Impact of a Hip Flexion Assist Device on Gait Performance in MS
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Background
- A large number of patients with multiple sclerosis (MS) experience chronic gait difficulties in the course of their disease.
- Weakness and spasticity frequently impact function in the lower limbs.
- An Ankle Foot Orthosis (AFO) can be used to compensate for distal lower extremity weakness and spasticity (foot drop), but does not compensate for proximal weakness. Orthoses involving lower extremity segments above the knee are more rarely used in MS, in part because of their weight.
- The No Flexion assist device (HFAD) was developed to enhance active hip flexion in the last phase of the gait cycle. The HFAD can be used in combination with an AFO.

Preliminary Data
The results of an uncontrolled 12-week pilot study (n=21) suggest that the HFAD is effective and safe:
- walking performance was significantly improved with the device
- lower extremity strength output (tested without the device) improved
- the main side effect was foot pain (not related to the proximal wound attachment) in 15% of patients.
- 95% of patients were overall satisfied with the use of the HFAD

The HFAD

Methods

Design (Figure 1): Randomized, single-blinded, controlled study over 8 +/- 2 weeks (V1: enrollment, V2: +/- 4 weeks, V3: +/- 8 weeks).

Intervention: Fitting of a customized HFAD, and training prior to use in active exercises.

Main inclusion criteria:
- The participant has definite multiple sclerosis as documented in the medical records.
- The patient is ambulatory (with or without assistance) and able to walk 100 yds to 1 mile per day.
- The patient presents with severe weakness (score of 3 or below on the lower extremity muscle testing) of the hip flexor group, in at least one lower extremity.

Main exclusion criteria:
- The patient has been treated for an exacerbation on MS within the past year.
- The patient currently receives physical therapy or has received physical therapy in the 2 months preceding enrollement.

Treatment Group

Outcome Measure(s) (V1, V2, V3)

- Safety: estimated using a mixture of data from V1 and V2.

Efficacy
- Preliminary data on 6 treatment subjects and 10 control subjects (Figure 2 and Table 1) were collected at V2 and V3.
- The treatment group showed significant improvements in the mTUG and the 10-m walk tests compared to baseline.
- The control group showed a slight non-significant improvement in the 10-m walk test.
- The preliminary data suggest that the HFAD may be effective in improving gait performance in patients with MS.

Safety
- No significant safety issues arose.

Adverse events:
- Treatment group: 1 infection, 1 fall (subject did not wear the HFAD at the time of the fall), 1 distal pressure ulcer.
- Control group: 3 infections, 2 falls, 1 distal pressure ulcer, and 2 knee pressure ulcers.
- None of the adverse events in the treatment group were felt to be related to the study device.
- The infections were urinary tract and respiratory infections.

Conclusions
Results from our preliminary analysis suggest that there is objective 10-minute walk and patient reported GMFM walking scores of 30-50% improvement of walking performance with the HFAD. The device is well tolerated, and there is a high level of patient satisfaction.

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