WalkAide® FES device Improves Gait Function and Quality of Life for People with Multiple Sclerosis on Ampyra

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BACKGROUND

Multiple Sclerosis (MS) affects nearly 2.5 million persons worldwide; 75% of MS patients experience difficulty with ambulation. A prevalent gait disturbance in this population is drop foot, an inability to dorsiflex during swing which leads to abnormal gait, decreased speed, endurance, and balance.

A current treatment of impaired gait speed is dalfampridine (Ampyra), which can result in an increase in gait speed in 35-45% of patients. The standard orthotic intervention for foot drop is an Ankle Foot Orthosis (AFO). An AFO is a plastic brace that maintains the ankle in a neutral ankle position during swing. Disadvantages of AFOs include movement restriction, muscle wasting, and user discomfort.

Peroneal Nerve Functional Electrical Stimulation (FES) is an alternative treatment for a foot drop. FES electrically stimulates the dorsiflexors resulting in active toe clearance and a more natural gait. FES activates muscles, increases circulation, improves voluntary muscle control and reduces muscle atrophy. Previous research has shown that FES can improve gait velocity, endurance, and symmetry.

PURPOSE

To determine the effect of the **WalkAide® FES** device on gait speed, endurance, impact of MS on walking ability and Quality of Life (QOL) for MS patients on a stable dosage of dalfampridine (Ampyra).

METHODS

Design: An un-blinded sequential case series of 16 subjects with MS.

Methods: Subjects were recruited from a client list of patients with MS, stable dosing of dalfampridine (Ampyra) and foot drop at Central Texas Neurology Consultants in Round Rock, Texas. Subjects completed 4 visits: Screening (without device), and Baseline, 1 month and 3 months (with device).

Screening: Subjects completed the Timed 25 foot walk (T25FW) and the 6 Minute Walk (6MWT) tests. Screening measures were taken without the **WalkAide®**. The Multiple Sclerosis Walking Scale 12 (MSWS 12) and the SF-36 questionnaires were also administered at screening prior to initiation of **WalkAide®** wear.

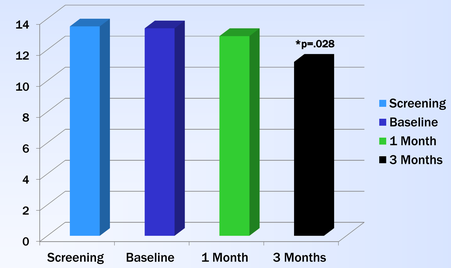
Follow-up visits: The T25FW, 6MWT, MSWS 12 and the SF-36 were repeated with the subject wearing the **WalkAide®** at a Baseline visit, a 1 month and a 3 month follow up visit.

RESULTS

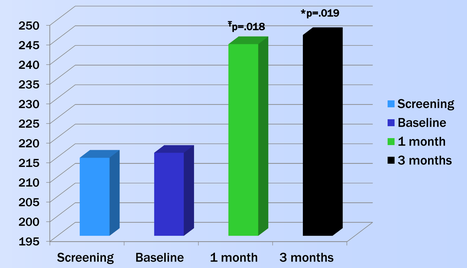
20 subjects were recruited for this study, 16 completed (7 males and 9 females). 3 subjects withdrew due to poor device tolerance, 1 subject did not meet inclusion criteria.

Table 1: Demographic Characteristics	N= 16, 7 male, 9 Female	
	Mean (years)	Range (years)
Age	53.6	36.1 - 68.1
Duration of disease	16.4	2.9 - 26.9
Duration of Ampyra prescription	1.9	.6 - 4.3

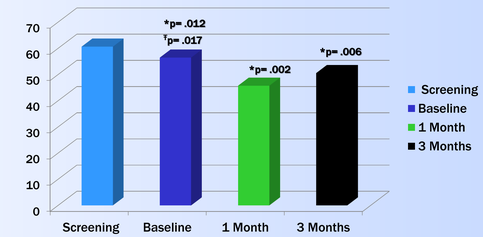
Timed 25 Foot Walk
Mean time in seconds



6 Minute Walk Test
mean distance in meters



Multiple Sclerosis Walking Scale 12
standardized score



SF-36 Subscale scores

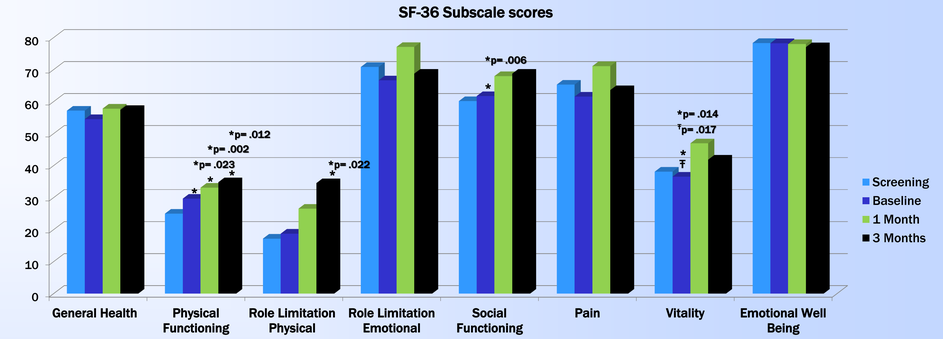


Table 2: Results (comparison of screening to follow-up values)				
	Screening	Baseline	1 Month	3 Months
T25FW (seconds)	13.50 ± 8	13.4 ± 8.4	12.9 ± 10.2	11.22 ± 7.66 (*p=.028)
6MWT (meters)	214.9 ± 94.8	216.1 ± 86.5	243.8 ± 94.7	246.06 ± 88.66 (*p=.019), (Ŧp=.018)
MSIS-12	60.6 ± 10.1	56.5 ± 9.5 (*p=.012)	45.7 ± 17.4 (*p=.002)	50.52 ± 13.62 (*p=.006), (Ŧp=.017)

Ŧ refers to significance between baseline and 1 month visits

CONCLUSIONS

Conclusions: Use of the **WalkAide®** significantly improves gait speed and endurance, decreases the negative impact of MS on walking ability and improves QOL for people with MS. Improvements were above and beyond benefits derived from a dalfampridine (Ampyra) regimen suggesting that the **WalkAide®** can augment pharmacological intervention and facilitate significant additional improvement in gait and function for people with MS.

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