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Comparison of Functional Electrical Stimulation and Ankle-Foot Orthosis to Improve Gait Quality in a Patient with Primary Progressive Multiple Sclerosis: A Case Report

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Abstract

Background: Loss of mobility is commonly reported by people with multiple sclerosis and can dramatically affect quality of life. Foot drop is a manifestation of the disease that increases fall risk. The purpose of this case report is to describe the clinical decision-making process used in determining the best method to correct foot drop for improving gait quality in a patient with multiple sclerosis. **Case Description:** This case examines a 67-year-old male with a history of primary progressive multiple sclerosis. He presented to therapy for this episode of care with functional foot drop and gait disturbances. **Intervention:** The patient trialed two devices that are commonly prescribed to correct foot drop: the WalkAide functional electrical stimulation (FES) device and an ankle-foot orthosis (AFO). The patient began using the WalkAide device during therapy sessions focusing on gait training and also wore it when ambulating at home. Later in the episode of care, the patient switched to using an AFO during physical therapy and at home. **Outcome Measures:** The primary measures considered for this patient were the 6-minute walk test (6MWT), 10-meter walk test (10MWT), and the Berg balance score (BBS). The patient had a 120 feet improvement on the 6MWT at discharge. The patient showed an increase of 8 points on the BBS, signifying a noticeable improvement in balance. When directly comparing fast gait speeds with each device with the 10MWT, the patient was able to walk at 0.45 m/s with the AFO and 0.35 m/s with the WalkAide. **Discussion:** This report supports the use of one of these devices to assist with foot drop as an adjunct to traditional physical therapy interventions in some patients with MS. The clinical decision between the devices should take into consideration objective measures of gait speed and balance, the observable kinematic effect on the ankle and knee, and the patient's preference. The patient in this case ultimately preferred the AFO due to the stability it provided at both his ankle and knee.

Introduction:

Multiple sclerosis (MS) is a chronic disease of the central nervous system that affects more than 900,000 people in the United States.[1] Common characteristics include chronic inflammation, demyelination, gliosis (plaques or scarring), and neuronal loss, which can lead to a variety of clinical manifestations. The factors that are most commonly reported to affect quality of life in this population are fatigue, balance and dizziness problems, and loss of mobility. These symptoms were reported in over 90% of respondents to a survey examining quality of life.[2] Of the four types of MS, primary progressive accounts for only 10% of all cases and is characterized by a steady decline as the disease progresses.[1] Medical treatment is limited for MS and there is a lack of research on proposed therapies. Symptomatic therapy is common and can include medications and physical therapy/exercise.

Mobility is one of the most impactful factors when assessing quality of life in individuals with MS. Maintaining and supporting ambulation needs to be a focus of physical therapy interventions in this population.[3] Motor deficits most commonly affect the lower extremities, with 85% of patients with MS reporting gait disturbances as their main complaint.[4] Individuals with MS typically walk with a slow speed, shorter stride length, and longer double limb support phase.[4] The energy cost of walking is greater for individuals with MS compared to the general population.[5] Higher variability in stance time and step length have also been found to be correlated with a higher energy cost of walking along with higher levels of reported disability.[5] Physical therapy interventions should aim to maintain mobility and reduce this energy cost by focusing on limiting gait variability.

Reduced dorsiflexion at initial contact is a kinematic change commonly detected in gait in individuals with MS.[3] This functional foot drop is a manifestation of the disease that affects gait quality and increases fall risk. Physical therapy interventions that focus on correcting foot drop include utilization of ankle-foot orthoses (AFO) and functional electrical stimulation (FES) devices. The goal of these devices is to approximate a more normal gait pattern by correcting for dorsiflexion weakness, imbalances of eversion/inversion, and redirecting torque at the knee.

Traditionally, passive dorsiflexion support during gait through the use of an AFO has been the treatment of choice for foot drop. AFOs have been shown to prevent foot drop throughout the gait cycle, reduce energy cost, enhance weight transfer over the weak leg, and improve ankle and knee kinematics in people with stroke.[6] While there is an abundance of research supporting the use of AFOs in patients with stroke, there is limited conclusive research on the effects of AFOs in patients with MS despite it being common practice to prescribe these orthotics to this population. One study examining the functional effect of AFOs in patients with MS found that there was no significant difference in gait velocity or performance on functional ambulation tasks when using an AFO compared to without the device.[7] More research is needed to evaluate the effect of an AFO on energy cost and the biomechanics of gait in this population.

More recently, FES devices have become increasingly available to promote active dorsiflexion during gait for patients with central neurologic diseases by stimulating the peroneal nerve. One example is the WalkAide device, which uses a tilt sensor to trigger an electrical stimulation during the swing phase.[8] A meta-analysis concluded that FES used for foot drop had a positive initial and ongoing effect on gait speed in short walking tests (0.05 and 0.08m/s change respectively), but not on gait speed in long walking tests.[9] However, using FES for foot drop provided no therapeutic effect on gait speed for either short or long walking tests.[9] In another study, perceived exertion was lower for those using a WalkAide device compared to those using an AFO, yet energy consumption and metabolic efficiency did not vary between devices.[10]

The choice of device to treat foot drop should take into consideration the patient's preference. In a survey investigating individual's subjective thoughts on the two devices, results showed variable pros and cons.[11] Common perceived benefits of both devices were reduced fatigue, improved gait quality, reduced trips and falls, assistance on hills and stairs, increased participation in life, greater confidence, and less mental effort when walking. Common perceived shortcomings for the two devices included being uncomfortable, wanting to avoid reliance on device, inconvenient for shoes and clothing, and social barriers.[11]

While there is a large quantity of research supporting the use of these devices to target foot drop, there is a gap in the knowledge of how the kinematic differences between devices affect the individual's quality of life and what role patient preference plays in deciding the best intervention. The purpose of this case study is to describe the clinical decision-making process used in determining the best method to correct foot drop for improving gait quality in a patient with MS.

Case Description:

The patient is a 67-year-old male, first diagnosed with primary progressive multiple sclerosis (PPMS) seventeen years prior at the age of 50. His symptom history included a gradual increase in ataxia, fatigue, lower extremity muscle tone, and lower extremity weakness that increasingly affected his daily functioning. Twelve years after diagnosis, at 63 years of age he began walking with a cane for stability. He reported his functioning declined more rapidly three years ago (age 64) after a urinary tract infection resulting in a fall that led to a hospitalization. After this he purchased a power scooter for longer mobility distances.

The patient has undergone three episodes of physical therapy care since his original diagnosis. All three involved concerns with his gait and fall history. Past therapists have tried many interventions to improve his foot drop including strength training and FES per patient report. The patient has tried to adopt a more active lifestyle and performs aquatic workouts three times per week, walks laps around his large shed (50 feet/lap) using a 4-wheeled walker (4WW), and has a home exercise plan that he has followed to maintain his strength. He presented to outpatient therapy for the current episode with ongoing concerns about his gait and balance. His chief concern was right lower extremity weakness and fatigue, that was the primary limiting factors of his mobility. He reported only walking household distances. He self-disclosed a significant fall history, reporting several falls in the last year. He reported his falls typically happen when his legs give out or if he catches his feet while walking. His primary goal of therapy was to be able to go on walks with his wife and pick up his grandkids.

Clinical Impression 1:

Reflecting on the initial information and history gathered, there were several factors that suggested the patient may be a strong candidate for gait training with either an AFO or a FES device. First, the patient reported occasionally catching his feet on the ground during gait leading to several falls. Gait devices have been shown to be effective at improving gait quality and functional foot drop in patients with central neurologic disorders.[12] Second, the patient has maintained the ability to ambulate home distances so the disease has not progressed to the point of losing functional gait. Third, the patient was motivated to improve his gait quality, speed, and safety so that he could have a better quality of life.

With these components in mind, the physical examination was designed to determine any strength or range of motion deficits, determine his tolerance of physical activity, and to rule in/out any conflicting diagnoses that would affect his ability to use a device for foot drop. Additionally, an area of consideration was the presence of lower extremity spasticity. This could greatly affect the patient's ability to use a device and participate in gait training.

Examination:

The patient demonstrated passive range of motion (ROM) within functional limits (WFL) for bilateral lower extremities. The patient did have excessive right knee hyperextension of 6 degrees. The patient exhibited strength impairments in bilateral lower extremities, with the right leg being weaker than the left leg. Per manual muscle testing, his right leg strength ranged from 2+/5 to 4/5 and his left leg strength ranged from 3+/5 to 5/5 (as shown in table 1). Of note, the patient had 3+/5 right ankle dorsiflexion strength. The patient also was found to have increased muscle tone according to the modified Ashworth scale. This was primarily found in his hamstrings (2/4 bilaterally) and hip adductors (right=2/4, left=1+/4). The patient reported normal sensation in bilateral lower extremities during a quick

sensory screen.

The patient was independent with bed mobility and supine to sit transfers. He required standby assistance for sit to stand transfers and chair to bed transfers using a 4WW. He was able to ambulate 200 feet with standby assistance and a 4WW. He presented with the following gait deviations: forward trunk posture, narrow base of support, decreased step length and height with the right lower extremity, hyperextension of the right knee during stance phase, diminished heel strike on right, and right toe drag during swing phase. The patient fatigued quickly, requiring a seated rest break after ambulation. The observed gait deviations increased with fatigue.

Table 1: Manual Muscle Test results

	Right	Left
Hip Flexion	4-	4
Hip Extension	3+	3+
Hip Abduction	2+	3+
Knee Flexion	4	4
Knee Extension	4-	5
Ankle Dorsiflexion	3+	5
Ankle Plantarflexion	4	5
Ankle Inversion	4	5
Ankle Eversion	4	5

The patient was unable to complete six continuous minutes of walking during the 6-minute walk test, walking 200 feet with several losses of balance in just over 4.5 minutes. His average gait speed was calculated at 0.22 m/s according to the 6-minute walk test algorithm. The patient scored a 27/56 on the Berg balance test indicating that he was at a high fall risk. His performance on objective measures are detailed in Table 2 below in the outcome measures section.

Clinical Impression 2:

Based on the objective evaluation of the patient, he was an appropriate candidate for trial of an AFO or a FES device to correct his functional foot drop and improve his gait quality. He had no significant ROM deficits that would interfere with the application of the devices and he retained the strength to ambulate. He did, however, present with functional foot drop, weak dorsiflexors on his right lower extremity, and decreased clearance of his right foot during swing phase of gait. These characteristics made him an excellent candidate for one of these devices.[6]

The plan of care for this patient was developed around gait and balance training to improve the quality and efficiency of his gait, as well as to decrease his fall risk. The objective measures were formally repeated during a re-evaluation after eight treatment sessions (about four weeks) and again at discharge after eight more sessions (about four weeks). In some instances, measures were reported during additional treatment sessions to compare his performance using an AFO versus a FES device. If the addition of an AFO or a FES device is effective, it is hypothesized that the patient's performance on the 6-minute walk test would improve, along with an increase in gait speed, a decrease in observable gait deviations, and a decreased fall risk.

Intervention:

The patient received several interventions throughout his course of treatment including generalized strengthening, gait training, neuromuscular re-education, and aerobic endurance training. The patient was seen two times per week for 60-minute sessions for a total of 16 visits (about eight weeks).

WalkAide: Gait training began immediately using a WalkAide FES device that was given to him during a previous episode of care several years ago. The patient reported only using it for a week before he was hospitalized for a medical issue and then did not use it after he returned home. He brought in the device and it was determined that the settings were not properly set for him. After contacting WalkAide, a representative came and co-treated during a physical therapy session to calibrate the device appropriately. The parameters were adjusted to decrease the stimulation time to improve the timing of when the device is stimulating the tibialis anterior in relation to the swing phase. The WalkAide was placed on his right lower leg, just below his knee after wetting the electrodes and lining them up so that they are directly on the tibialis anterior muscle. The patient was prescribed a 1

hour wear schedule for the WalkAide at home for the first week. It was then increased by 30 minutes per day, which continued for 2 weeks. The device was utilized in therapy during those two weeks to accompany the other gait training tasks. The patient continued to report occasional catches of his toes on the ground with use of the device and was unable to control his right knee hyperextension, so it was determined that the patient may benefit from use of a solid AFO instead to provide more stability at the ankle and knee joints as well as increasing foot clearance during the swing phase.

AFO: The patient was referred to a prosthetist for fitting for a custom solid AFO. The design included standard strapping with a lateral ankle strap position, full length foot plate, and was made out of 3/16" polypropylene. It took three weeks to fabricate the AFO and deliver it to the patient, so it was during week 5 of this episode that he began gait training with it. He was educated on donning and doffing the brace, the proper fit of the straps, and performing skin checks before and after use. The patient was started on a wear schedule of 1 hour at a time. The patient self-accelerated this wear schedule by using it for four hours on day 2. In therapy, the patient continued working towards goals by completing more complex gait challenges and longer distance ambulation with the AFO donned.

Other Interventions: Additional interventions were included in the plan of care to improve his strength, balance, and endurance. These included generalized strengthening of his lower extremities and trunk, neuromuscular re-education and high level dynamic balance exercises in standing, resisted ambulation, stair training, gait on uneven surfaces, cognitive tasks during gait, other complex gait tasks, and aerobic exercise on a Nustep recumbent stepper machine. These interventions were chosen to target specific areas of impairment that would improve the patient's functional mobility and were prescribed appropriately to work towards his goals. They were adjusted as needed throughout the plan of care to optimize gait training and patient safety. The ultimate goal was to increase the efficiency of the patient's gait to conserve energy and decrease fall risk. Although the conventional physical therapy interventions listed above are not the primary focus of this case report, they should not be overlooked as they were important in the overall physical recovery and improvements seen in this patient.

Outcome Measures:

The primary outcomes considered for this patient were the 6-minute walk test (6MWT), 10-meter walk test (10MWT), and the Berg balance score (BBS). The 6MWT is a measure used to assess walking endurance and aerobic capacity. It involves the patient walking around a set perimeter for six minutes. The distance is measured and reported along with any assistive devices used. The patient is allowed to take a standing rest break but if they need to sit, the test is ended and the distance is recorded. The BBS is used clinically to assess fall risk through static and dynamic balance activities. It involves a series of balance tasks that are scored on a scale from 0 to 4. Items are then added together and a total score is reported out of 56 points. The 10MWT measures gait speed over short distances. Walking speed has been linked to fall risk in older adults.[13] A path of ten meters is marked on the ground with additional marks at two meters and eight meters. The patient walks the entire ten meters but the therapist measures the middle six meters for time. The stopwatch begins when any part of the patient crossed the two meter mark and ends when any part of the patient crosses the eight meter mark. The time is recorded in seconds. The patient should perform two trials at a preferred walking speed. Then the patient should perform two trials at a fast walking speed. To calculate the individuals preferred and fast speeds, divide six meters by the average time of the two trials calculated. A clinician should also document any assistance provided or any assistive device used during the test.

The multiple sclerosis taskforce of the neurologic section of the American Physical Therapy Association highly recommends use of the 6MWT, 10MWT, and Berg balance test in the outpatient setting for this population.[14] The 6MWT has excellent intra-rater and inter-rater reliability (0.97 and 0.99) in the spinal cord injury (SCI) population. The 10 MWT has been shown to be reliable in both the SCI and the stroke population, with a test/retest between 0.94 and 0.99, intra-rater (0.87-0.95), and inter-rater (0.95-0.9). The Berg's intra-rater, inter-rater, and test retest reliability are all 0.98.[14] There is limited data published on the reliability of these tests for individuals with MS. The 6MWT and 10MWT have adequate to excellent validity, correlated with dependence in mobility (r=0.34-0.74) in individuals

with MS.[15] Walking speed during the 6MWT and the 10 MWT are strongly correlated (r=0.95). The BBS was shown to have acceptable validity to discriminate fallers from nonfallers in the MS population however may have a ceiling effect so therapists should use caution.[16]

Outcomes were reassessed at reevaluation (four weeks) and again at discharge (eight weeks) and are outlined in Table 2. The 10MWT was not tested as part of the initial and retest evaluations. This test was only used to compare the two foot drop interventions and is detailed in Table 3. The patient had a 120 feet improvement on the 6MWT at discharge. The MCID in stroke is 164 feet.[14] The MCID for this BBS in the MS population is 3 points.[14] The patient showed an increase of 8 points, signifying a noticeable improvement in balance in this patient. He was still at a high risk for falls supporting the use of a walker for all mobility. Taken together, the patient improved gait tolerance and balance during this episode of care.

Table 2: Objective measures results throughout episode of care

Test	Initial Evaluation (week 0)	Re-evaluation (week 4)	Discharge (week 8)
Berg Balance Test	27/56	31/56	35/56
6-minute Walk Test	200 feet (stopped at 4 min 35 sec)	Did not formally assess	320 feet

When comparing his performance on standardized gait tests using each device, the patient did not use an assistive device during the initial evaluation, used the WalkAide during the four-week re-evaluation, and used the AFO during the final assessment at discharge. It is difficult to determine whether the improvements seen were due to the different devices or the additional physical therapy interventions utilized in the plan of care. For that reason, it is challenging to compare the devices with these particular standardized outcome measures.

During the last week of therapy, however, gait speed was measured with the 10MWT while the patient wore the AFO and then the WalkAide. The patient was able to walk slightly faster while wearing the AFO (0.31m/s) compared to the WalkAide (0.29m/s), which was most noticeable during the trials that the patient was walking as fast as he could (0.45 and 0.35 respectively). The MCID for the 10MWT in the SCI population is 0.6 m/s,[14] indicating that this is a meaningful change. Both devices allowed the patient to walk significantly faster than at baseline (0.22m/s). Directly comparing his observable gait quality in the devices also favors the AFO. Most notably the patient's right knee hyperextension was resolved with the AFO, whereas it was inconsistent with the WalkAide. Subjectively, the patient preferred the AFO while walking because of the increased stability at the ankle that it provided. These comparisons are summarized in Table 3.

Table 3: AFO vs WalkAide Comparison

	AFO	Walkaide
Gait Quality	Consistent step length on R Consistent clearance of R foot during swing phase Heel strike with R Neutral R knee position during stance phase Increased speed	Heel strike with R Longer step length on R Occasional hyperextension of R knee during stance phase Increased speed *As patient fatigued, decreased clearance of R foot noted
10-meter Walk Test	0.31 m/s normal speed 0.45 m/s fast speed	0.29 m/s normal speed 0.34 m/s fast speed
Patient subjective response	"My foot feels secure and like I can trust it when I take a step"	"It works well at first but when I use it for a long time I catch my foot on the ground again"

Discussion:

The purpose of this case study is to describe the clinical decision-making process used in determining the proper method for improving gait quality by correcting foot drop in a patient with MS. This report supports the use of a device to assist with foot drop as an adjunct to traditional physical therapy interventions. These individuals generally walk with a higher variability in step length, step height, and foot placement. They therefore utilize more energy during gait compared to a healthy control because they not only have to drive the center of mass forward, but have to correct for their irregular foot placements to increase stability during gait. This can play a role in the person's fatigue levels and increase fall risk.[15] With fatigue and mobility as two of the largest concerns for individuals with MS, therapy interventions should focus on decreasing step variability to conserve energy and improve mobility. AFOs and FES devices may be able to help provide consistency with gait mechanics through an ongoing orthotic effect, thus decreasing variability with ambulation.[17]

Both devices assisted in addressing the target problem of foot drop and enhanced gait quality for this patient. When directly compared, the AFO appeared to improve ankle dorsiflexion at initial contact and prevented knee hyperextension where the WalkAide only addressed the dorsiflexion at the ankle and did not assist with knee kinematics. Also, the effects of the WalkAide seemed to diminish with fatigue as evident by the patient's decreased clearance of his foot while walking. The potential benefits of FES on foot drop may be limited by the neurodegenerative nature of MS compared to a more stable neurologic condition like a stroke with residual weakness.[9] Of note, the other gait training and strengthening interventions performed throughout the plan of care cannot be overlooked in explaining the progress seen in this patient.

Ultimately, the patient in this case report ended up choosing to use the AFO for ambulation despite having access to both devices. This decision was based upon the objective improvement in gait speed and balance when wearing the device, the observable effect on both ankle and knee stability, and the patient's preference. One might assume that an FES device would be superior as the more high-tech option that involves an active contraction that mimics "normal" walking. However, each patient is unique and will require a personalized clinical decision-making process to assess needs. There are many factors not mentioned during this report, such as cost differential, appearance, and convenience that may play a role in the patient's preference and the final decision.

Many of the studies looking at the impact of FES devices and AFOs in the MS population do not specify the type of MS that the patients have. In one study, one quarter of participants did not benefit from FES devices, implying that there may be a subset of the population that doesn't respond well to the intervention.[10] More studies should investigate if there are any patterns with how individuals respond by type of MS diagnosis. It is possible that because the patient in this case report had primary progressive multiple sclerosis that he was less likely to respond to FES.[2]

In summary, this report highlights that gait can improve with therapeutic intervention in patients with MS, and that while two different options to correct foot drop were helpful, one emerged to be the better choice for this patient. However, it cannot be determined that the improvements observed were a direct result of the interventions provided. It is important to analyze carefully the interventions chosen for physical therapy according to their effectiveness and how the patient is responding, and then make adjustments as necessary. This case illustrates the clinical decision-making process, showing that the best option may not be the first choice of the therapist, but may require some trial and error to achieve the best outcome for the patient. The combined treatment and foot drop interventions were safe and well tolerated in this patient. Further research is needed to establish guidelines to help therapists when deciding whether or not to add a device that targets foot drop into a physical therapy plan of care, considering type of MS, kinematic effects of the different devices, and patient preference.

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