Foot Drop Stimulation Versus Ankle Foot Orthosis After Stroke

30-Week Outcomes

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Background and Purpose—Drop foot after stroke may be addressed using an ankle foot orthosis (AFO) or a foot drop stimulator (FDS). The Functional Ambulation: Standard Treatment versus Electric Stimulation Therapy (FASTEST) trial was a multicenter, randomized, single-blinded trial comparing FDS and AFO for drop foot among people ≥3 months after stroke with gait speed ≤0.8 m/s.

Methods—Participants (n=197; 79 females and 118 males; 61.14±11.61 years of age; time after stroke 4.55±4.72 years) were randomized to 30 weeks of either FDS or a standard AFO. Eight dose-matched physical therapy sessions were provided to both groups during the first 6 weeks of the trial.

Results—There was significant improvement within both groups from baseline to 30 weeks in comfortable gait speed (95% confidence interval for mean change, 0.11–0.17 m/s for FDS and 0.12–0.18 m/s for AFO) and fast gait speed. However, no significant differences in gait speed were found in the between-group comparisons. Secondary outcomes (standard measures of body structure and function, activity, and participation) improved significantly in both groups, whereas user satisfaction was significantly higher in the FDS group than in the control group.

Conclusions—Using either an FDS or an AFO for 30 weeks yielded clinically and statistically significant improvements in gait speed and other functional outcomes. User satisfaction was higher in the FDS group. Although both groups did receive intervention, this large clinical trial provides evidence that FDS or AFO with initial physical therapy sessions can provide a significant and clinically meaningful benefit even years after stroke.

Clinical Trial Registration Information—URL: http://www.clinicaltrials.gov. Unique Identifier: NCT01138995. **(*Stroke*. 2013;44:1660-1669.)**

Key Words: electric stimulation ■ foot drop stimulation ■ gait ■ orthosis ■ rehabilitation ■ stroke

Stroke is one of the most significant causes of disability in adults. Damage to the motor cortex or corticospinal tract often results in contralateral hemiplegia with significant persistent distal weakness. Patients with this pattern of weakness are often unable to actively dorsiflex the foot during the swing phase of gait, which is referred to as drop foot. This gait impairment can result in compensatory movement patterns, slowed gait velocity, limited functional mobility, and increased risk of falls.[1–3]

The traditional treatment for persistent drop foot is an ankle foot orthosis (AFO) that holds the foot in a neutral position. The most common type of AFO is a solid plastic brace, although it may be made of metal or composite materials, with any number of modifications, including an articulated or hinged ankle joint. In general, AFOs have been found to support ankle dorsiflexion during swing phase and improve knee stability in early stance phase in individuals with drop foot.[2,4] However, there are several significant disadvantages of AFOs such as limited ankle mobility that may contribute to the development of contracture[4,5] and difficulty with standing from a chair,[6] along with discomfort and unfavorable aesthetics.[7]

An alternative to the more traditional AFO is the use of functional electric stimulation. Foot drop stimulators (FDS) use functional electric stimulation to stimulate the common peroneal nerve, activating the muscles that dorsiflex the foot during the swing phase of gait. The effect of FDS or an AFO on gait can be measured in several ways, but conflicting terms have previously been used in the literature.[8,9] We

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have attempted to provide clear operational definitions that describe the scope and timing of comparison,[10] as illustrated in Figure 1. The immediate effect refers to changes in gait that occur when initially wearing the device. A training effect above and beyond the immediate effect may occur as the patient uses the orthosis or FDS over time. The therapeutic effect refers to improvements in walking seen even without wearing an orthosis or FDS and may result from changes in neural plasticity, peripheral strength, cardiopulmonary system, or other systems. The total effect refers to the changes in gait that occur over time, and encompasses both the immediate and training effects.

The results of past FDS studies in stroke have had generally positive results on these different effects, using quasi-experimental and within-subject study designs.[11–13] Increased gait speed has been found consistently in patients with stroke comparing no orthotic with use of both FDS[9,14–16] and AFO.[17,18] Small, short-term studies using a within-subjects comparison of AFO and FDS in stroke found that both devices increased gait speed after 8 weeks.[11,13] The only long-term study of FDS on gait speed found a pattern of significant improvement even at 11 months in participants with a nonprogressive disorder (ie, stroke).[8] The only randomized controlled trial on AFO use in stroke found no significant improvement in gait speed after 3 months.[19] To date, no randomized controlled trials have directly compared surface FDS with AFO in people with drop foot after stroke. However, a randomized controlled trial that compared an implantable peroneal nerve stimulator showed significantly increased gait speed compared with the AFO/control group.[20]

The Functional Ambulation: Standard Treatment versus Electric Stimulation Therapy (FASTEST) trial was designed to compare FDS and AFO for drop foot among people ≥3 months after stroke, with a gait speed ≤0.8 m/s. This was a multicenter, randomized controlled, single-blinded trial. We hypothesized that after 30 weeks, participants randomized to the FDS group would demonstrate greater improvement in gait speed than participants randomized to the AFO group. This hypothesis was based on the anticipated total device effects, encompassing both the immediate and training effects, from the results of previous studies showing positive long-term effects of FDS on gait speed.[8,20] Other comparisons illustrated in Figure 1 were also assessed.

Methods

A detailed description of the trial design and the methods have been published previously,[10] with a brief summary provided here. Participants ≥3 months after stroke with gait speed ≤0.8 m/s were randomized to 30 weeks of wearing either a surface FDS (treatment group) or a standard AFO (control group). At 30 weeks, the control group crossed over to receive an FDS and was followed for an additional 12 weeks, whereas the original treatment group continued to use their FDS. This article reports on the primary and secondary outcomes at 30 weeks, before crossover.

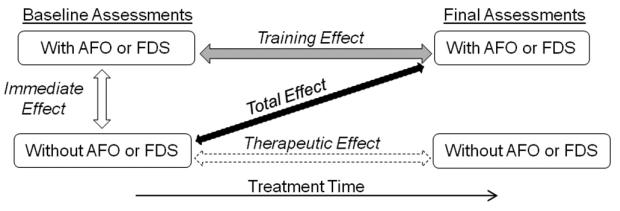

Figure 1. Illustration of comparisons of effect of ankle foot orthosis (AFO) or foot drop stimulator (FDS) on gait.

Participant Screening and Randomization

Participants were recruited at 11 clinical sites across the United States (see the online-only Data Supplement). Each site obtained Institutional Review Board approval, and informed consent was obtained before any study procedures.

Inclusion and exclusion criteria are presented in Table 1. The screening process included assessment by an independent orthotist and a physical therapist to verify that each participant demonstrated drop foot requiring an AFO, and to determine whether his or her current AFO was appropriate based on best practice points as described by a consensus document published by the International Society for Prosthetics and Orthotics,[21] as well as Medicare reimbursement guidelines. If the participant did not have an AFO, a new custom-made AFO was prescribed by the site team and paid for by the sponsor. If the current AFO needed modification, those modifications were prescribed by the site team and paid for by the sponsor. The specific type of AFO (eg, solid ankle, hinged, etc) prescribed for each participant was left to the discretion of the study team of each site. This process ensured that all subjects had an appropriate AFO when needed during the study, and occurred before randomization.

Once study eligibility was confirmed, random group assignment was performed by the sponsor using a web-based application prepared by the study statistician (S.W.). Covariate adaptive randomization[22] was used to ensure balanced group allocation at each site for age and time after stroke and known demographic confounders, within 4 subgroups: 3 to 6 months after stroke, >6 months after stroke, <65 years of age, and ≥65 years of age or Medicare beneficiary. For each new participant, the Web-based application determined imbalance corresponding to its covariate characteristics based on cumulative distribution of assignments up to that point. If there was assignment imbalance, the subject was allocated to the under-represented group with a P value of 2/3; otherwise, the subject was randomized with equal probability.

Interventions

During the first 6 weeks of the study, both groups received 8 dose-matched sessions of physical therapy (PT) led by a licensed physical therapist who had received training and competency assessment in the use of FDS. Regardless of group assignment, the first 2 to 4 therapy visits focused on education on device use (AFO or FDS), initial gait training, and an individualized home exercise program. The remaining sessions of PT focused on gait training with the assigned device.

FDS Group

The FDS used in this study was the NESS L300 Foot Drop System, manufactured by Bioness Inc. (Valencia, CA). The L300 comprised a functional stimulation cuff with integrated stimulation unit and electrodes, a control unit, and an in-shoe pressure sensor. The unit is initially configured by a clinician using a handheld computer interface. The pressure sensor detects heel off and initial contact events during gait. It transmits wireless signals to the stimulation cuff, which initiates/pauses the stimulation of deep and superficial branches of the peroneal nerve via 2 surface electrodes. The foot dorsiflexors and evertors are, therefore, activated to ensure foot clearance during the swing phase and prevent excessive ankle inversion during early stance, respectively.

Standardized protocols derived by the sponsor from >5 years of market experience were used by all sites for initial fitting of the FDS, gait training, wearing schedule, home exercise program, and participant education. Written skin care guidelines were reviewed and issued to the participant during the initial fitting and reviewed throughout the training period.

AFO Group

Education on use, care, gait training, home exercise program, and maintenance of the AFO was provided, along with a wearing

Table 1. Eligibility Criteria

Inclusion Criteria	Exclusion Criteria
At least 1 stroke ≥3 mo before study enrollment, resulting in drop foot	Fixed ankle contracture at ≥5 degrees of plantar flexion in the hemiplegic leg with the knee extended
Ankle dorsiflexion response with test stimulation in sitting and standing, and adequate ankle and knee stability during gait with test stimulation	Pain in the affected leg, rated ≥4 on a 10-point visual analog scale
Medically stable	Participating in PT, OT, new exercise program, or any other interventional clinical research studies without the sponsor's approval
Score ≥24 on the Mini Mental State Examination (MMSE), or have a competent caregiver if <24.	Botulinum toxin to the hemiplegic leg or arm within the past 6 wk or planned during the course of the study
Age ≥18 y or older	Expectation of a significant change in oral medications for spasticity
Able to walk ≥10 meters with a maximum of 1 person assist	Complete lower extremity hemisensory loss
Self-selected gait speed ≤0.80 m/s without orthotic effect	Use of any FDS device for foot drop for an accumulative >3 h within the last 6 mo before study enrollment
	Any electric or metallic implant; significant swelling/edema in the lower leg; chronic skin problems or cancerous lesion in close proximity to the site of FDS stimulation; pregnant or plan on becoming pregnant; unstable seizure disorder; orthopedic conditions that would affect ambulation; major untreated depression

FDS indicates foot drop stimulator; PT, physical therapy; and OT, occupational therapy.

schedule when needed (eg, new AFO). It is impossible to implement a sham control treatment for FDS because the participant can feel the stimulation and see their foot move. Moreover, some form of drop foot intervention is necessary for safe walking. Therefore, control participants received surface sensory stimulation with a transcutaneous electric nerve stimulation (TENS) device at each PT visit during the first 2 weeks. TENS intensity was set at the lowest stimulation level that yielded a sensory response without motor response, at a frequency of 100 pps and duration of 200 μsec.

Outcomes

Repeated outcome measures were obtained at baseline and after 6, 12, and 30 weeks. For baseline and 30-week sessions, including testing both with and without the device, see Figure 1. Well visit follow-ups were performed at weeks 16, 20, and 24, which included fall questionnaires and skin/AE assessment only.

Outcome testing was performed by physical therapists blinded to group assignment. The therapists all received training and passed an on-site competency test for consistency in outcomes assessment. To maintain blinding, a large piece of vinyl fabric was secured over the lower leg and shoe on the involved lower extremity to conceal the device and pressure sensor. All subjects wore an FDS control unit on their belt, regardless of group assignment.

Primary Outcome

Comfortable and fast walking speed were assessed was assessed with a 10-meter walk test.[23] Walking speed has been shown to be an important predictor of community ambulation, functional status, and survival.[24–26] The most commonly used assistive device at the time of assessment was used and documented, along with documentation of the amount of assistance provided.

Secondary Outcomes

Additional outcome measures were included, encompassing the breadth of the International Classification of Function model.[27] These included a measure of body structure and function (lower extremity Fugl-Meyer), several activity measures to assess functional mobility (Timed up and go), walking endurance (6-minute walk test [6MWT]), and balance (Berg balance scale; Functional reach test), and a participation-level measure (Stroke Impact Scale). All outcome measures are valid and reliable in people with stroke.[23,28–36]

Step activity monitors were worn on the uninvolved leg during all waking hours for 7 consecutive days in weeks 6 and 24 to quantify the amount of walking at home and in the community (StepWatch by Orthocare Innovations, LLC).[37]

A user satisfaction survey[16] was completed at week 12 (after completion of PT sessions) and again at week 30 in both groups. This 12-item survey had a total range of scores from 0 to 24, with a higher number indicating greater satisfaction with the device.

Adverse Events and Falls

The cumulative frequency and severity of adverse events (AEs), number of events per subject, and percentage of subjects experiencing an AE were reported from randomization to the 30-week visit. Fall incidence was obtained by self-report from participants and their caregivers retrospectively 6 months before baseline and at each study visit during the 30-week intervention period. Circumstances regarding each fall were collected, including any injury or medical attention received.

Statistical Analysis

Sample Size and Power Analysis

The original power analysis for this study resulted in the plan to enroll 176 eligible participants, allowing for a 25% dropout rate, which would result in 132 participants who would complete the study. This was estimated to provide 80% power to detect a clinically meaningful (0.1 m/s)[38] difference in walking speed change between groups using a 2-sample t test with a 2-sided 0.05 level. After the first planned interim analysis (September 2011), the enrollment goal was increased to 206. This increase allowed for (1) the addition of a primary hypothesis for a subgroup of persons with initially severe gait (<0.4 m/sec gait speed), and (2) the reduction of the risk of type II errors on several secondary outcomes. As a result of favorable trends in outcomes for participants with severe gait impairment, a hypothesis was added that participants in this subgroup randomized to the FDS group would demonstrate greater improvement in gait speed than those randomized to the AFO group. The sponsor elected to close enrollment at 197 participants.

Data Management and Quality

A secure Web-based electronic data capture system (Medidata Rave) was used for clinical data collection and management. Third party monitors performed regular visits at each site to review and verify all study data in source documents.

Data Analysis

Differences in demographic and baseline variables between groups were analyzed using *t* test or χ^2 test. Variables found to be significantly different between groups were used as covariates in the final analyses, in addition to the prespecified covariates of study site and whether a new AFO prescription was provided at study entry.

The primary intent-to-treat analysis involved 2 tests: 1 for the entire sample and the other for the severe subgroup. The study-wide error rate was controlled at the 0.05 level by applying the Hochberg step-up procedure.[39] Each statistical test was based on the Fisher combination of 2 *P* values: 1 from before and the other from after the first interim analysis. Both *P* values were derived from a linear model investigating whether the groups differ in walking speed improvement from baseline to 30 weeks, after controlling for the aforementioned covariates.

Outcomes for participants who could not complete the 30-week evaluation were imputed by a regression model that takes into account participant dropout bias (described in protocol article).[10] In addition, Wilcoxon rank-sum tests were conducted to compare secondary outcomes between the 2 groups. For simplicity, only the completers were analyzed, and there were no adjustment for covariates. However, the family-wise error rate for all secondary hypotheses testing was controlled at 0.05 level based on Holm step-down procedure,[40] which rejects a hypothesis only if its *P* value and each of the smaller *P* values are less than their corresponding critical values.

Results

Recruitment, Screening, and Randomization

More than 1200 potential subjects were screened by phone, via chart review, or in person. After initial screening, 389 subjects signed informed consent and participated in further in-person screening (Figure 2). A total of 197 participants were enrolled and randomized.

Participant Characteristics

Participant characteristics at baseline with between-group comparisons are presented in the online-only Data Supplement. The only significant differences between groups were in categories of sex (greater percentage of females in the treatment group) and stroke type (greater percentage of ischemic stroke in treatment group). Both were used as covariates in all subsequent analyses. It is notable that 118 of 197 (60%) participants received a new or modified AFO at study entry. A description of type of AFO at each site is provided in the online-only Data Supplement.

Primary Outcome: Gait Speed

At 30 weeks, both comfortable and fast gait speed improved significantly within both the FDS and AFO groups for total effect, as well as training and therapeutic effect ($P<0.001$ for all). In addition, the immediate effect was also significant within groups ($P<0.001$). The specific change values are presented in Table 2 for the entire sample and in the online-only Data Supplement for the severe subgroup. However, no significant differences were found between groups for comfortable gait speed improvement for either the entire sample (0.15±0.14 vs 0.14±0.16; $P=0.78$ with Fisher combination test) or in the severe subgroup (0.11±0.14 vs 0.11±0.11; $P=0.16$ with Fisher combination test). Figure 3 illustrates the trajectory of change of the entire sample for comfortable gait speed between groups over time, for both the training effect and the therapeutic effect. No sex-based or racial/ethnic-based differences were present for the primary outcome.

Secondary Outcomes

All outcome measures had similar patterns of change, with significant improvements noted within both groups but no significant between-group differences. Figure 4 illustrates comparisons for total orthotic effect, immediate orthotic effect, training effect, and therapeutic effect for several of the gait outcomes. Specific values for these changes in the entire sample and the severe subgroup are presented in the online-only Data Supplement. No between-group differences were noted in the number of steps per day, as measured with the step activity monitors at week 6 (1891 steps per day in control group; 2092 steps per day in treatment group) or week 30 (2069 steps per day in control group; 2369 steps per day in treatment group).

User Satisfaction

The total user satisfaction survey score measured at week 12 (after completion of PT sessions) was significantly higher in the treatment group than the control group (21.9±2.4 versus 19.0±4.4; 95% confidence interval of mean difference, 1.71–3.87; $P<0.001$), and these differences persisted at week 30 (21.8±2.9 versus 19.1±4.0; 95% confidence interval, 1.64–3.74). Analysis of scores for individual items is presented in the online-only Data Supplement.

Safety/AEs

Twenty serious AEs were reported, but none were related to the study or the device. The frequency and severity of AEs are summarized in the online-only Data Supplement. The total number of AEs was higher ($P<0.01$) in the treatment group: 82 FDS participants reported a total of 219 AEs, 130 (59%) of them related to device/procedure compared with 61 AFO participants who reported a total of 147 AEs, 50 (34%) of them related to device/procedure. However, nearly all of the related AEs were of mild severity (92% for FDS and 96% for AFO). Anticipated skin irritation issues accounted for 51 (40%) of study-related AEs in the treatment group. The number of participants who fell in the 2 groups during the study period was not significantly different, with a greater number of falls experienced in the control group.

Discussion

FASTEST is the largest randomized controlled trial comparing FDS and AFOs in persons with stroke to date. The hypothesis that participants randomized to the FDS group would demonstrate greater improvement in gait speed than participants randomized to the AFO group was not supported. Rather, the AFO and FDS groups both made statistically and clinically significant gains in gait speed and other outcomes across all domains of the International Classification of Function model. The observed gains were likely because of a composite effect of the devices, motor learning, and the PT intervention provided at the start of the study.

There may be several reasons why there were no between-group differences in the total effect or other comparisons

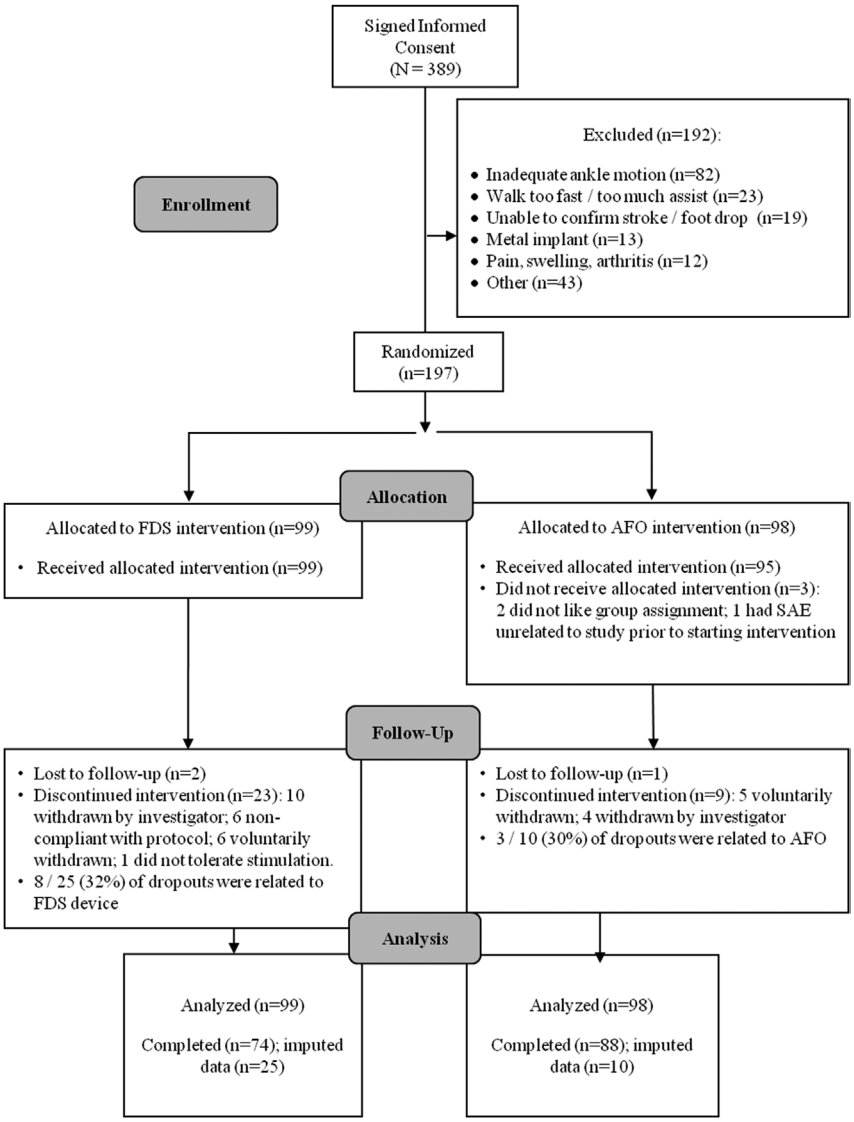

Figure 2. Consolidated standards of reporting trials (CONSORT) diagram. AFO indicates ankle foot orthotic; FDS, foot drop stimulator; and SAE, serious adverse event.

contrary to our hypotheses. To protect against selection bias favoring FDS, all participants were evaluated before randomization to ensure that their current AFO was safe and effective. The fact that more than half (60%) of participants enrolled in this study required a new or modified AFO was unexpected because the participants all had drop foot, were community dwelling, and had completed their PT before enrollment. Nonetheless, a majority did not have an AFO that met minimal standards for fitness and safety. Therefore, many individuals in the standard care control group received either a new or modified brace before randomization in addition to receiving the PT intervention. This might have contributed to the unexpected improvements in gait and other outcomes in this group.

Participants in both groups received 8 PT sessions over the first 6 weeks focused on gait training and an individualized home exercise program. As evidenced in Figure 3, the impact of PT may have been particularly prominent in the first 12 weeks after randomization. The PT sessions were essential for initial instruction and gait training with the FDS to maximize effectiveness and safety of gait as well as for monitoring for compliance and skin care. The beneficial impact of PT in persons with chronic stroke is well known.[41–43] Although potentially blunting differences between groups, our results support the value of PT as part of the initial deployment and management of either FDS or AFO for foot drop in patients with stroke.

The control/AFO group also received TENS during the PT treatment sessions in an attempt to provide sensory nerve stimulation as a sham treatment compared with the motor and sensory stimulation experienced with FDS. It is possible that TENS itself contributed to increased gait speed in the control group. Although a systematic review and meta-analysis stated there was insufficient evidence to make conclusions regarding the effectiveness of TENS,[9] several studies have shown increased gait speed after the use of TENS to the lower extremity combined with gait training in people with chronic stroke.[44–48]

It is notable that the immediate effect was statically significant for both devices. This finding speaks to the immediate impact of both devices and the degree of limitation that foot drop entails in persons after stroke and is consistent with

Table 2. Change in Outcomes by Treatment Group

		Overall (n=197)	Control (n=98)	Treatment (n=99)	*P* Value for Between Groups
Change in comfortable gait speed, m/s	Long-term device effect	0.15±0.15*	0.15±0.14*	0.14±0.16*	0.749
	Immediate device effect	0.08±0.11*	0.09±0.12*	0.07±0.10*	0.180
	Training effect	0.07±0.11*	0.06±0.11*	0.08±0.12*	0.379
	Therapeutic effect	0.10±0.14*	0.09±0.14*	0.10±0.14*	0.460
Change in fast gait speed, m/s	Long-term device effect	0.15±0.17*	0.17±0.18*	0.13±0.16*	0.125
	Immediate device effect	0.07±0.13*	0.09±0.15*	0.05±0.11*	0.018
	Training effect	0.08±0.14*	0.07±0.15*	0.08±0.14*	0.711
	Therapeutic effect	0.05±0.14*	0.05±0.14*	0.06±0.13*	0.466
Change in 6-min walk distance, m	Long-term device effect	44.7±56.9*	48.6±51.1*	40.9±62.1*	0.341
	Immediate device effect	22.5±41.2*	25.8±42.3*	19.3±39.9*	0.276
	Training effect	22.2±44.4*	22.9±42.5*	21.5±46.3*	0.834
	Therapeutic effect	13.7±46.1*	11.9±41.9*	15.6±50.1*	0.576
Change in Timed up and go (TUG) test, s	Long-term device effect	−5.16±17.66*	−4.38±21.37*	−5.93±13.06*	0.539
	Immediate device effect	−3.22±13.01*	−3.19±14.34*	−3.26±11.61*	0.970
	Training effect	−1.93±13.64*	−1.19±15.52	−2.67±11.51*	0.447
	Therapeutic effect	−1.27±11.95	−0.01±13.12	−2.52±10.58*	0.140
Change in Berg Balance Scale score	Long-term device effect	2.86±5.46*	3.75±4.62*	1.97±6.08*	0.022
	Immediate device effect	1.51±4.07*	2.12±4.21*	0.92±3.86*	0.039
	Training effect	1.34±4.79*	1.64±4.25*	1.06±5.27*	0.397
	Therapeutic effect	1.85±4.87*	2.05±4.57*	1.65±5.16*	0.564
Change in functional reach distance, inches	Long-term device effect	1.10±6.67*	1.09±6.30	1.12±7.05	0.969
	Immediate device effect	0.61±6.43	0.83±5.40	0.39±7.32	0.631
	Training effect	0.49±6.16	0.25±6.48	0.73±5.84	0.586
	Therapeutic effect	0.15±7.03	0.28±6.84	0.03±7.25	0.800
Change in Fugl-Meyer Lower Extremity score	Long-term device effect	0.71±3.42*	1.04±3.26*	0.38±3.56	0.178
	Immediate device effect	0.37±2.97	0.58±3.31	0.16±2.59	0.323
	Training effect	0.34±3.22	0.46±3.60	0.22±2.81	0.607
Change in Stroke Impact Scale (SIS) participation scores	Long-term device effect	7.79±17.83*	7.09±17.24*	8.48±18.47*	0.587
	Immediate device effect	1.56±14.86	1.51±14.81	1.62±14.99	0.960
	Training effect	6.23±16.19*	5.59±17.85*	6.86±14.41*	0.581
Change in SIS mobility scores	Long-term device effect	5.18±14.78*	3.19±14.30*	7.14±15.04*	0.061
	Immediate device effect	−1.27±11.17	−2.63±11.77*	0.08±10.42	0.088
	Training effect	6.45±13.51*	5.83±13.26*	7.06±13.79*	0.523

*$P<0.05$ for within group comparison.

other studies that have examined this effect with FDS.[14,16] It is expected that learning to walk with a new device occurs over time, as has been shown with other studies of FDS without a control or comparison group.[8,13,15,16] In the context of this trial, we defined a total effect of device use over time as distinct from a therapeutic effect that reflects change in walking without any device. However, these factors are not mutually exclusive. The therapeutic effect of functional electric stimulation was confirmed with a meta-analysis examining the results of 5 studies on gait speed in patients with stroke,[9] along with more recent studies.[8]

Although AFOs are commonly used to address foot drop after stroke, there is a surprisingly small amount of quality research to support the use of AFOs in neuromuscular disorders as noted by a recent review of literature.[49] The single randomized controlled trial that has been published on this topic did not find clinical or significant improvements in gait speed when comparing a standard polypropylene AFO (set in 5° of dorsiflexion) with a placebo AFO that allowed normal range of motion.[19] However, only 50% of patients in that study complied with wearing the AFO, which seems to confirm the issues related to prestudy AFO use in our study.

With regard to AFO alone, there is little to no data on the biological basis for effectiveness in persons with stroke. Kinematic studies have demonstrated the biomechanical advantage at the ankle, knee, and hip by passively supporting dorsiflexion during the swing phase of gait with an AFO.[2,4] We did observe a significantly improved total device effect for the Berg balance scale in the control AFO group compared with the FDS group. However, the magnitude of

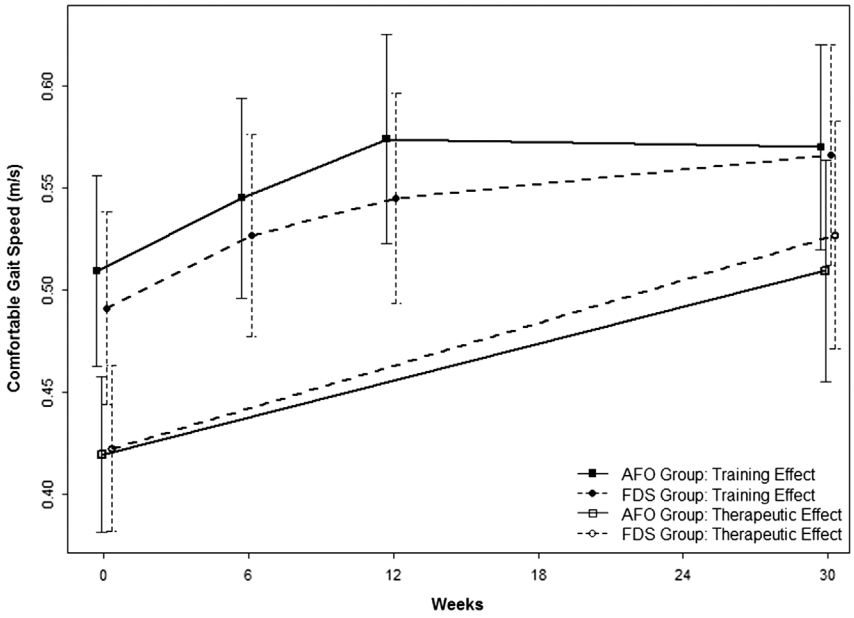

Figure 3. Trajectory of change in outcome measures week 0 to 30, illustrating the training effect (solid square and circle) and the therapeutic effect (open square and circle). AFO indicates ankle foot orthotic; and FDS, foot drop stimulator.

change was below the minimal detectable change (beyond measurement variation) in older adults[50] and less than the smallest real difference in people with chronic stroke.[51] The AFO may have mechanical attributes that are amenable for better performance of this test, especially in single limb stance activities, but the lack of difference in falls between groups indicates that this solo finding may have little clinical significance. The biological basis of the therapeutic effect observed in the AFO group in this study could be increased in peripheral muscle strength (unlikely given the relative immobilization of the ankle), neural plasticity, or improved cardiopulmonary conditioning. However, our study is not designed to distinguish these or other mechanisms. It should be noted that the 2005 Stroke Rehabilitation Guidelines from the American Heart Association make clear that AFOs should not replace functional exercise directed at regaining muscle strength and control, which suggests limited therapeutic benefit.[52]

With regard to FDS, there is a more extensive examination of the underlying biological effect.[53] Peroneal nerve stimulation has been found to alter surface electromyographical activity,[54] enhance cortical excitability,[55] and, in the upper extremity, alter activity on functional magnetic resonance imaging.[56] The latter study, and others,[57] also suggest that the combination of voluntary muscle contraction and functional electrical stimulation may be more effective in activating the cortex. Although no similar data exist for AFO, the relatively immobilizing effect of an ankle brace would be theoretically less desirable than the movement allowed with FDS use. In our study, a greater number of AEs were reported in the treatment group. Skin irritation from the FDS electrodes was an anticipated factor that has been previously reported,[58] but the majority of the AEs in both groups were of mild severity.

Although participants in both groups in our study had equivalent improvement in functional outcomes, there was a significant difference in the user satisfaction scores. This is consistent with multiple previously published studies with subjective reports or surveys favoring FDS over AFO.[11,12,58–60] Our user satisfaction survey was identical to that previously used by Hausdorff and Ring,[16] but that specific survey has not been previously used to compare FDS and AFO. Poor compliance with AFOs has been reported in people with foot drop,[19,61] and may have been a factor leading to the lack of adequate use of AFOs in many of the participants at enrollment into the study. Because an impressive improvement was seen with both devices, and nearly all AEs were mild and expected, the issue of compliance may be the single most importance factor in the functional improvements expected over long-term use of a device for foot drop. Although the number of steps per day assessed at 2 points during the trial was similar between groups, this study was not long enough to show the impact of compliance over a long term. An economic comparison of long-term use of AFO versus FDS would also be valuable but was outside the scope of this trial.

The average age of participants in this study was 61 years, which is comparable to the age of other large clinical trials in stroke rehabilitation,[62,63] and an average of 4.5 years after stroke. However, the average age for people hospitalized for stroke is 70 years, and the incidence of stroke increases with age.[64] Age is well known as a predictive factor of mortality and initial recovery,[65] although less is known about the influence of age on rehabilitation in the chronic phase of stroke.

A wide range of outcome measures were used in this trial, with substantive efforts toward standardization and blinding of assessments. However, other outcome measures may also be meaningful in comparing FDS with AFO based on previous research, including obstacle avoidance,[66] ankle dorsiflexion strength,[67] and cortical pathways used for muscle activation.[53] Furthermore, the development of a validated measure of user satisfaction is important to adequately capture the factors that lead to long-term compliance and the subjective experience of the individual with drop foot from stroke.

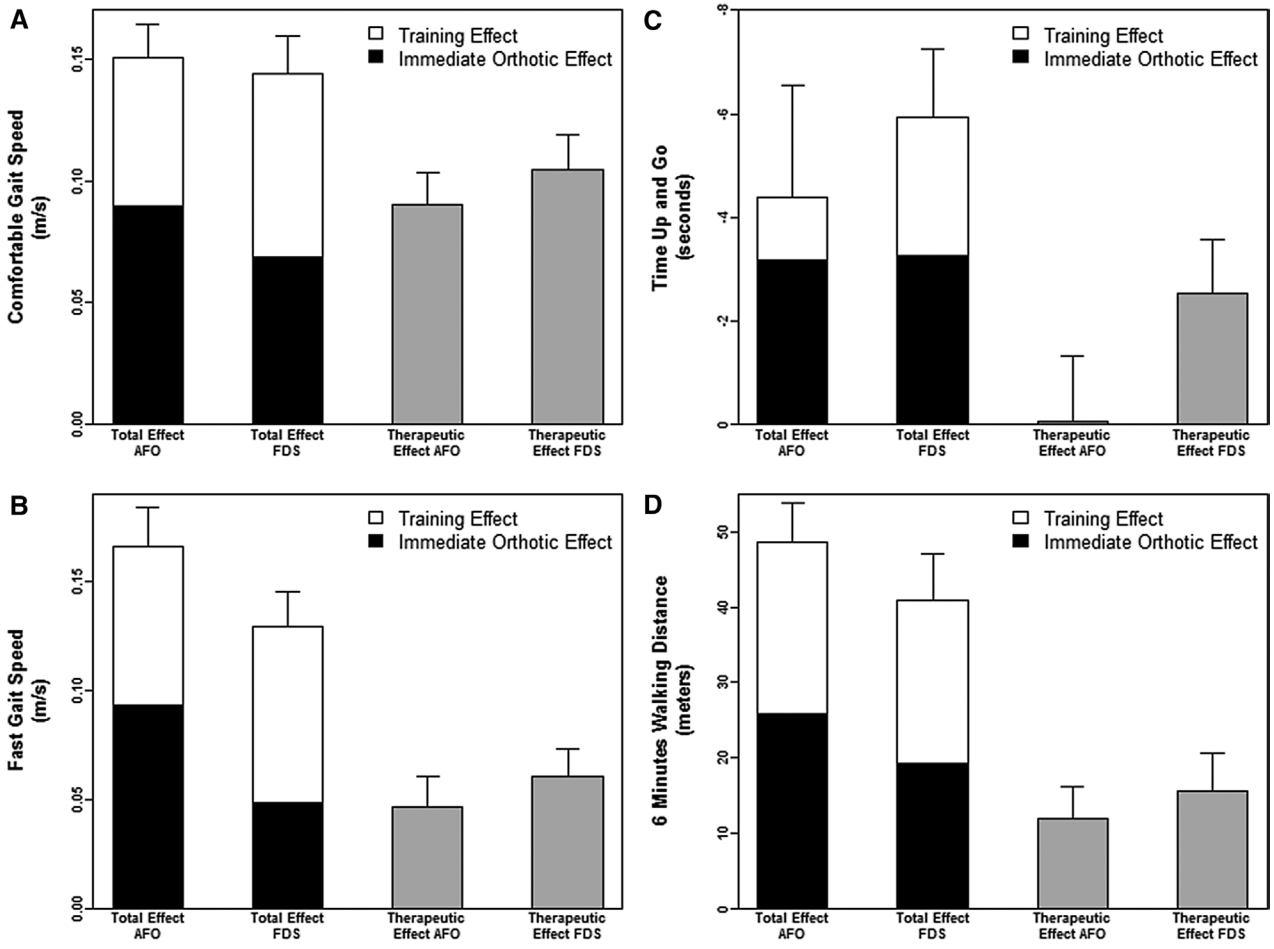

Figure 4. Illustration of total effect (immediate orthotic effect plus training effect) and therapeutic effect in ankle foot orthotic (AFO) and foot drop stimulator (FDS) groups for several outcome measures at 30 weeks: change scores for comfortable gait speed (**A**), fast gait speed (**B**), timed up and go (**C**), 6-minute walk distance (**D**).

Conclusion

We found that an AFO or an FDS used for 30 weeks after stroke had similar effects on gait speed. Still, with effect sizes ranging from 0.93 to 1.00, the FASTEST trial provides encouraging evidence that rehabilitation interventions for drop foot can have a positive impact even many years after stroke. These clinically relevant improvements in gait speed and other functional outcomes have important implications for healthcare reform and insurance coverage policy.

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