

Combined Effect of Botulinum toxin A therapy and Functional Electrical Stimulation in Dynamic Equinus: Preliminary results

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Abstract

Gait deviations in cerebral palsy are primarily due to spasticity and poor selective motor control. It is well documented that spasticity can be effectively controlled by the use of Botulinum toxin A (BTXA). In dynamic equinus deactivation of the spastic gastrocnemius muscle can give a “window of opportunity” to improve motor control in the weaker tibialis anterior muscle. It has been shown that Functional Electrical Stimulation (FES) can improve motor control.

This study proposed to combine BTXA therapy and FES to aid in correction of gait deviation in dynamic Equinus.

Five subjects participated in this trial as part of an on-going clinical trial to study the effects of FES in children undergoing BTXA therapy. BTXA therapy was delivered to the spastic gastrocnemius muscle, following which FES was delivered to the tibialis anterior muscle in the affected limb. The primary outcome measure was the ankle angle at the end of swing phase.

Preliminary results indicate an increase in ankle dorsiflexion at the end of swing phase following FES. Carry over was seen in three subjects after FES was withdrawn.

1 Introduction

Children with neurological disorders such as cerebral palsy exhibit an abnormal gait due to lack of selective motor control, dependence on primitive reflex pattern of walking, abnormal muscle tone, relative imbalance between muscle agonists and antagonists, and deficient equilibrium reactions [1]. Although the primary lesion in CP is non-progressive, the effects on the musculoskeletal system develop with growth. Secondary problems, including muscle imbalance, bony deformity and limited joint range of movement, may also develop [2]. In spastic type of CP the primary lesion in the

motor cortex gives rise to an increased muscle tone and poor selective motor control. Among the ambulant population of spastic cerebral palsied children, dynamic equinus is one of the most common form of gait deviation that is encountered.

It is well documented that spasticity can effectively be controlled by the use of Botulinum toxin A (BTXA)[3]. A systematic review of all studies carried out on the efficacy of BTXA therapy concluded that it should not be used as a standalone treatment and should be considered useful as a concomitant treatment [4]. In dynamic equinus deactivation of the spastic gastrocnemius muscle can give a “window of opportunity” to improve motor control in the weaker tibialis anterior muscle. It has been shown that Functional Electrical Stimulation (FES) can improve motor control in CP children [5].

This study proposed that FES can be used to activate the tibialis anterior muscle following deactivation of gastrocnemius muscle using BTXA, and this could help the child to achieve better selective motor control. This combination therapy of BTXA and FES could correct the gait deviation in dynamic equinus.

1.1 Research Question

Can the combination of BTXA and FES improve the ankle dorsiflexion at the end of swing phase in order to achieve a better pre-positioning of the foot at heel strike?

2 Methods

Five subjects participated in this trial as part of an on-going clinical trial to study the effects of FES in children undergoing BTXA therapy. Subject details are shown in Table 1. The subjects were recruited from the Paediatric Neurology clinic at Yorkhill Hospital NHS trust, Glasgow.

Subject	Age/Sex	Diagnosis and limb involved
1	7/M	Spastic hemiplegia with dynamic equines on the left
2	7/M	Spastic hemiplegia with dynamic equines on the left
3	8/F	Spastic diplegia with dynamic equines on the right
4	7/M	Spastic hemiplegia with dynamic equines on the left
5	11/F	Spastic hemiplegia with dynamic equines on the right

Table 1: Details of subjects in the study. M=Male and F=Female.

2.1 Study Design

A single-subject design with repeated measures was adopted to prospectively study the combined effects of BTXA therapy and FES. Each subject participated in the study for a period of twenty weeks. This period consisted of six study phases in the following order; Baseline phase (one week), BTXA phase (three weeks), first FES phase (four weeks), first control phase (four weeks), second FES phase (four weeks) and second control phase (four weeks). During the BTXA phase the subject underwent BTXA therapy for the gastrocnemius muscle on the affected side. During FES phases the subjects underwent FES assisted gait training with FES delivered to the tibialis anterior muscle on the affected side. During the control phases FES was withdrawn.

2.2 FES Application

FES was applied with a programmable electrical stimulator using surface electrodes. During the first week of the FES phases electrical stimulation was applied whilst the subject was seated. This allowed the subject to become accustomed to the electrical stimulation and at the same time helped the subject to identify the movement pattern that the stimulation produced i.e. ankle dorsiflexion. In the following weeks FES was integrated with gait training sessions. Stimulation was applied to the tibialis anterior muscle and a foot switch placed at the heel controlled the stimulation. Stimulation was carried out at a frequency of 30Hz with a pulse width of 300 μ s and a possible maximum intensity of 40 mA. Depending on the endurance of the subjects FES sessions lasted between 20 and 30 minutes

interspersed with short periods of rest, and these sessions were carried out daily.

2.3 Evaluation and Outcome measure

At the end of each study phase, ankle dorsiflexion at the end of swing phase was evaluated using three dimensional gait analysis (Vicon Motion Analysis System) and this was compared with the baseline phase. EMG recordings of tibialis anterior and gastrocnemius muscles, and a foot switch system that recorded foot contact pattern were used as evaluation tools simultaneously with the gait analysis.

During the evaluation subjects walked barefoot on a six-metre instrumented walkway with three force plates (one Kistler and two AMTI forceplates). A single six-metre walk was taken as a trial. Subjects carried out two separate sets of ten trials. A single gait cycle from each of these trials was processed using the Vicon clinical Manager (VCM). A set of five gait cycles were chosen from each set making a total of ten gait cycles, which were included for the analysis at the end of each study phase. During the evaluation following FES phases subjects first walked without the FES, and a separate set of trials were carried out with the FES. This method was adopted to ascertain carry over effects from the FES assisted gait training.

The primary outcome measure to evaluate the combined treatments was the ankle angle at the end of swing phase (100% of gait cycle). Ankle angle at the end of swing phase indicated the pre-positioning of the foot at heel strike.

2.4 Data Analysis

This study is ongoing and this paper focuses on the ankle kinematics of each subject. Statistical analysis of the data was carried out using Wilcoxon Signed ranks test. A difference was accepted as statistically significant at $p < 0.05$

3 Results

The primary outcome measure i.e. mean ankle angle at the end of swing phase (N=10), is presented for all five subjects in Table 2. The post-BTXA gait analysis for subject 1 was not carried out due to a technical problem.

Subjects	Baseline	Post BTXA	Post FES1
1 Mean	-11.57	NA	-5.90
p value			0.005 ↑
2 Mean	-16.29	-23.56	-17.97
p value		0.009 ↓	0.037 ↓
3 Mean	-17.58	-8.45	-13.47
p value		0.005 ↑	0.028 ↑
4 Mean	-9.31	-6.92	-3.82
p value		0.445	0.022 ↑
5 Mean	-4.11	-9.12	-10.26
p value		0.028 ↓	0.007 ↓
Subjects	Post Control 1	Post FES2	Post Control 2
1 Mean	-6.15	-3.38	-4.16
p value	0.005 ↑	0.005 ↑	0.005 ↑
2 Mean	-13.31	-11.12	-6.21
p value	0.959	0.508	0.013 ↑
3 Mean	-6.83	-4.96	-7.20
p value	0.007 ↑	0.005 ↑	0.013 ↑
4 Mean	-7.7336	-3.8914	-8.2324
p value	0.386	0.007 ↑	0.575
5 Mean	-10.03	-6.30	-9.19
p value	0.007 ↓	0.139	0.022 ↓

Table 2: Mean ankle angle at the end of swing phase (N=10) in all five subjects. Negative angles indicate foot in plantar flexion. P values are for comparison of each study phase with Baseline. ↑ = significant positive difference in ankle angle. ↓ = significant negative difference in ankle angle.

4 Discussion and Conclusions

The analysis of the outcome measures, showed positive gains in ankle dorsiflexion at the end of swing phase following FES in all subjects except subject 5 (Table 2). The evaluation following BTXA therapy did not yield any significant increase in ankle angle in subjects 2, 4 and 5, however subject 3 showed a significant improvement (p=0.005). This may have indicated that the BTXA had not yet taken effect. Subjects 1, 3 and 4 showed a significant increase in ankle dorsiflexion following both phases of FES which indicated a good carry over effect. Subjects 1 and 3 showed a steady increase in their ankle dorsiflexion, through all

study phases compared to the baseline measure and maintained this trend through out the study.

Subject 5 had an increase in ankle dorsiflexion following post FES 2 evaluation; however this trend did not follow during the second control phase. All evaluations following the baseline measure in Subject 5 showed a decrease in ankle dorsiflexion compared to baseline. Subject 5 being the oldest subject in the cohort, may possibly have an established gait pattern, however it is difficult to conclude at this preliminary stage without analysing all available data including the EMG and foot switch data.

Throughout the study verbal feedback from both subjects and parents was very positive.

The preliminary results and their analysis indicate that the FES improves the ankle dorsiflexion when combined with BTXA. It is also indicative that a prolonged use of FES may bring about a further increase in dorsiflexion and have carry over effects.

This study has demonstrated that it is feasible to combine BTXA therapy with FES and that this combination can improve ankle dorsiflexion.

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