

REVIEW

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Functional electrical stimulation for walking in adults with cerebral palsy: a service evaluation

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Abstract

Cerebral palsy (CP) is a neuromotor disorder which can lead to walking difficulties. Functional electrical stimulation (FES) is approved by The National Institute for Health and Care Excellence (NICE) for managing foot drop in upper motor neuron disorders, however there is limited evidence for its use in CP. We discuss a cohort of 26 patients with CP using FES for a 3 month period and longitudinal data for a subset of 11 patients that have used FES for at least 4 years. Patients were referred for the following common barriers to walking: reported falls (54%), foot drop (46%) and tripping (15%). After application of FES at baseline, there was a small clinically insignificant orthotic effect on walking speed (0.01 m/s on/off difference). However, orthotic effects became statistically and clinically significant at three months of continuous use (0.12 m/s on/off difference, $p=0.01$) and in the subset of 11 patients this remained significant at four years (0.24 m/s on/off difference, $p=0.01$). Patient reported walking satisfaction (numerical rating scale) improved when comparing no-FES versus FES at three months and at four years. FES is a safe, cost-effective treatment option and should be considered, for adults with CP who have walking difficulties.

Keywords Cerebral palsy, Foot drop, Functional electrical stimulation, Walking satisfaction, Walking speed

Introduction

Cerebral Palsy (CP) is an umbrella term covering a group of non-progressive disorders due to disturbance in the developing foetal or infant brain. The incidence is approximately 1.4 to 3 per 1000 live births [1–3]. It is primarily a neuromotor disorder but there can be associated impairments such as epilepsy, intellectual disability, or communication difficulties [2, 4].

CP is a lifelong disorder with most children now expected to live into late adulthood [3, 5, 6]. Although

the neurological injury responsible for CP is stable, adults with CP often experience ‘premature aging’ or so called ‘post impairment syndrome’ due to the abnormal development and stresses on the musculoskeletal system, this often results in ongoing problems with pain, fatigue and deterioration in strength [7–9]. This effect is noted in several studies that have highlighted earlier functional decline in adults with CP compared to a healthy population with up to 80% reporting a decline in walking ability, at an average age of only 35 years [7–11]. This decline in walking function has been associated with reduced balance, pain, fatigue, and weakness [7, 9, 12]. Adults with CP experience 5.83 times more falls than adults without CP and falls have been noted as a contributing factor to both worsening disability and reduced participation [5].

Several interventions have been shown to improve functional gait in children with CP, but little research has

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been conducted in adults. Ankle foot orthoses (AFO's) are the current standard of care as recommended in the UK National Institute for Health and Clinical Excellence (NICE) guidelines to improve walking efficiency for adults with CP [13], however it is known that children and adolescents often stop using AFO's because of issues with comfort or aesthetics [14]. More recently several small studies have shown favourable results for device compliance and gait kinematics with functional electrical stimulation (FES) for ambulatory children with CP although limited improvements in activity and participation were noted [15–17].

FES is electrical stimulation of muscles (usually surface stimulation but can be implanted electrodes) that have impaired motor control to induce functionally useful movement. When setting up FES for foot drop, two surface electrodes are usually utilised; one adjacent to the fibular head over the common peroneal nerve and the second over tibialis anterior, with the aim of eliciting dorsiflexion and eversion. Stimulation is timed to the swing phase of gait either through a footswitch placed in the shoe or via 3D motion detection. Alterations to parameters or electrode placement may be required depending on the individual's gait, comfort, or anatomy. NICE guidelines approve the use of FES to treat the effects of foot drop in neurological disorders of central origin including conditions such as stroke, multiple sclerosis (MS) or CP [18]. Common impairments in this cohort are muscle weakness, spasticity, clonus or dystonia which can lead to a functional foot drop and resultant reduced clearance or tripping when walking.

FES has been explored as an adjunct to help walking in both progressive and non-progressive neurological conditions [19, 20]. A positive 'orthotic effect' (immediate change in walking with FES application), and 'therapeutic effect' (change in walking ability over time) has been identified with FES use in adults following stroke [20]. Reduced falls, increased walking speed, and improved gait kinematics have all been demonstrated within stroke and MS populations [20, 21]. In addition, benefits including improving quality of life and reducing overactive bladder symptoms have been established in people with MS [22, 23]. FES has also been shown to be beneficial in conditions such as Parkinson's disease [24] and hereditary spastic paraplegia [25]. The evidence for use of FES in children and adolescents with CP is growing with a recent systematic review supporting the potential role of FES as an alternative to orthotics [26], however, despite the prevalence of adults living with CP there remains limited evidence of the role of FES to improve walking in this group. At a UK based specialist Neurological Hospital, we have a cohort of adults with CP who have been treated with FES to help with their gait disorder, we therefore carried out a service evaluation with the aim

of examining the impact of FES on their satisfaction and speed of walking to identify whether FES is a useful intervention to consider for people with CP.

Methods

This is a retrospective review of the clinical notes of adults eighteen years or older with a diagnosis of CP using FES for dropped foot at a UK based specialist Neurological Hospital; data were collected from visits taking place between 2016 and 2022 in an FES clinic. Inclusion for assessment in this clinic is any ambulatory adult with foot drop secondary to a neurological disorder of central origin. Standard FES treatment in our centre includes two set-up appointments and reviews at 6-weeks, 3, 6, 12, 18 and 24 months. Additional support is offered as required. The device used were Odstock Dropped Foot Stimulator (ODFS) Pace or Odstock 2-Channel Stimulator. Prior to the Covid-19 pandemic, all appointments were completed face-to-face but since June 2020 we have adopted a hybrid model of virtual and in-clinic support. Objective and patient reported outcome measures are completed during these appointments where possible depending on the mode of appointment.

Primary outcomes of walking speed and walking satisfaction were analysed at three months from starting FES treatment. Patients were asked to complete a numerical rating scale (NRS) verbally which assessed satisfaction with walking between two end points: extremely unsatisfied = 0, and extremely satisfied = 10 [27]. The 10 m walk test (10MWT) completed on a measured walkway in the physiotherapy gym, assessed gait speed with and without FES at a self-selected speed [28]. Orthotic effect (No FES/Orthotic versus FES) and therapeutic effect (changes over time) were analysed. For a subset of 11 patient who had used FES for 4 years or longer, secondary analyses were completed to explore benefit over time.

Statistical analysis was completed using SPSS Inc (Chicago, IL). A test of normality was completed using the Shapiro-Wilk test. This confirmed walking speed data was normally distributed and therefore paired t tests were completed to establish statistical differences for all of the walking speeds (FES on or off and comparing baseline and 3 months). Statistical significance was set at $p=0.05$. When statistical differences were significant Cohen's d effects sizes have been reported, effect size was established at 0.2 = small, 0.5 = medium and 0.8 = large [29]. The walking satisfaction numerical rating scale data was not normally distributed and so Wilcoxon's test was completed for non-parametric related samples. For secondary analyses at four years in the subset of 11 patients, after initial examination of p-p plots, frequency histograms and test of normality, non-parametric Wilcoxon signed rank test were chosen to explore orthotic and treatment effects at baseline and four years.

Results

Subjects

60 adults with CP were set up with FES between 2016 and 2022. Of these, 43 continue to use the device on a regular basis (72%). 17 (28%) have stopped using FES and returned their device. Reasons for cessation: too effortful to set up 53%, uncomfortable sensation 24%, skin irritation 6%, lost to follow up 17%. 59 of 60 patients completed a 10 m timed walk at initial assessment with and without FES. One patients' data was not recorded due to time constraints. The immediate orthotic effect of walking with FES demonstrated a mean velocity increase of 5% (-46–106% faster).

26 patients had complete outcome measures at baseline and three months and were included in the analysis (Table 1). Of these, 10 (38%) were not current orthotic users at commencement of FES but all 10 had used orthotics in childhood. 8 currently used a device to improve foot clearance and 8 used insoles to improve biomechanics in the stance phase of gait. The 8 individuals who wore insoles continued with these after provision

Table 1 Demographics of adults with CP used in statistical analysis ($n=26$)

	FES strategy – single channel stimulation to common peroneal nerve ($n=22$)	FES strategy – dual channel stimulation to bilateral common peroneal nerves ($n=4$)
Age (years, mean)	33.7 (SD 13.97)	35.9 (SD 14.30)
Gender, n (%of total)		
Female	11 (42.3%)	4(15.4%)
Male	11 (42.3%)	0 (0%)
GMFCS Subtype*		
1	2 (7.7%)	-
2	15 (57.69%)	-
3	5 (19.23%)	4 (15.4%)
Subtype		
Unilateral CP:	35 (59.32%)	0 (0%)
Bilateral CP:	14 (23.73%)	4 (15.4%)
Orthotic		
Custom ankle foot orthosis	5 (19%)	1 (4%)
Carbon fibre ankle foot orthosis	1 (4%)	-
Foot up splint	-	1 (4%)
Insole	8 (31%)	-
Gait speed at baseline	0.859 m/s	0.346 m/s
NRS confidence at baseline	3.28	3.0

*GMFCS: This is a 5-point scale that assesses mobility; 1 -walking, climbs stairs without rails, can run, jump. 2 -walks but may need some assistance like a stick for longer distances, 3- walks short distances with aid, wheelchair for longer distances, 4- rely on powered mobility but can drive themselves and may walk a few steps indoors, 5- require assistance for mobility, usually need head and posture management [32]

of FES. Patients were asked to subjectively identify their main concerns with walking at initial assessment; foot drop and falls were the most frequently reported issues (Table 2).

Primary outcomes between initial appointment and three months ($n=26$)

A statistically significant orthotic effect (FES on versus no FES) was found at three months (0.12 m/s on/off difference, $p=0.01$) the Cohen's d effect size for this difference was 0.23. Additionally, a statistically significant total orthotic effect was demonstrated between baseline (no FES) and three months with FES (0.15 m/s difference, $p=0.003$), Cohen's d effect size for this difference is 0.25. Table 3 shows 10 m walking speed at baseline and three months. Significance was established for patient reported walking satisfaction (NRS), at baseline 3.23 (SD 2.00) compared to 3 months 7.69 (SD 1.16), $Z=323.5$, $p<0.001$.

Secondary analysis ($n=11$)

Eleven subjects had used FES for 4 years or more. An orthotic effect was maintained over four years (See Figs. 1 and 2). There were no clinically adverse events reported among this cohort over the four years.

Therapeutic effect (baseline versus 4 years (without FES))

The was no statistical difference between baseline mean speed device off =0.58 m/s (SD 0.33) and 4 year mean speed device off =0.60 m/s (SD 0.36), t [11] = -0.39, $p=0.71$.

Orthotic effect at 4 years

There was a statistically significant difference between the walking speeds measured at the 4 year time point; device off 0.60 m/s (SD 0.36) and device on 0.84 m/s (SD 0.40), t [11] =-4.02, $p=0.01$ (CI -0.13, -0.35). Effects size for this difference, Cohens $d=0.20$.

Total orthotic effect (across 4 years)

There was a statistically significant difference between walking speed at baseline (device off) of 0.58 m/s (SD 0.33) (median 0.40 m/s) and walking speed with device on at 4 years (device on) 0.84 m/s (SD 0.40), t [11] = -2.86, $p=0.01$ (CI -0.09, -0.43),Cohens $d=0.31$.

Mean walking satisfaction NRS was 2.25 (SD 0.5) at baseline and 6.8 (SD 1.3) at 4 years, however there were only 4 data pairs to compare between baseline and 4 years. The Wilcoxon test was $Z=10$, $p=0.07$, indicating this difference is outside of statistical significance. However, type 2 error is possible here due to lack of sample.

Table 2 Baseline patient reported concerns with walking (n = 26)

Patient reported problem (n = 26)		Functional impact (n = 26)	
Foot drop	12 (46%)	Walking distance	4 (15%)
Tripping	4 (15%)	Falls/ trips	14 (54%)
Pain	1 (4%)	Walking speed	1 (4%)
Stiffness	3 (12%)	Walking quality/satisfaction	7 (27%)
Weakness	4 (15%)		
Balance	1 (4%)		
Fatigue	1 (4%)		

Table 3 Walking speed statistical analysis (n = 26)

	Baseline velocity m/s	3 months velocity m/s
No FES	0.83 (SD 0.37) *	0.87 (SD 0.33) **
FES	0.84 (SD 0.39) *	0.99 (SD 0.47) **

Orthotic effect at baseline * CI -0.06, 0.03, p = 0.6
 Orthotic effect at 3 months ** CI -0.55, -0.95, p = 0.01
 Therapeutic effect (baseline no FES vs. 3 months no FES) CI - 0.08, 0.012, p 0.14
 Total orthotic effect (baseline no FES vs. 3 months with FES) CI -0.26, - 0.06, p = 0.003

Discussion

Over three months both walking speed with FES and satisfaction of walking improved for adults with CP and this is demonstrated to be maintained over four years in a smaller subgroup. Prior to coming to our clinic only 31% of the 26 adults with CP were using a device for the correction of dropped foot, however 61% of people reported

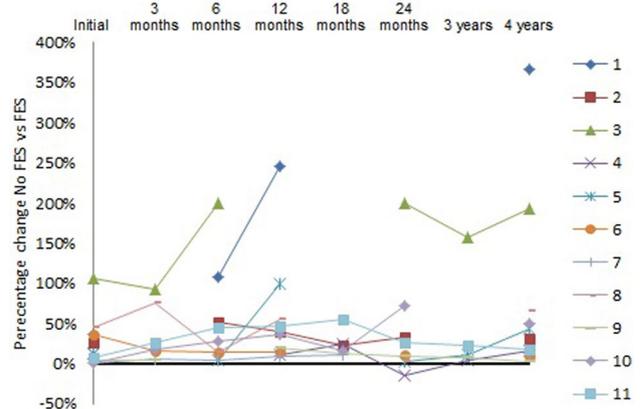


Fig. 2 Percentage change in walking speed comparing no FES to FES (n = 11)

either foot drop or tripping as their primary concern with their walking.

Improvements in walking performance in stroke and traumatic brain injury have demonstrated benefits in both cardiovascular fitness and activities of daily living [19, 21]. Jarvis et al. discussed the impact of walking speed on returning to social activities, education, or work. They demonstrated that individuals who walked slower than 0.93 m/s were less likely to return to work and had higher metabolic cost of walking [30]. This threshold value is important as within our cohort with FES the mean walking speed was increased from 0.84 m/s to 0.99 m/s over three months and maintained above 0.8 m/s in the four-year cohort demonstrating a meaningful improvement and maintenance at a level above that required for community ambulation which may impact positively on quality of life [31]. We can therefore

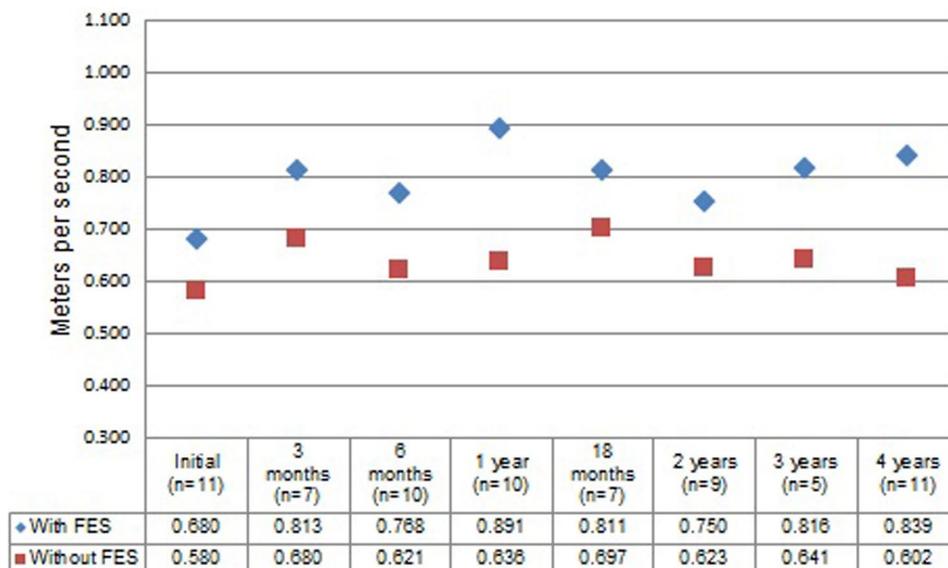


Fig. 1 Mean walking speed over four years with and without FES (n = 11)

hypothesise that improved walking efficiency in people with CP should have a positive impact in keeping people in education and employment with consequent economic and health benefits similar to those already proven for adults with MS [22].

More than two thirds (72%) of participants with CP remain actively under the FES service when reviewed over a six-year period. Studies of FES in MS and stroke predict up to 10% of dropouts per year which indicates usage and compliance may be higher in CP. However, the timing of this study which took place during the Covid-19 pandemic may have a strong influence on this. Many older adults living with long term health conditions limited activities and chose not to attend hospitals during this time meaning they may not have sought help to return devices or look for alternative walking aids.

Despite the retrospective nature of this data and the large number of missing data points, again partly due to the pandemic and transition to video appointments, this paper indicates the potential for FES to improve walking performance in adults with CP. We hypothesise that as the neuropathology of CP is non-progressive, extrapolation from large RCT's completed for stroke are appropriate and could further strengthen these preliminary findings [21, 22]. However, it is important to consider the impact that post impairment syndrome has in the CP population compared to the stroke population who generally have their neurological injury after musculoskeletal maturation and usually late in life. FES is already recommended in the NICE guidelines for foot drop secondary to neurological disorders of central origin on the grounds of clinical and cost effectiveness [19–21], however it remains difficult to access for many individuals. Unfortunately, most adults living with CP are not seen by Neurological or Rehabilitation teams and their care is coordinated by General Practitioners who may lack knowledge and confidence in considering FES as an appropriate intervention to trial. By improving awareness both within health professionals and the patient group we hope more people with CP can gain the opportunity to trial this intervention. Whilst we appreciate FES is not a cure for the underlying neurological impairment, even small changes in walking speed and efficiency can impact quality of life for people living with CP. Although AFO's remain the current standard of care it is important to consider FES for its flexibility in terms of aesthetics, footwear choice, patient preference, and adherence. The availability of FES will also vary in accordance with differing health care systems.

In conclusion, studies evaluating long term compliance and therapeutic effect of FES in CP should be considered to help in establishing both clinical and cost effectiveness. However, given studies in both progressive and non-progressive disease have demonstrated the cost effectiveness

of using FES we feel that FES should be considered and discussed for use in ambulatory adults with CP for the long-term management of walking impairments. Due to the complex biomechanics and hypertonicity in adults with CP, functional mobility should be assessed within a multidisciplinary clinic with defined pathways for assessment and provision of FES to ensure appropriate patient selection and support ongoing optimisation and device compliance [32].

Author contributions

R.W. and V.S. wrote the main manuscript. B.B. completed statistical analysis. All authors reviewed the manuscript.

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Data availability

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

No ethics approval was required for this review as data were collected as part of routine appointments within the FES service and analysed retrospectively.

Consent for publication

Informed consent was obtained from all patients for whom identifying information is included in this article.

Competing interests

The authors declare no competing interests.

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