PROSTHETICS, ORTHOTICS, DEVICES

Efficacy and Safety of a Hip Flexion Assist Orthosis in Ambulatory Multiple Sclerosis Patients

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ABSTRACT. Sutliff MH, Naft JM, Stough DK, Lee JC, Arrigain SS, Bethoux FA. Efficacy and safety of a hip flexion assist orthosis in ambulatory multiple sclerosis patients. Arch Phys Med Rehabil 2008;89:1611-7.

Objective: To evaluate the efficacy and safety of a hip flexion assist orthosis (HFAO) in ambulatory patients with multiple sclerosis (MS).

Design: Fourteen week pre- and postintervention uncontrolled trial.

Setting: Outpatient rehabilitation clinic within an MS center.

Participants: Ambulatory MS patients (N=21) with unilateral (or unilateral predominant) hip flexor weakness.

Intervention: Subjects were fitted with the HFAO on the weaker side, trained to use the device, and given a wear schedule. Subjects completed 2 baseline evaluations and follow-up testing at 8 and 12 weeks.

Main Outcome Measures: Lower-extremity manual muscle testing, pain, and gait performance (Timed 25-Foot Walk, Timed Up & Go, 6-minute walk test, Mellen Center Gait Test). Subject satisfaction was evaluated by using a 9-item custom questionnaire.

Results: There was a statistically significant improvement of strength in the affected lower extremity at 8 and 12 weeks (effect size [ES]=0.63; ES=1.32, respectively), of pain at 12 weeks only (ES=−0.64), and of all gait tests at 8 and 12 weeks (ES range, 0.38–1.33). The overall mean satisfaction score at 12 weeks was 39 (maximum score, 45). No serious adverse events were recorded during the study. The most frequent side effect of the HFAO was low back pain (19%). No side effects led to discontinuation of the HFAO use during the study.

Conclusions: The HFAO was safe and well tolerated. HFAO use was associated with significant improvement of gait performance as well as improvement of strength in the lower extremity fitted with the HFAO. Subjective reports suggest that there was an increase in daily life activity level.

Key Words: Gait; Multiple sclerosis; Orthotic devices; Rehabilitation.

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A LARGE NUMBER OF patients with MS experience chronic gait disturbance in the course of their disease.[1] This functional limitation can be caused by various impairments, including weakness, spasticity, ataxia, imbalance, sensory loss, decreased ROM, and pain. Orthoses are prescribed to compensate for focal weakness. In MS, the most frequently used lower-extremity orthosis is the AFO. Orthoses involving lower-extremity segments above the knee are more rarely used, in part because of their weight. In MS patients with a combination of ankle dorsiflexor and hip flexor weakness, an AFO will often fail to restore satisfactory foot clearance because it does not compensate for the hip flexion deficit. As a result, some patients are dissatisfied and tend to discontinue the use of their AFO. Hip flexor weakness causes a very inefficient gait. Hip hiking and hip circumduction are common compensatory strategies, but they create additional long-term stress on the hip joint, resulting in increased energy cost and less safe ambulation.

We developed a lightweight active HFAO[a] that can be used alone or in combination with an AFO. Its design is meant to be light, comfortable, and easy to put on and take off. We conducted a pilot study to evaluate the effectiveness and safety of the HFAO in ambulatory MS patients with unilateral or unilaterally predominant hip flexor weakness.

Description of the HFAO

The device is composed of a proximal waist attachment (fig 1), a medial and a lateral dynamic tension band (fig 2), and a distal connector (fig 3) that attaches to the shoelaces. All of these elements are adjustable to fit the patient's anatomy and biomechanic gait characteristics. The HFAO was carefully designed and calibrated to supplement the hip flexors and knee flexors in the affected limb. Additionally, dorsiflexion assistance is provided from the distal attachment.

METHODS

The study was approved by our institutional review board. Subjects were recruited among patients who had been referred

List of Abbreviations

ADLs	activities of daily living
AFO	ankle-foot orthosis
FES	functional electric stimulation
HFAO	hip flexion assist orthosis
MAS	Modified Ashworth Scale
MCGT	Mellen Center Gait Test
MMT	manual muscle testing
MS	multiple sclerosis
PNS	peripheral neuromuscular stimulation
ROM	range of motion
6MWT	6-minute walk test
T25FW	Timed 25-foot Walk
TUG	Timed Up & Go

From the Department of Quantitative Health Sciences (Lee, Arrigain) and the Mellen Center for Multiple Sclerosis Treatment and Research (Sutliff, Stough, Bethoux), The Cleveland Clinic Foundation, Cleveland, OH; and Geauga Rehabilitation Engineering, Chardon, OH (Naft).

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Fig 1. HFAO: waist attachment.

Fig 3. HFAO: distal connector.

to physical therapy for intervention on gait limitations. Patients with definite MS as documented in the medical records who were ambulatory (defined as ability to walk with or without a walking aid a minimum distance of 30m [100ft]), had a score of 3/5 on MMT of the hip flexor group in 1 lower extremity, and were not currently receiving physical therapy elsewhere were invited to enroll. Patients were excluded if they presented with severe chronic low back pain (pain score $\geq$4/10 for back pain on a numeric rating scale for pain), skin breakdown, recent surgical incision in the abdominal or knee areas, stomas or surgically implanted devices in the abdominal area contraindicating local pressure (surgeon was contacted to give clearance as appropriate), severe cognitive deficits precluding informed consent and/or adequate use of the device, or the inability to don or doff the orthosis independently.

After informed consent was obtained, a first baseline physical evaluation was conducted. One week later, a second baseline evaluation was performed, and the subject was properly fit and trained to use the HFAO. Instructions were provided regarding the wear schedule, and donning and doffing proficiency were verified through the subject's return demonstration. The subject then went home with the device, and written instructions relative to all training aspects were provided. Study subjects were required to remove the HFAO before driving an automobile or before operating any machinery that required foot control. The subjects returned for a follow-up evaluation at 3, 8, and 12 weeks after the first baseline visit. The device was adjusted as needed during the visits. The scores of the 2 baseline visits were averaged and used as baseline data, and the scores from the fourth and fifth visits after receiving the HFAO were analyzed separately as outcome data. The third visit (at 3wk) was scheduled during the break-in period of the HFAO based on the wear schedule so these data were not considered for either baseline or outcome data.

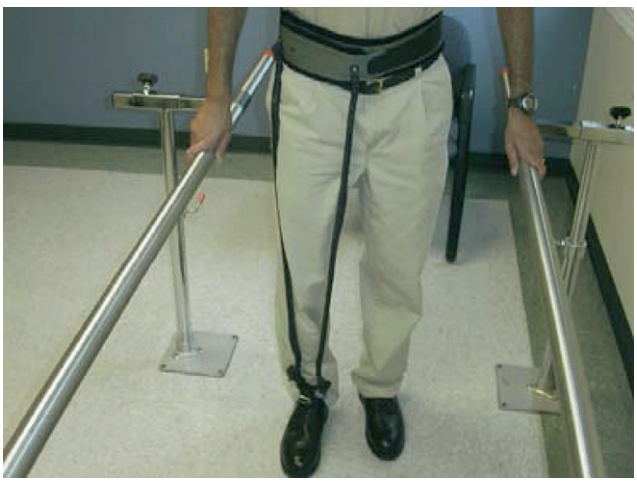

Fig 2. HFAO: tension bands.

Outcome Measures

Impairment measures included the following:

1. Passive ROM, which was tested at the hip, knee, and ankle in both legs.
2. MMT, which allows one to rate muscle strength on an ordinal scale from 0 (no contraction) to 5 (normative strength). Testing was performed bilaterally on the hip flexors, hip abductors, hip extensors, knee flexors, knee extensors, ankle dorsiflexors, and ankle plantarflexors. MMT scores for all muscle groups were averaged in each leg.
3. MAS[2] scoring, which reflects resistance to passive mobilization of a limb or limb segment. Scores range from 0 (no increase in tone) to 4 (affected part[s] rigid in flexion or extension). Although criticized for its conceptual and psychometric flaws,[3] the Ashworth Scale (in its different versions) remains the most widely used measure of spasticity. Resistance to passive movement was tested bilaterally on the hip adductors, knee extensors, knee flexors, and ankle plantarflexors. MAS scores for all muscle groups were averaged in each leg.
4. A numeric rating scale for pain on which subjects were asked to rate their level of pain from 0 (no pain) to 10 (maximal pain), and pain location was recorded.

Gait performance was evaluated with the following tools:

1. The T25FW, which is a widely used test of walking speed on a short distance. The T25FW is among the 3 components of the Multiple Sclerosis Functional Composite, an outcome measure used in clinical trials of disease-modifying therapies for MS.[4] Subjects were instructed to walk 25 feet (7.5m) as fast as possible but

Table 1: Patient Characteristics

Characteristics	Values
Mean age ± SD (y)	52.8±8.8
Sex (% female)	57
Mean disease duration ± SD (y)	14.9±7.8
Disease course	48% relapsing-remitting, 14% secondary progressive, 24% primary progressive, 14% progressive-relapsing

safely. Two trials were conducted, and the average time between the 2 trials was calculated.

2. The TUG,[5] which measures the time needed to stand up, walk 3m (10ft), turn 180°, walk back 3m, turn 180° again, and return to a sitting position. The TUG associates balance and gait performance components and has been extensively used in neurologic populations.
3. The 6MWT, which assesses walking endurance, was initially validated for cardiovascular and respiratory disorders[6] but has been extensively used in neurologic disorders as well.[7] The distance walked over 6 minutes was recorded.
4. The MCGT, which is a custom-made gait course reproducing the diversity of terrains, obstacles, and maneuvers encountered in real life. If the subject is able to complete the whole course, the time needed to complete is recorded. In addition, scores are given on a 0 to 10 scale for speed, completion, and safety. The total ordinal score ranges from 0 to 30, with a higher score indicating a better performance. The MCGT has been used in clinical practice with excellent feasibility and safety. Preliminary validation results show that the MCGT is feasible and acceptable, correlates strongly with other gait tests, and is sensitive to change.[8]

All gait tests were performed without the HFAO at baseline examinations (baseline, 1wk) and with the HFAO at follow-up examinations.

Subject satisfaction was assessed at each follow-up visit by using a 9-item custom questionnaire. Subjects were asked to rate their level of satisfaction with the HFAO on a scale from 1 (very dissatisfied) to 5 (very satisfied), regarding the following elements: overall satisfaction, ease of donning and doffing, appearance of the HFAO, comfort, durability, effect of HFAO on balance, gait quality, ability to walk distances, and ADLs. The overall score ranges from 9 to 45.

To minimize the variations caused by fatigue and heat sensitivity, all visits were conducted at the same time of day (within 1h) and in a climate-controlled environment. All tests were performed in identical sequence at each visit. Subjects were also asked to report any complications with the HFAO itself or any physical complications such as pain or skin irritation.

Statistical Analysis

Descriptive statistics were generated at each endpoint. Scores for baseline 1 and baseline 2 visits were averaged into a global baseline score. Changes in scores between baseline and 8-week or 12-week follow-up visits were evaluated by using the Wilcoxon signed-rank test. In addition, effect sizes were calculated by using the following formula: ([mean value at follow-up] – [mean value at baseline])/SD at baseline. All statistical tests are 2 sided, and the significance level was set at P equal to .05. Statistical analyses were performed with SAS.[b]

RESULTS

Twenty-four subjects were enrolled, and 21 completed the study (dropout rate, 12.5%). Of the 3 subjects who dropped out, one had an MS relapse, one was noncompliant with visits, and one returned the HFAO, stating that the device was "too ugly to wear." The demographic and disease characteristics of the subjects are detailed in table 1.

The Effect of the HFAO on Impairments

Lower-extremity ROM and MAS scores did not change significantly between baseline and follow-up visits. There was a statistically significant improvement of lower-extremity MMT scores between baseline and both follow-up visits but only in the leg wearing the HFAO. There was a statistically significant improvement of pain scores at 12 weeks only (tables 2, 3).

The Effect of the HFAO on Gait Performance

There was a statistically significant improvement of performance on all gait tests at 8 and 12 weeks. There was a trend

Table 2: Baseline and Change Scores for All Outcome Measures and for Comparisons Between Baseline and Follow-Up Visits

Outcome Measure	Baseline	Change at 8 Weeks*	Change at 12 Weeks*
MMT affected leg†	2.5±0.6	0.1±0.2 **(.01)**	0.3±0.2 **(<.001)**
MMT unaffected leg	4.1±0.8	0.0±0.1 (.61)	0.1±0.1 (.07)
MAS affected leg†	4.0±2.5	−0.4±1.0 (.16)	−0.1±1.3 (.73)
MAS unaffected leg	1.8±2.4	−0.2±0.9 (.28)	0.2±1.3 (.51)
Pain	1.6±1.8	−0.3±2.2 (.61)	−1.2±1.6 **(.004)**
T25FW (s)	18.9±19.1	−5.1±9.7 **(<.001)**	−5.2±11.6 **(.001)**
6MWT (m)	647.7±423.6	159.2±119.5 **(<.001)**	124.7±118.2 **(<.001)**
TUG (s)	24.5±19.4	−6.4±12.3 **(<.001)**	−4.5±12.0 **(.014)**
MCGT time to complete (s)	97.5±66.9	−21.1±37.6 **(.001)**	−18.2±30.4 **(.004)**
MCGT speed score (0–10)	2.9±2.6	0.7±1.0 **(.004)**	0.7±1.0 **(.011)**
MCGT completion score (0–10)	9.7±0.9	0.2±0.8 (.75)	0.3±0.8 (.25)
MCGT quality score (0–10)	5.9±2.4	1.1±2.8 (.15)	1.4±2.4 (.019)
MCGT total score (0–30)	18.5±5.0	1.9±3.4 **(.013)**	2.4±2.8 **(.001)**

NOTE. Values are mean ± SD (P value). Boldface denotes significance at $P<.05$.
*Wilcoxon signed-rank test.
†The affected leg is the predominantly weaker leg that used the HFAO when walking.

Table 3: Effect Size of Change Between Baseline and 8 or 12 Weeks

Outcome Measure	8 Week	12 Week
MMT affected leg*	0.63	1.32
MMT unaffected leg	0.12	0.44
MAS affected leg*	−0.14	−0.04
MAS unaffected leg	−0.09	0.08
Pain	−0.14	−0.64
T25FW	−0.53	−0.45
6MWT	1.33	1.05
TUG	−0.53	−0.38
MCGT time to complete (s)	−0.56	−0.60
MCGT speed score (0–10)	0.70	0.66
MCGT completion score (0–10)	0.21	0.37
MCGT quality score (0–10)	0.38	0.59
MCGT total score (0–30)	0.56	0.83

*The affected leg is the predominantly weaker leg that used the HFAO when walking.

toward a slight decrease in performance between week 8 and week 12 (see tables 2, 3).

Subject Satisfaction

The level of satisfaction with the HFAO was high. The overall mean satisfaction score ± SD was 39.9±4.0 at 8 weeks and 39.0±7.1 at 12 weeks, out of a maximum possible score of 45. The distributions of responses for individual items are presented in figure 4. The lowest satisfaction scores were relative to the appearance of the HFAO.

Safety

No major adverse events occurred over the course of the study. Minor complications are listed in table 4. The most frequent problem was low back pain. None of these problems were severe enough to lead to the discontinuation of AFO wear during the study. In most cases, simple remedial measures were effective in controlling the problem. The design of the HFAO was modified after the study to prevent some of these issues from recurring.

Durability

Each subject was able to keep the device permanently after the 12-week study period. We only had 1 mechanical problem that required replacement of a part. This problem occurred with the plastic connecting bridge, which connects the distal end of the dynamic tension bands to the adjustable distal connector (shoelace strap) at the ankle level. This connecting bridge had to be replaced after it cracked. However, this failure occurred in the same subject who had retrofitted the HFAO with a spacer, so these altered mechanics may have led to the failure. Three subjects also requested extra shoelace straps, which allowed them to wear the HFAO with different shoes without removing the strap.

DISCUSSION

The results of this pilot study show that the HFAO is a safe and effective device in MS patients with unilateral (or unilaterally predominant) hip flexor weakness.

Despite the methodologic limitations (discussed later), the magnitude of the changes observed between baseline evaluation without the HFAO and follow-up evaluations with the HFAO, as well as the stability of results across outcome measures and across study visits, suggest that there was a true benefit when using the HFAO. There were few dropouts, further suggesting that the device was effective and well tolerated. The dropout rate in rehabilitation studies is generally above 20% versus 12.5% in our study.[9]

Lower-extremity strength increased significantly but only on the side with the HFAO (although there was a trend for improvement of strength in the contralateral leg at 12 weeks). The improvement of motor power has not been reported with passive orthoses such as AFOs. Several mechanisms could explain the improvement of motor control with the HFAO. Subjects may have been walking more in their daily activities and reversed the effects of deconditioning at the muscular level. However, if this were the only mechanism, one would expect a concomitant improvement in both lower extremities. A direct training effect of the HFAO, through assisted hip flexion, would account for the asymmetrical improvement. Also, it is possible that the improvement of gait pattern with the HFAO triggered changes in the functional organization of the central nervous system.

Gait speed during T25FW testing improved significantly with HFAO use. In addition to statistical significance, the magnitude of the effect size suggests that the improvement is clinically significant. Schwid et al[10] have established that a change of 20% in T25FW performance is clinically significant in MS. The average improvement in the time to walk 25ft in our subjects was 27% at 8 and 12 weeks. Most of the literature on gait speed improvement with orthoses in central nervous system disorders involves the use of AFOs in hemiplegic stroke patients. In this population, improvements of 28%,[11] 20%,[12] and 11%[13] were reported. In most of these studies, the before-after measurements were performed on the same day. A single case study comparing a hip-knee-ankle-foot sling with an AFO in a hemiplegic stroke survivor showed a 64.7% improvement of gait speed with the sling versus 29.4% with the AFO.[14] We also found an interesting study[15] of AFO use in MS in which

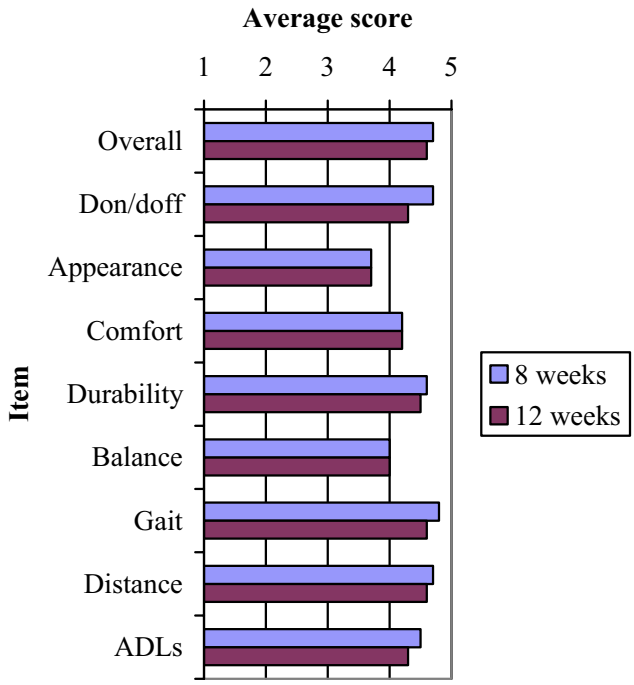

Fig 4. The average satisfaction scores at 8 and 12 weeks (1=not at all satisfied; 5=very satisfied).

Table 4: Complications Related to HFAO Use

Complication	Incidence	Percentage Resolved	Methods Used to Attempt to Resolve Complications	Outcome
Low back pain	4/21	75	Reinforce adherence to wear schedule during first 2 weeks. Trunk stretching and strengthening exercise issued on completion of study.	One patient reported having increased back pain for the first week, which subsequently resolved. Trunk-strengthening exercises are now issued at the time of the initial PT evaluation before receiving HFAO.
Contralateral knee pain	1/21	100	Preexisting degenerative joint disease in contralateral knee was exacerbated by increased walking with HFAO. Aquatic exercise encouraged on completion of study.	Aquatic exercise $\times$ 6wk resolved the knee pain. The patient continues with aquatic exercises independently and wears the HFAO only for walking long distances (eg, stores, malls).
Ipsilateral skin irritation at knee	2/21	50	In both cases, the patient experienced medial knee rubbing from the elastic band because of excess genu valgum. A rigid "spacer" at the ankle bridge widened the attachment points of the elastic bands and resolved the rubbing.	The spacer mechanism has been redesigned to be stiffer and broader, thus eliminating this problem.
Skin irritation over ITB pump	1/3 subjects with a baclofen pump	0	(1) Loosen waist belt, which allows skin pressure relief over pump site; (2) also tried a narrower belt that rode below the ITB pump site.	This is a very thin patient and both methods helped but were not ideal. The skin pressure was reported to be too great on the posterior margin of the iliac crests so HFAO wear was limited to $<$60min.
Mid-foot pain	2/21	100	Cease HFAO wear until pain subsides and then resume HFAO wear using a shoe with a more rigid sole.	The shoe with the rigid sole resolved this problem in both cases. However, mid foot instability (eg, Lis Franc instability) is a precaution for HFAO wear.
Difficulty with don and doff	1/21	100	Hemiplegic patient had a D-ring added to waist belt to allow single hand to tighten waist belt.	The D-ring allowed the patient to don and doff the HFAO independently.

Abbreviations: ITB, intrathecal baclofen; PT, physical therapy.

the study authors reported a decrease in walking speed with an AFO (although performance was better with a dynamic AFO than with a static AFO). PNS to correct foot drop, a dynamic device that produces contraction of the ankle dorsiflexors, did not improve performance on gait tests in a recent pilot study in a small sample of MS patients.[16]

We also found a statistically significant improvement of walking distance with the HFAO, with a large effect size. This suggests that the HFAO, in addition to gait speed, improves gait endurance. A recently published study[17] in older adults determined that the smallest meaningful change in the distance walked in 6 minutes is approximately 20m. In our study, 76% of subjects satisfied this criterion at 8 weeks and 62% at 12 weeks. The average improvement of 6MWT distance was 24% at 8 weeks and 19% at 12 weeks. A study of AFO versus FES after incomplete spinal cord injury

found an average improvement of 6MWT distance of 17% with AFO, 10% with FES, and 23% with a combination of AFO and FES.[18]

We added the TUG to our gait assessments because we were concerned that the elastic effect of the HFAO would compromise subjects' ability to stand up from a sitting position and could even be unsafe. In fact, all subjects were able to stand up independently and safely with the HFAO. Some difficulty standing up was observed in the weakest subjects, but the increase in gait speed compensated for this, resulting in a net improvement of the time needed to complete the TUG.

These 3 gait tests are performed indoors and on level ground. For this reason, one may question the real effectiveness of the HFAO on the ability to perform mobility-related ADLs. Several elements are in favor of such an effect. First, the MCGT, which incorporates more challenging activities (climbing up and down stairs and a ramp, stepping up and down a curb, walking on the equivalent of a grassy surface) showed significant improvement in the time needed for completion, with equivalent magnitude of gain compared with the more simple tests. Second, there are published data[19,20] on correlations between gait tests performed in the clinic and real-life ambulation performance. Finally, most of our subjects reported a subjective improvement of gait performance (90% of subjects at 8 weeks and 81% at 12 weeks reported that they were satisfied with the effect of the HFAO on gait quality), suggesting that the results observed on limited objective tests in the clinic were also felt in everyday life.

Several mechanisms can be proposed to explain the improvement of quantitative gait performance between HFAO-off and HFAO-on evaluations. On direct observation, the biomechanical quality of gait while using the HFAO was improved. We noticed an increase in stride length on the affected side with HFAO use. There was also a reduction in gait anomalies that were observed at baseline, such as decreased ipsilateral hip circumduction and decreased ipsilateral hip hiking. Mechanical testing of the HFAO showed the production of favorable moments at the hip, knee, and ankle at all phases of the gait cycle. Improvement in gait pattern is likely to reduce musculoskeletal stress on the joints and to improve the ease of walking. We can also hypothesize that the HFAO increases the energetic efficiency of gait, even though this parameter was not measured. Finally, the improvement in lower-extremity strength (tested without HFAO at all visits), albeit of small magnitude, most likely contributes to the improvement in gait speed and endurance.

We did not find any consistent and significant effect of the HFAO on spasticity or passive ROM. Overall, our subjects exhibited low levels of spasticity at baseline and no significant limitations of passive ROM. Three of the subjects in the study had a baclofen pump. Skin irritation over the pump was a problem in one of these subjects who was very thin; changes in the abdominal belt improved the situation. Our experience suggests that these interventions can be combined in select patients to optimize functional outcomes.

Study Limitations

We acknowledge several limitations to our study. The selection of a convenience patient sample, the relatively small size of the sample, and the strict inclusion and exclusion criteria make it difficult to generalize the results. Evaluators (and obviously subjects) were not blinded to the intervention. There was no control group; therefore, we were unable to evaluate a possible placebo effect or an overall spontaneous increase in exercise and/or activity because of participation in the study. Because we did not evaluate gait performance with and without HFAO at follow-up (because of time limitations), it was not possible to differentiate the direct effect of the brace versus its indirect effect through increased lower-extremity strength and daily mobility. We did not evaluate compliance with HFAO wear schedule formally and its potential influence on outcomes. Finally, we did not follow subjects for more than 12 weeks, and this did not allow us to measure long-term compliance, safety, and efficacy of the device as the disease may progress.

CONCLUSIONS

The HFAO appears to be an effective low-cost orthotic option for MS patients suffering from unilateral or unilaterally predominant hip flexor weakness causing gait disturbance based on the results of this pilot study. Beyond the immediate direct effect on gait performance, the HFAO appears to have an indirect effect on activity level in daily life, with resulting improvement of lower-extremity strength and endurance. The device is also safe, provided that detailed oral and written instructions as well as proper training are provided. Complications were minor and reversible in most cases. Most patients appeared to be satisfied with the device. The HFAO needs to be further tested in a randomized controlled study and over a longer period of time. Overall, considering the prevalence and negative impact of weakness in the upper and lower extremities, there is a need to develop and test more active devices for MS patients and to investigate the mechanisms through which they improve performance.

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Suppliers

a. G.R.E. Prosthetics & Orthotics, 13376 Ravenna Rd, Chardon OH 44024.
b. Version 8.2; SAS Institute, 100 SAS Campus Dr, Cary, NC 27513-2414.