Preliminary Results of a Randomized Controlled Trial of a Hip Flexion Assist Device in MS.

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BACKGROUND AND GOAL

A large number of patients with multiple sclerosis (MS) experience chronic gait disturbance in the course of their disease. [1] Two commonly occurring impairments, weakness and spasticity, were shown to correlate with gait deviations. [2]

The hip flexion assist device (HFAD) was developed to address the gait deviation associated with weakness of hip flexor muscles, and can be used alone or in combination with an ankle foot orthosis (AFO).

The results of an uncontrolled pilot study of the HFAD in 21 subjects showed significant improvement in walking performance on several tests at 8 and 12 weeks, and showed no significant safety concerns. [3]

The goal of this single blind randomized controlled trial is to further explore the efficacy of the HFAD on various aspects of walking performance and to confirm safety findings on a larger patient sample.

METHODS

Patients diagnosed with MS and with hip flexor strength rated 3/5 or less on manual muscle testing, underwent baseline assessments (V1), and were randomized to the treatment group (daily HFAD wear) or to the control group (no intervention). Follow-up assessments were conducted at 4 weeks (V2) and 8 weeks (V3).

Outcomes included walking endurance (2-minute walk), maximum walking speed (Timed 25 Foot Walk), lower extremity muscle strength (hand-held dynamometer) and spasticity (Modified Ashworth Scale), and subject-reported ambulation (MS Walking Scale-12). Subject satisfaction and adverse events were recorded.

An analysis of covariance (ANCOVA) was used to compare the HFAD and control groups on baseline to 8-week change in outcome measures.

Bibliograpy

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Table 1 – Baseline Characteristics

Parameters	All randomized (n=37)	Treatment Group (n=17)	Control Group (n=20)
Age in years	53 +/- 9	52 +/- 9	53 +/- 10
Sex (% women)	70%	65%	75%
Disease duration in years	19 +/- 10	18 +/- 11	19 +/- 9
Current disease course	43% RR, 46% SP, 5.5% PP, 5.5% PR	59% RR, 41% SP	30% RR, 50% SP, 10% PP, 10% PR
Number of comorbidities	0.9 +/- 1.2	1 +/- 1.2	1 +/- 1.2
Disease-modifying therapy (% yes)	54%	53%	55%
Dalfampridine (% yes)	13%	18%	10%
Number of concomitant meds	6 +/- 3	6 +/-3	6 +/- 3
Assistive device used	14% none, 32% unilateral, 54% bilateral	12% none, 35% unilateral, 53% bilateral	15% none, 30% unilateral, 55% bilateral
AFO (% yes)	54%	53%	55%

All values are expressed as mean +/- SD unless otherwise specified

RESULTS

We are presenting results from an interim analysis on 37 subjects (17 in the HFAD group, 20 in the control group). There were no statistically significant differences in baseline characteristics between the groups (Table 1). The average daily time of HFAD wear was 4.3 +/- 3.6 hours.

Efficacy

- There was a trend favoring the treatment group) for the 2-minute walk test (ANCOVA, p=0.07) . (Figure 1)
- No difference was observed for the Timed 25-Foot Walk, lower extremity strength, or Modified Ashworth Scale.
- There was a statistically significant between-group difference in change for MS Walking Scale total score between V1 and V3, favoring the treatment group (p=0.048). (Figure 2)
- The level of subject satisfaction with the HFAD was high, with the exception of device appearance, both at V2 and V3. (Figure 3)

Safety

One subject in the control group was excluded due to frequent falls. One fall occurred in the treatment group (subject was not wearing the HFAD) Four subjects in the treatment group reported lower extremity musculoskeletal pain (one ankle sprain, the subject was not wearing the HFAD at the time of the incident; the other subjects reported muscle or knee pain, which improved after temporarily discontinuing or reducing HFAD wear.

Figure 1 – 2-minute walk

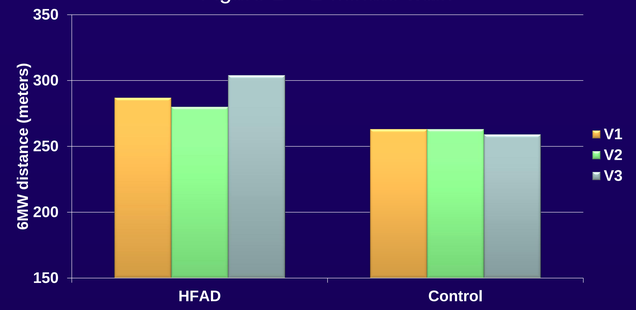

Figure 2 – MS Walking Scale-12

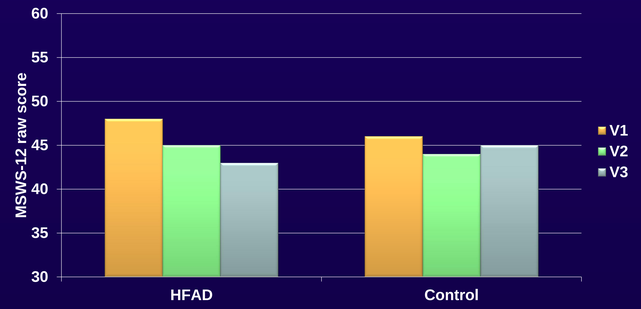

Figure 3 – Subject satisfaction