The effect of Neuromuscular Electrical Stimulation on Congenital Talipes Equinovarus following correction with the Ponseti method: A Pilot Study

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Introduction

Congenital Talipes Equinovarus (CTEV) or clubfoot is the commonest congenital orthopaedic condition with an incidence of 1.5 per 1000 in the UK. The current approach to treatment of CTEV is non operative, with two main methods being utilised.

The primary approach is the Ponseti method, consisting of serial manipulation and casting to correct the deformities (cavus, adductus, varus and equinus), followed by use of a foot abduction brace to maintain the corrected foot position (Ponseti and Smoley 1963, Morcuende et al. 1994, Ponseti 1996). In most cases, an Achilles tenotomy is performed prior to the final cast. The second accepted non operative treatment method is the French functional method (Bensahel et al. 1990, Bensahel et al. 1994). This approach includes daily manipulation and taping to correct foot position concurrent with manual muscle stimulation to strengthen the weak muscles, and use of a continuous passive motion machine.

Satisfactory initial correction is reported following both approaches (Morcuende et al. 1994, Bensahel et al. 1990, Bensahel et al. 1994), however, maintenance of correction has been reported to be problematic. In the Ponseti approach the foot abduction brace is worn full time (23 hours out of 24) for 3 months after initial correction is achieved, and at night for approximately 2-3 years. The French functional method aims to achieve maintenance of the corrected foot position by attempting to strengthen the weak peroneal muscles through manual muscle stimulation.

In a prospective non randomised study comparing the two approaches, Faulks and Richards (2009) reports relapse in 37% of feet treated by the Ponseti method that had achieved initial correction, and in 29% of feet treated by the French functional method. Maintenance of the initial correction achieved by the Ponseti method is directly correlated with compliance of use with the foot abduction brace (Dobbs et al. 2004, Haft et al. 2007, Lehman et al. 2003, Colburn and Williams 2003, Bor et al. 2009). Compliance with the foot abduction brace is variable, with reports in the literature ranging from 50 to 100% (Haft et al. 2007, Lehman et al. 2003, Shack and Eastwood 2006, Bor et al. 2009, Faulks and Richards 2009) In addition, early recurrence of deformity, or relapse defined as a loss of foot abduction and/or dorsiflexion and/or a recurrence of metarsus adductus (Ponseti 1996) is also reported in some cases where there is full compliance with the brace regime (Dobbs et al. 2009, Changulani et al. 2006, Haft et al. 2007). The French functional approach requires substantial time from parents and therapist and expertise which could be a key factor affecting clinical uptake and effectiveness (Dobbs 2004).

Clubfoot is a complex condition with the deforming forces, (muscle imbalance with Posterior and Anterior Tibial muscles overpowering the evertor muscles, together with soft tissue tightness) continuing their action after passive correction is achieved (Ponseti 1996).This muscle imbalance sometimes requires an Anterior Tibial tendon transfer after walking age (Ponseti 1996, Farsetti et al.2006.) A dynamic intervention that can effect a visible and repeated active muscle contraction of the evertor muscles at an early stage may be an effective addition to the current treatment methods addressing this muscle imbalance .

Neuromuscular Electrical Stimulation (NMES) is the electrical stimulation of skeletal muscle through motor or sensory nerves applied at intensity sufficient to cause a muscle to contract. Electrical stimulation has been used for many years for the rehabilitation of muscle activity following neurological damage. It has been applied therapeutically for improving gait and Range of Motion (ROM) (Carmick 1993 and 1995, Comeaux et al. 1997, Dubowitz et al. 1988, Durham et al. 2004, Hazlewood et al. 1994, Herbst and Ulla 2002).

There is only one report in the literature of use of NMES to increase range of motion to correct foot deformity in the treatment of CTEV (Kirsch and Pape 1992). Although limited in terms of number of patients (2 children and one adult) and information on

stimulation parameters, the study suggested this approach had potential to improve range of motion, muscle balance, foot position and gait, and called for further work to address this concept of treatment.

The aim of this pilot study was to investigate the feasibility of using electrical stimulation in infants with clubfoot deformity, and to give preliminary data on its potential to increase or maintain range of motion (ROM) and facilitate peroneal muscle activity, following initial correction achieved with the Ponseti method. If this proves to be a practicable approach, it could be an important adjunct to treatment in preventing recurrence of deformity and reducing operative procedures after walking age.

We chose to assess the feasibility and effect of this intervention in young infants (less than 12 months old) immediately post initial correction in order to address the possible causes of relapse before stiffness and contracture reoccur.

Methods

In this study an A^1BA^2 approach was used. The 'A' refers to an intervention phase and the 'B' to a non intervention phase. Each phase lasted six weeks.

Two groups of infants were investigated; a study or an intervention group and a control group with eight feet in each group.

There was no evidence in the literature on which to base duration of each phase, so 6 weeks was chosen to minimise inconvenience to the families participating by coordinating with routine clinic reviews.

The control group was age and severity matched before the Ponseti treatment started (presentation) and at the beginning of this study (i.e. before the children were fitted with the foot abduction brace), as original severity could be associated with a poorer prognosis for correction. The severity was matched using the Pirani score (Pirani et al. 1995, Dyer and Davis 2006, Flynn et al. 1998.

Ethical approval was granted by the Local Research Ethics Committee, and written informed consent was received from the children's parents or guardians.

The inclusion criteria were: diagnosis of idiopathic CTEV, have been enrolled onto a programme of serial manipulation and casting treatment using the Ponseti method, parent's motivated to carry out programme, and tolerance of the stimulator as

assessed during the first stimulation session. Exclusion criteria were: previous use of stimulation, previous treatment or surgery, and other neurological conditions causing any movement disorder or spasticity. The infants were referred from five hospitals in the London area.

Procedure

In the intervention phases stimulation was applied to the evertor muscles of the foot. Electrode positioning is shown in Figure 1. The aim was to achieve a muscle contraction sufficient to produce an active movement of the foot into eversion, with or without dorsiflexion, as eversion is the key movement.

The Microstim MS2V2 exercise stimulator (Odstock Medical Limited, Salisbury NHS Trust) was used. It has an ON: OFF cycle of 14:14 seconds, with a 2 second ramp at the beginning and end of each burst of stimulation. A frequency of 40Hz was used, and pulse width is fixed at 330 μs. The stimulation intensity was set where a visible movement of the foot was achieved and the sensation did not cause any distress to the infant. Parents were instructed to use the stimulation for a total of 30 minutes a day, at a time convenient to them and which did not interfere with the boots and bars regime, for example, before the child's bath.

Table 1 provides an overview of the activities carried out at each stage of the study. The control group followed the same timeframe and measurements were taken accordingly. The parents also filled a diary for compliance with the foot abduction brace.

At each review session an assessment was carried out covering: the child's development, parental perceptions of their child's tolerance of the stimulation, and any difficulties in the daily routine with both the stimulation and the brace. Evertor muscle activity was assessed qualitatively following manual stimulation. The response was considered "good" if an active eversion was observed, a "flicker" if the muscle was seen to contract under the skin without any movement of the foot, and absent when there was no activity detected. The option of testing movement against resistance was not applicable for this age group. The two examiners then assessed the foot using the Pirani severity score. Measures of ankle range of motion into dorsiflexion with knee flexed (ADFKF) and extended (ADFKE), and calf

circumference (CC), were also taken following a protocol developed by Gelfer et al. (2009). Goniometric measures of eversion range were not considered to be reliable so were not collected.

At the end of the second intervention phase (A^2) all parents in the study group were asked to complete a questionnaire designed to assess ease of using the stimulator, how stimulation was tolerated by the infant, and whether they would have liked to continue using the stimulation.

Setting

The data collection for the study and control group was taken at the infants' local hospital at their routine appointment with the treating physiotherapist. The infants were either awake or napping, but generally relaxed and were unconcerned by the examination. The stimulation setup, when required, was held after data collection was complete. Parents were encouraged to setup the stimulator themselves after the first explanation, to ensure safe practice and to assess whether the desired muscle response was achieved.

Data Analysis

Due to the sample size data was analysed using non- parametric statistics.

In order to determine the change in the outcome measures over the study period for the study group and the control groups independently, the Friedman test was chosen. If the Friedman test showed significance, the Wilcoxon test was used to compare each measurement to the one before it, in order to determine at what point in time the change took place, altogether three times for each measure.

For Calf Circumference, a change over time was expected in both groups due to physiological growth and the difference between the two groups was determined using the non parametric equivalent of the *t*-test, the Mann-Whitney test.

Significance was set to be lower than 0.05.

Results

Eight feet were included in each group, and all participants completed all stages of the study. The median age at the beginning of the study was 2.7 months for the study

group (age range: 2.2 - 6 months) and 2.1 for the control group (age range: 1.8 - 6 months). The median Pirani score at presentation was 5.5 for the study group and 5.0 for the control group. Since the Pirani score is of an interval type, with 0.5 being the smallest interval, the mean is more relevant than the median. The mean Pirani score at presentation was 5.2 for the study group and 5.5 for the control group. The mean Pirani score (PS) at the beginning of the study was 1.7 for the study group and 1.3 for the control group. The difference was found to be insignificant (p= 0.16 for PS at birth and p= 0.33 for PS at T1). The ankle dorsiflexion at the beginning of the study was also compared between the two groups and was found to be insignificant (p=0.8 at T1).

The compliance with the foot abduction brace for all participants during the 18 weeks following correction was 85%. Two infants didn't comply with the brace, one in the study and one in the control group. The foot deformity in the infant in the control group recurred, and the deformity of the foot in the study group remained corrected The compliance with the stimulation was 100%. One infant had to stop using the stimulation for less than a day due to a technical problem.

Active evertor activity:

Initially seven out of the eight feet had "good" active evertor activity and one had absent activity in both the study and the control groups. There was no change in the activity after the first phase of the study. After the second phase two feet had absent evertor activity in the control group, which remained in the third phase. The study group had no change in the activity in the second phase, but there was an improvement in the foot with the absent activity from 'absent' to 'flicker' during the third phase. The summary of the results is presented in Table 2.

Ankle dorsiflexion knee flexed (ADKF) and Extended (ADKE):

The Friedman and Wilcoxon results including the mean, median, standard deviation and the IQR for the study and control groups for ADKF and ADKE are presented in Tables 3 and 4 respectively.

For ADKF there was a significant difference between the sessions in the study group (p=0.01) and not in the control group (p=0.10). The significant difference was

between T2 and T1 (p=0.02) and between T4 and T3 (p=0.03). There was no significant difference between T3 and T2 (p=0.40).

For ADKE there was a significant difference between the sessions in the study group (p=0.01) and not in the control group (p=0.12). The significant difference was between T4 and T3 (p=0.02). There was no significant difference between T3 and T2 (p=0.18) or between T2 and T1 (p=0.06).

Calf Circumference (CC):

The Friedman and Wilcoxon results including the mean, median, standard deviation and the IQR for the study and control groups for CC are presented in Table 5.

There was a significant difference between the sessions in both the study and the control groups (p=0.01). The difference was between all the sessions (p=0.01, p=0.02, p=0.02 in the study group and p=0.02, p=0.01, p=0.01 in the control group).

Since the change over time in CC was expected to be significant for all infants due to normal growth, the differences between each consecutive outcome measure were compared between the study and the control group using the Mann-Whitney test presented in Table 6. The difference between the study and control group didn't reach a significant level, but there was a trend toward a greater increase in the study group during the two periods when stimulation was applied.

The Pirani score:

The Friedman and Wilcoxon results including the mean, median, standard deviation and the IQR for the study and control groups for the Pirani score are presented in Table 7.

There was a significant difference between the sessions in both the study and the control groups (p=0.01 and 0.03 respectively). There was a significant change between sessions T2 and T1 (p=0.02) and between T4 and T3 (p=0.05) in the study group and between T2 and T1 (p=0.47) in the control group.

There were no relapses (i.e. Pirani score did not increase) in any feet in the study group during the 18 weeks follow up of this study, but there was one relapse in the control group. The infant whose foot relapsed was not compliant with the foot abduction brace.

Qualitative analysis of the questionnaire:

Overall the subjective response from the parents was consistent. None of the parents felt there was any negative effect of the stimulation and all parents stated the stimulator was easy to operate (ten on a scale of one-ten Likert scale, where 1 represented 'very difficult' and 10 'very easy'). None of the parents felt their child was unhappy with the stimulation and all parents stated they would have liked their child to continue with stimulation after the study was over.

Discussion

This study evaluated the feasibility of electrical stimulation (ES) as an adjunct to the Ponseti treatment of clubfoot deformity in infants and its potential to address factors which lead to early recurrence of the deformities. No previous studies reporting electrical stimulation in infants were found in the literature.

Acceptability of the intervention was assessed by parent questionnaire. Improvement in or maintenance of activity of the everter muscles, and ankle ROM were chosen as outcome measures, as they reflect factors associated with relapse (muscle inbalance, recurrent stiffness and consequent loss of ankle range). Measurement of CC was used to determine changes in muscle bulk, which could be associated with changes in activity of the evertor muscles.

High compliance rates with applying the stimulation (100%) reported on the parent questionnaire suggest that ES was an acceptable adjunct to treatment. There were no negative responses from the parents and the infants were reported not to be distressed by the stimulation. In this study, evertor activity was assessed as good in 14 of the 16 feet at the start of the study, with absent activity in 1 foot in each group. Qualitative grading of evertor muscle activity following ES showed an improvement in activity in the foot in the study group where evertor activity was absent and no deterioration in activity in the others. There was no improvement in the absent activity in the foot in the control group, and deterioration in activity in a second foot in the control group, suggesting that ES may have the potential to maintain and develop muscle activity, which could address muscle inbalance.

The increase in CC in the study group compared to the control group didn't reach significance level, but a trend toward increased bulk was identified in the study group only in the times stimulation was given. Achieving sufficient increase in muscle

volume in order to reach a statistically significant level in an infant calf circumference is challenging especially when the muscles being stimulated contribute a small percentage of the calf volume. Imaging methods such ultrasound or MRI might be more appropriate.

Loss of range at the ankle is indicative of relapse, due to poor alignment of the ankle joint and the hindfoot which compromises range of motion. ADKF and ADKE were significantly increased in the study group compared to the control group during the phases when stimulation was applied.

Relapse of the deformity is reported to be directly correlated with compliance with the foot abduction brace (Dobbs et al. 2004, Haft et al. 2007, Lehman et al. 2003, Colburn and Williams 2003, Bor et al. 2009). In our study there were two cases of non compliance with the brace, one infant in the control and one in the study group. The infant in the control group had an increase of 2 in the Pirani score. There was no recurrence in the infant in the study group who was compliant with the stimulation protocol. These are interesting observations and although we are unable to draw any definite conclusions from them, it suggests that further investigation in terms of a larger study with longer follow up times is warranted.

As stated in the Introduction, relapse in a proportion of feet is expected following full non operative correction for congenital clubfoot. Relapse after correction is attributed to peroneal insufficiency (Singer and Fripp 1958, Ponseti 1996, Farsetti et al.2006). In early relapse the approach is to recast until the correction is achieved. After walking age the surgical technique of anterior tibial tendon transfer to the lateral side of the foot to correct the invertor-evertor imbalance is employed. This procedure has become an important part of management of the clubfoot deformity. Kuo et al., (2001) compared full tendon transfer or split tendon transfer with similar results. The different surgical variations have the same rationale behind them; to balance the muscles of the foot because in relapsing clubfoot the anterior tibial muscle does not work as a dorsiflexor-evertor but an invertor of the foot, which may be due to a more medial insertion of the tendon than in normal feet. The rationale behind this surgical treatment and its success supports the idea of using electrical stimulation in an attempt to reduce relapses and hence reducing the need for this surgery.

This study was conducted in order to establish the feasibility of adding ES to the foot abduction brace component of the Ponseti method, and the potential for ES to reduce relapse and improve ROM and CC. This was a small exploratory study, and results must be interpreted in this light, however preliminary results suggest ES may have the potential to maintain or improve evertor muscle activity and ankle range of motion. Additional studies with larger group sizes, and a longer follow up period are necessary in order to recommend this novel addition to the current treatment methods.

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Tables:

Table 1 The schedule of study procedures for the study group

* The Ponseti treatment begins soon after birth and lasts 4-8 weeks

The study group schedule					
	Ponseti *	Start of A^1	End of A^1	End of B	End of A^2
Informed consent		✔			
Static measures and Pirani score		✔	✔	✔	✔
Diaries of brace collected			✔	✔	✔
Diaries of stimulator collected			✔		✔
Stimulator set up		✔		✔	
Questionnaire					✔
Check of equipment		✔		✔	
Return of stimulator			✔		✔

Table 2 Evertor activity for the study and control groups

T1- first measurement (at the beginning of A^1)
T2- second measurement (at the end of A^1)
T3- third measurement (at the end of B)
T4- fourth measurement (at the end of A^2)

Evertor activity			
		Study (n=8)	**Control (n=8)**
Evertor activity T1	Good	7	7
	'Flicker'	0	0
	Absent	1	1
Evertor activity T2	Good	7	7
	'Flicker'	0	0
	Absent	1	1
Evertor activity T3	Good	7	6
	'Flicker'	0	0
	Absent	1	2
Evertor activity T4	Good	7	6
	'Flicker'	1	0
	Absent	0	2

Table 3 ADKF – the change during the study period

T1- first measurement (at the beginning of A[1])
T2- second measurement (at the end of A[1])
T3- third measurement (at the end of B)
T4- fourth measurement (at the end of A[2])
ADKF- Ankle Dorsiflexion Knee Flexed
[1] - in degrees

ADKF												
	Study group (n=8)						**Control group (n=8)**					
	Mean[1]	Sd[1]	Median[1]	IQR[1]	P-value Friedman	P-value Wilcoxon	Mean[1]	Sd[1]	Median[1]	IQR[1]	P- value Friedman	
T1	21	17	20	32	**0.01**		28	18	30	34	0.10	
T2	32	15	35	34		**T2/T1 0.02**	36	19	38	35		
T3	34	17	34	18		T3/T2 0.40	38	17	40	26		
T4	38	16	36	20		**T4/T3 0.03**	38	17	40	24		

Table 4 ADKE– the change during the study period

T1- first measurement (at the beginning of A[1])
T2- second measurement (at the end of A[1])
T3- third measurement (at the end of B)
T4- fourth measurement (at the end of A[2])
ADKE- Ankle Dorsiflexion Knee Extended
[1] - in degrees

ADKE												
	Study group (n=8)						**Control group (n=8)**					
	Mean[1]	Sd[1]	Median[1]	IQR[1]	P-value Friedman	P-value Wilcoxon	Mean[1]	Sd[1]	Median[1]	IQR[1]	P- value Friedman	
T1	16	18	17	30			23	19	30	34		
T2	25	16	27	19		T2/T1 0.06	28	18	34	31		
T3	27	16	30	23	**0.01**	T3/T2 0.18	30	20	36	30	0.12	
T4	32	17	33	26		T4/T3 **0.02**	32	21	36	28		

Table 5 CC- the change during the study period

T1- first measurement (at the beginning of A[1])
T2- second measurement (at the end of A[1])
T3- third measurement (at the end of B)
T4- fourth measurement (at the end of A[2])
CC- Calf Circumference
[1]- In millimetres

CC												
Study group (n=8)							**Control group (n=8)**					
	Mean[1]	Sd[1]	Median[1]	IQR[1]	P-value Friedman	P-value Wilcoxon	Mean[1]	Sd[1]	Median[1]	IQR[1]	P- value Friedman	P -value Wilcoxon
T1	156	21	152	39	**0.01**		155	22	147	40	**0.01**	
T2	174	14	168	23		**T2/T1 0.01**	168	17	165	22		**T2/T1 0.02**
T3	183	14	183	27		**T3/T2 0.02**	180	16	178	21		**T3/T2 0.01**
T4	192	13	194	21		**T4/T3 0.02**	186	15	187	18		**T4/T3 0.01**

Table 6 CC– the change between the study and control groups

2-1- the difference between the second and first measurements
3-2- the difference between the third and second measurements
4-3- the difference between the fourth and third measurements

	Study group (n=8)	**Control group (n=8)**	**Mann-Whitney value**	**p-value**
	Rank	**Rank**		
CC 2-1	10.0	7.0	20.0	0.23
CC 3-2	7.6	9.4	24.5	0.44
CC 4-3	10.3	6.7	17.5	0.13

Table 7 The Pirani score- the change during the study period

T1- first measurement (at the beginning of A^1)
T2- second measurement (at the end of A^1)
T3- third measurement (at the end of B)
T4- forth measurement (at the end of A^2)
PS- Pirani Score

Pirani												
Study group (n=8)							**Control group (n=8)**					
	Mean	Sd	Median	IQR	P-value Friedman	P-value Wilcoxon	Mean	Sd	Median	IQR	P- value Friedman	P -value Wilcoxon
T1	1.7	1.0	1.50	1.4	**0.01**		1.3	0.9	1.0	1.3	**0.03**	
T2	0.7	0.4	0.50	1.0		**T2/T1 0.02**	0.7	0.9	0.3	1.0		**T2/T1 0.05**
T3	0.6	0.5	0.50	0.9		T3/T2 0.31	0.8	1.4	0.3	1.3		T3/T2 0.70
T4	0.4	0.4	0.50	0.5		**T4/T3 0.05**	0.7	1.4	0.0	0.9		T4/T3 0.16

Figures:

Figure 1 - Electrode position for stimulation of the evertor muscles