

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

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Abstract

Dynamic Equinus is a widespread issue among the ambulant population of children with spastic type of cerebral palsy. The initial contact typically characterised by an absence of heel strike is often clinically observed as a gait deviation. This gait deviation primarily results 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.

Ten subjects participated in a 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 outcome measures used to evaluate the study were the angle of ankle dorsiflexion at the end of swing phase, and the mode of initial contact.

The results of the study show an increase in ankle dorsiflexion in most of the subjects following a combined BTXA therapy and FES, there was also a corresponding increase in the frequency of heel strike as a mode of initial contact in some subjects.

1. INTRODUCTION

Cerebral Palsy is a term that encompasses a range of non-progressive syndromes of posture and motor impairment that result from an insult to the developing central nervous system¹. The most common cause for severe physical disability in childhood is Cerebral Palsy

In spastic type of cerebral palsy the primary lesion in the motor cortex gives rise to an increased muscle tone or spasticity and poor selective motor control. Although the primary lesion in cerebral palsy 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 develop². Spasticity associated with cerebral palsy results in significant limitations to mobility in children with cerebral palsy. This influences the child's development, reduces independent mobility and thereby restricts the ability to participate in daily activities

Standard treatment procedures have, in most cases, attempted to treat the physical manifestations such as stiffness rather than the underlying mechanisms that bring about spasticity and lack of motor control. The neurological and musculo-skeletal pathology in spastic cerebral palsy, that underpins the abnormal movement patterns needs to be addressed and is fundamental to planning logical and successful interventions³. This has justified the use of interventions such as FES and BTXA therapy which are minimally invasive but can still precisely target the underlying mechanisms.

FES has been shown to improve gait parameters, although its effect on spasticity has not been conclusively demonstrated. A systematic review of all the studies carried out on the efficacy of BTXA therapy concluded that it is generally considered useful as a concomitant treatment⁴. This evidently indicates that although it can reduce spasticity, BTXA should not be used as a standalone treatment but should be combined with intervention that improves the component of lack of selective motor control.

1.1. Aim and Research Question

The principal aim of this Study was to investigate the combined effect of FES and BTXA therapy to correct gait deviation in children with spastic type of cerebral palsy with spasticity of the gastrocnemius muscles resulting in dynamic equinus. Hence The principal research question of this study was:

Can the combination of FES and BTXA therapy be used to improve walking in children with cerebral palsy?

1.2. Secondary aims and objectives

The secondary aims of this study were to

- Investigate the change in initial contact of the foot during stance phase of gait cycle following the combined intervention of BTXA therapy and FES.
- Investigate the duration of initial contact of the foot during stance phase of gait cycle following the combined intervention of BTXA therapy and FES..

2. METHODS

Ten subjects (male n=8 and female n=2) with spastic type of cerebral palsy participated in the study, and 8 subjects completed the study successfully (male n=6 and female n=2). The subjects ranged between 5 and 11 years of age. Two subjects had diplegia and six had hemiplegia.

2.1 Study Design

Due to the heterogeneous nature of CP population 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. A three week period was allotted to the BTXA phase for the BTXA therapy to produce its effect on the spastic gastrocnemius muscle. 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.

FES was delivered to bilateral tibialis anterior for Subject 8 who had a bilateral dynamic equinus.

At the end of each phase evaluations were conducted to assess the outcome of each of the phases individually.

The study was carried out the Bioengineering Unit, University of Strathclyde, in collaboration with the Paediatric Neurology Clinic at Yorkhill Hospitals NHS trust, Glasgow. Prior to the commencement of the study ethics approval was obtained from both the ethics committees of University of Strathclyde and Yorkhill Hospital NHS trust.

FES was delivered using a portable three channel programmable stimulator. A closed loop control

strategy was used to turn on the stimulation during the swing phase of the gait cycle. A foot switch system using force sensing resistors or FSRs (Interlink Electronics Inc., Camarillo, California) was used to detect the swing phase of gait cycle. The stimulation was applied using surface electrodes (Pals[®] Ultra Flex Neurostimulation electrodes, manufacture by Nidd Valley Medical Ltd. UK). Stimulation was carried out at a frequency of 30Hz with a pulse width of 300 μ s and a possible maximum intensity of 20- 40 mA. Depending on the endurance of the subjects, FES sessions lasted between 20 and 30 minutes interspersed with short periods of rest, and carried out daily.

2.2 Outcome measures

The proposed hypotheses was that the effect of the combined treatment of BTXA and FES having a positive outcome on the correction of gait deviation in dynamic equinus will be evident by the subject having an initial heel strike rather than the usual fore foot contact. This implies that the combined treatment has increased the ankle dorsiflexion at the end of swing phase, resulting in a heel strike.

Ankle angle at the end of swing phase was hence used as the primary outcome measure based on this premise. A change in ankle dorsiflexion following BTXA therapy and FES combination will help ascertain its effect in correction of gait deviation in dynamic equinus. The vicon motion analysis system (Oxford Metrics, UK) was used for this purpose and the Vicon Clinical Manager (VCM) was used to process the data.

The secondary outcome measures proposed were based on the various domains that the combined BTXA therapy and FES can have its effects on, and are as follows

- Change in foot contact pattern during initial contact, across the various study phases.
- Change in duration of initial contact across the various study phases.

A foot switch system using four force sensing resistors for each foot was used to record the foot contact pattern.

The data from the foot switches were collected simultaneously during gait analysis and was interfaced with the Vicon motion analysis system. The subjects were asked to walk over a 6 metre walkway, and all post-FES evaluations were carried out without the assistance of FES to ascertain the carry-over effect.

3. RESULTS

The results demonstrated an increase in ankle dorsiflexion at the end of swing phase (Table 1) in most of the subjects when compared to their baseline measures.

Subject 3 who showed an overall 62% increase in his ankle kinematics also showed a corresponding increase in the number of heel strike compared to baseline. At baseline Subject 3 had 23% of his initial contacts as heel strike and this increased to 54% at the end of the study. The duration of heel strike also increased from 0.93% of the stance phase to 1.14% of the stance phase.

Subjects	Baseline	Post BTXA	Post FES1
1 Mean	-2.3	NA	-1.21 ↑
2 Mean	-11.57	NA	-5.90 ↑
3 Mean	-16.29	-23.56	-17.97
4 Mean	-17.58	-8.45 ↑	-13.47 ↑
5 Mean	-9.31	-6.92 ↑	-3.82 ↑
6 Mean	-4.11	-9.12	-10.26
7 Mean	-20.23	-23.59	-12.65 ↑
8 Mean (Right)	-31.59	-21.38 ↑	-6.43 ↑
8 Mean (Left)	-39.33	-23.38 ↑	-8.76 ↑
Subjects	Post Control 1	Post FES2	Post Control 2
1 Mean	1.25 ↑	-6.51	-0.71 ↑
2 Mean	-6.15 ↑	-3.38 ↑	-4.16 ↑
3 Mean	-13.31 ↑	-11.12 ↑	-6.21 ↑
4 Mean	-6.83 ↑	-4.96 ↑	-7.20 ↑
5 Mean	-7.73 ↑	-3.89 ↑	-8.23 ↑
6 Mean	-10.03	-6.30 ↑	-9.19 ↑
7 Mean	0.31 ↑	-7.54 ↑	0.34 ↑
8 Mean (Right)	-1.71 ↑	-4.89 ↑	-0.42 ↑
8 Mean (Left)	-4.32 ↑	-3.61 ↑	-1.39 ↑

Table 1 Mean ankle angle at the end of swing phase (N=10) in all subjects, except subject 1(N=5). Negative angles indicate foot in plantar flexion. Increases in ankle dorsiflexion compared to baseline are highlighted in bold with ↑ to indicate increase.

4. DISCUSSION AND CONCLUSIONS

The results indicate so far that an increase in ankle dorsiflexion at the end of swing phase following a combined BTXA therapy with FES can effect a change in the gait pattern. Preliminary results of this study⁵, demonstrated these results were sustainable in some subjects even after the withdrawal of FES indicating a carry over effect. The corresponding changes in the initial contact pattern indicate a change in gait deviation. However use of heel strike as a consistent means of initial contact was difficult to achieve. This is may be due to the short duration of intervention, and the subjects pattern of forefoot contact which had been reinforced from a very early stage.

This study has clearly demonstrated the feasibility of applying this novel combined BTXA therapy with FES among an ambulant cerebral palsy population with Dynamic equines. Further studies with a larger sample size may aid in defining the target population that may benefit from this novel combined intervention of FES and BTXA therapy.

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