal that FES may be "perceived" as limiting the exertion that pwMS experience with walking for prolonged periods. This was especially noted with participants who reported higher fear of falling and had been diagnosed for longer duration. Overall, participants trended toward longer duration and distance and faster walking with use of FES compared to AFO. Studies with better design (i.e. more complete baseline data), including a no-device condition, and longer follow-up are desired to strengthen conclusions of this study. It should be noted that 7 of the participants had bilateral foot drop, and as a group the participants displayed slow walking speeds under both conditions, 0.57m/s and 0.55 m/s with FES and AFO, respectively.
Title/Autor/Year	**A randomized trial to investigate the effects of functional electrical stimulation and therapeutic exercise on walking performance for people with multiple sclerosis** **Barrett et al. 2009[9]**		
Purpose/Design/Subjects	**Interventions/Outcomes**	**Results**	**Conclusions**
Purpose: assessed the effects of single channel common peroneal nerve stimulation on objective aspects of gait relative to exercise therapy for people with secondary progressive multiple sclerosis (SPMS). Design: Randomized control trial Subjects:	Methods/Procedures: Two-group randomized 18-week trial FES group (n=20): use of the Odstock Dropped Foot Stimulator (ODFS) according to best clinical practice with increased daily wear times to reach unrestricted at 2 weeks. Exercise group (n=24): simple home exercises aimed at improving trunk and pelvis stability, lower limb muscle length and strength, and balance and control of movement in various positions from lying to standing. Exercises were chosen by physical therapists from a list	The only significant between-group difference observed after 18 weeks was for 10mWT gait speed: the exercise group walking faster than the FES-assisted group (+0.08m/s, 0.01-0.15), p=0.028 The FES group did not show any significant within-group changes for any measures with or without stimulation. However, when comparing the two conditions within the FES group, active FES showed significant increases in gait speed and distance in 3 min. compared to no FES, but no difference in PCI. For the exercise group, a	The results indicate that a simple home exercise program may be more beneficial in providing therapeutic effects that lead to increase in gait speed and endurance in walking performance in persons with SPMS. There was no significant difference in PCI values among groups and thus no conclusions can be drawn in favor of either intervention in regards to energy expenditure. Comments:

N=44, diagnosis of SPMS and unilateral foot drop	as appropriate for each individual. To be performed 1-2x daily for 30 min at home. After initial week with set-up, instruction, and practice (2 appointments), follow-up assessments were performed at 6, 12, and 18 weeks and plans/devices were adjusted as appropriate. Assistive devices were allowed as long as consistent. Outcomes measured: 10mWT (gait spead) Physiological Cost Index (PCI) Distance walked in 3 minutes (3MWD)	significant increase in both walking speed and distance walked in 3min was observed within-group.	Exercise was shown to be more beneficial in leading to improvements in walking performance in a cohort of persons with SPMS. FES was not observed to result in therapeutic effects such as has been observed in patients experiencing foot drop following stroke. FES was, however, associated with a significant orthotic effect with device use. The amount of walking during each follow-up session should be considered as potentially leading to fatigue and affecting the results of walking performance tests. This study did not perform intention-to-treat analysis as most data was missing for participants who did not finish the study, and there was a lack of blinding. It should also be considered that the FES group demonstrated higher mean walking speed at baseline, 0.79 m/s vs 0.68m/s in the exercise group, a factor which has been shown to possibly affect the objective gait improvements of pwMS to FES.
Title/Autor/Year	**Functional Effect of an Ankle Foot Orthosis on Gait in Multiple Sclerosis** **Sheffler et al. 2008[10]**		
Purpose/Design/Subjects	**Interventions/Outcomes**	**Results**	**Conclusions**
Purpose: to determine whether an ankle foot orthosis improves gait velocity and tasks of functional ambulation in multiple sclerosis (MS). Design: cross-sectional quasi-experimental Subjects: n=15 3 male, 12 female Average age: 51.3 (37-69) years	Methods/Procedures: Subjects performed T25FW and components of the Modified Emory Functional Ambulation Profile (mEFAP) under two conditions: first with no dorsiflexor assistive device, second with an AFO. Subjects underwent baseline sensory testing (light touch), muscular strength assessment, and balance assessment (BBS) without AFO prior to ambulation testing. Outcomes measured: 1. T25FW	There were no significant differences in any outcomes with or without the AFO. Comparison of mean times for measures revealed that mEFAP carpet and floor components and T25FW times were less with the use of an AFO but not statistically or clinically significant.	There was no significant increase in gait velocity or timed performance of mEFAP functional ambulation components with the use of an AFO compared to no AFO in the study subjects. None of the covariables explained differences in performance using regression analysis. Comments:

Median time since diagnosis: 7.0 (1.4-16) years MS Type: 12 RRMS, 3 SPMS >6 mos post-diagnosis Evidence of dorsiflexion and eversion weakness At least 3 mos prior experience ambulating with a prescribed AFO Ability to ambulate a min of 30 ft with minimal assistance or less without use of AFO Exclusion: absent sensation in ipsilateral lower limb, ankle PF contracture, concomitant neurological diagnosis, significantly impaired cognition, or medical instability	2. mEFAP ((1) 5-m walk on a hard floor; (2) 5-m walk on a carpeted surface; (3) rising from a chair, 3-m walk, and return to a seated position (the "timed up-and-go" test); (4) standardized obstacle course; and (5) stair ascent and descent. * Each component evaluated as individual scores for the study Times scores were analyzed for each condition and statistically compared to type and duration of MS, Berg Balance score, selected lower-extremity motor scores, contralateral lower-extremity motor deficit, ipsilateral sensory deficit, and AFO type		Most of the subjects, with the exception of Subject 1, showed only modest gait impairment with no device at baseline, which may have contributed to little observed benefit from AFO use on the outcomes assessed. 4 of the subjects also had contralateral motor deficits and all but 4 subjects had hip flexion strength 3 or less. The outcomes used in this study utilize relatively short walking distances and therefore may not capture differences in performance as well as longer ambulation tests. Subjects averaged a greater time on the TUG with the use of an AFO, and the authors imply that this could theoretically be due to restrictions in necessary ankle ROM for sit-to-stand by an AFO depending on type. However, those individuals with a hinged AFO type did not consistently perform better on this measure, indicating that other factors may be contributing (i.e. strength, balance, assistive device use). Finally, the AFO condition was performed second for every subject, and one cannot rule out the effects of either a learning effect or conversely, the effects of fatigue. Overall, this study does not strongly support that AFOs result in significant benefits in regards to gait velocity or functional ambulation tasks, but it should be considered that most of the subjects were minimally impaired in these measures at baseline and other factors may explain the lack of benefit observed. Further study should include gait kinetics and

			kinematics, longer ambulation tests, and energy cost of walking.
Title/Autor/Year	**Spatiotemporal and Kinematic Effect of Peroneal Nerve Stimulation Versus an Ankle-Foot Orthosis in Patients With Multiple Sclerosis: A Case Series** **Sheffler et al. 2009[11]**		
Purpose/Design/Subjects	**Interventions/Outcomes**	**Results**	**Conclusions**
Purpose: To compare the effect of a surface peroneal nerve stimulator (PNS) versus an ankle-foot orthosis (AFO) on spatiotemporal and kinematic parameters of gait in patients with multiple sclerosis. Design: Case series, quasi-experimental intervention Subjects: n=4 Inclusion criteria: diagnosed with MS >6 mos, ankle DF strength ≤ 4/5, and previous use of physician-prescribed AFO Able to ambulate at least 30 ft continuously with minimal assistance or less without AFO Exclusion criteria: absence of sensation in the ipsilateral lower extremity, ankle plantarflexion contracture, ataxia evident on ambulation, concomitant neurologic diagnosis, severely impaired cognition, or medical or neurological instability.	Methods/Procedures: Each subject underwent quantitative gait analysis under 3 conditions with rests between each trial: - No device - AFO (previously physician-prescribed) - PNS (ODFS) Subjects were required to complete a familiarity and usage period with the PNS (minimum of 4 weeks daily use for ambulation) Condition order was not randomized with the PNS condition performed last to "eliminate the concern that the "no device" or AFO performance might have been enhanced by a "carryover" effect from the previous application of the PNS device." Walking trials were 10 meters at self-selected speed, and with appropriate assistive device for safety. Outcomes measured: Spatiotemporal measures: walking speed, stride length, cadence, double support time Kinematic parameters: peak pelvic obliquity during swing, peakcontralateral hip abduction during stance, peak knee flexion and hip flexion during swing,ankle dorsiflexion at initial contact, and peak ankle internal rotation during swing.	The ankle dorsiflexion angle was significantly greater for the PNS condition for 3 of 4 subjects. The other spatiotemporal and kinematic parameters were variable among subjects and conditions.	PNS and AFO had variable effects on spatiotemporal and kinematic parameters in the subjects of this case series. PNS explained a significant increase in dorsiflexion angle at initial contact in 3 out of 4 subjects. Further study with larger sample size, controlling for baseline characteristic differences, and more accurate QGA practices is required to determine the clinical significance of observed results Comments: Subject 1 had less limitation in DF and eversion strength, which may explain the lack of significant difference in ankle DF at initial contact between no device and AFO conditions. Subject 2 had the most impaired DF and Eversion strength and showed the most improvement in spatiotemporal measures with PNS compared with other conditions. Subjects 3 and 4 did not show any significant spatiotemporal differences between conditions. It should also be noted that 3 of the 4 subjects are only mild-moderately below normal walking speed with no device, while Subject 2 is severely below normal walking speed (0.23 m/s). This, and other variability in subject disability and impairments may likely explain such variable results. While this study may indicate statistical significance in

			differences between conditions, it really does not allow inference of any clinical significance. For example, the greatest difference observed for gait speed between conditions was 0.05m/s.
Title/Autor/Year	**Dorsiflexion Assist Orthosis Reduces the Physiological Cost and Mitigates Deterioration in Strength and Balance Associated With Walking in People With Multiple Sclerosis** **McLoughlin 2015[12]**		
Purpose/Design/Subjects	**Interventions/Outcomes**	**Results**	**Conclusions**
Purpose: To evaluate the effect of wearing a dorsiflexion assist orthosis (DAO) on walking distance, physiological cost, fatigue, and strengthand balance measures after a modified 6-minute walk test (6MWT) in people with multiple sclerosis (MS). Design: Randomized crossover trial. Subjects: n=34, 26 women Mean age: 49.1 ± 10.4y EDSS: 3.7 ± 0.7 (3-6) Time since diagnosis: 8.2 ± 7.9y Inclusion criteria: (1) a diagnosis of MS; (2) a moderate level of disability, although able to ambulate as indicated by an Expanded Disability Status Scale (EDSS) score of 3.0 to 6.0 (www.neurostatus.neta); and (3) able to walk for 6 minutes un-aided or with a walking stick. Exclusion Criteria: (1) reported an exacerbation of MS within the past 3 months; (2) used prescribed medication for	Methods/Procedures: Modified 6MWT was performed with a Foot-up DAO device and without Participants were randomized to condition order and performed the second assessment within 2 weeks. Pre and post-assessments of strength, standing balance, and self-report fatigue were completed at each visit. Outcomes measured: Modified 6MWT: walk back and forth on 10m walkway as fast as possible 1. 6MWD 2. PCI 3. Perceived fatigue (VAS) before and after Secondary measures: 1. knee extensor strength 2. dorsiflexor strength 3. Postural sway 4. spatiotemporal gait parameters (speed, cadence, stride length over 10m walkway pre and post 6MWTs)	There was not a significant difference in 6MWD between conditions. There was a significantly reduced PCI (-7%) with DOA use compared to without. Fatigue increased for both conditions, but less with DOA use (not significant between conditions). Less reduction in knee extensor strength and less increase in postural sway was observed after the DOA condition.	Wearing a DAO device did not significantly reduce perceived fatigue or increase 6MWD, but reduced the physiological cost of walking and lessened the effects on knee extensor strength and postural control after the modified 6MWT. This may have important implication in rehabilitation of ambulation and mobility in pwMS Comments: The DAO device shows promise in assisting with drop foot in pwMS and may serve to limit the effects of fatigue during prolonged walking in mildly impaired patients. More research is needed to determine the orthotic effects and kinematic and kinetic implications an whether these are clinical significance. Future research should also compare this device design to other available treatments for foot drop in MS (i.e. AFO and FES). Overall the DAO device showed trends towards preserving knee and ankle strength after prolonged walking, and decreasing postural control deterioration and physiological cost of functional ambulation. The subjects in this study were only slightly impaired in walking speed at baseline with no device

mobility or fatigue such as fampridine, amantadine, or modafinil; (3) had significant cardiac or respiratory illness; (4) suffered from severe depression; or (5) had musculoskeletal impairments and/or pain that severely limited walking			(1.15m/s) which may have limited the potential for benefits from intervention. Future research should include participants with more impaired walking. Why wouldn't posterior leaf spring AFO design accomplish similar results?? Compare to Bregman study results in synthesis
Synthesis:	Overall, there is a paucity of evidence that focuses on the use of AFOs and/or FES for addressing foot drop in MS, despite AFOs being the standard treatment choice in this population. The evidence included in the above articles suggest that both AFOs and FES are effective treatment options for pwMS with foot drop secondary to dorsiflexor weakness, and that they may both result in increases in gait speed and distance, and a decrease in the objective physiological cost of walking. The study by Bregman et al., which only included 3 participants with MS and focused on polypropylene AFOs of the posterior leaf spring type, demonstrated that walking with an AFO resulted in increased gait speed and reduced energy cost in 2 participants.[7] It should be noted that the pwMS in this study that did not show a benefit (nor a loss) was able to walk nearly twice as fast as those that did (1.13 m/s vs. 0.48 and 0.52 m/s).[3,7] AFOs resulted in a significant (12.1%) reduced energy cost of walking and a significantly higher walking speed (0.10 $\pm$ 0.12 m/s greater) in the study group overall, which included 4 participants post-stroke. A potential significant design flaw in this study is the use of a 6MWT for physiological cost of walking measure but not spatiotemporal analysis. The latter was performed after the 6MWT and a rest period and over a shorter walking distance. This may neglect the spatiotemporal and kinematic effects of an AFO in subjects as they experience fatigue in prolonged walking. The 2008 study by Sheffler et al. not only assessed gait speed, but also functional aspects of ambulation. Overall the results favored the use of an AFO for all measures except the TUG assessment, indicating that AFOs may lead to increases in gait speed and functional mobility in pwMS. As in the Bregman study, the participant with the most significant limitation demonstrated the most benefit with AFO use. Again, in the study by Boes et al., there is evidence to support the benefits of AFO for walking distance and energy cost in comparison to no device and a portable powered AFO (PPAFO) intended to assist with dorsiflexion and plantarflexion. The advantages of the AFO vs no device in this study were not statistically significant, but the subjects were mostly of higher disability and many used assistive devices to walk, which may have led to limited benefit of the studied interventions including the prescribed AFO. Finally, McLoughlin et al. studied the effects of a dorsiflexion assist orthotic (DAO) on walking in pwMS and found that it did not lead to an increase in distance or speed in the 6MWT, but that PCI, and preserved lower extremity strength and postural control were improved. This indicates that devices that dynamically assist dorsiflexion in foot drop may lead to benefits that could decrease fatigue and limit falls risk with prolonged walking. Furthermore, this device is more accessible, affordable, and allows more sensory input to the bottom of the foot. Further research should be carried out to compare DAOs to AFOs and FES. Lack of significant increase in speed or distance in this study may be due to limited disability in the subjects at baseline (average gait speed 1.15m/s with no device). In general, the small amount of evidence in this field indicates that AFOs indeed have the potential to lead to significant benefits in walking speed, distance, and endurance. These effects are more likely for persons with greater disability There is very little evidence available that compares AFOs to FES in pwMS. The Sheffler 2009 and Khurana 2017 articles above include this comparison, while the RCT by Barrett et al. compares FES to an 18-week home exercise program. Overall, FES has demonstrated benefits in gait speed, endurance, and kinematics comparable to AFOs with some variable results. The Khurana study indicates that patients may tend to be able to walk for increased prolonged periods of time with the use of FES compared to AFO, and have significantly less perceived exertion. The literature supports the use of FES for its orthotic effects in pwMS, but does not demonstrate a therapeutic effect (carry-over). Barrett et al. demonstrated that an exercise program may lead to		

	comparable increases in gait speed over short distances but less so over longer distances. A follow-up to this study indicated that FES use was associated with fewer falls than the exercise group, higher satisfaction with walking performance, and increased confidence with community ambulation.[3,13] Studies on this topic are hampered by methodological limitations. Most include very small samples and do not account for baseline confounding variables such as EDSS, balance, type of MS, type of AFO, etc. This reflects the heterogeneity of MS pathology and clinical presentation to an extent. Given the above evidence, it can be concluded that both AFOs and FES are effective treatment options for foot drop and can lead to increased walking speed, distance, and energy cost. FES may lead to a lower patient-reported exertion level. In general, both are more useful for patients with more baseline disability. Further research should include larger samples and analysis of subgroups based on specific levels of disability, type of MS, and/or type of AFO. Furthermore, study design and outcome measures used in research should consider MS disease pathology, such as fatigue and balance, that can alter obtained results (i.e. simply using a timed short distance gait speed measure may not be a valid representation of a patient's overall walking ability).

QUALITATIVE Research: Patient perspective and acceptance of orthotics

Title/Author/Year	What is the opinion of patients with multiple sclerosis and their healthcare professionals about lower limb orthoses? A qualitative study using focus group discussions Swinnen et al. 2018[14]		
Purpose/Design/Subjects	**Outcomes/Results**	**Conclusions**	**Clinical Implications**
Purpose: "to collect patients' and healthcare professionals' opinions about lower limb orthoses (LL-orthoses): 1) the positive and negative aspects; 2) the differences in wearing them according to location; and 3) their recommendations for future modifications." Design: Qualitative study Subjects: Patients with MS (n=20): Inclusion criteria: adults, Dutch speaking, PwMS with an EDSS score <8.5 and prescribed with an LL-orthosis. Exclusion criteria: not cognitively able to participate 50% female, 50% used AFO Healthcare providers (n=7) with working experience with PwMS who are using LL-orthotics, 3 PTs, 2 OTs, 1 Nurse, 1 Psychologist Methods/Procedures: One-hour focus group discussions	Results: Total of 4 discussion sessions (3 with patients, 1 with providers) Categories were created based on discussion topics: functionality, aesthetics, physiologic discomforts, price, usability, personal factors, and opinion and reaction of others	Functionality was an important positive factor for both groups, especially for health providers. Aesthetics was stressed more by patients than healthcare providers, but still recognized as a factor by providers. Physiologic discomfort that discouraged orthotic use included pain, heat, and allergic reaction to material. Usability issues arise with mechanical features of orthosis, patient's ability or burden of putting the equipment on or taking off. Personal factors recognized in both groups were readiness and willingness to use orthoses and safety/confidence while wearing one. There was an overall effect of location on wearing practices, such that most patients reported not wearing the orthosis at home. Other locations (i.e. rehab center) were more inconsistent.	Comments: Highlights the importance of user satisfaction in the successful prescription of orthoses to treat lower limb dysfunction in pwMS. Up to 23% of patients have been reported to be "non-users". Overall, this qualitative study using focus groups highlights common thoughts of both patients and healthcare providers related to the use of lower limb orthosis. Common themes stress functionality, but there was not a true unanimous position on many other issues related to orthoses. This highlights that every pwMW should be evaluated on an individual basis to determine what factors may encourage or discourage the use of an AFO. It should be noted that discussion groups included patients with a variety of different types of LL orthoses and differing levels of walking ability (EDSS scores), which likely contributes to inconsistent opinions regarding orthotic use.
Title/Author/Year	**Neurological patients and their lower limb orthotics: An observational pilot study about acceptance and satisfaction Swinnen et al. 2017[15]**		
Purpose/Design/Subjects	**Outcomes/Results**	**Conclusions**	**Clinical Implications**
Purpose: "The aim was to determine the satisfaction and acceptance of a lower limb orthotic device." Design: Qualitative observational Subjects: n=33 Stroke: 13 MS: 17 SCI: 1	Outcomes measured: 1. D-Quest 2.0: published and clinically used questionnaire to assess orthotic user satisfaction 2. MIRAD-ACCORT questionnaire: novel 5-part questionnaire constructed ad hoc to measure	This study found that factors associated with functionality, safety, and comfort were more important than aesthetics and psychological aspects of OD use.	This study indicates that patients overall value functionality and comfort in orthotic use. The majority of participants used AFOs of the "foot lifter" type, however, analysis did not look at results with regard to type of device, gender, diagnosis, age and duration of disease, or overall

Other: 2 Methods/Procedures: Administration of 2 patient-report questionnaires in a semi-structured interview	reasons for acceptance of a lower limb OD Results: According to the D-Quest, highest satisfaction was found for safety (85%), weight (82%), effectiveness (82%), and dimensions (76%). Most important aspects of ODs were reported to be ease of use (58%), effectiveness (48%), and comfort (45%).		disability level. These are crucial factors that require more careful research with better design to determine factors that may more specifically lead to more successful treatment of neurological disease in patients via orthotic prescription.
Synthesis:	These articles (from the same Dutch research group) add qualitative data regarding patient perspectives of satisfaction and acceptance with the use of prescribed orthotics for the lower extremity. The 2018 study also includes data from a discussion group comprised of various healthcare providers. Understanding patient perspectives is paramount to the successful treatment of patients with orthotics. These studies indicate that while patients and providers generally agree that functionality, safety, and effectiveness rank high in importance, patients may consider aesthetics, comfort, and burden more so than providers. There is little published evidence regarding patient perspective of orthotics, and while these studies include pwMS as a focus and a majority using “foot lifter” devices in the 2017 study, there is a lack of generalizability due to poor design. There is a wide variety of disability levels among participants and no analysis of data according to subgroups (i.e. EDSS level, full-time wear, orthotic type, gender, etc). Further study should include more subjects and consider these confounding variables in analysis in order to draw more specific conclusions that could guide more successful orthotic prescription and adherence. Overall, clinicians should consider functionality and safety first, but give more importance to specific patient preferences in treating foot drop in MS with orthotics. Other individual clinical characteristics that would be important to consider when choosing orthotics in pwMS include heat dissipation, orthotic weight, and fatigue.		

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