Correction of Dropped Foot
FES and AFOs

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Dropped foot following an upper motor neurone lesion, may be addressed by either passive means using an ankle foot orthosis (AFO), or using an active intervention such as Functional Electrical Stimulation (FES). FES may have several advantages in comparison to AFOs:

- AFOs add weight to the lower leg, which can result in greater effort to lift the leg forward compared to FES.
- The active movement produced by FES enables a greater use of the patients own musculature that may result in greater gait efficiency. Stimulation of the common peroneal nerve can improve knee and hip flexion, enabling easier ground clearance and therefore reduced compensatory movement, compared to fixing the ankle joint alone.
- FES may promote a more normal movement pattern by modulation of the lower limbs tone patterns in gait. This has been shown by the reduction of spasticity in the quadriceps after three months of FES use and in the preservation of normal stretch reflexes in long term FES users.
- FES does not restrict dorsiflexion, making ‘sit to stand’ and stair climbing easier. Because of the lack of restriction, FES is often considered more comfortable to use than an AFO.
- The restriction of movement by the AFO may reduce the possibility of relearning normal movement.
- An AFO can limit the choice of footwear due to the bulk of the device in the shoe. This can also make AFOs difficult to fit each time they are used.

This paper reviews the comparative evidence for the use of FES and AFOs.

Clinical Practice

All patients who are seen in the Salisbury FES clinic are referred to the clinic by a GP or medical consultant. Over half of the patients referred for FES have tried alternative methods of dropped foot correction prior to the referral for FES. In an audit of the Salisbury FES clinic in 2003 it was found that of all patients referred for dropped foot correction following a stroke; 44% were current AFO users while 19% had rejected an AFO (30% of those originally supplied with an AFO) and 37% had never used an AFO. In a randomised controlled trial of the Odstock Dropped Foot Stimulator in secondary progressive MS, which recruited from patients referred to the same clinic, 23% were current AFO users at recruitment while 30% had rejected AFOs (57% of those originally issued) and 47% had never used an AFO. In a clinical audit, 67 people with multiple sclerosis (pwMS) who were FES users were asked about their use of AFO immediately prior to starting FES use. Twenty-five were using AFOs while 27 had used and rejected AFOs and 15 had never used an AFO. Walking speed was measured in 20 of the 25 who were using an AFO, both with and without the AFO and FES at the beginning of treatment. There was no significant difference found in walking speed between wearing an AFO and walking unassisted. However, walking was 0.08 ms\(^{-1}\) (p>0.001) faster with FES compared to walking unassisted. It is likely that in the majority of cases the motivation for referral for FES was to improve walking more effectively than had been possible using a splint. Hence while this may result in selection
bias in this data, it also indicates that there is significant number of people with a dropped foot who are dissatisfied with the gait assistance provided by AFOs.

Clinical Trials

The majority of report trials for the correction of dropped foot using FES have not used AFOs as a comparator intervention. This, in the case of the UK, may have been because AFO has not been universally used so may not be considered as “Standard Care”. Moreover, there has been little in the way of trials examining the effectiveness of AFOs and a systematic review of the literature found there has been no examination of the long-term implications of wearing an AFO. However, 10 studies were found that have compared the effect of AFOs and FES, two in sub-acute stroke, six in chronic stroke and two in MS.

Wright et al. compared the use of FES or AFO on the gait of 22 participants who were in the recovery stage following a stroke within the last 6 months. They were randomly assigned to use either an Orthomerica Supra-Lite AFO or an Odstock Dropped Foot Stimulator (ODFS) to manage their dropped foot and followed over a 24-week period. Both groups demonstrated significant improvements in walking speed and physiological cost index (t-test, p<0.05). Both groups showed significantly increased endurance in their walking range (t-test, p<0.05). This general recovery was also demonstrated by significant improvements in the Rivermead Mobility Index (t-test, p<0.05). No significant changes in spasticity were observed measured using the Ashworth scale. No significant differences between the groups were observed by ANCOVA on any of these measurements. However, further analysis of the original data examining the change in walking speed over the first 12 weeks, the period that common peroneal stimulation alone was used, showed that the FES improved unassisted walking speed by a mean of 0.14 ms\(^{-1}\) compared with an increase of 0.09 ms\(^{-1}\) in the AFO group a statistically significant difference (p = 0.004) shown using a Mann Whitney U test, suggesting FES had a better training effect than AFO use. This study can be criticised for the relatively small sample size in a population that was changing through natural recovery.

Kottink et al. examined the effect of a 2-channel peroneal nerve stimulator (deep and superficial branches) on walking speed and daily activities, in comparison with the usual treatment in chronic stroke survivors with a drop foot. Twenty-nine stroke survivors with chronic hemiplegia with drop foot took part in the randomised controlled trial lasting 26 weeks. The intervention group (n=14) received the STIMuSTEP implanted dropped foot stimulator while the control group continued to use their conventional AFO. After 26 weeks, the FES group showed a 23% improvement in walking speed measured with the 6-minute walking test, whereas the improvement in the control group was only 3% (p= 0.010). Comfortable walking speed measured on a 10m walkway was also significantly improved in favour of the FES group (p= 0.038). The study concluded that use of FES led to a significant improvement in gait performance in comparison to AFO and that this was a clinically relevant effect.

Ring et al. reported a case series of 15 patients (mean age: 52.2 +/- 3.6 years) with prior chronic hemiparesis resulting from stroke or traumatic brain injury (5.9 +/- 1.5 year) whose walking was impaired by foot drop and were regular AFO users. The device (NESS L300) was introduced over a 4-week adaptation period during which participants increased their daily
use of FES, while using the AFO for the rest of the day. The device was then used for a further 4 weeks throughout the day. Gait was assessed over a 6-minute walk while wearing force-sensitive insoles, walking with FES and with the AFO in a randomized order. Gait speed and stride time (inverse of cadence) were determined, as were gait asymmetry index and swing time variability. After the 4-week adaptation period, there were no differences between walking with the FES and walking with the AFO (p > .05). After 8 weeks, while there was a trend to improved walking speed the change was not statistically significant, whereas stride time improved from 1.48 +/- 0.21 seconds with the AFO to 1.41 +/- 0.16 seconds with FES (P < .02) and swing time variability decreased from 5.3 +/- 1.6% with the AFO to 4.3 +/- 1.4% with FES (p = .01). A gait asymmetry index improved by 15%, from 0.20 +/- 0.09 with the AFO to 0.17 +/- 0.08 with FES (P < .05). The authors concluded that compared with AFO, FES appeared to enhance balance control during walking and, thus, more effectively manage foot drop. A criticism of the study design, is that the trial period was relatively short, as the evidence from other studies suggests gait appears to change over a longer period of time. The patients’ perceptions of the FES device were very positive with 13 of the 15 patients reporting that they felt more stable with the device and 14 patients indicated that their gait looked more normal. Compared with the AFO all 15 patients preferred to use FES for daily ambulation.

Bulley et al. performed a qualitative study to explore experiences, preferences and choices relating to the use of AFOs and FES for foot-drop by both people who have had a stroke and their carers\(^8\). The design was a semi-structured interview that explored individual experiences through a phenomenological approach. The Interpretative Phenomenological Analysis framework was used to enable organisation and interpretation of qualitative interview data. Nine FES users who were between 2 and 9 years’ post stroke and four carers took part in the study. The FES users were chosen to represent a wide range of walking abilities. Participants described experiences, preferences and choices relating to AFO and FES use. All but one person expressed a preference for FES use and related this to being able to move the ankle more freely; walk more normally, safely and independently and with greater comfort. Several people also used AFOs when the FES equipment failed or when travelling or walking near water. One person rationed their use of FES on a daily basis due to allergic reactions. In conclusions, the consensus in this sample demonstrated positive and negative experiences of both FES and AFO use. Participants weighed up the pros and cons, and despite predominant preferences for FES, many also used AFOs due to some drawbacks of FES. In the questionnaire survey by Taylor et al. 56% of FES users who had previously used an AFO before starting FES reported that they no longer used it while 31% had reduced their use of the AFO and 13% had stayed the same or increased their use of an AFO\(^11\). In the latter case the AFO was required to provide additional stability while walking with FES, the combined effect of the both devices being more effective than either device alone.

Sheffler et al. reported a case series of 4 people with multiple sclerosis (pwMS) and dorsiflexion weakness\(^9\). Quantitative gait analysis was used to assess the effect of three interventions; (1) no device, (2) AFO, and (3) FES at a single point-in-time assessment. One-way analysis of variance was used to compare intra-subject performance under the 3 device conditions. FES was shown to significantly increase ankle dorsiflexion angle at initial contact, as compared with both no device and the AFO, in 3 of the 4 subjects. However, walking speed, stride length, cadence, and double support time; kinematic parameters included peak pelvic obliquity during swing, peak
contralateral hip abduction during stance, peak knee flexion and hip flexion during swing and peak ankle internal rotation during swing were more variably affected by the device conditions.

The authors concluded that with the exception of ankle dorsiflexion angle at initial contact, FES and AFO have a variable effect on spatiotemporal and kinematic gait parameters in individual subjects with multiple sclerosis. The study can be criticised for its small size and lack of time for the participants to become used to using FES compared to their experience with AFOs. Further studies are indicated to determine the clinical significance of intra-subject differences between device conditions.

Khurana et al compared the energy expenditure related to AFO or FES use by measuring Oxygen consumption and perceived level of effort while walking in a group of twenty pwMS19. Measurements were taken on two separate occasions separated by 1 to 4 weeks. In each case the order the devices were used was reversed. It was found that while walking speed was faster with AFOs walking was more metabolically efficient with FES and was also perceived as less effort. It is not reported how much experience of each device participants had prior to the measurements being taken.

van Swigchem R, et al. performed an RCT to determine whether community-dwelling chronic stroke patients wearing an AFO would benefit from changing to an FES device (NESS L300)10,15. 26 community-dwelling chronic hemiplegics received the FES device in replacement of their AFO. Comfortable walking speed over 10 m was measured at baseline with the AFO and after 2 and 8 weeks with both the AFO and FES. The level of physical activity was assessed with a pedometer, and patients' satisfaction was assessed with a questionnaire at baseline and at week 8 regarding the AFO and FES, respectively. The ability to avoid obstacles placed on a treadmill was also assessed. It was found that the AFO and FES were equally effective with regard to walking speed and activity level. However, participants were more successful at avoiding obstacles by stepping over them as they are placed on a treadmill when using FES than an AFO and this appeared to be a more significant effect for those with a lower motricity index indicating greater muscular weakness. This suggests that FES may provide greater ground clearance than AFOs, possibly by facilitation of knee and hip flexion. This may mean that FES users may require reduced compensatory movements in comparison to AFO users, possibly reducing the effort of gait. The participants were more satisfied with functional electrical stimulation than with their AFO regarding the effort and stability of walking, quality of the gait pattern, walking distance, comfort of wearing and appearance of the device. It was concluded that the patients judged FES superior to their AFO, but measurements of walking speed and physical activity could not objectify the experienced benefits of functional electrical stimulation. It is also possible that a greater period of FES use may lead to increased benefit.

While not a comparative study with AFOs, Scott et al investigated the kinematic effect of FES in 12 people with relapsing remitting multiple sclerosis who were new users of functional electrical stimulation21. Gait kinematics were recorded using 3D gait analysis. Walking ability was assessed through the 10-metre and the 6-minute walk tests. All assessments were performed with and without the assistance of functional electrical stimulation. Ankle dorsiflexion at initial contact (p = 0.026) increased by 5.9º reducing the risk of the toe dragging on the ground. Knee flexion was also increased at initial contact by 2.4º (p = 0.044) reducing knee hyperextension and hence helping to protect the knee joint. The peak knee flexion during swing increase by 8.9º
(p = 0.011) increasing ground clearance through swing, again reducing the risk of the toe catching the ground. The increased peak dorsiflexion in swing of nearly 4 degrees during functional electrical stimulation assisted walking approached significance (p = 0.069). The 10-m walk time was significantly improved by functional electrical stimulation (p = 0.004) but the 6 min walk test was not. It was concluded that the acute application of functional electrical stimulation resulted in an orthotic effect through a change in ankle and knee kinematics and increased walking speed over a short distance. Although no comparison was made, equivalent changes in kinematics may not be expected from AFO use, as AFOs do not have a direct effect on the swing phase of gait.

Sheffler et al. performed a randomised controlled trial to investigate the effect on neuroplasticity by comparing the training effect between AFO (ankle foot orthosis) and FES users\(^\text{16}\). 110 stroke survivors were randomly allocated to either a group who use the ODFS or a group who used a custom made AFO. Subjects were treated for 12 weeks and followed up for 6 months’ post treatment. Both groups received 2 sessions per week of physiotherapy gait training over the first 5 weeks of the study reducing to 1 session a week in the following weeks. After the intervention period the participants returned to using an AFO if they had used one prior to the study. The principal outcome measure was the Fugl-Meyer Assessment (FMA), an impairment level test designed to detect change in motor function. Secondary measures were the modified Emory Functional Ambulation Profile (mEFAP - a test that derives a score based on measurement of walking speed in 5 different scenarios) recorded without FES (training effect only) and the Stroke Specific Quality of Life (SSQOL) scale.

Overall there was no significant change in FMA in either group over the course of the study. However, significant improvements were seen in both mEFAP and SSQOL both at 12 and 24 weeks. The improvement in walking speed (mEFAP) is consistent with the previous RCTs and suggests that there was a reduction in impairment that the FMA was insufficiently sensitive to measure. Only one of the 16 item in the lower limb section of the FMA relates to ankle dorsiflexion and the three-level scoring system allows only fully (2) partial (1) or absent (0) for each tested movement. It was noted that participants in the FES group who had no active dorsiflexion prior to treatment had some active movement after the intervention. This was not seen in the AFO group. The study concluded that there was no evidence of a motor relearning effect on lower limb motor impairment in either FES or AFO groups. However, both the FES and usual-care groups demonstrated significant improvements in functional mobility and quality of life during the treatment period, which were maintained at 6-month follow-up. The study design can also be criticised for being somewhat removed from standard clinical practice as participants received considerably more physiotherapy gait training than is common making it difficult to separate the effect of the interventions and reducing its relevance to standard care.

Sheffler et al. also investigated the training effect of FES use on the kinematic parameters of gait of the participants in the above study\(^\text{24}\). Kinematic gait analysis was performed at the beginning and end of treatment and 12 and 24 weeks after the intervention was removed. All measurements were taken without FES. Both groups demonstrated a significant improvement in cadence, stride length, walking speed which were found to be associated with increased peak hip and ankle push off power at terminal stance and increased hip flexion at heel strike. Improvements were maintained at follow up. The study indicates that gait training with either FES or AFO is effective at improving the kinematic parameters of gait in chronic stroke.
Another RCT comparing FES and AFOs was performed by Kluding et al. The Functional Ambulation: Standard Treatment versus Electric Stimulation Therapy (FASTEST) trial was a multicentre, randomized, single-blinded trial comparing FES and AFO for drop foot among people ≥3 months after stroke with gait speed ≤0.8 m/s. The restriction of gait was designed to focus on people who would be defined as having restricted community walking or who are confined to walking in their home only, using the functional walking Category. Perry et al. related walking speed to functional independence defining people with a walking speed of less than 0.4 ms⁻¹ as household walkers, between 0.4 and 0.58 ms⁻¹ as non-limited community walkers, between 0.58 and 0.8 ms⁻¹ as limited community walkers and over 0.8 ms⁻¹ as non-limited community walkers. 197 participants were randomized to 30 weeks of either FES or a standard AFO. They were of 61.14 ± 11.61 years of age with a mean time after stroke 4.55 ± 4.72 years. Both groups received 8 physiotherapy sessions during the first 6 weeks of the trial. The study showed that significant improvements from baseline to 30 weeks in comfortable gait speed and fast gait speed. However, no significant differences were found between-groups. Secondary outcomes (six-minute walking distance, Timed Up and Go test, Berg balance test, Stroke Impact Scale (SIS) participation and mobility scores) improved significantly in both groups. The improvement in the Berg balance test was greater in the AFO group but not of clinically meaningful difference. There was a strong trend towards the FES group achieving a bigger change in the SIS mobility score. User satisfaction was significantly higher in the FDS group than in the control group. The authors concluded that using either an FES or an AFO for 30 weeks gave clinically and statistically significant improvements in gait speed and other functional outcomes. Like the Sheffler et al study, it was demonstrated that an intervention to improve walking can have a significant impact, many years after stroke, at a point previously believed to be after the time in which improvements could be achieved.

The Kluding study can be criticised for several reasons. Firstly, the AFO group received sensory level stimulation (TENS- Transcutaneous Electrical Stimulation) to the common peroneal nerve to control for the sensory effect of FES experienced by the FES group. Consequently, the AFO did not receive as standard orthotic intervention and may have received a facilitatory effect from the TENS, due to activation of the la afferents. Secondary, the authors noted that 60% of participants in the AFO group were using inadequate orthoses before the study began. It is possible that the improved orthotic prescription could have been responsible for the training effect.

Everaert et al. performed a randomised controlled cross over trial to compare the effect of FES and AFOs on the gait of people who have a dropped foot in the first year of recovery following a stroke. Participants, none of whom had used either device before, were randomly assigned to 1 of 3 parallel arms for 12 weeks. In arm one, 38 participants used FES or the first six weeks followed by six weeks use of an AFO. In arm two, 31 participants used an AFO first followed by FES. In arm three, 24 participants used an AFO through the whole duration of the study. The primary outcomes were walking speed and Physiological Cost Index (PCI) recorded while performing a 6-minute Figure-of-8 walking test. Secondary measures included 10-m walking speed and perceived safety during this test, general mobility, and device preference for arms 1 and 2 for continued use. Walking tests were performed both with and without devices at 0, 3, 6, 9, and 12 weeks. Both FES and AFO had a significant orthotic effect, increasing walking speed and distance when either device was used. A therapeutic effect was also recorded in both
groups. A significant orthotic effect on PCI was also seen in AFO users but not FES users. There was a strong trend that FES had a greater therapeutic effect on speed than an AFO, while an AFO had a greater orthotic effect. Users felt equally safe with both devices, but significantly more users preferred the FES. A strength of this study was that neither intervention had been used by participants at entry to the study. However, the intervention periods of 6 weeks may have been 2 short for full adaptation of gait style as other studies have shown gait continues to improve over several months.

In the largest RCT to date Bethoux et al. compare the effect of FES and AFOs on gait and quality of life in a group of 495 individuals with foot drop with established hemiplegia (mean 6.9 years’ post stroke)\(^1\). Participants were randomly allocated to either an FES group or an AFO group for 6 months. Performance was measured using walking speed by the 10-Metre Walk Test (10MWT), a composite of the Mobility, Activities of Daily Living/Instrumental Activities of Daily Living, and Social Participation sub-scores on the Stroke Impact Scale (SIS), and device-related serious adverse event rate. Further assessments were the distance walked in 6 minutes, the GaitRite Functional Ambulation Profile (FAP), the modified Emory Functional Ambulation Profile (mEFAP), the Berg Balance Scale (BBS), the Timed Up and Go Test, individual SIS domains and the Stroke-Specific Quality of Life measures. 399 participants completed the study. FES proved equivalent to the AFO for all primary endpoints. Both the FES and AFO groups improved significantly on the 10MWT. Within the FES group, significant improvements were found for SIS composite score, total mFEAP score, individual Floor and Obstacle course time scores of the mEFAP, FAP and BBS, which were not seen in the AFO group but again, no between-group statistical differences were found. This may be because and over conservative Bonferroni adjustment was used in the statistical analysis. The exclusion of participants with a walking speed over 0.8ms\(^{-1}\) reduces the external validity of the study as it common for some stroke survivors to walk faster. It was also notable that the participants in the FES group had a slower walking speed than the AFO group at base line.

**Discussion and conclusion**

In total 11 studies were found that made a comparison between an FES device and an AFO. Where patient preference was given, a consistent preference for FES was expressed. However, only the studies that examined the kinematic effects of using FES or FES use over an extended period of time were able to demonstrate statistically significant changes in gait parameters. This would suggest that FES may have a long-term training effect on gait that while immediately apparent to many of its users, takes time to become establish in a new gait pattern. No study indicated that AFOs produced better gait quality than FES suggesting that FES can be considered at least as effective as AFOs.

While walking, speed is a common proxy measure for overall gait quality and is therefore the most commonly chosen outcome measure it is notable that it was not reported in any of the studies as one of the main factors leading to the preference for FES. Instead, Bulley et al. reported the stated reasons were being able to move the ankle more freely, walk more normally, safely and independently and with greater comfort. Additional factors were identified by van Swigchem et al. including the ability to walk further distances and the cosmoses of the
FES device compared to AFOs. Perhaps surprisingly, while it may have been expected that AFOs would provide greater stability, the contrary effect was reported by both van Swigchem et al. and Ring et al. and FES was considered to provide increased safety in relation to AFOs in the study by Bulley et al. This may be due to the improved knee and ankle kinematics reported by Scott et al. at initial contact, leading to improved weight acceptance in the stance phase. This may relate to the improved gait symmetry and balance reported by Ring et al. Improved ground clearance related to increased knee flexion in swing may also account for the reduction in effort of walking with FES compared with AFOs, reported by Khurana et al. although this was not reported in the study by Everaert et al. Increased independence and increased walking distance may indicate that FES may be associated with greater participation. This may account for the improvements seen in quality of life by FES users, but not AFO users, in the study by Bethoux et al.

It can be concluded that while FES and AFOs can provide effective improvement in gait, FES has properties valued by many of its users that are often insufficiently provided by AFOs and that long-term use of FES can lead to a measurably improved gait. Due to their considerably different modes of action on the user, the devices should not be considered as equivalent.

References


