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ESCUELA ACADÉMICO PROFESIONAL DE TECNOLOGÍA MÉDICA "TERAPIA FÍSICA Y REHABILITACIÓN"

"EFECTIVIDAD DE LA ESTIMULACIÓN ELÉCTRICA NEUROMUSCULAR EN EL TRATAMIENTO DE NIÑOS CON PARÁLISIS CEREBRAL: REVISIÓN SISTEMÁTICA DE ENSAYOS CLÍNICOS ALEATORIZADOS."

TRABAJO DE SUFICIENCIA PROFESIONAL PARA OPTAR EL TÍTULO DE LICENCIATURA EN TECNOLOGÍA MÉDICA - TERAPIA FISICA Y REHABILITACION.

Presentado por:

Bachiller:

ALVA MENDOZA, ROXANA ANYELA

ROJAS RAMÍREZ, MIRIAN

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DEDICATORIA

A Dios y nuestros padres por el don de la vida y darnos la fuerza necesaria para seguir adelante, porque Siempre nos apoyaron incondicional durante formación profesional.

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Agradecemos a Dios por darnos la vida y hacer posible la realización de este Trabajo; por enseñarnos lo maravilloso que es la vida, la naturaleza y todo lo creado por él, desde el desplazamiento de un simple gusano, hasta lo grandiosidad en la formación de un diamante, por mostrarnos que en su creación nada ocurre al azar y todo tiene una causa.

Asesor:

Mg. Juan Carlos Benites Azabache

Jurado:

Presidente:

Mg.Juan Carlos Benites Azabache

Secretaria:

Lic. Mónica Judith García Bendezú

Vocal:

Lic. Juana García Cárdenas

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RESUMEN

Objetivos: Verificar mediante la revisión sistemática la efectividad de la estimulación eléctrica neuromuscular en el tratamiento de los niños con parálisis cerebral en el aumento de la fuerza muscular, medida de la función motora gruesa, control de la marcha, deglución en niños con parálisis cerebral frente al tratamiento convencional.

Fuente de datos: Se llevó a cabo una revisión sistemática en las bases de *DATOS PUBMED, EBSCOHOST, PEDRO DATABASE, SCIELO-SCIENTIFIC ELECTRONIC LIBRARY ONLINE Y GOOGLE ACADÉMICO.* La búsqueda fue realizada en los meses de octubre, noviembre y diciembre de 2016, el riesgo de selección en los estudios individuales, fue realizado analizando la calidad metodológica según la escala de *PEDRO*.

Criterios de elegibilidad, participantes e intervenciones: Se sometieron los resultados a los criterios de inclusión/exclusión para determinar la validez de los estudios en la revisión.

Resultados: Los estudios identificados fueron: número de registros identificados en las búsquedas, N = 39: *PEDRO DATA BASE (8), PUBMED (18), EBSCOHOST (16), SCIELO-SCIENTIFIC ELECTRONIC LIBRARY ONLINE* (1*) Y GOOGLE ACADÉMICO* N= 9. En el tamizaje se encontraron 10 estudios duplicados y en el proceso de elegibilidad fueron excluidos 34 estudios; por no cumplir criterio de inclusión (56) y presentar criterio de exclusión (9). Finalmente fueron incluidos 5 estudios.

Limitaciones: El presente estudio realizado por la compilación de ensayos clínicos tubo la limitación por el hecho que muchos de las compilaciones se

encuentran en otros idiomas y estos son muy dificultosos para poder proporcionarse las traducciones pertinentes , por otro lado los equipos con los cuales se han hecho los estudios han sido de diferentes marcas y modelos lo cual no homogenizó la aplicación de la prueba ,para obtener resultados mucho más homogéneos que requiere toda investigación. Sin embargo, el presente trabajo se pudo realizar gracias a que se contó con el apoyo de personas que nos traducían los artículos y que la prueba se realizó con corrientes de estimulación eléctrica neuromuscular a todos los participantes.

Conclusiones: Existe efectividad de la estimulación eléctrica neuromuscular en el tratamiento de niños con parálisis cerebral. Demostrando que la corriente de estimulación eléctrica neuromuscular aumenta la fuerza muscular y es significativamente efectivo en niños con parálisis cerebral los cuales han sido comparados con otros métodos o técnicas de recuperación en todos los ensayos clínicos revisados, que se han realizado en las diferentes zonas rescatables para el aumento de la fuerza muscular.

Palabras claves: Parálisis cerebral, estimulación eléctrica neuromuscular.

ABSTRACT

Objectives: To verify through the systematic review the effectiveness of neuromuscular electrical stimulation in the treatment of children with cerebral palsy in the increase of muscle strength, measurement of gross motor function, gait control, swallowing in children with cerebral palsy versus treatment conventional.

Data source: We carried out a systematic review in the bases of *DATA PUBMED, EBSCOHOST, PEDRO DATABASE, SCIELO-SCIENTIFIC ELECTRONIC LIBRARY ONLINE AND GOOGLE ACADEMIC.* The search was performed in October, November and December 2016, the risk of selection in the individual studies, was performed by analyzing the methodological quality according to *PEDRO* scale.

Eligibility criteria, participants and interventions: The results were submitted to the inclusion / exclusion criteria to determine the validity of the studies in the review.

Results: The identified studies were: number of records identified in searches, *N = 39: PEDRO DATA BASE (8), PUBMED (18), EBSCOHOST (16), SCIELO-SCIENTIFIC ELECTRONIC LIBRARY ONLINE (1) AND ACADEMIC GOOGLE* N = 9. At screening, 10 duplicate studies were found and 34 studies were excluded in the eligibility process; for failing to meet inclusion criteria (56) and presenting exclusion criteria (9). Finally, 5 studies were included.

Limitations: The present study performed by the compilation of clinical trials was limited by the fact that many of the compilations are in other languages and these are very difficult to be able on the other hand, the teams with which the

studies have been made have been of different brands and models which did not homogenize the application of the test, in order to obtain much more homogeneous results that all research requires. However, the present work could be performed thanks to the support of people who translated the articles and the test was performed with currents of electrical stimulation neuromuscular to all participants.

Conclusions: There is effectiveness of neuromuscular electrical stimulation in the treatment of children with cerebral palsy. Proving that the neuromuscular electrical stimulation current increases muscle strength and is significantly effective in children with cerebral palsy who have been compared with other recovery methods or techniques in all the reviewed clinical trials that have been performed in the different redeemable areas the increase of muscular strength.

Key words: Cerebral palsy, neuromuscular electrical stimulation.

CAPÍTULO I: INTRODUCCIÓN

1.1. Introducción

La parálisis cerebral infantil es un trastorno que implica entre otros problemas, alteraciones de desarrollo del tono postural y de las actividades motoras de carácter persistente (aunque no invariable), que condiciona una limitación en la actividad, secundario a una agresión no progresiva, a un cerebro inmaduro. En esta definición, se incluye el concepto, fundamental de que: en la Parálisis Cerebral (PC) el trastorno motor estará acompañado frecuentemente de otros trastornos (sensitivos, cognitivos, lenguaje, perceptivos, conducta, epilepsia, musculo esqueléticos) cuya existencia o no, condicionarán de manera importante el pronóstico individual de estos niños.[1]

A nivel epidemiológico se tiene que:

- La prevalencia global de PC en los países industrializados oscila de 2 a 2,5/1000 RN vivos.[1].
- Más alta en los RN de muy bajo peso y muy baja edad gestacional, según la mayoría de los autores. [1]
- En los países en desarrollo la prevalencia es más alta debido a lo ya dicho y a una mayor frecuencia de asfixia perinatal.[1]
- La prevalencia de la PCI se incrementó en los nacidos con muy bajo peso, en los años 80, sin embargo, la encuesta de parálisis cerebral en Europa ha encontrado una tendencia a la baja desde 1980 a 1996.[1]

La lesión cerebral en la PCI es, por definición, estática, sin embargo, los niños con PCI pueden empeorar paulatinamente si no son tratados adecuadamente. El abordaje debe ser individualizado, en función de la situación en que se encuentra el niño (edad, afectación, capacidades, entorno familiar, escolar, etc.). Los objetivos básicos del manejo son: 1) en el aspecto motor; 2) atención a los trastornos asociados, y 3) prevenir alteraciones sobre el desarrollo global.[1]

Electroestimulación neuromuscular. Es la estimulación eléctrica del músculo inervado, que se realiza a través de las fibras nerviosas motoras que lo inervan. Se clasifica la estimulación eléctrica neuromuscular (EENM) como la estimulación eléctrica del músculo inervado, que se realiza a través de las fibras nerviosas motoras que lo inervan.

Estimulación eléctrica muscular (EEM), definida como la estimulación que se aplica directamente en el músculo denervado, y cuyo objetivo primordial es mantener su trofismo. La excitación directa de las fibras musculares con electrodos de contacto se produce si el músculo se encuentra denervado.se utiliza en el tratamiento de la atrofia por denervación.

La Electro estimulación Neuromuscular, puede producir potenciales de acción en el nervio y en el músculo, que son indistinguibles de los generados por la acción del sistema nervioso. También puede activar las fibras nerviosas sensibles periféricas y las del sistema vegetativo o autonómico. El efecto visible o palpable de la estimulación eléctrica es la contracción muscular. El músculo inervado responde con una contracción al estímulo eléctrico que le llega a su placa motriz a través del nervio correspondiente. [2]

Estimulación eléctrica neuromuscular NMES contribuye a mejorar la amplitud articular del movimiento.*Hazelwood* y sus compañeros de trabajo encontraron un aumento Rango de movimiento en la flexión dorsal del tobillo y tobillo en niños con parálisis cerebral hemipléjica después de estimulación eléctrica de los músculos tibiales anteriores .Un ensayo controlado aleatorio de la terapia eléctrica Estimulación en niños con parálisis cerebral Mejora de la función con un aumento de Puntaje en la medida de la función motora gruesa (GMFM).Después del tratamiento. Se propone que NMES El músculo de la pantorrilla de los niños con parálisis cerebral no Sólo mejorar el resultado motor, sino también mejorar la percepción sensorial del niño. Como un beneficio adicional, La entrada sensorial proporcionada por NMES incorporó enfoque específico de la tarea en el aprendizaje motor Mejorar el patrón en el ciclo de andar. [3]

1.2. Justificación.

La presente investigación cobra su importancia ya que nos permite conocer la importancia de la estimulación neuromuscular para el aumento de la fuerza muscular, de estudios de ensayos clínicos ya realizados cuya factibilidad y viabilidad se ha podido realizar ya que se contó con evidencia para su revisión.

El presente estudio cobra un valor teórico ya que nos permite la revisión de estudios, que nos van a permitir aportar con conocimiento que ha aplicación la electroterapia en niños con PC, práctica que es poco habitual y en el que existen resistencias sin mayor fundamento científico.

A nivel práctico los resultados de la revisión sistemática permitirán al fisioterapeuta clínico tener evidencia del uso de la electroterapia en pacientes

con parálisis cerebral, en relación al tipo de electroestimulación, dosis y tipos de aplicación, así como los resultados más importantes como el control de la marcha, control de tronco, fuerza muscular, y control postura como herramientas complementarias a la terapia de neurodesarrollo

El aporte a universidad de esta revisión esta en relación a las líneas de investigación de la facultad y la carrera de terapia física y rehabilitación; esta RS está alineada a las siguientes líneas de investigación aprobadas para la carrera: Línea 3: Neurorrehabilitación. b) valoración de la marcha en pacientes neurológicos. Así como también a la Línea 4: Alteraciones posturales

1.3. Formulación del Problema

La revisión sistemática formula su problema en términos de pregunta de la siguiente manera:

¿Cuál será la efectividad de la estimulación eléctrica neuromuscular para el tratamiento de niños con parálisis cerebral?

1.4. Objetivo General.

Conforme al problema planteado el enunciado del objetivo será:

Verificar la efectividad de la estimulación eléctrica neuromuscular en el tratamiento de niños con parálisis cerebral**.**

Objetivos Específicos

- Determinar la efectividad de la estimulación eléctrica neuromuscular para el aumento de fuerza en la función motora gruesa, en niños con parálisis cerebral.

- Determinar la efectividad de la estimulación eléctrica neuromuscular para el aumento de fuerza en el control de la marcha, en niños con parálisis cerebral.

- Determinar la efectividad de la estimulación eléctrica neuromuscular para mejorar la capacidad/funcionalidad en la deglución, en niños con parálisis cerebral.

CAPÍTULO II: MÉTODOS

Para la elaboración de esta revisión sistemática fueron utilizadas las directrices propuestas por el *PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses)* [2]1 y sus extensiones 1-2.[2].[3]

PRISMA es un conjunto mínimo de elementos basado en evidencia para escribir y publicar revisiones sistemáticas y metaanálisis, consta de 27 ítems terminología, formulación de la pregunta de investigación, identificación de los estudios y extracción de datos, calidad de los estudios y riesgo de sesgo, cuándo combinar datos, meta análisis y análisis de la consistencia, y sesgo de publicación selectiva de estudios o resultados.[3]

De acuerdo a la sugerencia de la Escuela Académico Profesional de Terapia Física se modificaron los Ítems de *PRISMA* adaptándolos al instructivo de elaboración de tesis de la Universidad Privada Norbert Wiener en: Introducción, justificación, planteamiento del problema y objetivo.

2.1. Criterios de Elegibilidad.

Se utilizaron como criterios de elegibilidad conforme a la estructura Población, Intervención, Comparación y *Outcome* (PICO):

- **Población** **:** Niños con parálisis cerebral
- **Intervención** **:** Estimulación eléctrica neuromuscular
- **Comparación** **:** Tratamiento habitual/ placebo

- **Outcome** (resultados): Funcionalidad función fuerza muscular en motora gruesa, deglución y marcha
- Además, se incluyeron otros criterios de elegibilidad. Publicaciones de los últimos 13 años para estimar la evidencia en este espacio de tiempo.
- Publicaciones en todos los idiomas español e ingles

2.2. Fuentes de Información.

Se realizó una revisión sistemática de la literatura para: Verificar mediante la revisión sistemática la efectividad de la estimulación eléctrica neuromuscular en la fuerza muscular, medida de la función motora gruesa, control de la marcha, deglución en niños con parálisis cerebral frente al tratamiento convencional

Se realizó la búsqueda de las bases de datos y buscadores especializados hasta el 23 julio de 2016: *PUBMED, EBSCOHOST, PEDRO DATABASE, SCIELO-SCIENTIFIC ELECTRONIC LIBRARY ONLINE Y GOOGLE ACADÉMICO,* los cuales se muestran en la **tabla 1.**

Tabla 1. Fuente de información

FUENTE DE INFORMACIÓN	ENLACE WEB	TIPO	ACCESIBILIDAD	PROPIETARIO/ ADMINISTRADOR
PUBMED	http://www.ncbi.nlm.nih.gov/pubmed	Motor de búsqueda y Base de Datos	Libre	Biblioteca Nacional de Medicina de los Estados Unidos
PEDRO DATABASE	http://www.pedro.org.au/spanish/	Motor de búsqueda y Base de Datos especializada en fisioterapia	Libre	Centro de Fisioterapia Basada en la Evidencia en el George Institute for Global Health
EBSCOHOST	https://www.ebscohost.com/	Base de datos multidisciplinaria, académica y de investigación, contiene: Sport discus Medic Latina Academic Search Premier	Suscripción	Elton B. Stephens Company
SCIELO - SCIENTIFIC ELECTRONIC LIBRARY ONLINE	http://www.scielo.org/	Biblioteca electrónica publicación electrónica de ediciones completas de las revistas científicas	Libre	FAPESP (http://www.fapesp.br) - la Fundación de Apoyo a la Investigación del Estado de São Paulo, BIREME (http://www.bireme.br) - Centro Latinoamericano y del Caribe de Información en Ciencias de la Salud
GOOGLE ACADÉMICO	https://scholar.google.com/	Buscador especializado en literatura científica-académica	Libre	Google Inc.

2.3. Búsqueda.

Los términos de búsqueda que se utilizaron tuvieron en un primer momento la identificación como terminología *MESH (Medical Subject Headings) y DECS (Descriptores en Ciencias de la Salud)* bajo desambiguación en español e inglés, de no ubicarse se aproximó la terminología a su denominación técnica más común.

TABLA 2. BÚSQUEDA DE TÉRMINOS MESH/DESH

	TERMINO 1	**TÉRMINO 2**	**TÉRMINO 3**	**TÉRMINO 4**	**TÉRMINO 5**
TÉRMINO ESPAÑOL	Parálisis cerebral	Estimulación Eléctrica	Neuromuscular Funcionalidad	Placebo	Niños
DECS	Sí	Sí	Si	si	si
TÉRMINO INGLÉS	Cerebral Palsy	Electric Stimulation	Neuromuscular Junction	Placebo Effect	Child
MESH	Sí	Sí	Si	si	Si
Sinónimos	CP (Cerebral Palsy) Cerebral Palsy, Dystonic-Rigid Cerebral Palsies, Dystonic-Rigid Cerebral Palsy, Dystonic Rigid Dystonic-Rigid Cerebral Palsies Dystonic-Rigid Cerebral Palsy Cerebral Palsy, Mixed Mixed Cerebral Palsies Mixed Cerebral Palsy Cerebral Palsy, Monoplegic, Infantile Monoplegic Infantile Cerebral Palsy Infantile Cerebral Palsy, Monoplegic Cerebral Palsy, Quadriplegic, Infantile Quadriplegic Infantile Cerebral Palsy Infantile Cerebral Palsy, Quadriplegic Cerebral Palsy, Rolandic Type Rolandic Type Cerebral Palsy	Therapeutic Electrical Stimulation Electrical Stimulation, Therapeutic Stimulation, Therapeutic Electrical Therapeutic Electric Stimulation Electric Stimulation, Therapeutic Stimulation, Therapeutic Electric Electrical Stimulation Therapy Stimulation Therapy, Electrical Therapy, Electrical Stimulation Therapy, Electric Stimulation Stimulation Therapy, Electric Electrotherapy Interferential Current Electrotherapy Electrotherapy, Interferential Current	Junction, Neuromuscular Junctions, Neuromuscular Neuromuscular Junctions Myoneural Junction Junction, Myoneural Junctions, Myoneural Myoneural Junctions Nerve-Muscle Preparation Nerve-Muscle Preparations Preparation, Nerve-Muscle Preparations, Nerve-Muscle	Effect, Placebo Effects, Placebo Placebo Effects	Children

	TERMINO 1	TÉRMINO 2	TÉRMINO 3	TÉRMINO 4	TÉRMINO 5
	Cerebral Palsy, Congenital Congenital Cerebral Palsy Little Disease Little's Disease Spastic Diplegia Diplegias, Spastic Spastic Diplegias Diplegia, Spastic Monoplegic Cerebral Palsy Cerebral Palsies, Monoplegic Cerebral Palsy, Monoplegic Monoplegic Cerebral Palsies Cerebral Palsy, Athetoid Athetoid Cerebral Palsy Cerebral Palsies, Athetoid Cerebral Palsy, Dyskinetic Cerebral Palsies, Dyskinetic Dyskinetic Cerebral Palsy Cerebral Palsy, Atonic Atonic Cerebral Palsy Cerebral Palsy, Hypotonic Hypotonic Cerebral Palsies Hypotonic Cerebral Palsy Cerebral Palsy, Diplegic, Infantile Diplegic Infantile Cerebral Palsy Infantile Cerebral Palsy, Diplegic Cerebral Palsy, Spastic Spastic Cerebral Palsies Spastic Cerebral Palsy				

Se realizó la estrategia de búsqueda en las bases de datos: *PUBMED, EBSCOHOST, PEDRO DATABASE, SCIELO-SCIENTIFIC ELECTRONIC LIBRARY ONLINE Y GOOGLE ACADÉMICO.* **(Tabla 3).** Todas las búsquedas se restringieron desde enero del 2006 hasta julio del 2016 debido que queríamos centrarnos específicamente en las literaturas publicadas en los últimos 13 años y en varios idiomas.

TABLA 3: ESTRATEGIA DE BÚSQUEDA

BASE DE DATOS/ FUENTES	ESTRATEGIA	ENTRADA
PUBMED	Neuromuscular electrical stimulation in children with cerebral palsy	[All Fields]) AND ("cerebral palsy"[MeSH Terms] OR ("cerebral"[All Fields] AND "palsy"[All Fields]) OR "cerebral palsy"[All Fields])) AND Clinical Trial[ptyp]
EBSCOHOST	Neuromuscular electrical stimulation in children with cerebral palsy	Neuromuscular electrical stimulation in children with cerebral palsy.
PEDRO DATABASE	Neuromuscular electrical Stimulation in Children with cerebral palsy	Búsqueda simple
SCIELO - SCIENTIFIC	Neuromuscular Electrical Stimulation cerebral	Búsqueda simple
GOOGLE ACADÉMICO	Allintitle: neuromuscular electrical stimulation in children with cerebral palsy	Entrada simple

2.4 Selección de los estudios.

El proceso de selección de estudios tuvo las siguientes etapas:

- Registro de salidas a las estrategias de búsqueda: A las salidas (listado de estudios) determinadas por las estrategias de búsqueda establecidas en los buscadores y bases de datos consultadas, se incluyó el dato de fecha de búsqueda y número de estudios identificados. El tratamiento de este listado se realizó en una base de datos que consignaba a cada artículo según título, autor, Journal, fecha, volumen y número.
- Fase eliminación de duplicados: Se procedió a depurar los resultados, eliminando los estudios duplicados e integrándolos en una base de datos preladas alfabéticamente según el título.
- Fase de análisis y selección: Una vez obtenida la lista de estudios no duplicados se procedió a ordenar la base de datos según autor y año y título, se analizaron los artículos en base a sus títulos y resúmenes, finalmente las copias del texto completo para determinar la elegibilidad de acuerdo a los criterios de inclusión y exclusión. Se clasificaron según la elegibilidad de los estudios, en tres categorías: Estudios incluidos, estudios eliminados por no cumplir algún criterio de inclusión y estudios eliminados por cumplir algún criterio de exclusión. Esta fase culminó cuando se obtuvo un listado de estudios seleccionados los cuales fueron ordenados por Autor (año) y título.

2.5. Riesgo de sesgo en los estudios individuales.

El riesgo de selección en los estudios individuales fue realizado analizando la calidad metodológica según la escala de *PEDRO* [4–6] que contiene 11 criterios de los cuales él Nº1 no se puntúa.

La puntuación total va del 0 al 10, según los siguientes criterios.

Tabla 4. Riesgo de sesgo

https://www.pedro.org.au/spanish/downloads/pedro-scale/

ITEMS	
1	Los criterios de elección (no se suma a la puntuación total) Nota sobre la administración: Este criterio se cumple si el artículo describe la fuente de obtención de los sujetos y un listado de los criterios que tienen que cumplir para que puedan ser incluidos en el estudio.
2	Asignación aleatoria Los sujetos fueron asignados al azar a los grupos (en un estudio cruzado, los sujetos fueron distribuidos aleatoriamente a medida que recibían los tratamientos) Nota sobre la administración: Se considera que un estudio ha usado una designación al azar si el artículo aporta que la asignación fue aleatoria. El método preciso de aleatorización no precisa ser especificado. Procedimientos tales como lanzar monedas y tirar los dados deberían ser considerados aleatorios. Procedimientos de asignación cuasi-aleatorios, tales como la asignación por el número de registro del hospital o la fecha de nacimiento, o la alternancia, no cumplen este criterio.
3	La asignación fue oculta Nota sobre la administración: La asignación oculta (enmascaramiento) significa que la persona que determina si un sujeto es susceptible de ser incluido en un estudio, desconocía a qué grupo iba a ser asignado cuando se tomó esta decisión. Se puntúa este criterio incluso si no se aporta que la asignación fue oculta, cuando el artículo aporta que la asignación fue por sobres opacos sellados o que la distribución fue realizada por el encargado de organizar la distribución, quien estaba fuera o aislada del resto del equipo de investigadores.
4	Comparabilidad inicial Los grupos fueron similares al inicio en relación a los indicadores de pronóstico más importantes Nota sobre la administración: Como mínimo, en estudios de intervenciones terapéuticas, el artículo debe describir al menos una medida de la severidad de la condición tratada y al menos una medida (diferente) del resultado clave al inicio. El evaluador debe asegurarse de que los resultados de los grupos no difieran en la línea base, en una cantidad clínicamente significativa. El criterio se cumple incluso si sólo se presentan los datos iniciales de los sujetos que finalizaron el estudio.
5	Todos los sujetos fueron cegados Nota sobre la administración: Cegado significa que la persona en cuestión (sujeto, terapeuta o evaluador) no conocía a qué grupo había sido asignado el sujeto. Además, los sujetos o terapeutas solo se consideran “cegados” si se puede considerar que no han distinguido entre los tratamientos aplicados a diferentes grupos. En los estudios en los que los resultados clave sean auto

ITEMS	
	administrados (ej. escala visual analógica, diario del dolor), el evaluador es considerado cegado si el sujeto fue cegado.
6	Todos los terapeutas fueron cegados Nota sobre la administración: Cegado significa que la persona en cuestión (sujeto, terapeuta o evaluador) no conocía a que grupo había sido asignado el sujeto. Además, los sujetos o terapeutas solo se consideran "cegados" si se puede considerar que no han distinguido entre los tratamientos aplicados a diferentes grupos. En los estudios en los que los resultados clave sean auto administrados (ej. escala visual analógica, diario del dolor), el evaluador es considerado cegado si el sujeto fue cegado.
7	Todos los evaluadores fueron cegados Nota sobre la administración: Cegado significa que la persona en cuestión (sujeto, terapeuta o evaluador) no conocía a qué grupo había sido asignado el sujeto. Además, los sujetos o terapeutas solo se consideran "cegados" si se puede considerar que no han distinguido entre los tratamientos aplicados a diferentes grupos. En los estudios en los que los resultados clave sean auto administrados (ej. escala visual analógica, diario del dolor), el evaluador es considerado cegado si el sujeto fue cegado.
8	Seguimiento adecuado Las medidas de al menos uno de los resultados clave fueron obtenidas de más del 85% de los sujetos inicialmente asignados a los grupos. Nota sobre la administración: Este criterio sólo se cumple si el artículo aporta explícitamente tanto el número de sujetos inicialmente asignados a los grupos como el número de sujetos de los que se obtuvieron las medidas de resultado clave. En los estudios en los que los resultados se han medido en diferentes momentos en el tiempo, un resultado clave debe haber sido medido en más del 85% de los sujetos en alguno de estos momentos.
9	Análisis de intención de tratar Se presentaron resultados de todos los sujetos que recibieron tratamiento o fueron asignados al grupo control, o cuando esto no pudo ser, los datos para al menos un resultado clave fueron analizados por "intención de tratar" Nota sobre la administración: El análisis por intención de tratar significa que, donde los sujetos no recibieron tratamiento (o la condición de control) según fueron asignados, y donde las medidas de los resultados estuvieron disponibles, el análisis se realizó como si los sujetos recibieran el tratamiento (o la condición de control) al que fueron asignados. Este criterio se cumple, incluso si no hay mención de análisis por intención de tratar, si el informe establece explícitamente que todos los sujetos recibieron el tratamiento o la condición de control según fueron asignados.
10	Entre el grupo de las comparaciones Los resultados de comparaciones estadísticas entre grupos fueron informados para al menos un resultado clave. Nota sobre la administración: Una comparación estadística entre grupos implica la comparación estadística de un grupo con otro.

ITEMS	
	Dependiendo del diseño del estudio, puede implicar la comparación de dos o más tratamientos, o la comparación de un tratamiento con una condición de control. El análisis puede ser una comparación simple de los resultados medidos después del tratamiento administrado, o una comparación del cambio experimentado por un grupo con el cambio del otro grupo (cuando se ha utilizado un análisis factorial de la varianza para analizar los datos, estos últimos son a menudo aportados como una interacción grupo x tiempo). La comparación puede realizarse mediante un contraste de hipótesis (que proporciona un valor “p”, que describe la probabilidad con la que los grupos difieran sólo por el azar) o como una estimación de un tamaño del efecto (por ejemplo, la diferencia en la media o mediana, o una diferencia en las proporciones, o en el número necesario para tratar, o un riesgo relativo o hazard ratio) y su intervalo de confianza.
11	Apunte estimaciones y variabilidad El estudio proporciona medidas puntuales y de variabilidad para al menos un resultado clave. Nota sobre la administración: Una estimación puntual es una medida del tamaño del efecto del tratamiento. El efecto del tratamiento debe ser descrito como la diferencia en los resultados de los grupos, o como el resultado en (cada uno) de todos los grupos. Las medidas de la variabilidad incluyen desviaciones estándar, errores estándar, intervalos de confianza, rango intercuartílico (u otros rangos de cuantiles), y rangos. Las estimaciones puntuales y/o las medidas de variabilidad deben ser proporcionadas gráficamente (por ejemplo, se pueden presentar desviaciones estándar como barras de error en una figura) siempre que sea necesario para aclarar lo que se está mostrando (por ejemplo, mientras quede claro si las barras de error representan las desviaciones estándar o el error estándar). Cuando los resultados son categóricos, este criterio se cumple si se presenta el número de sujetos en cada categoría para cada grupo.

La escala *PEDRO* considera dos aspectos de la calidad de los ensayos, a saber, la "credibilidad" (o "validez interna") del ensayo y si el ensayo contiene suficiente información estadística para hacerlo interpretable. No mide la "relevancia" (o "generalización" o "validez externa") del ensayo, o el tamaño del efecto del tratamiento. [7]

La mayor parte de los criterios de la lista "se basan en la *lista Delphi,* desarrollada por *Verhagen* y sus colegas. La lista *Delphi* es una lista de características de ensayo que se consideran que están relacionadas con la "calidad" del ensayo por un grupo de expertos de ensayos clínicos. La escala *PEDRO* contiene elementos adicionales sobre la adecuación del seguimiento y comparaciones estadísticas entre grupos. Un elemento presente en la lista *Delphi* (relativo a los criterios de elegibilidad) está relacionada con la validez externa, por lo que no se corresponde con las dimensiones de la calidad evaluada por la escala de *PEDRO.* Este elemento no se emplea para calcular la puntuación del método que se muestra en los resultados de búsqueda (Es por lo que una escala de 11 elementos tan solo ofrece una puntuación sobre 10). Este elemento, sin embargo, se ha conservado por lo que todos los elementos de la lista *Delphi* están presentes en la escala *PEDRO*." [7]

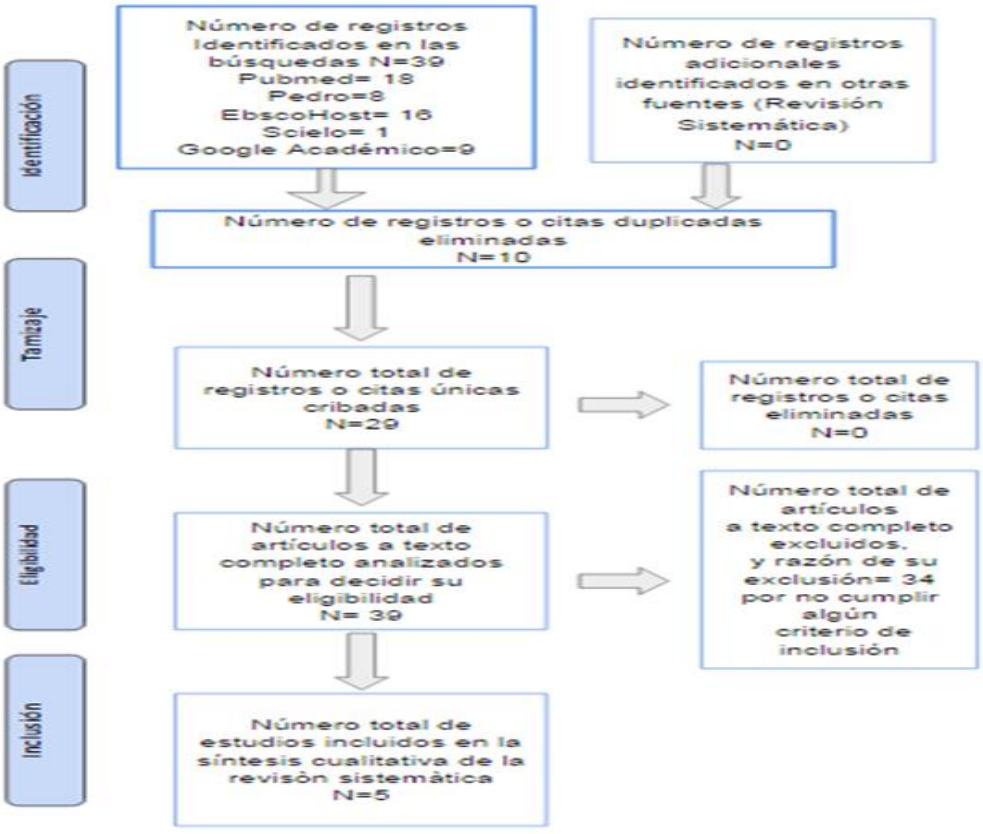
CAPÍTULO III: RESULTADOS

3.1. Selección de estudios.

Los estudios identificados fueron 39 en *PEDRO DATA BASE (8), PUBMED MEDLINE (18), EBSCOHOST (16), SCIELO-SCIENTIFIC ELECTRONIC LIBRARY ONLINE (1) Y GOOGLE ACADÉMICO (9).*

En el tamizaje se encontraron 10 estudios duplicados y en el proceso de elegibilidad fueron excluidos 34 estudios por no cumplir algún criterio de inclusión. Finalmente fueron incluidos 5 estudios.

Gráfico 1. Selección de estudios



Fuente: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed100009

3.2. Características de los estudios

Los estudios seleccionados fueron en su totalidad estudios clínicos controlados y randomizados según sus criterios de inclusión/exclusión y cuyo objetivo principal era verificar la efectividad de la estimulación eléctrica neuromuscular en niños con parálisis cerebral. Según pico puede apreciarse en la tabla siguiente.

TABLA 5:CARACTERÍSTICAS DE LOS ESTUDIOS

AÑO Y AUTOR	TÍTULO	POBLACIÓN	INTERVENCIÓN	COMPARACIÓN	VARIABLES DE SALIDA(MEDICIÓN)
Chan NNC, Smith AW, Lo SK.2004	Eficacia de la electricidad neuromuscular Estimulación en el mejoramiento de la cinética del Caminando en niños con parálisis cerebral. Efficacy of neuromuscular electrical Stimulation in improving ankle kinetics during Walking in children with cerebral palsy.	12 niños (4-11 años), Criterio de inclusión: diplejía espástica o hemiplejia.	G.E NMES Zonas: Tobillo dorsiflexores, Tríceps sural Dosis:	G1. Realizaron Banda sin fin G2. Se aplicó. electro estimulación	Análisis de la marcha en tres dimensiones y cinco mediciones clínicas utilizando la medida de la función motora gruesa (GMFM). Cambios cinéticos en cociente momento en el tobillo (AMQ) y el cociente de la energía del tobillo (APQ) no fueron significativos.
Mohanty, Patitapaban, Monalisa Pattnaik, and Anjushree Sarkar.2016	Efecto de la estimulación eléctrica neuromuscular sobre el Glúteo Mayor y Cuádriceps en Parálisis Cerebral en niños con marcha agazapada. Effect of Neuromuscular Electrical Stimulation on Gluteus Maximus and Quadriceps in Cerebral Palsy Children with Crouch Gait.	40 niños (13 mujeres, 27 varones Edad: 5 a 11 años	GE. NMES Zonas: m. Glúteo >, m. Cuádriceps. Dosis: 15 min. 5 días/semana, 6 semanas.	G C: Ejercicios convencionales (Fuerza aeróbicos, flex.)	Fuerza Muscular: Glúteo >, M. Cuádriceps: – Esfigmomanómetro modif. (Hg/cm2) Función Motora: GMFM (D y E)

AÑO Y AUTOR	TÍTULO	POBLACIÓN	INTERVENCIÓN	COMPARACIÓN	VARIABLES DE SALIDA(MEDICIÓN)
Song W, Park J, Lee J, Kim M.2015	Efectos de la estimulación neuromuscular de las funciones de deglución en niños con parálisis cerebral. Effects of neuromuscular electrical stimulation on swallowing functions in children with cerebral palsy.	20 niños (6a.±)	2 veces a la semana durante 8 semanas	G1. Se aplicó EENM G2. Tratamiento sensorio motor(OST)	Escala de comportamiento de funciones orales en la alimentación, la escala de evaluación conductual de las funciones orales de alimentación(BASOFF) La escala de calificación para cada comportamiento es de o a 5. Una puntuación de 0 representa pasivo completamente pasivo al proceso de la alimentación, mientras que una puntuación de 5 indica una respuesta funcional normal.
Stackhouse SK, Binder-Macleod SA, Stackhouse CA, McCarthy JJ, Prosser LA, Lee SC.2007.	Estimulación eléctrica neuromuscular Versus entrenamiento Isométrico de Fuerza en Niños con Diplejía Espástica con Parálisis cerebral. Neuromuscular electrical stimulation versus volitional isometric strength Training in children with spastic diplegic cerebral palsy.	11 niños (7 y 12 años) Criterios de inclusión: PC diplejía espástica.	El grupo de entrenamiento de fuerza voluntaria a realizar Tiempo:1 serie MVIC 3 veces por semana durante 12 semanas	G1. NMES G2. Entrenamiento de fuerza voluntaria	Se midió la dosis de entrenamiento NMES los cuádriceps y tríceps sural Con respecto al MVIC del paciente obtenido en 3 momentos: pre-entrenamiento, después de 6 semanas de Entrenamiento y post-entrenamiento.
Van Der Linden ML, Hazlewood ME, Hillman SJ, Robb JE. 2008.	Estimulación eléctrica funcional para los dorsiflexores y Cuádriceps en niños con Parálisis Cerebral. Functional Electrical Stimulation to the Dorsiflexors and Quadriceps in Children with Cerebral Palsy.	14 niños (8a. ± DE)	2 semanas de ES cíclico Tiempo: 1 hora x 6 días	G1.SE APLICO FES G2. Efecto ortótico directo	El grupo de tratamiento recibió 2 semanas de estimulación eléctrica neuromuscular, seguido de 8 semanas de FES utilizan en el hogar y la escuela.

GC: Grupo control

GE: Grupo experimental

OST: Tratamiento sensoriomotor oral

FES: Estimulación eléctrica funcional

NMES: Estimulación Eléctrica Muscular.

GMFM: Medida de la función motora gruesa

MVIC: Fuerza isométrica voluntaria máxima del contacto

BASOFF: Escala de evaluación conductual de las funciones orales en la alimentación

3.3. Evaluación de la calidad pedro

Las puntuaciones obtenidas en la escala *PEDRO* (véase tabla 6) obtuvo en promedio un puntaje de 5/10, no se evaluó un estudio que no tuvo carácter experimental, según se detalla en la siguiente tabla 6

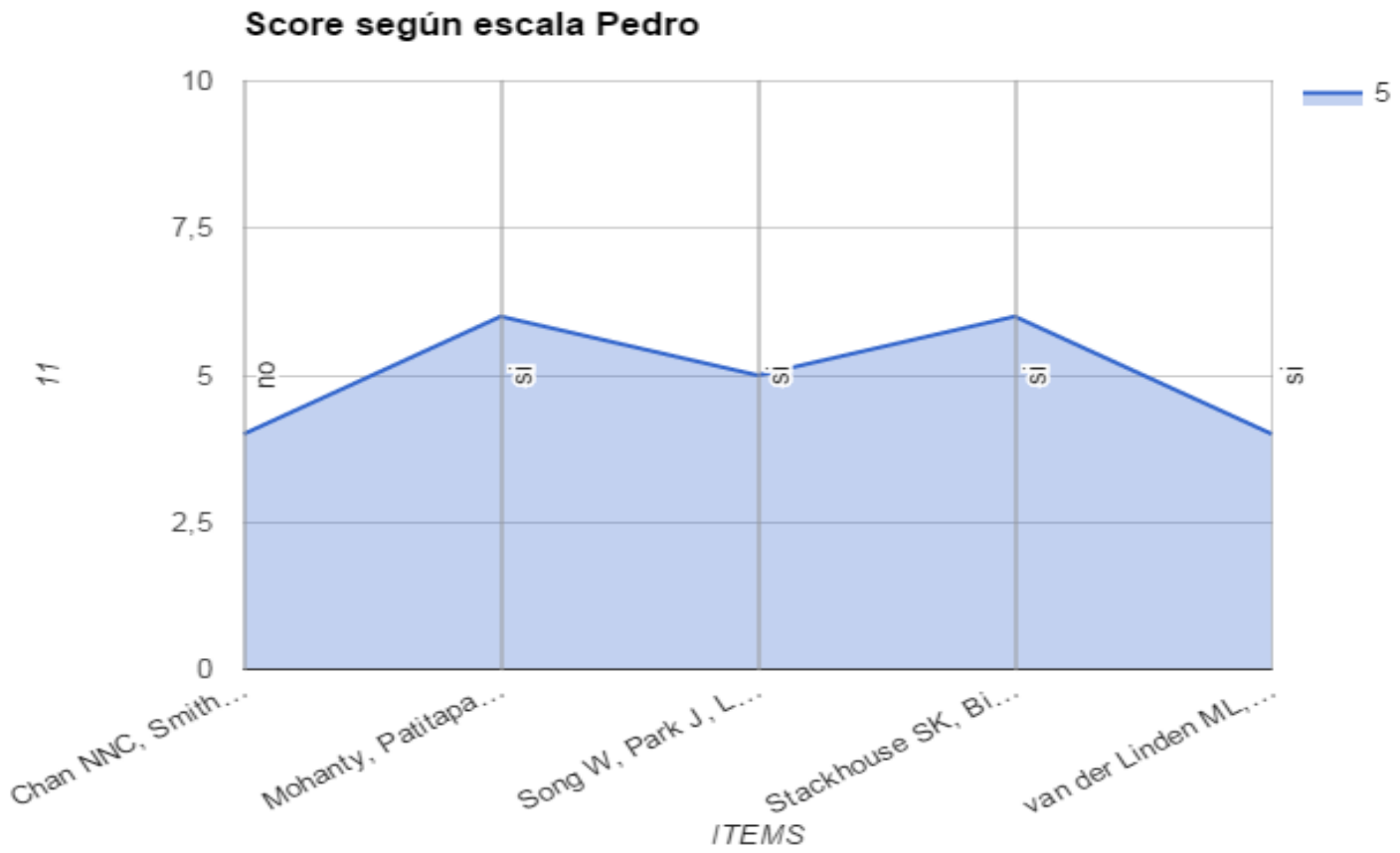
De la tabla 6 se puede extraer que en todos los estudios se realizó la asignación aleatoria, contrariamente, es posiblemente advertir que en ningún estudio se sesgo a los terapeutas, porque al realizarse el procedimiento terapéutico para saber necesariamente cuando aplica una técnica real o un placebo, debido a esto, podría ser interesante mejorar algunos de estos aspectos en estudios futuros para así incrementar la calidad metodológica de los estudios y con ello reducir el riesgo de sesgo.

La evaluación de la calidad según la escala de *PEDRO* obtuvo en promedio un puntaje de 5/10, de los cuales (23, 32,33) fueron revisados y calificados primariamente por las autoras y verificados posteriormente por el Lic. Sergio Bravo Cucci, según se detalla en siguiente tabla 6.

TABLA 6: EVALUACIÓN DE CALIDAD

EVALUACIÓN DE LA CALIDAD - ENSAYOS CLÍNICOS CONTROLADOS						
ITEMS		**Chan NNC, Smith AW, Lo SK.2004**	**Mohanty, Patitapaban, Monalisa Pattnaik, and Anjushree Sarkar.2016.**	**Song W, Park J, Lee J, Kim M.2015.**	**Stackhouse SK, Binder-Macleod SA, Stackhouse CA, McCarthy JJ, Prosser LA, Lee SC.2007.**	**van der Linden ML, Hazlewood ME, Hillman SJ, Robb JE. 2008.**
1	Los criterios de elección	NO	SI	SI	SI	SI
2	Asignación aleatoria	SI	SI	SI	SI	SI
3	La asignación fue oculta	NO	SI	NO	SI	NO
4	Comparabilidad inicial	NO	SI	SI	SI	NO
5	Todos los sujetos fueron cegados	NO	NO	NO	NO	NO
6	todos los terapeutas fueron cegados	NO	NO	NO	NO	NO
7	todos los evaluadores fueron cegados	NO	NO	NO	NO	SI
8	Seguimiento adecuado	SI	SI	SI	SI	NO
9	Por intensión de tratar el análisis	NO	NO	NO	NO	NO
10	Entre el grupo de las comparaciones	SI	SI	SI	SI	SI
11	Apunte estimaciones y variabilidad	SI	SI	SI	SI	SI
	Promedio=5	4	6	5	6	4

GRÁFICO 2: SCORE SEGÚN ESCALA PEDRO



Nivel de calidad según Pedro.

3.4. Síntesis de los resultados.

Presentar los resultados de todos estudios.

TABLA 7: RESULTADOS

Autor y año	Propósito y participantes	Intervención y medición	Resultados/Hallazgos
Chan NNC, Smith AW, Lo SK.2004	El objetivo principal de este estudio fue determinar el efecto de la EENM en músculo tríceps sural en la mejora de la marcha y el funcionamiento de los niños con parálisis cerebral. Doce niños de 4 a 11 años, con diplejía espástica o hemiplejia fueron reclutados y asignados al azar a los dos grupos experimentales.	Doce sujetos Con diplejía espástica o hemiplejia de 4 a 11 años de edad Fueron reclutados y asignados al azar a uno de los dos Grupos, BSF+ NMES o BSF. Se realizaron ocho medidas repetidas con análisis de la marcha en tres dimensiones y cinco mediciones clínicas utilizando la medida de la función motora gruesa (GMFM). Cambios cinéticos en cociente momento en el tobillo (AMQ) y el cociente de la energía del tobillo (APQ) no fueron significativos, ya sea inmediatamente o en conjunto en ambos grupos.	Tanto los grupos de BSF + MNES y la banda sin fin mostraron una mejoría en los resultados funcionales. La tendencia en los cambios de la puntuación GMFM sugiere que las mejoras fueron mayores en el grupo de BSF + EENM. También hubo una tendencia que muestra una cierta mejora inmediata en AMQ y APQ.
Mohanty, Patitapaban, Monalisa Pattnaik, and Anjushree Sarkar.2016	El propósito de la Estudio fue investigar los efectos de la EENM sobre el Glúteo mayor y la fuerza del Cuádriceps en la parálisis cerebral Los niños con la marcha agazapada y el efecto subsiguiente en su función motora gruesa. se reclutaron 40 niños (13 mujeres, 27 varones, grupo de 5 a 11 años) para el estudio de La sección pediátrica del departamento de fisioterapia del Instituto Nacional de Rehabilitación de Swami Vivekanand	Los niños fueron asignados al azar a cualquiera de los dos grupos. Grupo 1: La estimulación neuromuscular y el ejercicio convencional (Grupo 2: ejercicio convencional (grupo control) (n = 20). Recopilación de datos Glute0 mayor y la fuerza muscular del Cuádriceps se midió La función del esfigmomanómetro modificado y de la función motora Medida por GMFM (dimensiones D y E).	El efecto combinado de la estimulación eléctrica con el convencional La terapia muestra mejoría en la fuerza del glúteo mayor y Cuádriceps en los niños con parálisis cerebral con marcha agazapada, esto también muestra La mejora global como medida de la función motora GMFM. La fuerza de los músculos glúteo máximo y cuádriceps en ambos Los grupos mejoraron, sin embargo, al final del tratamiento El grupo experimental mostró una mejora considerablemente mayor. Los sujetos en el grupo experimental mostraron más cambios significantes. Que el grupo de control en su función motora gruesa.

Autor y año	Propósito y participantes	Intervención y medición	Resultados/Hallazgos
Woo Jin Song, Ji Hyuk Park b, Joo Hyun Lee b, Min Young Kim.2015	El propósito de esta investigación fue investigar los efectos de la EENM y del tratamiento sensoriomotor oral (OST) en niños con PC y disfagia. 20 niños, (6a.±) Fueron asignados al azar en dos grupos: Experimental y Control.	Los participantes fueron asignados aleatoriamente a El grupo experimental (n^0:10) o el grupo control (N^0:10}). Ambos grupos recibieron OST por terapeutas ocupacionales En un departamento de rehabilitación. Ambos grupos de control y tratamiento fueron equipados con FES para el análisis de la marcha en la segunda y la evaluación final	El grupo experimental demostró una mejoría significativa en: cierre del labio Deglución, capacidad de ingestión de alimentos sin exceso de pérdida, capacidad para beber líquido, capacidad para tragar líquido sin exceso de pérdida y capacidad para tragar sin tos ($p<0,05$).
Stackhouse SK, Binder-Macleod SA, Stackhouse CA, McCarthy JJ, Prosser LA, Lee SC.2007.	El propósito de esta investigación fue determinar si la NMES isométrica o el esfuerzo voluntario (VE) podría aumentar la fuerza muscular, la función motora gruesa, y la marcha en niños con diplejía espástica con parálisis cerebral (SDCP). 11 niños (7 y 12 años	Once niños con diplejía espástica fueron asignados a un grupo de entrenamiento NMES o Un grupo de entrenamiento volitivo. Los participantes en el grupo NMES tenían electrodos implantados Percutánea para activar los músculos cuádriceps femorales y tríceps sural. Se midió la dosis de entrenamiento NMES los cuádriceps y tríceps sural Con respecto al MVIC del paciente obtenido en 3 momentos: pre-entrenamiento, después de 6 semanas de Entrenamiento y post-entrenamiento.	El grupo formado por NMES tuvo mayores aumentos en la producción de fuerza normalizada para Ambos mueven el cuádriceps femoral y el tríceps sural. Del mismo modo, sólo el grupo NMES mostró un aumento En la velocidad de caminar después del entrenamiento. Los cambios en la activación muscular voluntaria explicaron aproximadamente 67% y 37% de los cambios observados en la MVIC de los grupos NMES y entrenamiento isométrico, respectivamente. Cuádriceps femoral máximo CSA aumentó significativamente para el grupo NMES solamente.
Van Der Linden ML, Hazlewood ME, Hillman SJ, Robb JE. 2008.	Evaluar los efectos de la estimulación eléctrica funcional (FES) de los dorsiflexores del tobillo y el cuádriceps en niños con parálisis cerebral. 14 niños (edad media de 8 años) fueron asignados al azar a un grupo de tratamiento o control.	Catorce de los niños fueron emparejados lo más estrechamente posible sobre el tipo de CP, Utilizando el Cuestionario de Evaluación Funcional12 y edad. De cada uno de los siete pares resultantes, un Asignados al azar al grupo de tratamiento mientras que el otro Hijo del par fue asignado al grupo de control. El grupo de tratamiento recibió 2 semanas de estimulación eléctrica neuromuscular, seguido de 8 semanas de FES utilizan en el hogar y la escuela.	El grupo formado por FES aplicado en los dorsiflexores de tobillo mostro mejoras significativas en la marcha de los niños con Parálisis cerebral.se hicieron intentos para activar el cuádriceps, pero esto resulto imposible debido al corto tiempo de la oscilación de los niños.

BSF: Banda sin fin **NMES:** Electro estimulación neuromuscular **OST:** Tratamiento sensoriomotor oral **CSA**: Area de la sección transversal

CAPÍTULO IV: DISCUSIÒN

4.1. Discusión

Sobre la aplicación de EEM y NMES en la fuerza muscular, apreciamos que Chan et al. (2004) [3] verificó la eficacia de la NMES para la mejora de la cinética muscular a diferencia de *Mohanty et al.* (2016) [11] que utilizó la NMES para la mejora de la fuerza muscular, también se diferenciaron porque el primero utiliza una aplicación a nivel distal (músculos de tobillo) versus el segundo que estimula músculos proximales de miembro inferior. También podemos diferenciarlos por el tipo de PC; Chan et al. (2004) [3] utiliza una población de paciente dipléjicos y *Mohanty et al. (*2016) [11] pacientes con PC espásticos, el rango de edades en ambos es similar.

Sobre las zonas de aplicación; *Song W et al.(* 2015) [13] verificó la eficacia de la NMES, demostrando una mejora significativa en todas las subcategorías a diferencia de *Stackhouse SK et al.(*2007) [12] que utiliza la MNES tuvo mayores en la producción de fuerza ,también se diferencia porque el primero utiliza una aplicación en músculos faciales versus el segundo estimula músculos proximales del miembro inferior(cuádriceps y tríceps sural).También podemos diferenciarlos por la el tipo PC; *Song W et al.(*2015) [13] utiliza una población en niños con PC y disfagia y *Stackhouse SK et al.(*2007) [12] pacientes con PC con diplejía espástica, el rango de edades en ambos es similar.

A nivel de zonificación de aplicación entre músculos del miembro inferior *Mohanty P et al.*(2016) [11] verificó la eficacia de la MNES que utiliza para la mejora de la fuerza muscular, también se diferencia porque utiliza una aplicación en los músculos proximales a nivel de miembro inferior (Glúteo

mayor y cuádriceps) a diferencia *Stackhouse SK et al.(*2007) [12] que utiliza la EENM para la mejora de la fuerza muscular de miembros inferiores proximales (cuádriceps y tríceps sural) versus *van Der Linden et al.(*2008) [14] utiliza FES en los miembros proximales y distales del miembro inferior (dorsiflexores y cuádriceps) tiene mejoras significativas en los dorsiflexores en la marcha en los niños con PC. También podemos diferenciarlos por el tipo de PC; *Mohanty et al.* (2016) [11] utiliza una población de pacientes con PC espásticos, *Stackhouse SK et al.* (2007) [12] pacientes con diplejía espástica y *Van Der Linden et al.* (2008) [14] utilizo pacientes con PC en general, el rango de edades es similar.

4.2. Limitaciones

A la búsqueda de los artículos para su previa selección, se encontró que varios de ellos estaban en idioma extranjero (coreano) y que dificulta la elección inmediata, para definir si se incluían o no en las revisiones de estudio final; sin embargo el presente estudio se logró realizar ya que la Universidad Privada Norbert Wiener cuenta con una suscripción y acceso a la base de *DATOS PUBMED, EBSCOHOST, PEDRO DATABASE, SCIELO-SCIENTIFIC ELECTRONIC LIBRARY ONLINE Y GOOGLE ACADÉMICO,* son de acceso libre y que han sido herramientas básicas para la realización del presente estudio.

Otro factor limitante es las características heterogéneas las poblaciones de niños con PC dada las tipologías y gravedades de los cuadros, que prácticamente hacen diferente a un paciente de otro.

4.3. Conclusiones.

Tras la revisión y análisis de los artículos se puede concluir que:

Existe efectividad de la estimulación eléctrica neuromuscular en el tratamiento de niños con parálisis cerebral. Demostrando que la corriente de estimulación eléctrica neuromuscular aumenta la fuerza muscular y es significativamente efectivo en niños con parálisis cerebral los cuales han sido comparados con otros métodos o técnicas de recuperación en todos los ensayos clínicos revisados, que se han realizado en las diferentes zonas rescatables para el aumento de la fuerza muscular, pues se ha demostrado la existencia de:

La efectividad de la estimulación eléctrica neuromuscular para el aumento de fuerza en la función motora gruesa, en niños con parálisis cerebral.

Que existe efectividad de la estimulación eléctrica neuromuscular para el aumento de fuerza en el control de la marcha, en niños con parálisis cerebral; y la existencia de la efectividad de la estimulación eléctrica neuromuscular para mejora la capacidad/funcionalidad en la deglución, en niños con parálisis cerebral.

Finalmente, se concluye que por los estudios revisados y analizados nos revelan que la estimulación eléctrica neuromuscular practicada en niños con parálisis cerebral para el aumento de la fuerza en la función motora gruesa, el aumento de la fuerza en el control de la marcha y mejora la capacidad/funcionalidad en la deglución, en niños con parálisis cerebral, lo cual nos indica que este tipo de corriente es beneficiosa en estos tres aspectos mencionados.

Consideramos necesario mayores estudios experimentales que nos permita obtener mayor evidencia científica para poder tener mayor consistencia del logro de los estudios ya realizados.

Abreviatura y Acrónimos

- **T=**Tratamiento
- **DF=** Dorsiflexores
- **N=**Fisioterapia normal
- **PC=**Parálisis cerebral
- **BSF=** Banda sin fin
- **GGI=** Gillette Gait Index
- **VE=** Esfuerzo voluntario
- **DE=**Desviación estándar
- **IC=**Intervalos de confianza
- **VCM=** Vicon clínica Manager
- **PCI** = Parálisis cerebral infantil
- **SNC=** Sistema nervioso central
- **ES=** Estimulación eléctrica cíclica
- **FES=** Estimulación eléctrica funcional
- **OST =** Tratamiento sensoriomotor oral
- **APQ =**Cociente de potencia de tobillo

- **CSA=**Área de la sección transversal
- **GMFM**= Medida de la función motora gruesa
- **NMES=** Estimulación eléctrica neuromuscular
- **SDCP=** Diplejía espástica parálisis cerebral
- **XN=** Análisis de la marcha realizado número de ensayo
- **MVIC=** Fuerza isométrica voluntaria máxima del contrato
- **ROM=** Aumentar la amplitud de movimiento
- **BASOFF=** Escala de evaluación conductual de las funciones orales en la alimentación

CAPÍTULO V: FINANCIAMIENTO

Este trabajo fue financiado íntegramente por los autores, quienes participaron conjuntamente con el asesor Lic. Sergio Bravo Cucci en el diseño del estudio, la recolección y análisis de los datos y la preparación del manuscrito.

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Los autores declaran no tener conflicto de interés para la realización de este estudio.

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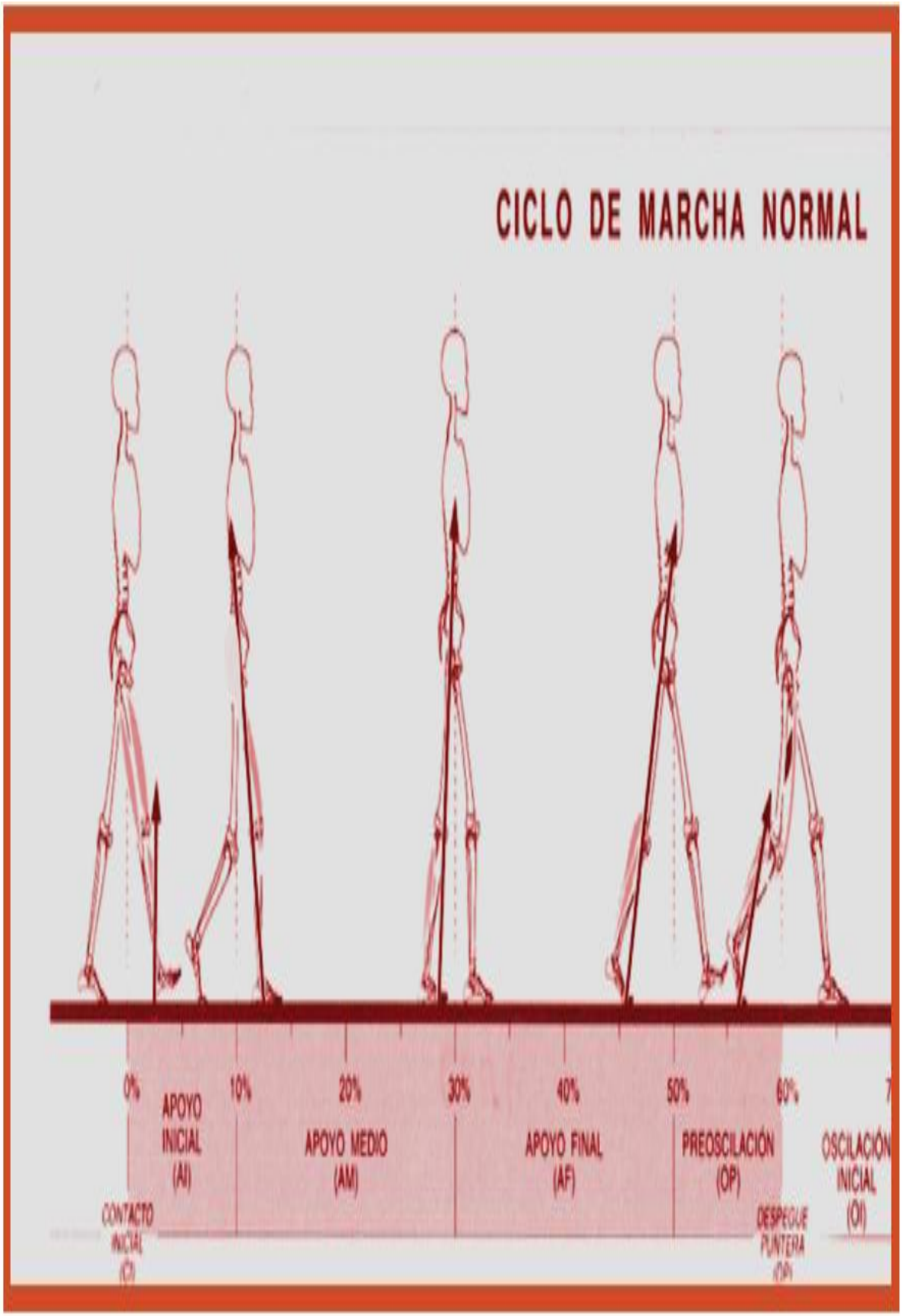
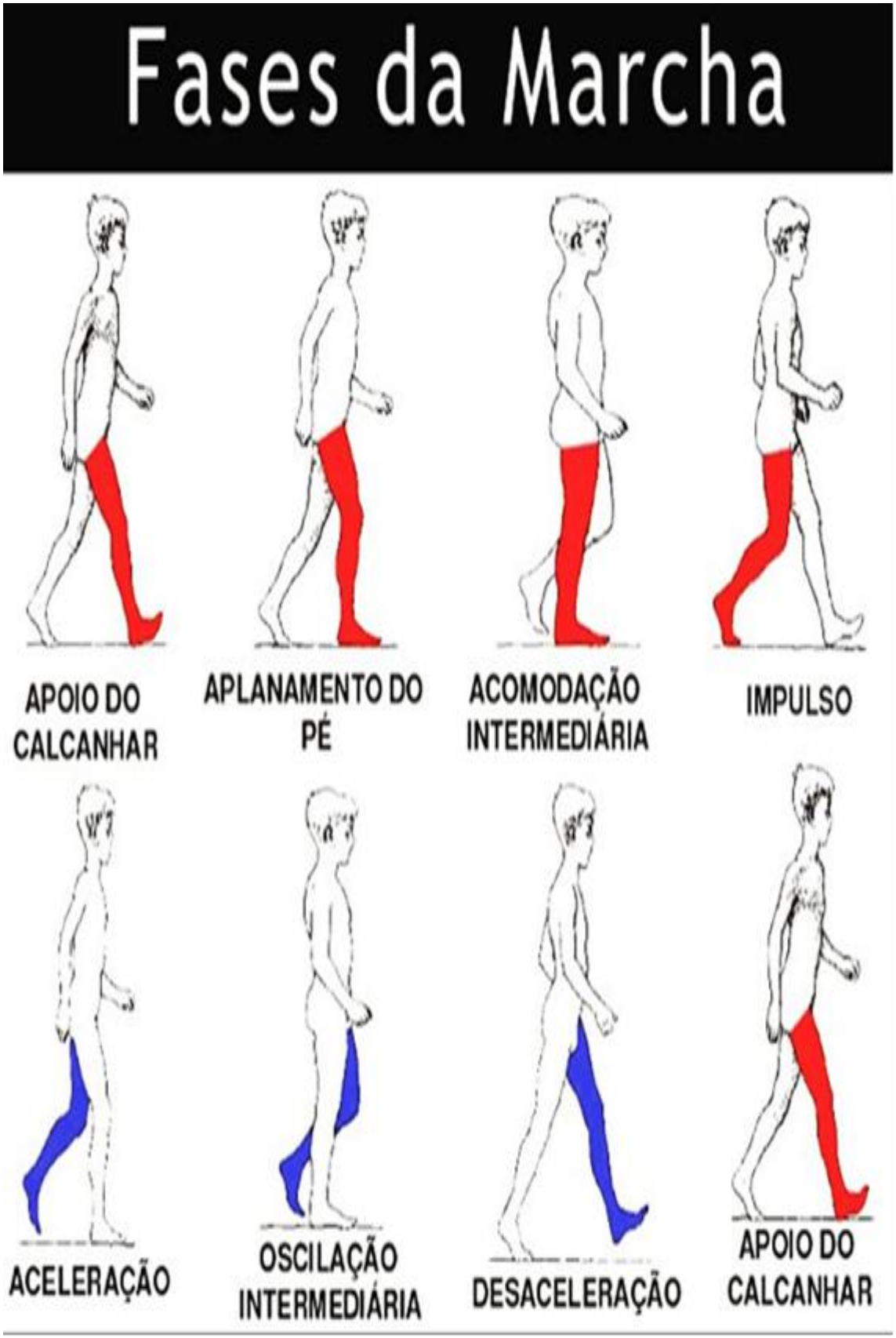
ANEXO I

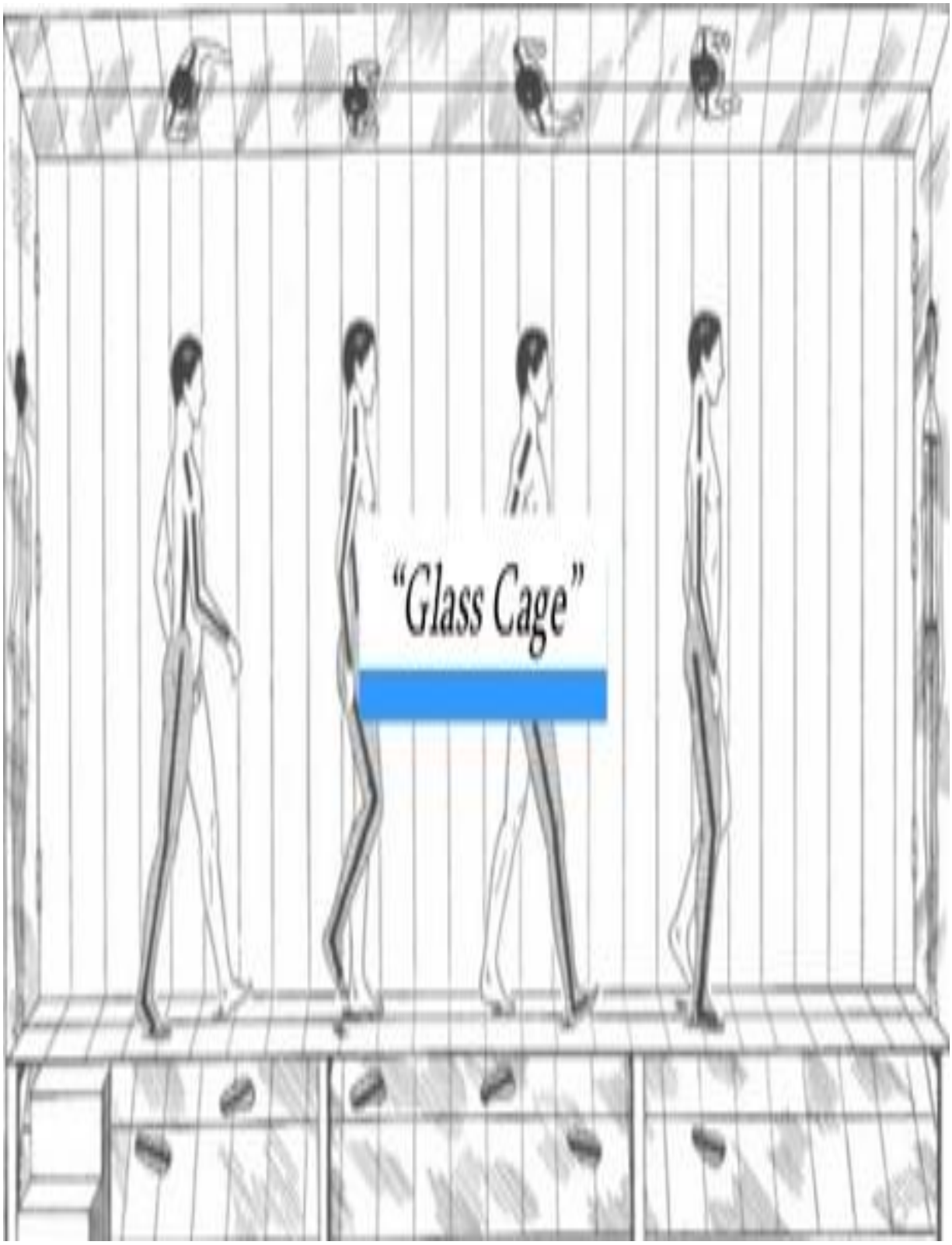
Instrumentos utilizados en la medición de los estudios involucrados

CICLO DE LA MARCHA NORMAL




Fases da Marcha
APOIO DO CALCANHAR
APLANAMENTO DO PÉ
ACOMODAÇÃO INTERMEDIÁRIA
IMPULSO
ACELERAÇÃO
OSCILAÇÃO INTERMEDIÁRIA
DESACELERAÇÃO
APOIO DO CALCANHAR

Análisis de la marcha en 3D



FICHA DE EVALUACIÓN DE PEDRO DATA

Escala PEDro-Español		
1. Los criterios de elección fueron especificados	No ❑ Sí ❑	dónde:
2. Los sujetos fueron asignados al azar a los grupos (en un estudio cruzado, los sujetos fueron distribuidos aleatoriamente a medida que recibían los tratamientos)	No ❑ Sí ❑	dónde:
3. La asignación fue oculta	No ❑ Sí ❑	dónde:
4. Los grupos fueron similares al inicio en relación a los indicadores de pronostico más importantes	No ❑ Sí ❑	dónde:
5. Todos los sujetos fueron cegados	No ❑ Sí ❑	dónde:
6. Todos los terapeutas que administraron la terapia fueron cegados	No ❑ Sí ❑	dónde:
7. Todos los evaluadores que midieron al menos un resultado clave fueron cegados	No ❑ Sí ❑	dónde:
8. Las medidas de al menos uno de los resultados clave fueron obtenidas de más del 85% de los sujetos inicialmente asignados a los grupos	No ❑ Sí ❑	dónde:
9. Se presentaron resultados de todos los sujetos que recibieron tratamiento o fueron asignados al grupo control, o cuando esto no pudo ser, los datos para al menos un resultado clave fueron analizados por "intención de tratar"	No ❑ Sí ❑	dónde:
10. Los resultados de comparaciones estadísticas entre grupos fueron informados para la menos un resultado clave	No ❑ Sí ❑	dónde:
11. El estudio proporciona medidas puntuales y de variabilidad para al menos un resultado clave	No ❑ Sí ❑	dónde:

ANEXOS II

Texto Completo de estudios involucrados

Functional Electrical Stimulation to the Dorsiflexors and Quadriceps in Children with Cerebral Palsy

Mariëtta L. van der Linden, PhD, M. Elizabeth Hazlewood, MCSP, Susan J. Hillman, MSc, CEng, and James E. Robb, MD, FRCS

School of Health Sciences (M.L.v.d.L.), Queen Margaret University, Edinburgh, Scotland, UK; Anderson Gait Analysis Laboratory (M.E.H.), Edinburgh, Scotland, UK; National Centre for Training and Education in Prosthetics and Orthotics (S.J.H.), University of Strathclyde, Glasgow, Scotland, UK; and Royal Hospital for Sick Children (J.E.R.), Edinburgh, Scotland, UK

Purpose: To assess the effects of functional electrical stimulation (FES) of the ankle dorsiflexors and quadriceps in children with cerebral palsy. **Methods:** Fourteen children (mean age 8 years) were randomly allocated to a treatment or control group. The treatment group received 2 weeks of neuromuscular electrical stimulation followed by 8 weeks of FES used at home and school. The control group continued with its usual physiotherapy program. Assessment took place at baseline and before and after the treatment period. Both control and treatment groups were fitted with FES for gait analysis at the second and final assessments. **Results:** In both groups, FES of the ankle dorsiflexors resulted in a significant ($p < 0.01$) effect on gait kinematics. However, no long-term treatment effect of using FES for 8 weeks was found. **Conclusions:** FES for selected children with cerebral palsy, receiving adequate support, can be a practical treatment option to improve gait kinematics. **(Pediatr Phys Ther 2008;20:23–29)** *Key words: cerebral palsy, child, electric stimulation therapy/methods, gait, human movement system, motor skills, physical therapy/methods, articular range of motion, treatment outcome, walking*

INTRODUCTION

Functional electrical stimulation (FES) is the electrical stimulation of muscles that have impaired motor control to produce a contraction to obtain functionally useful movement.[1] FES as a treatment option in children with cerebral palsy (CP) was first proposed by Gracanin[2] and has several possible benefits. It may be used to achieve a direct "orthotic" effect during gait, for example, by triggering the ankle dorsiflexors to lift the foot in swing, or to trigger the quadriceps to extend the knee in stance. Possible long-term "therapeutic" effects of FES include a reduction in the tendency for muscle atrophy and improved motor control by improving the effectiveness of neural pathways.[3]

Previous case reports on the effects of surface FES to the lower limb in children with CP have shown promising results,[4–7] but only a few studies have included more than two children.[8–10] Using a case experimental design, Postans and Granat[8] applied different FES strategies in children, six with diplegia and two with hemiplegia to investigate the direct orthotic effect of FES. Three children in their study showed clinically significant improvements, achieving the predefined target of a 5° increase in dorsiflexion in midswing and at initial contact when FES was switched on. In another study by Durham et al,[9] FES was applied for 3 months to the dorsiflexors of 10 children with hemiplegia. No therapeutic effect was found, but the authors concluded that FES resulted in an improved foot-contact pattern on the affected side when the FES was switched on, hence an orthotic effect, although no statistical significance was reported. Finally, in the study of Comeaux et al,[10] 14 children received a daily therapy session consisting

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Pediatric Physical Therapy

Address correspondence to: *Mariëtta L. van der Linden, PhD, School of Health Sciences, Queen Margaret University, Queen Margaret University Drive, Musselburgh EH21 6UU, Edinburgh, Scottland, UK. E-mail: mvanderlinden@qmu.ac.uk*
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TABLE 1
Subject Characteristics of the Children in the Treatment Group and Control Group

	Treatment Group				Control Group			
Diagnosis	FES to	Age (yrs)	FAQ Score	Orthoses	FES to	Age (yrs)	FAQ Score	Orthoses
Diplegic	Right Q	5	8	Fixed AFOs	Right Q	11	7	AFO and GRO
Monoplegic	Left DF	7	9	Hinged AFO	Right DF	5	10	Hinged AFO
Hemiplegic	Right DF	13	10	None	Right DF	7	8	Fixed AFOs
Diplegic	Right Q	11	8	None	Right Q	10	9	Hinged AFOs
Hemiplegic	Left DF	5	9	Fixed AFO	Left DF	8	9	Fixed AFO
Diplegic	Left DF	10	9	Fixed AFOs	Right DF	11	8	None
Hemiplegic	Left DF	5	7	Fixed AFO	Left DF	5	8	Fixed AFO

DF indicates dorsiflexor; Q, quadriceps; AFO, ankle foot orthosis; GRO, ground reaction orthosis; FAQ, Functional Assessment Questionnaire.[12]

of gait and pregait activities for 14 weeks. In addition to this therapy, electrical stimulation using a remote switch was applied to the gastrocnemius (treatment 1) and the gastrocnemius and tibialis anterior (treatment 2) three times a week for 4 weeks. They reported a significant orthotic effect of both treatments on ankle dorsiflexion at initial contact measured on the video screen using a manual goniometer.

To the authors' knowledge, however, no randomized controlled trials have investigated both the orthotic and therapeutic effects of surface FES in children with CP. The aim of this exploratory trial was to provide effect sizes and data on the orthotic and therapeutic effects of FES required for a future appropriately powered randomized controlled trial. The null hypothesis was that there is no orthotic effect; hence no difference was expected in gait parameters between FES "on" and FES "off" and no therapeutic effect, hence no difference was expected between the control and experimental group. A second aim of this study was to investigate the feasibility of using FES equipment at home and school for children with CP.

METHODS

Participants

Physiotherapists and consultants in Edinburgh, Scotland and surrounding areas were asked to identify children with CP aged between 4 and 15 years who had either toe or forefoot contact or increased knee flexion during stance. Candidates for FES applied to the dorsiflexors (DF group) were those children who had decreased dorsiflexion in swing of more than two standard deviations compared with children developing typically and who made initial contact by the toe or forefoot. Candidates for FES to the quadriceps (Quads group) were those children who had increased knee flexion at initial contact and during stance of more than two standard deviations compared with a group of children assessed at our gait laboratory who were developing typically.[11] Exclusion criteria were significant shortening of the muscles or joint limitation, ie, $>10°$ of plantarflexion from neutral when the knee was extended, $<40°$ of straight leg raise, or a hip flexion contracture of $>15°$. Children with significant athetosis, dystonic or dyskinetic CP, with cardiac conditions, uncontrolled epilepsy, or severe learning difficulties were also excluded.

Twenty-four invitations were issued for participation in the study, and 18 children with CP were recruited initially. However, after the baseline assessment three children did not fit the inclusion criteria. One girl in the control group failed to attend the third assessment. Fourteen children were matched as closely as possible on type of CP, function using the Functional Assessment Questionnaire[12] and age. Of each of the resulting seven pairs, one child was randomly allocated to the treatment group while the other child of the pair was allocated to the control group. Randomization was performed by drawing identical tokens from a bag. Details of the 14 children who completed the study are shown in Table 1. The Local Research Ethics Committee approved the study and parents gave written, informed consent before their child's participation.

Study Protocol

All children were invited to the gait analysis laboratory three times, at baseline, after the 2-week period of cyclic electrical stimulation (cyclic ES) for the treatment group and after the 8-week period of FES for the treatment group. During the first session, 3D gait analysis was performed of the child's usual walking pattern to determine whether the child fit the inclusion criteria and which muscle group was to be targeted.

At the second and third visit to the gait laboratory, all children in both the treatment and control groups were fitted with FES. Once the electrode position, footswitch position, and stimulation parameters were optimized, gait analysis was performed both with the stimulator switched on and off. The FES parameters for the treatment group at the third assessment were the same as those used at home.

The first and third session also included a physical examination of the range of motion of the joints targeted by FES. The joint and muscle ranges were assessed by passive manipulation, inhibiting spasticity by applying a slow stretch and appropriate positioning of the child and the examiners hands. The ranges were measured with a manual goniometer. The same observers performed all assessments. The researcher who measured range of motion and performed the data analysis was blind to group allocation.

Cyclic Electrical Stimulation

Weakness in children with CP[13] may result in an inability to trigger the muscles effectively in the initial stages of FES. It was therefore hypothesized that 2 weeks of cyclic ES, sometimes called neuromuscular electrical stimulation, with the aim of improving the strength of the target muscles[14] and to familiarize the child with the sensation of the electrical stimulation would make the application of FES more effective. For this reason, after the first baseline assessment, the children in the treatment group received 2 weeks of cyclic ES for an hour a day, 6 days a week to either the ankle dorsiflexors or the knee extensors. The stimulator used was the Neurotrac2™ (Verity Medical, Chilbolton, Hampshire, UK), which has an asymmetrical rectangular biphasic waveform.

An experienced pediatric physiotherapist made an initial home visit and instructed the child's parents on the use of the stimulator and electrode placement and also provided detailed written instructions. Follow-up home visits were made weekly during treatment to monitor and adjust the electrode positioning. The parents also had a contact phone number available (all hours) if any problems occurred. While receiving the cyclic ES the children were allowed to move around as normal but asked to avoid "rough and tumble" or water play. In the first week, stimulation comprised of 30 minutes at 40 Hz (duty cycle of 6 seconds on, 14 seconds off), followed by 30 minutes at 10 Hz (duty cycle: 6 seconds on, 10 seconds off) to avoid muscle fatigue. In the second week, stimulation comprised of 60 minutes at 40 Hz (duty cycle: 6 seconds on, 14 seconds off). Pulse duration was 100 microseconds for the dorsiflexors and 150 microseconds for the quadriceps for the first 30 minutes of the first week and during the full 60 minutes during the second week. One hundred microseconds was found to be sufficient to elicit an adequate contraction of the dorsiflexors, with least discomfort in the small muscles of these children. The quadriceps required a greater pulse duration to trigger a contraction. For the second 30 minutes in the first week this was 75 microseconds for both muscles to reduce the level of contraction thereby avoiding fatigue, while maintaining a low level of stimulation to continue the familiarization process. The ramp from zero to full stimulation lasted 0.8 seconds for both weeks. During the 2 weeks of cyclic ES, the parents gradually increased the intensity of stimulation under the guidance of the physiotherapist until a good contraction of the target muscles was achieved and tolerated by the child. "Good" was considered a visible contraction of the muscle, and resulted in appropriate movement of the target joint.

For both cyclic ES and FES, the motor points as defined by Scott[15] were used as an initial guide for the attachment of the gel electrodes (PALS, Platinum Blue, Nidd Valley Medical, Knaresborough). The square 4×4 cm^2 electrodes were found to be most comfortable for all children and lasted for 2 to 4 weeks. For the DF group, the electrode positions were adjusted until straight sagittal plane dorsiflexion was achieved, hence avoiding excessive inversion and eversion. This was generally achieved with the proximal electrode over the motor point of the tibialis anterior and the distal electrode often placed over the extensor digitorum. For the Quads group, the proximal electrode was sited over the anterolateral side of the thigh and the distal electrode over the motor point of vastus medialis. Electrode positions were adjusted by moving the electrodes until a maximum contraction of the selected muscle with the least discomfort was obtained, without excessive overflow to other muscle groups or any unwanted movement of the limb. The stimulation was also adjusted so that the muscles were not contracting at the limit of range to avoid potential damage.

Functional Electrical Stimulation

The single-channel Odstock Dropped Foot Stimulator (ODFS III, Biomedical Engineering and Medical Physics, Salisbury, UK) was used for FES. This stimulator has an asymmetrical biphasic voltage driven waveform. Output amplitude ranged from 20 to 70 mA and the stimulation frequency was 40 Hz. Output time, extension time, and ramp were adjusted for each subject. The level of intensity of the ODFS III was adjusted by increasing the pulse duration and ranged from approximately 3 to 350 microseconds. The same electrodes and the selection of their position were used as described above for the cyclic ES.

Footswitches were used inside the child's shoe to trigger the dorsiflexors immediately as the foot was raised from the ground. The settings were adjusted for each child so that dorsiflexors remained stimulated throughout swing to aid clearance and prepositioning of the foot before stance, and continuing briefly into loading to avoid foot-slap. The quadriceps muscles were triggered at initial foot contact and through loading. If necessary, the stimulation extended into midstance to maintain the knee extension, taking care to avoid delaying the initiation of knee flexion. Attempts were made to trigger the quadriceps in terminal swing, but this proved impossible because of the short swing time of these children.

Footswitches supplied by the stimulator manufacturer were used initially. These were later replaced by in-house manufactured footswitch strips (Fig. 1), which could be cut to an appropriate length for each child. In the first 2 weeks of the 8-week treatment, the pulse duration which, in these units, increases the intensity of the stimulation, and the duration of the daily use of FES, were gradually increased by the parents under the guidance of the physiotherapist to achieve a comfortable and effective level of stimulation. As with the cyclic ES, the families were visited weekly by the same physiotherapist. The children wore the units all day but removed them for sports activities. The physiotherapist also visited the child's school to inform and instruct teachers or auxiliaries, and parents were asked to keep a diary of stimulator use.

Gait Analysis

Three-dimensional gait analysis was undertaken using a 50 Hz six-camera Vicon 370 motion analysis system

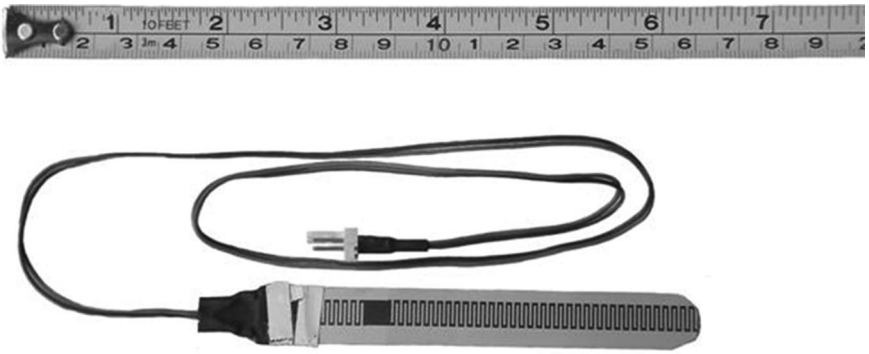

Fig. 1. Custom made footswitch. The length and position of which was adjusted to the child's foot contact pattern.

(Oxford Metrics, Oxford, UK) and one Kistler force plate (Kistler Instrumente AG, Winterthur, Switzerland).

For those children who were candidates for FES to the quadriceps, gait analysis was performed with the children wearing their normal shoes and orthoses. Barefoot gait was assessed for the DF group.

Markers were placed on the lower limbs and pelvis according to the Vicon Clinical Manager (VCM) manual. Six to 10 trials were captured for each condition (FES off and FES on).

Ankle and knee angles and walking speed were calculated using the VCM software. In addition, the foot–floor angle at initial contact was derived from the foot orientation. A negative angle foot–floor indicates initial contact by the toe/forefoot, zero indicates flat foot initial contact, and a positive angle indicates initial contact by the heel.

The Gillette Gait Index (GGI) formerly known as the Normalcy Index[16] is a measure of the amount of gait deviation compared with the gait of an average person without impairments. The GGI was computed from a selection of gait parameters derived from 3D gait analysis. The higher the score, the higher the deviation from the average person without impairments.

Physical Examination

An experienced physiotherapist performed passive range of dorsiflexion of the ankle both with the knee flexed and extended, and a second experienced professional made a measurement of the range using a manual goniometer. Intra-assessor coefficient of repeatability[17] was 9.3° and 10.0° for dorsiflexion with the knee flexed and extended, respectively, for measurements 1 week apart.

Questionnaires

The parents of the children in both groups completed the Functional Assessment Questionnaire.[12] The scores on this questionnaire range from 1 to 10, with 10 indicating the highest functional level. After the final visit to the gait analysis laboratory, the parents of the children in the treatment group were also given a questionnaire regarding their experience with FES.

Data Analysis

Two effects of FES during gait were investigated. First, the direct orthotic effect was determined by comparing the effects when the FES was switched off to those when FES was switched on during the same assessment. This "orthotic effect" was assessed for the children in both the treatment and control group. Second, the long-term "therapeutic effect" was investigated by comparing the differences in range of motion and gait parameters between the last and first assessment between the treatment and control group.

Statistical Analysis

The orthotic effect was investigated using paired Student *t* tests. The therapeutic effect was investigated by comparing values from the first and third assessment between the control and treatment group using repeated measures ANCOVA with the values at baseline as a covariate. For all statistical tests the level of significance was set at $p < 0.05$.

No separate statistical analysis was performed on the results of the children who received FES to the quadriceps because of the small number of children in this group (n = 4).

RESULTS

Compliance and Practical Issues of FES in the Treatment Group

One of the two children in the treatment group who received FES to the quadriceps completed the 2-week cyclic ES but only used FES for 1 week at home as he did not want to wear it to school. Although he came back for the third assessment, this child was excluded from the analysis for a therapeutic effect.

For one child the problem of excessive triggering of the peroneal muscles resulting in excessive eversion was not successfully resolved until after 6 weeks when the electrodes were reduced to very thin strips. The original footswitches broke easily and had to be replaced with more robust, pressure-sensitive strip footswitches (Fig. 1) manufactured in-house for all children. The families were provided with a spare switch and therefore minimal time was lost because of this problem. The in-house switches proved suitable for active children and made triggering more effective when they were running or toe walking, as the switch worked over the entire length of the sole.

TABLE 2
Orthotic Effect of Applying FES to the Dorsiflexors (n = 10)

	Second Assessment			Third Assessment		
	FES off (SD)	FES on (SD)	Change (%95 CI)	FES off (SD)	FES on (SD)	Change (%95 CI)
Peak dorsiflexion in swing (°)*	−8.4 (7.5)	−6.1 (6.6)†	2.3 (−1.5 to 6.0)	−8.7 (8.8)	−4.9 (7.1)†	3.8 (−2.0 to 9.6)
Foot–floor angle (°)‡	−4.3 (9.0)	−1.7 (9.0)†	2.7 (−1.8 to 7.2)	−5.9 (9.6)	−2.2 (8.4)†	3.6 (−1.8 to 9.1)
Knee flexion angle at IC (°)	17.2 (7.7)	15.8 (9.1)	−1.4 (−6.1 to 3.3)	17.4 (9.6)	17.6 (9.7)	0.1 (−3.1 to 3.4)
Speed (m/sec)	1.01 (0.11)	0.94 (0.10)†	−0.07 (−0.20 to 0.05)	1.04 (0.14)	1.01 (0.15)§	−0.03 (−0.1 to 0.04)

Mean, standard deviation (SD) and 95% confidence intervals (CI) of the change in the ankle and knee kinematics and walking speed at the second and third assessments.

* Negative sign indicates a lack of dorsiflexion.

† Significantly different between FES off and FES on ($p < 0.01$).

‡ A positive foot–floor angle indicates initial contact by the heel; a negative angle indicates toe or forefoot initial contact.

§ Significantly different between FES off and FES on ($p < 0.05$).

IC indicates initial contact.

TABLE 3
Orthotic Effect of Applying FES on the Quadriceps (n = 4)

	Second Assessment			Third Assessment		
FES	FES off (SD)	FES on (SD)	Change (%95 CI)	FES off (SD)	FES on (SD)	Change (%95 CI)
Foot–floor angle (°)*	−1.8 (5.2)	−1.3 (6.1)	0.5 (−1.3 to 2.3)	−0.3 (3.4)	0.0 (3.8)	0.3 (−1.9 to 2.5)
Knee flexion at IC (°)†	26.0 (10.1)	24.7 (11.0)	−1.3 (−5.6 to 3.0)	27.7 (9.5)	27.3 (9.7)	−0.5 (−2.7 to 1.7)
Peak knee extension (°)†	−16.7 (11.4)	−13.9 (13.7)	−2.2 (−9.3 to 4.9)	−20.1 (10.8)	−16.6 (13.0)	−3.5 (−11.5 to 4.5)
Speed (m/sec)	0.97 (0.23)	0.96 (0.17)	−0.01 (−0.13 to 0.11)	0.93 (0.11)	0.97 (0.05)	0.03 (−0.11 to 0.17)

Mean, standard deviation (SD) and 95% confidence intervals (CI) of the change in the ankle and knee kinematics, and walking speed at the second and third assessments.

* A positive foot–floor angle indicates initial contact by the heel; a negative angle indicates toe or forefoot initial contact.

† Negative sign indicates a lack of extension, hence flexion.

IC indicates initial contact.

Orthotic Effect of FES to the Dorsiflexors

Table 2 shows the ankle and knee kinematics at the two sessions with and without FES for the 10 children who received FES to the dorsiflexors. Both peak dorsiflexion in swing and foot–floor angle were significantly improved ($p < 0.01$) with FES in both sessions. Individual improvements for both dorsiflexion and foot–floor angles were as much as 8.8°. Nine of 10 children walked slower when the FES was switched on during both the first and second session. This resulted in a small but significant decrease in average walking speed of 0.07 m/sec ($p < 0.01$) in the first session and of 0.03 m/sec ($p < 0.05$) in the second session. FES to the dorsiflexors did not significantly affect the knee kinematics.

Orthotic Effect of FES to the Quadriceps

Table 3 shows the average knee kinematics of the four children in the Quads group. At the second visit to the gait analysis lab, two of the four children showed a decrease in knee flexion during stance of 6.1° and 6.2° when FES was switched on, while during the third visit the same children showed improvements of 8.6° and 4.6°. The differences between FES off and on conditions in the other two children were 2° or less. FES on the quadriceps had little or no effect (<1.5°) on the foot–floor angle and knee extension at initial contact.

Analyzing the orthotic effect of FES in the dorsiflexors and quadriceps groups together, a statistically significant ($p < 0.01$) effect was found for the GGI, which is a measure of the deviation of "overall" gait pattern from normal. FES resulted in improvements of 8 and 11 points during the first and second FES session, respectively.

Therapeutic Effect

Table 4 summarizes the long-term treatment effect of using 2 weeks of cyclic ES and 8 weeks of FES. The Functional Assessment Questionnaire, the deviation of the gait pattern from normal (GGI), foot–floor angle, dorsiflexion angle in swing, and passive dorsiflexion with the knee flexed showed a trend toward improvement or less deterioration in the treatment group compared with the control group with effect sizes between 0.3 and 0.9. However, none of the changes between first and third assessment were significantly different between the control and the treatment group.

Parental Questionnaire

The parents of one child did not return the questionnaire on their opinion of using the FES stimulator but were interested in continuing to use the stimulator. Regarding the ease of use of the stimulator, the parents of one 13-year-old replied "very easy," three found it not difficult, one

TABLE 4
Therapeutic Effect of Applying Cyclic ES for 2 Weeks and FES for 8 Weeks

	Treatment Group			Control Group			
	T1 (SD)	T3 (SD)	Change (95% CI)	T1 (SD)	T3 (SD)	Change (95% CI)	Effect Size
Gillette gait index*	86 (82)	76 (40)	−10 (−94 to 74)	72 (37)	94 (55)	22 (−24 to 68)	−0.9
FAQ*	8.7 (1.0)	9.0 (0.8)	0.3 (−0.7 to 1.3)	8.4 (1.0)	8.5 (1.1)	0.1 (−0.8 to 1.0)	0.3
Speed (m/sec)*	0.93 (0.20)	1.01 (0.17)	0.08 (−0.17 to 0.33)	1.01 (0.09)	1.01 (0.11)	0.00 (−0.17 to 0.17)	0.05
Knee flexion at IC (°)*	19.9 (9.1)	20.3 (11)	0.4 (−10.3 to 11.0)	15.6 (9.8)	16.5 (10)	0.9 (−12.8 to 14.6)	−0.1
Foot–floor angle (°)†	0.3 (5.5)	−0.4 (6.6)	−0.7 (−3.5 to 2.1)	−8.7 (6.3)	−11.4 (9.4)	−2.7 (−12.2 to 6.9)	0.3
Dorsiflexion swing (°)†	−3.3 (2.3)	−2.0 (4.0)	1.3 (−6.9 to 9.5)	−12.8 (4.4)	−15.3 (6.8)	−2.6 (−15.6 to 10.4)	0.9
Passive dorsiflexion, knee flexed (°)†	3.2 (14)	10.4 (9.7)	7.2 (−4.5 to 18.9)	−0.2 (5.7)	0.2 (3.3)	0.4 (−9.7 to 10.5)	0.7

All gait measures were derived when FES was switched off. Mean values, standard deviations (SD), and 95% confidence intervals (CI) of the change between the third assessment (T3) and baseline (T1).

Negative dorsiflexion indicates a lack of dorsiflexion. A positive foot–floor angle indicates initial contact by the heel; a negative angle indicates toe or forefoot initial contact.

* All children in the study.

† Only children who received FES to the dorsiflexors.

IC indicates initial contact.

found it difficult, and one very difficult. The main problems quoted were the leads becoming disconnected and removing and attaching the electrodes.

No skin problems were encountered with the square PALS electrodes. All children except one used the stimulator 4 to 6 days or more a week and for 6 or more hours a day. Three children used the stimulator only in the home and school. The other children wore it all day, except during physical education and swimming. One child quite liked using the stimulator, three did not mind, one just tolerated, and one disliked it. The 11-year-old child who disliked it did not use the FES stimulator after the first week as he felt embarrassed about the leads and electrodes and was also participating in many sports activities which meant removing and attaching the electrodes and leads several times a day.

On the question as to whether the parents thought using FES was a practical treatment for a child that age, two (ages 11 and 5 years) replied "no," one (age 7 years) "yes" but only in the home and school (normal activities), and three (ages 5, 10, and 13 years) replied "yes." All parents except one found using the stimulator quite demanding of their time. Finally, of the parents of the children who used the FES stimulator for most of the 8 weeks, all except one thought they had seen an improvement in the child's walking or motor skills.

DISCUSSION

FES to the dorsiflexors resulted in a statistically significant orthotic effect on peak dorsiflexion in swing and the foot–floor angle at initial contact, giving individual improvements up to 8.8° for both foot–floor angle and peak dorsiflexion in swing. Winter[18] showed that a change in joint angle of as little 2° could significantly alter foot clearance. In the current study, the statistically significant changes in the ankle kinematics with FES ranged from 2.3° to 3.8° and could thus be regarded as clinically significant.

When FES to the dorsiflexors was switched on, nine of the 10 children walked slightly slower. Many children with CP have difficulty controlling forward progression. The small but significant decrease in speed when the FES was on may reflect a more controlled gait pattern because of the improved foot contact.

Individual improvements as a result of FES to the quadriceps ranged from 4.6° to 8.6°, hence higher than found for the dorsiflexors. However, an effect of FES to the quadriceps was only found for two of the four children. The other two did not tolerate a level of stimulation to the quadriceps high enough to result in a visible contraction. None of these four children tolerated a particularly long pulse duration (probably less than 200 microseconds, the dial on these units does not allow us to be exact). However, the two children who did achieve an effective contraction were slender, the other two were not. Children with large amounts of adipose tissue are therefore not likely to be good candidates for FES.

A statistically significant orthotic effect of FES was also found for the GGI. FES resulted in improvements of 8 and 11 points during the first and second FES session, respectively. However, it should be noted that Romei at al.[19] suggested that changes in the GGI of 12 or less are not clinically significant.

Because of the limited number of subjects in each group, this exploratory trial only allowed an analysis of effect sizes of the therapeutic effect of using cyclic ES for 2 weeks and FES for 8 weeks. The treatment group (n = 7) showed a trend toward an improvement in passive dorsiflexion compared with the control group (7.2° vs 0.4°). The standardized effect size of the difference between the two groups was 0.7 which means a group size of 33 would be required to detect a significant difference in passive dorsiflexion at $p < 0.05$ and a power of 80%.[20] To detect a significant improvement in dorsiflexion in swing and the GGI (effect size of 0.9) at $p < 0.05$ with a power of 80%, 20

children in each group would be required. A low effect size of 0.3 was found for the foot–floor angle. It is possible that this lack of therapeutic effect may be because electrical stimulation requires no voluntary control and is therefore unlikely to result in motor learning.

During the initial 1 to 4 weeks of FES all children in the treatment group tolerated the stimulation to a level of visible contraction and movement of the limb. In contrast, Postans and Granat[8] found that six of the 21 children initially recruited did not tolerate the stimulation. Two weeks of cyclic ES in this study may have helped the patients' understanding and acceptance of the electrical stimulation in contrast to Postans and Granat's experience.

Results from the parental questionnaire showed that reasons for not using the stimulator were embarrassment, skin problems (unrelated to the use of the stimulator), and not being practical for "non-standard activities," eg, playing out of doors or organized sports. It proved less of a burden when used by older children, who could take responsibility for the units themselves. Older children are often reluctant to continue to use their ankle foot orthoses, and FES may be a practical alternative. The younger children whose parents and schools were very supportive also managed well. FES may therefore be considered for children as young as 4 years, with sufficient supervision and support. However, as the effect of FES can be very dramatic to see, it should be made clear to the parents and children that FES is purely an assistive device, and is not a cure for impaired motor control in CP.

A common problem in studies involving children with CP is the limited number of suitable subjects who can be recruited and the variability of children with CP resulting in low statistical power.[14,21] This, and the fact that we studied the effect of FES on two different muscle groups are the main limitations of this study. However, we feel that our results inform clinicians about the feasibility and practical issues of using FES for children with CP. It also provides an estimation of the sample size required in future randomized controlled trials on the effects of FES in children with CP.

CONCLUSION

This exploratory trial showed that FES applied to the dorsiflexors resulted in significant improvements in the gait of children with CP. The researchers also reported on both the positive and negative experiences of parents and children who used FES every day for 8 weeks. In our opinion, FES for children with CP can be a practical treatment option to improve gait kinematics in a carefully selected group of children, receiving adequate support from therapist, parents, and teaching staff.

Further randomized controlled trials with a group size of at least 20 subjects should be carried out to investigate whether daily use of FES results in a long-term therapeutic effect on joint range of motion, gait kinematics, and functional ability.

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Efficacy of Neuromuscular Electrical Stimulation in Improving Ankle Kinetics During Walking in Children with Cerebral Palsy

Nerita N.C. Chan, MSc; **Andrew W. Smith**,[1] PhD; **Sing Kai Lo**,[2] PhD

Abstract: Neuromuscular electrical stimulation (NMES) applied to the triceps surae muscle is claimed to be effective in improving gait in children with cerebral palsy. The main aim of this study was to determine the effect of NMES on the triceps surae muscle in improving the gait and function of children with cerebral palsy. Twelve children with spastic diplegia or hemiplegia were recruited and randomly assigned to the two experimental groups. The period of the study was 8 weeks (2-4-2 week design). The initial 2 weeks was the control period, in which usual treatment was given to both groups of patients with a pre- and post-treatment assessment. The middle 4 weeks was the experimental period, in which the Treadmill+NMES group received NMES plus treadmill walking training and the Treadmill group underwent treadmill walking training only. Assessment was performed at 2-week intervals. The final 2 weeks was the carryover period, in which treatment to be tested was stopped and reassessment performed again at the end of week 8. An additional treatment and post-treatment assessment were given at weeks 2, 4 and 6 to test for the immediate effect of treatment. Altogether, eight repeated measures with three-dimensional gait analysis and five clinical measurements using the gross motor function measure (GMFM) were performed. Kinetic changes in ankle moment quotient (AMQ) and ankle power quotient (APQ) were not significant either immediately or cumulatively in both groups. Improvement in trend was observed in both groups immediately but not cumulatively. Using the GMFM, functional changes were detected in standing (GMST, $p < 0.001$) and in walking (GMWK, $p = 0.003$) using a "time" comparison. Significant interaction was also detected in GMWK using "treatment by time" ($p = 0.035$). The difference between the two groups was not significant on "treatment" comparison of both GMST and GMWK. Both groups showed improvement in GMST and GMWK cumulatively but there was no difference between the two groups. The effects in both groups could be carried over to 2 weeks after interventions stopped. Both the Treadmill+NMES and Treadmill groups showed improvement in functional outcomes. The trend in the changes of the GMFM score suggested that improvements were greater in the Treadmill+NMES group. There was also a trend showing some immediate improvement in AMQ and APQ.

Key words: cerebral palsy, electrical stimulation, gait

Introduction

A common deviated gait pattern in children with cerebral palsy is equinus gait or toe walking. The presence of spasticity in the triceps surae muscle is the major cause of this equinus gait. It is believed that an imbalance in the ankle joint caused by a spastic calf muscle inhibits the development of the ankle dorsiflexors, making them weak and elongated [1]. Neuromuscular electrical stimulation (NMES) is one physiotherapy modality com-

Physiotherapy Department, Tuen Mun Hospital, Hong Kong SAR, China, [1]Department of Sport & Exercise Science, University of Auckland, New Zealand, and [2]Institute for International Health, University of Sydney, Australia.
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Reprint requests and correspondence to: Nerita Chan, Physiotherapy Department, Tuen Mun Hospital, Tuen Mun, Hong Kong SAR, China.
E-mail: neritachan@yahoo.com

monly used to decrease muscle spasticity [2–4] and to strengthen the weakened antagonist muscles [5–7]. Typically, NMES is applied to antagonist muscles (ankle dorsiflexor) to achieve an antispastic effect on agonist muscles (triceps surae) by way of reciprocal inhibition [8]. Previous studies suggest that applying NMES to ankle dorsiflexors should improve the gait pattern in children with cerebral palsy [9,10]. However, clinical experience and some literature indicate that this approach is not always successful. For instance, Carmick applied NMES to ankle plantarflexors, contrary to standard practice, and found improvement in foot posture, gait pattern, balance and efficiency of movement in children with cerebral palsy [11,12]. However, the efficacy of the application of NMES to agonist muscles has not been demonstrated to date. Thus, the purpose of the present study was to determine the efficacy of applying NMES to triceps surae muscles in order to improve ankle joint kinetics during walking in children with cerebral palsy.

Ankle joint dynamics during gait

Normally, the ankle joint will slightly dorsiflex at heel contact followed by plantarflexion as the foot is carefully lowered to the floor. This is achieved by slight concentric followed by eccentric contraction of the dorsiflexors. Once the foot is flat on the floor and the body is moving over the stationary foot, the ankle joint dorsiflexes as the tibia rotates forward over the foot. This motion is controlled eccentrically by the triceps surae muscle and continues until just after the heel rises slightly from the floor, at which point the triceps surae reverses from contracting eccentrically to a more rapid and forceful concentric contraction. This period is referred to as "push-off" (or "pre-swing"). Push-off continues until the ankle is fully plantarflexed and, along with knee flexion, the foot leaves the ground, initiating the swing phase.

The observed kinematics of the ankle joint during stance are caused by the underlying kinetics. At initial heel contact, the ankle joint moment of force is slightly dorsiflexor, but for most of the stance, the moment of force is increasingly plantarflexor until the start of push-off, where it decreases rapidly to near zero when the foot leaves the ground (solid line, Figure 1). Ankle power throughout stance is mostly negative, indicating that the triceps surae works eccentrically absorbing energy. As push-off begins, a large positive power burst occurs, reflecting the forceful concentric contraction of the triceps surae as it works to propel the body forward (solid line, Figure 2).

Ankle joint dynamics during gait in children with cerebral palsy

The equinus gait pattern of children with cerebral palsy results from abnormal activities of the triceps surae complex throughout the stance phase of gait. During weight acceptance, overactivity of the ankle plantarflexor causes an abnormal first rocker [13], with the triceps surae preventing the heel from being the first point of contact with the ground. From mid-stance until late-stance (or "pre-swing"), as the triceps surae muscle is eccentrically stretched, there is an abnormal stretch reflex, resisting the lowering of the heel to the floor and producing the abnormal motion of the second rocker [13–15]. Due to the presence of plantarflexor weakness, push-off is prohibited and a crouched gait results. Children with hemiplegia have a lower average level of power generated by ankle plantarflexors [16]. The ankle on the hemiplegic side only provides one-third of total work, whereas two-thirds of the total concentric work is found in normal subjects [17].

In children with a spastic calf muscle, the advancement of the tibia over the foot in stance may result in a premature stretch of the spastic triceps surae and corresponding firing of the muscle [18], resulting in an "early heel raise" in mid-stance (Figure 3). A common pattern of "double bump"plantarflexor moment is usually found in children with cerebral palsy. The initial peak (a) will occur with greater magnitude before mid-stance than the peak (a') occurring during terminal stance (dashed line, Figure 1). The pattern of plantarflexor moment in non-disabled children will only include the terminal peak. Any interventions that help to decrease the initial

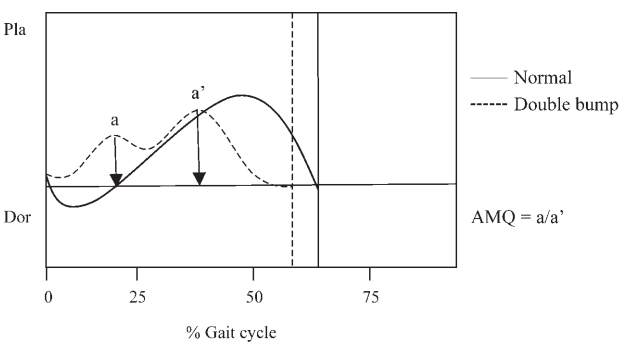

Figure 1. Typical ankle plantarflexion moment of children with cerebral palsy. AMQ = ankle moment quotient.

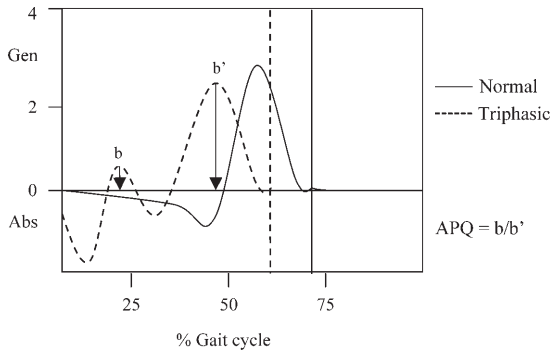

Figure 2. Typical ankle power of children with cerebral palsy. APQ = ankle power quotient.

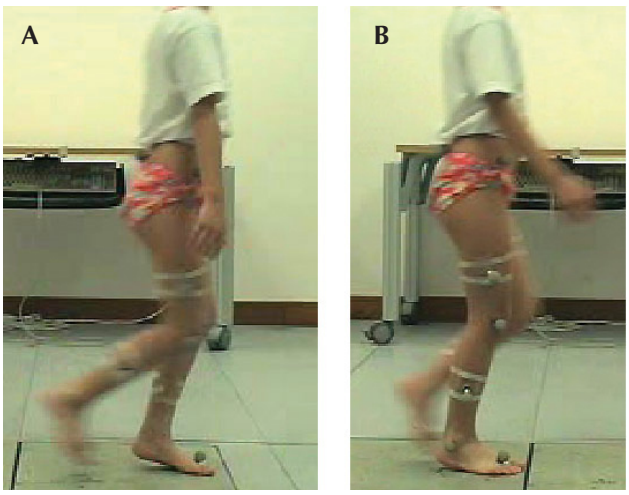

Figure 3. The pattern of "early heel raise" on the spastic leg in children with cerebral palsy. (A) Typical "early heel raise" in mid-stance. (B) Foot remains flat on the ground in mid-stance (normal leg).

peak and increase the terminal peak would improve the gait pattern in children with cerebral palsy. Thus, the ratio of initial peak over terminal peak (a/a') or ankle moment quotient (AMQ) can be used to measure the change and, hence, the degree of improvement in ankle plantarflexor moment [19].

Similarly, double power generation occurs in children with cerebral palsy as opposed to substantial power absorption in the second rocker in non-disabled children [18,20]. The pattern of the total ankle power curve for children with equinus gait is typically "triphasic" (dashed line, Figure 2). An early initial deep trough of power absorption occurs as the child lands on his/her toes, followed by a premature burst of power generation in mid-stance (b) before a final peak of power generation at terminal stance (b'). Ankle power quotient (APQ), the ratio of initial power generation over the final power generation in the ankle (b/b'), can be used to measure the change in ankle power after intervention [19]. A decrease in the ratio reflects an improvement in ankle joint power generation and absorption.

Neuromuscular electrical stimulation

NMES contributes to improving joint range of motion. Hazelwood and co-workers found an increase in passive range of movement at the ankle and ankle dorsiflexion strength in children with hemiplegic cerebral palsy after electrical stimulation of the anterior tibial muscles [10]. A randomized controlled trial of therapeutic electrical stimulation in children with cerebral palsy showed significant improvement in function with an increase in score on the gross motor function measure (GMFM) after treatment [21]. It is proposed that NMES applied to the calf muscle of children with cerebral palsy would not only improve the motor outcome, but also improve the child's sensory awareness [22,23]. As an additional benefit, the sensory input provided by NMES incorporated in the task-specific approach in motor learning will enhance the pattern in the gait cycle.

Methods

Subjects and design

An ABA experimental design was adopted. Twelve subjects with spastic diplegia or hemiplegia aged 4–11 years were recruited and randomly assigned to one of two groups, Treadmill+NMES or Treadmill. All subjects met the inclusion criteria: spasticity over the triceps surae muscle of at least grade 1 on the Modified Asthworth Scale and an independent walker with equinus gait pattern. Subjects with fixed contracture and passive range of motion of the ankle of less than 10° of dorsiflexion were excluded.

Table 1 shows the schedule for treatments, gait analyses and administration of the GMFM. Both groups were tested at the beginning and end of a 2-week period with their usual conventional physiotherapy to establish baseline measurements. Following this was a 4-week treatment period (weeks 3–6). Treatment frequency was three times per week. In weeks 4 and 6, a gait analysis was performed after the sixth treatment of that particular 2-week period. An additional treatment was performed in the gait laboratory session at weeks 2, 4 and 6, followed by post-treatment gait analysis to test the immediate effect. The carryover effect was tested 2 weeks after the treatment was terminated (week 8). Therefore, the whole study period was 8 weeks and involved five visits to the gait analysis laboratory with eight repeated measures.

Procedures and measurement

A portable NMES with remote control leads (Respond Select; Empi Inc, St Paul, MN, USA) was used in this study. NMES was applied to the triceps surae muscle while patients walked on a treadmill for a period of 15 minutes. A therapist triggered the stimulation during each stance phase of the affected limb(s). Children in the Treadmill group walked for 15 minutes with no NMES. The NMES parameters were set at a frequency of 30–35 pulses/second and an intensity of stimulation of visible muscle contraction. The speed of the treadmill was set according to the child's usual walking speed (0.45–0.80 m/s). For gait analysis, a Vicon 370 (Vicon Motion Systems Ltd, Oxford, UK) with two AMTI force platforms (Advanced Mechanical Technology Inc, Watertown, MA, USA) was used to measure the kinetic change during gait. Five sets of kinetic data were taken in each session of gait analysis and the data averaged. The kinetic data were evaluated by comparing changes in AMQ and APQ. A decrease in either AMQ and/or APQ

Table 1. Schedule of tests

Week	0	1	2		3	4		5	6		7	8	
Therapy		N	N		TTT	TTT		TTT	TTT		N	N	
Gait analysis	X_1			X_2TX_3			X_4TX_5			X_6TX_7			X_8
GMFM	G_1			G_2			G_3			G_4			G_5

N = normal physiotherapy; T = treatment (either Treadmill+neuromuscular electrical stimulation or Treadmill); X_n = gait analysis performed$_{test\ number}$; GMFM = gross motor function measure; G_n = GMFM administered$_{test\ number}$.

denotes improvement [19]. The kinetic data of both legs of children with spastic diplegia and the data on the affected leg for spastic hemiplegia were included in the analysis. In addition, children completed the "standing" and "walking" domains of the GMFM, which were designed to measure the change in function after intervention.

Statistical analysis

Data were analysed with SPSS version 10 (SPSS Inc, Chicago, IL, USA). Descriptive statistics were primarily used to analyse demographic data. Gait analysis data and GMFM scores were analysed by repeated measures analysis of variance. The change in the control period, immediate effect, cumulative effect and carryover effect of each group were compared.

Results

The demographic data of the subjects are summarized in Table 2. All subjects had 100% compliance with the treatment and tests.

Kinetic change

Immediate effect

The kinetic change in the AMQ immediately after treatment was compared between the Treadmill+NMES and Treadmill groups. Changes in AMQ at weeks 2, 4 and 6 are shown in Table 3 and Figure 4. Most tests showed a decrease in AMQ in both groups. However, no significant interactions were detected ($p = 0.533$). There were no significant changes on time comparison ($p = 0.146$) and treatment comparison ($p = 0.503$). However, from the trend in mean difference, we could see that both groups showed a positive immediate effect after treatment.

The same trend was observed in the APQ; the ratio decreased, showing a positive effect after treatment in both groups (Table 3, Figure 5). No significant interaction was found ($p = 0.138$). No significant changes on time comparison ($p = 0.402$) and treatment comparison ($p = 0.643$) were found. The only significant change was observed between treatments at week 4 ($p = 0.015$), meaning that there were significant differences between treadmill walking with NMES and treadmill walking alone.

Cumulative effect

The cumulative effect of NMES on the kinetic data during gait was assessed by comparing the AMQ and APQ at weeks 2, 4 and 6. There was no significant interaction ($p = 0.134$) in APQ. On time comparison, no significant difference was detected ($p = 0.199$); the only significant change was detected on treatment comparison between the two groups ($p = 0.037$), implying that the two groups were different, but there was no evidence of significant improvement over time in either group.

Functional change

The changes in function at weeks 2, 4 and 6 were significant in both walking and standing domains (Figure 6, Table 4). A significant interaction ($p = 0.035$) was observed in the walking domain for time comparison ($p = 0.003$), but there were no significant differences

Table 2. Demographic data of subjects

Group	Gender (M/F)	Diagnosis (diplegia/hemiplegia)	Limbs studied	Age (yr)	
				Range	Mean ± SD
Treadmill+NMES	4/2	2/4	8 ($n = 6$)	5–8	6.3 ± 1.03
Treadmill	5/1	5/1	11 ($n = 6$)	4–11	6.5 ± 2.74

SD = standard deviation; NMES = neuromuscular electrical stimulation.

Table 3. Descriptive statistics for immediate kinetic change: ankle moment quotient (AMQ) and ankle power quotient (APQ)

	Test no.	*n*	Mean ± SD	95% Confidence interval
AMQ				
Treadmill+NMES	3–2	8	0.127 ± 0.2563	–0.006, 0.319
	5–4	8	–0.006 ± 0.1638	–0.228, 0.108
	7–6	8	–0.229 ± 0.6285	–0.658, 0.200
Treadmill	3–2	10	–0.009 ± 0.2534	–0.265, 0.008
	5–4	10	–0.009 ± 0.2509	–0.236, 0.006
	7–6	10	–0.230 ± 0.525	–0.614, 0.153
APQ				
Treadmill+NMES	3–2	6	0.409 ± 0.9696	–0.324, 1.142
	5–4	6	–0.433 ± 0.8138	–0.949, 0.008
	7–6	6	–0.296 ± 1.4883	–1.241, 0.649
Treadmill	3–2	10	–0.352 ± 0.6786	–0.920, 0.215
	5–4	10	–0.128 ± 0.3349	–0.527, 0.272
	7–6	10	–0.294 ± 0.7621	–1.026, 0.438

SD = standard deviation; NMES = neuromuscular electrical stimulation.

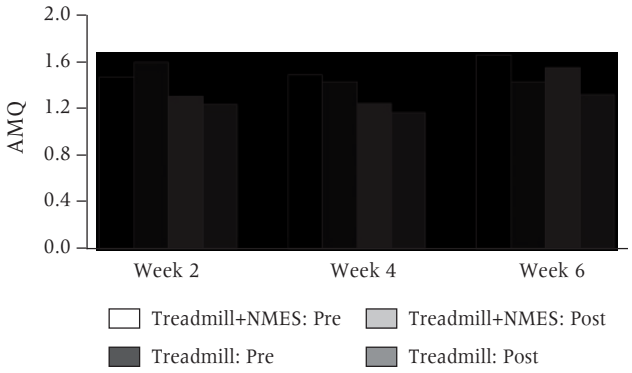

Figure 4. Change in ankle moment quotient (AMQ) immediately after treatment. NMES = neuromuscular electrical stimulation.

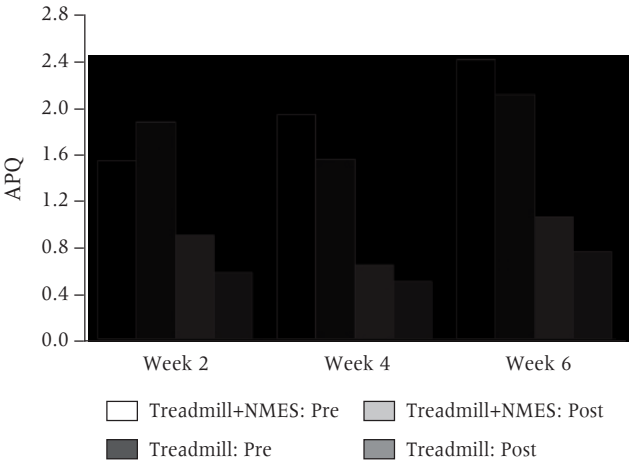

Figure 5. Change in ankle power quotient (APQ) immediately after treatment. NMES = neuromuscular electrical stimulation.

between treatments ($p = 0.181$). Paired *t* test showed that there were significant changes in both groups over time ($p = 0.045$ for Treadmill+NMES; $p = 0.014$ for Treadmill). For the standing domain, no significant interaction ($p = 0.212$) was observed, the only significant change was noted on the time comparison ($p < 0.001$). However, from the trend of mean difference, there was greater improvement in the Treadmill+NMES group than in the Treadmill group. Moreover, on comparing the change at week 8 after treatment was stopped, no significant difference ($p > 0.68$) was detected. This non-significant difference, together with the fact that the mean values were almost identical at weeks 6 and 8, provided some indication that the effect gained at week 6 could be maintained and carried over to 2 weeks post-intervention.

Discussion

There was no obvious cumulative effect on the kinetics in the gait analysis but a positive effect was observed immediately after treatment. Both AMQ and APQ decreased, although the changes were not significant. This may be due to the small sample. As the change in gait was transient, we suggest that the effect of NMES on the triceps surae is due to a change in spasticity. This was also suggested by Comeaux et al in 1997 [24]: the constant state of activity in the spastic gastrocnemius may be interrupted by the on-off nature of the NMES so that the spasticity is decreased. The immediate positive effect of treadmill walking may be due to the decrease in spasticity caused by stretching of the calf. The forward momentum of the treadmill could decrease plantarflexor activity [25].

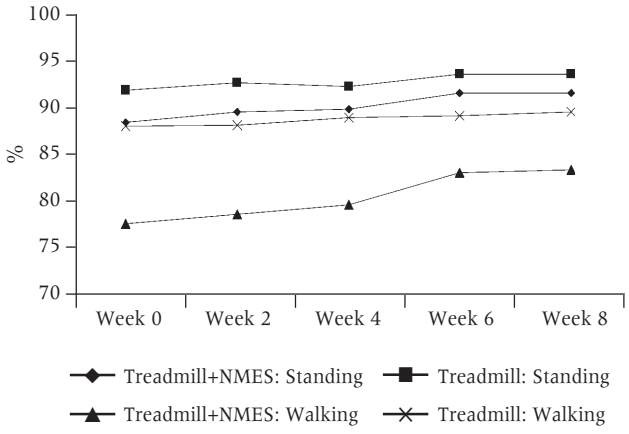

Figure 6. Change in gross motor function measure. NMES = neuromuscular electrical stimulation.

A significant difference between treatments (p = 0.037) was noted in the cumulative effect on the APQ, but not in the "time" and the interaction between "treatment and time". This coincided with the finding that the Treadmill+NMES and Treadmill groups had different baseline APQs. In the Treadmill+NMES group, baseline APQ was more than 1.5, whereas in the Treadmill group, it was less than 1.0. A ratio above 1.0 means that the power generated in mid-stance is higher than that in terminal stance. Cupp et al showed that the magnitude of power generation in late stance (A2 event) increases as the subject's age increases from 4 to 7 years [26]. No significant difference was seen between the ankle kinetics of the 8- to 10-year-old group and the adult group. Subjects in the Treadmill group were older than those in the Treadmill+NMES group, which may account for the difference in the kinetics variation between the groups.

Another drawback in comparison of kinetic changes is the use of AMQ and APQ. A ratio depends on two data to reflect a change. Either changing the first peak or the second peak may lead to a change in the ratio. Variation sometimes occurred in the peak power in the terminal stance phase, and some subjects used different maximum peak power in the push-off phase even in the same session of assessment. The variation in gait data may be due to various factors affecting the child's performance, such as emotional state and concentration span. Gait analysis data are less repeatable in spastic children than non-disabled children [27].

The changes in functional outcomes measured using the GMFM standing and walking domains were significantly different. The score improved in both the Treadmill+NMES and Treadmill groups, and this improvement was maintained after treatment stopped. However, no statistically significant difference was found between the two groups. The functional items that changed were mainly balance items such as single-leg standing (items 57 and 58), single-leg hopping (items 82 and 83) and jumping (items 80 and 81). Improvement in these items means that the functional stability of the child improved. The intervention that we examined was targeted on the triceps surae muscle and ankle plantarflexion is thought to be a postural muscle that provides ankle and knee stability [28]. Katoh et al found that maturation of the plantar flexors leads to improvement in balance, which is related to shortening of the duration of the stance and

Table 4. Descriptive statistics of cumulative gross motor function measure (GMFM): walking (GMWK) and standing (GMST)

	Test no.	*n*	Mean ± SD	95% Confidence interval
GMWK				
Treadmill+NMES	2	8	77.588 ± 20.85	66.207, 88.968
	3	8	79.238 ± 20.26	68.140, 90.335
	4	8	83.163 ± 18.00	72.948, 93.377
Treadmill	2	11	88.618 ± 9.57	78.913, 98.324
	3	11	89.655 ± 9.43	80.191, 99.118
	4	11	89.909 ± 9.59	81.198, 98.620
GMST				
Treadmill+NMES	2	8	89.725 ± 7.53	85.329, 94.121
	3	8	90.688 ± 7.13	86.444, 94.931
	4	8	92.638 ± 6.35	88.669, 96.606
Treadmill	2	11	93.427 ± 4.4	89.679, 97.176
	3	11	93.436 ± 4.4	89.818, 97.055
	4	11	94.855 ± 4.46	91.47, 98.239

SD = standard deviation; NMES = neuromuscular electrical stimulation.

acceleration phases [29]. Moreover, the improvement in balance items was obvious clinically, as reported by both parents and therapists. Motor learning on walking with a treadmill may also contribute to the functional gain.

Conclusions

NMES of the triceps surae muscle had a positive effect on gait and function. Improvement was observed in AMQ and APQ immediately but not cumulatively. The changes were noted from the trend as no statistical significance could be proved because of the small sample size. The change in the functional outcome was more dominant in this study. Both GMFM standing and walking domains were significantly different on "time" comparison ($p < 0.003$). Both groups showed improvement but there was no significant difference between the two groups. The effect of functional gain could be maintained to 2 weeks after the intervention stopped. Further study of the mechanism of effect in functional electrical stimulation and the effect of treadmill walking is beneficial for evidence-based practice.

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Research Article Open Access

Effect of Neuromuscular Electrical Stimulation on Gluteus Maximus and Quadriceps in Cerebral Palsy Children with Crouch Gait

Patitapaban Mohanty*, Monalisa Pattnaik and Anjushree Sarkar

Swami Vivekanand National Institute of Rehabilitation Training and Research, Olatpur, Bairoi, Cuttack, India

***Corresponding author:** Patitapaban Mohanty, Swami Vivekanand National Institute of Rehabilitation Training and Research, Olatpur, Bairoi, Cuttack, India, Tel: +91 9437487139; E-mail: ppmphysio@rediffmail.com

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Abstract

Background: Cerebral palsy (CP) is a persistent disorder of movement and posture caused by non-progressive pathological processes of the immature brain. This is the natural history of the gait disorder in children with more severe diplegia and in the majority of children with spastic quadriplegia. One of the most common movement abnormalities among children with cerebral palsy is a crouched gait. Neuromuscular electrical stimulation (NMES) is the application of electrical current transcutaneously to innervated, superficial muscle to stimulate muscle fibers, augment muscle contraction, increase range of motion (ROM), and increase sensory awareness. The purpose of the study was to investigate the effects of NMES on Gluteus maximus and Quadriceps strength in cerebral palsy children with crouch gait, and the subsequent effect on their gross motor function.

Methods: Total 40 children (13 females, 27 males, age group 5 years to 11 years) were recruited for study from the paediatric section of physiotherapy department of Swami Vivekanand National Institute of Rehabilitation Training and Research according to the inclusion and exclusion criteria and were randomly allotted in 2 groups. All were randomly assigned to either the stimulation (group 1) or control group (group 2). The stimulation group received neuromuscular electrical stimulation to gluteus maximus and quadriceps muscles for 15 minutes each, 5 days/week for a period of 6 weeks.

Results: Both the groups showed significant improvement in strength of gluteus maximus and quadriceps of CP children with crouch gait, but experimental group showed significantly more improvement as compared to control group. There was also statistically significant difference in dimension D and E (standing and walking) of the gross motor function measure between the experimental group and control group.

Conclusion: This study has shown that neuromuscular electrical stimulation in addition to conventional exercise is found to be effective in improving strength and function than conventional exercise alone.

Keywords: Cerebral palsy; Crouch gait; Neurological surgery

Introduction

Cerebral palsy (CP) is a persistent disorder of movement and posture caused by non-progressive pathological processes of the immature brain. The prevalence of CP is between 1.5 and 2.5 per 1000 live births and spastic subtypes are represented in 64.6% of patients with CP [1].

This is the natural history of the gait disorder in children with more severe diplegia and in the majority of children with spastic quadriplegia. One of the most common movement abnormalities among children with cerebral palsy is a crouched gait [2].

Crouch gait, a common movement pattern in individuals with cerebral palsy, is characterized by excessive dorsiflexion or calcaneus at the ankle in combine with excessive flexion at the knee and hip [2]. It suggests the failure of the mechanisms responsible to maintain the body in an upright position. The three muscle groups known as the antigravity muscles are the hip extensors (gluteus maximus and hamstrings), the knee extensors (vasti) and the ankle plantar flexors (soleus). These muscles are primarily responsible for keeping the body in the upright position. Inability of one or more of these muscles to function adequately results in a crouch gait and is observed as body collapsing into a flexion posture [3].

Lever arm dysfunction also contributed to crouch gait. With hip and knee in flexed position, as seen in crouch, the lever arm at knee becomes longer compared to that at the hip. Hence, hamstrings now function more effectively as knee flexors than as hip extensors. With increasing knee flexion, lever arm of hamstrings as knee flexor increases and with increasing hip flexion lever arm for rectus as hip flexor increases.

Neuromuscular electrical stimulation (NMES) is the application of electrical current transcutaneously to innervated, superficial muscle to stimulate muscle fibers, augment muscle contraction, increase range of motion (ROM), and increase sensory awareness [4-6]. Electrical stimulation as a treatment option for cerebral palsy (CP) has been proposed after several studies in recent years.

Strength training programs designed for individuals with cerebral palsy and crouch gait have targeted the hip and knee extensors [7]. It improves strength in targeted muscles without increased spasticity [8,9] and has positive effect on gait and gross motor function [7].

Therefore, the present study intends to evaluate the effect of neuromuscular electrical stimulation on gluteus maximus and quadriceps in cerebral palsy children with crouch gait by conducting pre-test and post-test evaluations of the treatment effects.

Methodology

Total 40 children were recruited for study from the paediatric section of physiotherapy department of Swami Vivekanand National Institute of Rehabilitation Training and Research according to the inclusion and exclusion criteria and were randomly allotted in 2 groups. To be included in the study, the child had to meet the following inclusion criteria: Children diagnosed as spastic cerebral palsy, age group 5 years to 11 years, able to walk in crouch gait with or without support, cognitive function is normal or near normal, able to accept and follow verbal instructions and cooperative. Exclusion criteria were children with mental retardation, children with spastic hemiplegia, athetoid, ataxic cerebral palsy, child with instable seizures and behavioral disorders, musculoskeletal or neurological surgery within 1 year prior to study, botulinum toxin injections within 6 months prior to study.

Procedure

Spastic children with crouch gait with or without support were evaluated. After meeting the inclusion and exclusion criteria, informed consent was taken from the parents/caregivers of the subjects and then children were randomly allocated to either of the two groups. Group 1: neuromuscular stimulation and conventional exercise (experimental group) (n=20), Group 2: conventional exercise (control group) (n=20) were treated by conventional exercises.

Children were given stimulation in side lying position for gluteus maximus and in sitting position for quadriceps. During the application of neuromuscular electrical stimulation, the child was positioned with the knee flexed (70-80 degree) and the hamstring was not in the lengthened position to reduce the amount of stimulation required to attain a forceful contraction and therefore improve comfort. The intervention period was of 6 weeks duration, neuromuscular stimulation for 15 minutes each muscles, 5 days/week. Parameters used: Waveform- balance, symmetrical, biphasic; Pulse duration - 300 ms; Frequency - 50 pulse/sec; Stimulation time: Rest time - on: off - 5: 15; Ramp up – 1 sec, Ramp down-1 sec; Intensity - maximum tolerable intensity was used to produce a visible contraction but as tolerated by the child.

Data collection

Gluteus maximus and Quadriceps muscle strength was measured by modified sphygmomanometer and gross motor function measure were measured by GMFM (dimension D and E). The data was collected blindly by two testers independently throughout the study. Pre–test measurement was taken on recruitment of the subject and Post-test measurement was taken after 6 weeks of treatment.

Data analysis

Data were analyzed using 2 × 2 ANOVA with one between factor (group) with two levels (pre-test and post-test) and one within factor (time) with two levels (pre-test and post-test) for strength. Between groups difference for GMFM was done by Mann Whitney U test. An alpha level of 0.05 of significance was set. Analysis was performed using SPSS package 16 version.

Results

The combined effect of electrical stimulation with conventional therapy shows improvement in strength of gluteus maximus and quadriceps in cerebral palsy children with crouch gait, this also shows the overall improvement as a measure of gross motor function in GMFM. Strength of gluteus maximus and quadriceps muscles in both the groups improved significantly however at the end of the treatment experimental group showed significantly more improvement. The subjects in the experimental group showed more significant change than control group in their gross motor function.

Strength of Gluteus maximus (Left)

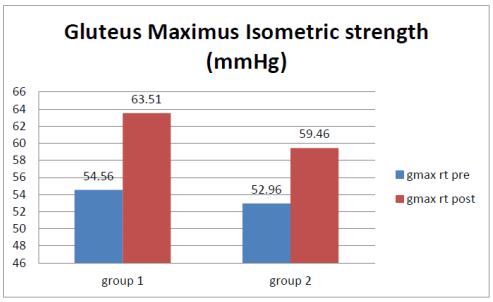

Figure 1: Change in strength of gluteus maximus. gmax rt pre-gluteus maximus right pre, gmax rt post-gluteus maximus right post.

Figure 1 illustrates that both the group's experimental (NMES + Conventional therapy) and control (Conventional therapy) improved in strength from pre to post treatment measurements after 6 weeks.

There was main effect for time, f (1, 38; 0.05) =347.893, p<0.001 and a main effect for time x group interaction, f (1, 38; 0.05) =11.396, p<0.002.

There was no main effect for group as f (1, 38; 0.05) =0.168, p<0.684.

Post Hoc analysis showed that both the groups improved significantly however at the end of the treatment experimental group showed significantly more improvement.

Strength of Gluteus maximus (Right)

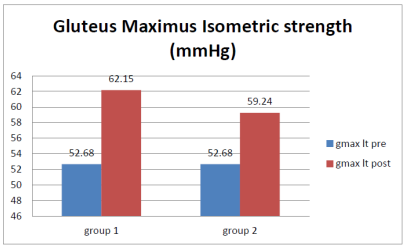

Figure 2: Change in strength of gluteus maximus. gmax It pre-gluteus maximus left pre, gmax It post- gluteus maximus left post.

Figure 2 illustrates that both the group's experimental (NMES + Conventional therapy) and control (Conventional therapy) improved in strength from pre to post treatment measurements after 6 weeks.

There was main effect for time, f (1, 38; 0.05) =248.560, p<0.001 and a main effect for time × group interaction, f (1, 38; 0.05) =6.242, p<0.017.

There was no main effect for group as f (1, 38; 0.05) = 0.615, p<0.438.

Post Hoc analysis showed that both the groups improved significantly however at the end of the treatment experimental group showed significantly more improvement.

Strength of Quadriceps (Left)

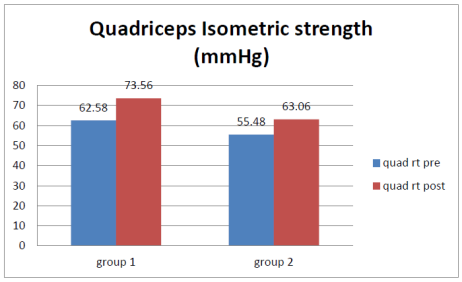

Figure 3: Change in strength of quadriceps. Quad rt pre-quadriceps right pre, quad rt post-quadriceps right post

Figure 3 illustrates that both the group's experimental (NMES + Conventional therapy) and control (Conventional therapy) improved in strength from pre to post treatment measurements after 6 weeks.

There was main effect for time, f (1, 38; 0.05) =281.721, p<0.001 and a main effect for time x group interaction, f (1, 38; 0.05) =11.347, p<0.002.

There was no main effect for group as f (1, 38; 0.05) =2.696, p<0.109.

Post Hoc analysis showed that both the groups improved significantly however at the end of the treatment experimental group showed significantly more improvement.

Strength of Quadriceps (Right)

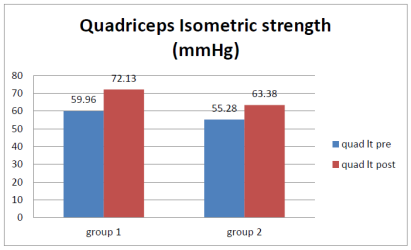

Figure 4: Change in strength of quadriceps. Quad lt pre- quadriceps left pre, quad lt post- quadriceps left post.

Figure 4 illustrates that both the group's experimental (NMES + Conventional therapy) and control (Conventional therapy) improved in strength from pre to post treatment measurement after 6 weeks.

There was main effect for time, f (1, 38; 0.05) = 240.193, p<0.001 and a main effect for time x group interaction, f (1, 38; 0.05) = 8.052, p<0.007. Also there was main effect for group as f (1, 38; 0.05) = 4.153, p<0.049.

Post Hoc analysis showed that both the groups improved significantly however at the end of the treatment experimental group showed significantly more improvement.

Gross Motor Function Measure (GMFM)

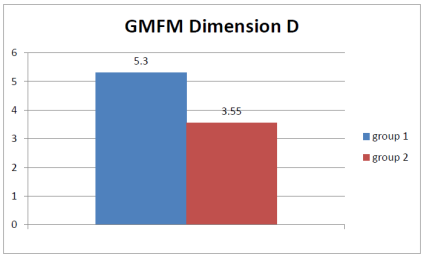

Figure 5: Change in GMFM-D scores.

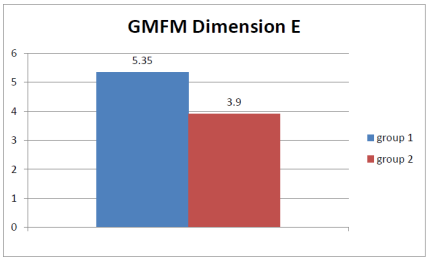

Figure 6: Change in GMFM-E scores.

Figures 5 and 6 demonstrate the subjects in the experimental group showed more significant change than control group in their gross motor function. There is statistically significant difference in dimension D (standing) of the gross motor function measure in the experimental group with the significance level of 0.003, Mann Whitney U score: 91.5 and Z score: -3.007 and dimension E (walking) of the gross motor function measure in the experimental group with significance level of 0.011, Mann Whitney U score: 109.5 and Z score: -2.550.

Discussion

Overall results of the study show both groups improved significantly for strength of gluteus maximus and quadriceps (left and right side). However, the improvement was significantly more in experimental group. The change in function, GMFM Dimension D and E, from pre to post was also significantly more in experimental group.

Both the groups improved in 6 weeks treatment for strength but the improvement was more in stimulation group i.e., In group 1 gluteus maximus strength increased by 17.98% (left) and 16.4% (right), quadriceps strength increased by 20.3% (left) and 17.55% (right). In group 2 gluteus maximus strength increased by 12.45% (left) and 12.27% (right), quadriceps strength increased by 14.65% (left) and 13.66% (right).

Gross motor function measure (GMFM)- The present study shows that there was significant improvement in function in both the groups but subjects in the experimental groups showed more significant change than control group in their gross motor function, dimension D with mean ranks 5.3 and 3.5 and dimension E with mean ranks 5.35 and 3.9 respectively.

The experimental group showed improvement greater than control group; the reason behind it, children with CP are unable to fully activate their voluntary muscles as compared to typically developing children, NMES, an alternative strength training technique, it actually excites the motor nerve going to muscle and causing the muscles to contract with Maximum voluntary isometric contraction (MVIC) force and increase cross-sectional area (CSA) of the muscle. Strength training by NMES does promote neural and muscular adaptations. Strength and function are directly proportional to each other as evident by previous studies.

The result of the present study is found to be similar to the study done by ML van der Linden [10] on Electrical stimulation of Gluteus maximus in children with cerebral palsy: effects on gait characteristics and muscle strength to determine whether electrical stimulation of the gluteus maximus would improve hip extensor strength in children with cerebral palsy (CP). Twenty-two ambulant children (diplegic, hemiplegic, and quadriplegic) were randomly assigned to either the stimulation or control group. The stimulation group received electrical stimulation of the gluteus maximus of the most affected legs for 1 hour a day, 6 days a week for a period of 8 weeks. Measurements of hip extensors strength were made before and after treatment for both groups. And found that both groups were improved equally in strength. Daichman et al. [11] did a study on the effect of NMES home program on impairments and functional skills of a child with spastic diplegic CP to examine the effects of neuromuscular electrical stimulation (NMES) on impairments and functional skills of a 13-year-old child with spastic diplegic cerebral palsy (CP). NMES was administered to the right quadriceps muscles every other day for six weeks. Pre and post testing included assessment of strength using a hand-held dynamometer. After intervention, right quadriceps strength increased from 16.3 ± 3.06 to 41.7 ± 4.2 Newtons. A study was done by Karen J. Dodd et al. [7] on a systemic review of the effectiveness of strength training programs for people with cerebral palsy to determine whether strength training is beneficial for people with cerebral palsy. The articles are selected on the basis of (i) population (people with CP), (ii) intervention (strength training or a progressive resistance exercise program), and (iii) outcomes (changes in strength, activity, or participation) and found that training can increase strength and may improve motor activity in people with cerebral palsy without any adverse effect. Dr. Lalit Arora et al. [12] studied effect of electrical stimulation on spasticity in spastic diplegic cerebral palsy children and results showed that decreased spasticity and improved knee ROM. Camrick J. [5] studied clinical use of neuromuscular electrical stimulation for children with cerebral palsy and results showed that the functional changes that occur with the application of neuromuscular electrical stimulation to the lower extremity may be a useful physical therapy tool when used with task-oriented functional activities. Electrical stimulation may enhance muscle contraction and provide sensation so that a child can add a weak response with effective results and assist in improving motor control.

Conclusion

The study revealed that the effect of conventional strengthening exercise protocol along with Neuromuscular Electrical Stimulation (NMES) in cerebral palsy children with crouch gait is more effective than conventional strengthening exercise protocol alone to improve muscle strength and motor function.

Limitation

Small sample size, Carry over effect of the study has not been studied.

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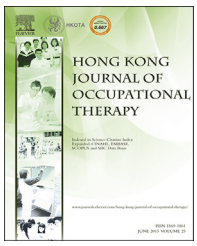

ORIGINAL ARTICLE

Effects of Neuromuscular Electrical Stimulation on Swallowing Functions in Children with Cerebral Palsy: A Pilot Randomised Controlled Trial

Woo Jin Song [a], **Ji Hyuk Park** [b,*], **Joo Hyun Lee** [b], **Min Young Kim** [a]

[a] *Department of Rehabilitation Medicine, CHA Bundang Medical Center, CHA University, Seongnam-si, Gyeonggi-do, South Korea*
[b] *Department of Occupational Therapy, Yonsei University, Wonju, South Korea*

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Summary *Objective/Background:* Oral-motor and sensory dysfunctions are primary reasons for difficulties with swallowing in children with cerebral palsy (CP). Neuromuscular electrical stimulation (NMES) has been shown to provide positive effects on the swallowing function in adult populations with various neurological disorders. However, there is a lack of studies regarding the effects of NMES in children with dysphagia. The aim of the present study was to investigate the effects of NMES and oral sensorimotor treatment (OST) by occupational therapists in children with CP and dysphagia.
Methods: The present study was a two-group experimental design. Participants were randomly assigned to either the experimental group ($n = 10$) or the control group ($n = 10$). The NMES group received both NMES and OST, with NMES on the pharyngeal level for 20 minutes after OST, while the control group received OST and sham–NMES only. The treatment sessions occurred twice a week for 8 weeks.
Results: The experimental group demonstrated a significant improvement in: lip closure while swallowing, ability to swallow food without excess loss, ability to sip liquid, ability to swallow liquid without excess loss, and ability to swallow without cough ($p < .05$).
Conclusion: This study demonstrated that OST and NMES facilitated swallowing functions than OST and sham–NMES in children with CP and dysphagia. Future studies need to utilise

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* Corresponding author. Department of Occupational Therapy, Yonsei University, 1 Yonseidae-gil, Wonju, Kangwon-do, South Korea.
E-mail address: otscientist@yonsei.ac.kr (J.H. Park).

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video fluoroscopy swallowing study for outcome measurements in a large participant group.

Introduction

Cerebral palsy (CP) is a chronic movement disorder resulting from an abnormal development or injury in the immature brain. Children with CP demonstrate various movement disorders, including muscle weakness, abnormal postural responses, coordination failure, and slow muscle contraction, which cause functional problems, including abnormal gait (Shkedy Rabani et al., 2014), hand dysfunction (Klingels et al., 2012), and dysphagia (Arvedson, 2013; Scott, 2014). These functional dysfunctions frequently limit participation in daily activities. In children, eating is one of the most important activities of daily living, especially for development and quality of life (Kitazumi, 1998). Dysphagia causes malnutrition and negatively impacts development in patients with CP. Approximately 75% of children with CP have dysphagia, and that statistic increases to 86% in patients with quadriplegia (Morris & Klein, 1987). Children with CP have some difficulty with postural balance, postural control, and oral-motor control, which are all necessary for proper eating. Oral-motor and sensory dysfunctions are primary reasons for difficulties with swallowing in children with CP (Arvedson, 2013).

Oral sensory dysfunction causes dysphagia in children with CP (Arvedson, 2013; Arvedson, Rogers, Buck, Smart, & Msall, 1994). Children with CP have a difficulty recognizing oral sensation for localization of the input, because the sensory threshold is different from normal (Arvedson et al., 1994; Erasmus et al., 2009). Due to an abnormal oral sensory threshold, it is difficult to determine where the stimulation occurs within the oral area, including the lips, cheeks, tongue, and oral plates (Weindling, Cunningham, Glenn, Edwards, & Reeves, 2007). During the oral phase of swallowing, sensory information is essential for chewing and controlling the bolus of food. The touch and pressure receptors of the tongue and oral-cavity surfaces transmit sensory information to the brainstem and cerebral cortex to guide tongue shape and pharyngeal pressure according to bolus volume and viscosity (Ali, Cook, Laundl, Wallace, & de Carle, 1997). In a study of oral sensory dysfunction, an oral splint blocking sensory stimuli from the bolus significantly decreased pharyngeal pressure, and delayed the onset of hyoid motion and relaxation of upper oesophageal sphincter (Ali et al., 1997). The sensory stimuli thus modulate the swallowing process (Steele & Miller, 2010). Therefore, various sensory modalities have been used to treat dysphagia in CP (Arvedson, Clark, Lazarus, Schooling, & Frymark, 2010b).

Oral sensory stimulation by occupational therapists has been applied to improve the feeding ability in children with CP (Arvedson et al., 2010b). Vibration stimuli in the oral region normalise the abnormal muscle tone during feeding activities. Oral sensory stimulation, including thermal, tactile, and pressure stimuli, was also shown to reduce tongue thrust and the bite reflex disturbing the swallowing process, and to improve the chewing and swallowing functions in children with CP (Arvedson, Clark, Lazarus, Schooling, & Frymark, 2010a; Arvedson et al., 2010b; Erasmus et al., 2009; Scott, 2014). Oral-sensory-stimulation protocols have been widely used to treat dysphagia in children (Arvedson et al., 2010a). In addition, peripheral electrical stimuli have been applied as an intervention protocol to improve oropharyngeal swallowing in neurological disorders, including stroke (Carnaby-Mann & Crary, 2007), traumatic brain injury (Clark, Lazarus, Arvedson, Schooling, & Frymark, 2009), Parkinson's disease (Baijens et al., 2012), and CP (Christiaanse et al., 2011; Rice, 2012). In brain-imaging studies, electrical pharyngeal sensory stimulation induced the activation of areas in the cerebral cortex related to swallowing, such as the sensorimotor cortex (Fraser et al., 2002). Additionally, the amplitude of pharyngeal electromyography significantly increased after a 10-minute peripheral sensory stimulation with 10 Hz (Hamdy, Rothwell, Aziz, Singh, & Thompson, 1998).

In adults with neurological disorders, previous studies have demonstrated that neuromuscular electrical stimulation (NMES) improved swallowing functions. In stroke patients, NMES improved the ability to safely swallow, as measured by the functional oral intake scale (FOIS), and reduced feeding tube-dependent dysphagia in acute stroke (Kushner, Peters, Eroglu, Perless-Carroll, & Johnson-Greene, 2013). In Parkinson's disease with oropharyngeal dysphagia, NMES improved the quality of life in swallowing disorder (Heijnen, Speyer, Baijens, & Bogaardt, 2012). A few previous studies have suggested that NMES might provide positive effects on swallowing function in paediatric patients (Christiaanse et al., 2011; Rice, 2012). However, there remains a lack of studies investigating the effects of NMES on oral functions related to feeding in CP with dysphagia. Therefore, the aim of this study was to investigate the therapeutic effects of oral sensorimotor treatment (OST) and NMES on oral functions in children with CP and dysphagia.

Methods

Participants and study design

A total of 20 children participated voluntarily in this study. The participants were recruited in 50 outpatient settings of a university hospital by convenience sampling. All of them were diagnosed as having CP with dysphagia. The inclusion criteria were as follows: (a) diagnosed with CP by a rehabilitation doctor, (b) dysphagia confirmed by video fluoroscopy swallowing study (VFSS) or rehabilitation doctors, (c) no disorder in vision or hearing, (d) no seizure disorders,

and (e) no pacemaker. All parents of the participants signed consent forms after an investigator explained the purpose and experimental process.

The design of the present study was two-group experimental. The participants were randomly assigned to either the experimental group ($n = 10$) or the control group ($n = 10$). Both groups received OST by occupational therapists in a rehabilitation department. The participants in the experimental group received an additional 20-minute treatment with NMES after OST, while the participants in the control group received OST and sham—NMES only, twice weekly for 8 weeks.

Intervention

Treatment sessions began with OST. OST included various sensory stimuli applied to both groups the cheeks, chin, lips, tongue, and oral palate using human fingers, a vibrator, and an ice stick. The upper and lower lips were pressed with four fingers to apply sensory stimuli. Also, these areas nearby the lips were provided with sensory stimuli using an ice stick and a vibrator. In the same manner, various sensory stimuli were applied to the cheeks, chin, tongue, and oral palate 10 times each. After OST for 10 minutes, NMES was provided for 20 minutes to the experimental group. The NMES device was attached with surface electrodes to each participant in both groups, but the device was not turned on in the control group. The participants were sitting in an upright position in a chair with a headrest during the treatment sessions. During NMES, the occupational therapist facilitated voluntary swallowing by having the participant swallow a thickened liquid. The therapist sat facing the participant during the treatment session. The therapy room was separated from the public to help each participant concentrate on the treatment sessions without disturbances. Evaluations were conducted immediately prior to and after the experimental or control treatments.

NMES was provided with a dual-channel device (Simplus DP 200; Cybermedic Corp., Iksan, South Korea). The parameters of electrical stimuli were 80 Hz of 300 milliseconds with 1-second interval. For channel 1, two sets of electrodes were placed horizontally over the throat between the jaw and hyoid, approximating the belly of the digastric muscles. For channel 2, another two sets of electrodes were placed horizontally between the hyoid and thyroid notch, approximating the infrahyoid muscles. The current intensity was determined by palpation for muscle contraction. Muscle contraction was experienced without pain. The typical current level ranged from 3 mA to 5 mA.

Outcome measures

Behavioural Assessment Scale of Oral Functions in Feeding

The Behavioural Assessment Scale of Oral Functions in Feeding (BASOFF) was developed to measure variations of nine behaviours related to feeding, including jaw closure, lip closure over a spoon, tongue control, lip closure while swallowing, swallowing food without excess loss, chewing food (tongue/jaw control), sipping liquids, swallowing liquids without excess loss, and swallowing food without coughing (Ottenbacher, Dauck, Gevelinger, Grahn, & Hassett, 1985). The rating scale for each behaviour is from 0 to 5. A score of 0 represents a completely passive response to the feeding process, while a score of 5 indicates a functionally normal response. The interrater reliability coefficients for BASOFF were between .72 and .76. The test—retest reliabilities were .68 and .79 in the previous study on BASOFF. In this study, the interclass correlation coefficient (ICC) was .93 ($p < .05$). For ICC, 20% of the participants ($n = 4$) were evaluated independently by two occupational therapists.

American Speech—Language—Hearing Association's National Outcomes Measurement System swallowing scale

The American Speech—Language—Hearing Association (ASHA)'s National Outcomes Measurement System (NOMS) swallowing scale was used to determine the severity of dysphagia (Mullen, 2004; Mullen & Schooling, 2010; Schooling, 2003). The ASHA NOMS is a multidimensional tool developed to assess supervision and diet level, and represents functional status, which is rated on a scale from 1 to 7. Level 7 means that a participant has the ability to eat independently without limitation of swallowing function, while level 1 indicates that a participant does not have ability to swallow anything safely by mouth. To estimate the interrater reliability in the present study, ICC was computed from a set of swallowing level data collected independently by two occupational therapists using the ASHA NOMS swallowing scale. Twenty percent of the participants ($n = 4$) were evaluated to calculate ICC, which was .801 in this study ($p < .05$).

Data analysis

The Mann—Whitney U independent sample test and chi-square test were used to identify the potential baseline differences between groups. The Wilcoxon signed-rank test was used to evaluate changes between pre- and post-intervention groups. The differences in functional changes between the two groups were analysed by the Mann—Whitney U independent sample test. The level of statistical significance was set at $p < .05$. All data were analysed using Predictive Analytics Software 18 (IBM SPSS Software).

Results

The results of the chi-square test indicated that there was no significant difference in the distribution of sexes or types of CP between the groups ($p > .05$), which was confirmed by the chi-square test. The Mann—Whitney U independent sample test showed that there was no significant difference in age between the groups ($p > .05$). The demographics of the participants are summarised in Table 1.

The results are summarised in Table 2. There was no significant difference in oral function, including BASOFF and ASHA NOMS (control: $5.00 \pm .94$, NMES: 4.60 ± 1.07), between the groups in the pretest ($p > .05$). The total BASOFF score increased significantly in both groups ($p < .05$). The NMES group demonstrated a significant improvement in all subcategories, while the control group

Table 1 Demographic Characteristics of Participants ($n = 20$).

	Control ($n = 10$)	NMES ($n = 10$)
Age (y)	6.00 ± 2.40	6.20 ± 2.78
Sex		
Male	6	7
Female	4	3
Type of CP		
Hemiplegia	4	2
Diplegia	3	5
Quadriplegia	2	3
Flaccid	1	0

Note. CP = cerebral palsy; NMES = neuromuscular electrical stimulation; y = year.

showed no significant improvement in three subcategories, including jaw closure, sipping liquid, and swallowing liquid without excess loss ($p < .05$). In a comparison of functional changes between the groups, the NMES group demonstrated a significantly greater improvement than the control group in lip closure while swallowing, swallowing food without excess loss, sipping liquid, swallowing liquid without excess loss, swallowing without cough, and total score ($p < .05$). In the ASHA NOMS swallowing scale, there was no significant change between or within the groups.

Discussion

The present study was a pilot randomised trial investigating the therapeutic effect of NMES in CP with dysphagia. This study demonstrated that OST and NMES facilitated swallowing functions than OST and sham—NMES in children with CP and dysphagia. Thus, this study indicated that NMES might be an effective tool for dysphagia in the paediatric population. Some previous studies have demonstrated similar therapeutic effects on adults with dysphagia.

NMES demonstrated a significant improvement for swallowing function in the adult population. In a preliminary meta-analysis, NMES demonstrated positive overall effects on swallowing in dysphagia due to various aetiologies, including stroke, cancer, head trauma, and respiratory failure (Carnaby-Mann & Crary, 2007). The seven analysed studies, including two controlled trials and five pre—post trials, included a total of 255 patients. The absence of publication bias was revealed by a funnel plot. A significant summary effect size of NMES for swallowing was reported (Hedges *g*, .66; 95% confidence interval, .47—.85; $p < .001$). The average improvement in swallowing function across all seven studies was 20% after the NMES treatment. This preliminary meta-analysis concluded that NMES may be an effective treatment in the rehabilitation of dysphagia for an adult population. However, in paediatric populations with dysphagia, the effects of NMES are still controversial, and there are not sufficient studies (Christiaanse et al., 2011; Rice, 2012).

A retrospective study reported that NMES did not demonstrate a significant difference from oral-motor therapy in a paediatric population with dysphagia (Christiaanse et al., 2011). In this study, the treatment group included 47 participants, and the control group included 46 participants. The participants did not have homogeneous diagnoses, but various diagnoses such as Down syndrome, CNS anomalies, pulmonary disease, congenital heart disease, and preterm birth. The experimental group received weekly 30—45-minute NMES sessions of oral-motor stimulation or food ingestion, while the control group received weekly 45—60-minute sessions of oral-motor therapy. The results demonstrated that both groups significantly improved on the FOIS, but the amount of change between groups was not significant. Although this study was the report on the evaluation of NMES in a large

Table 2 Comparisons of Swallowing Functions Between and Within Groups ($n = 20$).

Outcome measure	Control ($n = 10$)		NMES ($n = 10$)		Functional changes	
	Pre	Post	Pre	Post	Control	NMES
BASOFF						
Jaw closure	3.60 ± 1.50	3.80 ± 1.39	3.60 ± 1.07	4.20 ± .78*	.20 ± .42	.60 ± .51
Lip closure over a spoon	2.90 ± 1.37	3.50 ± .85*	2.80 ± .91	3.80 ± .63*	.60 ± .96	1.00 ± .66
Tongue control	2.80 ± 1.31	3.20 ± 1.22*	2.90 ± .99	3.40 ± .69*	.40 ± .51	.50 ± .52
Lip closure while swallowing	2.70 ± 1.05	3.10 ± .99*	2.60 ± 1.07	3.50 ± 1.17*	.40 ± .51	.90 ± .56*
Swallowing food without excess loss	2.70 ± 1.05	3.10 ± .99*	2.60 ± 1.07	3.50 ± 1.17*	.40 ± .51	.90 ± 1.17*
Chewing food	2.50 ± 1.17	3.00 ± 1.15*	2.80 ± .78	3.40 ± .84*	.50 ± .52	.60 ± .51
Sipping liquid	2.80 ± 1.39	3.00 ± 1.63	2.60 ± .84	3.50 ± 1.17*	.20 ± .42	.90 ± .84*
Swallowing liquid without excess loss	2.80 ± 1.39	3.00 ± 1.63	2.60 ± .84	3.50 ± 1.17*	.20 ± .42	.90 ± .56*
Swallowing without cough	2.70 ± 1.05	3.10 ± .99*	2.60 ± 1.07	3.50 ± 1.17*	.40 ± .51	.90 ± .56*
Total score	25.6 ± 11.29	28.70 ± 10.84*	25.10 ± 8.64	32.30 ± 8.79*	3.30 ± 2.94	7.20 ± 3.22*
ASHA NOMS	5.00 ± .94	5.10 ± 1.10	4.60 ± 1.07	4.90 ± 1.10	.10 ± .70	.30 ± .48

Notes: Data are presented as mean ± SD. ASHA NOMS = American Speech—Language—Hearing Association's National Outcomes Measurement System swallowing scale; BASOFF = Behavioral Assessment Scale of Oral Functions in Feeding; NMES = neuromuscular electrical stimulation.
*$p < .05$.

paediatric population, the results indicated that NMES was equally effective with oral-motor interventions in the paediatric population. However, an additional analysis demonstrated that the FOIS level improved significantly more in children with acquired dysphagia than in the control group. This result may support the potential therapeutic effects of NMES on dysphagia in a paediatric population with acquired dysphagia.

A previous case series with five participants reported that NMES with oral-motor stimulation improved the swallowing function in children with pharyngeal dysphagia (Rice, 2012). The average age was 17 months (3—32 months). All participants were diagnosed with pharyngeal dysphagia due to multiple aetiologies, such as genetic defect, perinatal asphyxia, bronchopulmonary dysplasia, and failure to thrive. The 1-hour NMES sessions were performed twice a week. The number of treatment sessions varied across children from 11 to 63. The current intensity (0—25 mA) was adjusted for each participant to the maximum tolerated level. Between the NMES sessions, parents or caregivers were asked to provide oral-motor stimulation using z-vibe, nuk brushes, and flavoured chewy tubes. Modified barium swallow studies were performed to evaluate the swallowing function after the treatment sessions. In all five participants, NMES improved the swallowing function. Although there are some limitations, including varied treatment times for each child and multiple aetiologies, this case series provides support that NMES has positive effects on the swallowing function in children with pharyngeal dysphagia.

The present study showed that NMES had positive effects on the swallowing function related to the oral and pharyngeal phases. Swallowing is a complex motor performance, including voluntary and involuntary motor components through multiple neural networks from the oral phase through the oesophageal phase (Steele & Miller, 2010). Since appropriate sensory inputs affect both voluntary and involuntary motor outputs throughout the swallowing process, the therapist in a previous study guided voluntary swallowing by providing various sensory stimulations in paediatric patients (Arvedson et al., 2010b). Peripheral sensory stimulation, including NMES, influences multiple pathways, including both cortical and brainstem pathways, to trigger swallowing, alter motor output, and activate ascending pathways (Fraser et al., 2002; Hamdy et al., 1998; Steele & Miller, 2010). This neuroscientific evidence may be an explanation for the positive effects of NMES on swallowing function. Although NMES is more related to the pharyngeal phase of swallowing than to the oral phase, the present study demonstrated that NMES significantly improved function related to the oral phase, including lip closure while swallowing. The swallowing function is the integrated process of oral and pharyngeal phases; improved functions related to the pharyngeal phase might lead to an improvement in the oral phase, particularly the jaw closure. Clinically, NMES is a very practical intervention tool for dysphagia in the paediatric population. The development of NMES provides a therapeutic tool for occupational therapists to provide sensory stimulation on the pharyngeal area.

One of the limitations of this study was the small number of participants. Also, the distribution of CP type was different between the groups. And, we did not consider that the NMES score can increase due to maturation of participants before comparing the effects of NMES in two groups. In addition, the pharyngeal swallowing function was measured by an indirect method of observing the behaviour rather than a direct method, such as VFSS. Despite these limitations, the present study was the pilot study to demonstrate the positive therapeutic effects of NMES in CP. Future studies need to utilise VFSS for outcome measurements in a large participant group. Furthermore, various NMES protocols need to be investigated in paediatric populations with dysphagia.

Conclusion

We investigated the therapeutic effects of OST and NMES on the swallowing function in children with CP with dysphagia. The results demonstrated that NMES facilitated oral function related to swallowing, including lip closure while swallowing, ability to swallow food without excess loss, ability to sip liquid, ability to swallow liquid without excess loss, and ability to swallow without cough. Thus, this study suggested that NMES might be an effective therapeutic tool to facilitate OST for dysphagia on children with CP and dysphagia.

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Neuromuscular Electrical Stimulation Versus Volitional Isometric Strength Training in Children With Spastic Diplegic Cerebral Palsy: A Preliminary Study

Scott K. Stackhouse, PT, PhD, **Stuart A. Binder-Macleod, PT, PhD, FAPTA**, **Carrie A. Stackhouse, MS**, **James J. McCarthy, MD**, **Laura A. Prosser, MPT**, and **Samuel C. K. Lee, PT, PhD**

Department of Physical Therapy, Arcadia University, Glenside, PA (SKS); Department of Physical Therapy, University of Delaware, Newark (SAB-M, LAP, SCKL); and Shriners Hospitals for Children, Philadelphia, PA (CAS, JJM, LAP, SCKL)

Abstract

Background—To date, no reports have investigated neuromuscular electrical stimulation (NMES) to increase muscle force production of children with cerebral palsy (CP) using high-force contractions and low repetitions.

Objective—The aims of this study were to determine if isometric NMES or volitional training in children with CP could increase muscle strength and walking speed and to examine the mechanisms that may contribute to increased force production.

Methods—Eleven children with spastic diplegia were assigned to an NMES training group or to a volitional training group. Participants in the NMES group had electrodes implanted percutaneously to activate the quadriceps femoris and triceps surae muscles. The volitional group trained with maximal effort contractions. Both groups performed a 12-week isometric strength-training program. Maximum voluntary isometric contract ion (MVIC) force, voluntary muscle activation, quadriceps and triceps surae cross-sectional area (CSA), and walking speed were measured pre- and post-strength training.

Results—The NMES-trained group had greater increases in normalized force production for both die quadriceps femoris and triceps surae. Similarly only the NMES group showed an increase in walking speed after training. Changes in voluntary muscle activation explained approximately 67% and 37% of the changes seen in the MVIC of the NMES and volitional groups, respectively. Quadriceps femoris maximum CSA increased significantly for the NMES group only.

Conclusions—This study was the first to quantitatively show strength gains with the use of NMES in children with CP. These results support the need for future experimental studies that will examine the clinical effectiveness of NMES strength training.

Address correspondence to Samuel C. K. Lee, PT, PhD, Research Associate, Shriners Hospitals for Children, 3551 N. Broad St, Philadelphia, PA 19140. sclee@shrinenet.org.

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Keywords

Cerebral palsy; Strength training; Electrical stimulation; Muscle activation; Cross-sectional area; Hypertrophy

Low muscle force production in children with cerebral palsy (CP)[1] can potentially be explained by several observed factors: decreased central nervous system (CNS) motor unit recruitment and discharge rates,2 increased antagonist coactivation during agonist contractions,3,4 and changes in muscle morphology, including atrophy.[5–7] Although strength training for a variety of patient problems has received much attention,[8–11] it is not typical practice with clinicians who treat individuals with CNS dysfunction. This bias against the use of strength training for patients with CNS dysfunction is due to the unsubstantiated belief that high-effort voluntary contractions may promote an increase in muscle spasticity and tone.[12] Recently, however, strength training in individuals with post-stroke hemiparesis and CP has produced positive effects.[13–18] For example, strength-training studies in children with CP have demonstrated improvements in gait speed, stride length, amount of knee flexion at foot strike, and gross motor function.[13,14,18] A systematic review by Dodd and colleagues[19] of strength training in children with CP concluded that existing evidence suggests that training can improve muscle force production. There were no reports of increased spasticity following training in the reviewed literature. The authors suggested that more rigorous studies are needed to make any definitive conclusions.

Children with CP demonstrate large deficits in voluntary muscle activation compared to typically developing children (~20%–40% less).[2] Using voluntary contractions for strength training children with CP, therefore, may not produce forces that are sufficient to induce muscle hypertrophy. Neuromuscular electrical stimulation (NMES) is an alternative strength-training technique used to treat adults with deficits in voluntary muscle activation following total knee arthroplasty20–22 A number of studies have reported the use of NMES in children with CP23–28; however, none of these studies has adequately documented strength or has used NMES protocols that have been shown to increase strength in other populations.[10,29–32]

This study compared the effects of NMES and voluntary isometric strength training in children with spastic diplegia due to CP using high-force (targeted forces ≥ 50% of maximum voluntary isometric contractions), low-repetition contractions (1 × 15,3 times a week) and investigated which physiologic mechanisms contribute to changes in force production. We hypothesized that the NMES-trained group would experience greater gains in isometric force production, muscle cross-sectional area, and walking speed after a 12-week program compared to a voluntary trained group. Conversely we hypothesized that the voluntary-trained group would experience greater gains in voluntary muscle activation than the NMES group because of a practice effect from performing MVICs throughout the training period. The data presented in this preliminary report are part of an ongoing randomized trial to examine if NMES training can improve muscle strength, walking speed, and energy expenditure during gait over that of volitional training in children with spastic diplegia.

METHODS

Participants

Children between the ages of 8 and 12 years (at the time of recruitment) with spastic diplegic CP were recruited from an outpatient clinic at Shriners Hospitals for Children, Philadelphia, Pennsylvania, USA. They were assigned to a group that would perform either

NMES or volitional training. A physical therapist and an orthopedic surgeon screened children to determine if they were eligible to participate in this study. Inclusion criteria were as follows: (1) a diagnosis of spastic diplegic CP; (2) a designation of level II or III on the Gross Motor Function Classification System[33]; (3) between the ages of 7 and 12 years at time of recruitment; (4) cleared for risk of hip subluxation or dislocation; (5) < 40 degrees scoliosis; (6) well-controlled seizures or seizure-free; (7) visuo-perceptual skills and cognitive/communication skills sufficient to follow multiple step commands and to attend to tasks associated with data collection; (8) no history of lower extremity surgery in the previous 12 months; (9) passive range of motion of at least 20 degrees of hip abduction, a popliteal angle ≤ 45 degrees, and ankle dorsiflexion to at least neutral with the knee extended and the foot in subtalar neutral; (10) ≤ 10 degrees flexion contracture at the hips and ≤ 5 degrees flexion contracture at the knee.

Eleven children participated in this study. These children were drawn from 12 participants in a pilot study with three groups—NMES, volitional and control. Four children were randomized to the electrical stimulation group, 5 to the volitional group, and 3 to the control group. Two of the children originally randomized into the control group elected to reenter the study in the NMES group after initial participation. The results from these 2 children were pooled with the original 4 participants in the NMES group for this analysis to increase statistical power. Because we had low power with only 3 participants in the control group, we report the data from the 2 treatment groups, the NMES group consisting of 6 children (3 males; mean age, 10 years 7 months; SD, 2 years 5 months) and the volitional group consisting of 5 participants (3 males; mean age, 10 years 5 months; SD, 2 years 4 months). All children and parents or guardians were informed of the purpose and experimental methods of this study and gave written and verbal consent and assent to participate. The experimental procedures were approved by the Human Subjects Review Boards of the University of Delaware and Temple University (for Shriners Hospitals for Children, Philadelphia).

Experimental Procedures

Electrode implantation—Children who were assigned to the NMES group had percutaneous intramuscular electrodes implanted bilaterally to stimulate the quadriceps femoris and gastrocnemius muscles. While under general anesthesia electrodes (Memberg electrodes, NeuroControl Corporation, Cleveland, OH, USA) were implanted close to the femoral nerve for stimulation of the quadriceps femoris and near the motor points of the medial and lateral gastrocnemius muscles. The muscle was first stimulated percutaneously with a 26-gauge needle connected to the cathode lead of the stimulator. When the desired stimulated response was obtained, the depth of the probe was measured and the angle of insertion with respect to the skin was noted. Sequentially, a 19-gauge sheath and then a 15-gauge sheath were placed over the probe to widen the opening. Next, the probe and inner sheath were removed and the electrode, mounted on a 26-gauge needle, was inserted into the 15-gauge sheath. The stimulated response was tested periodically during the procedure to ensure that the desired response was maintained. The 15-gauge sheath was removed, and the electrode tip remained anchored within the muscle. The electrodes were then routed subcutaneously to a common exit site on the anterior-medial thigh. The exit sites for the electrodes were covered with gauze and self-adhesive occlusive dressings. Patients were allowed to heal for 2 to 3 weeks before stimulation began.

NMES Strength Training

Once patients healed, they returned to establish training dosages and to become accustomed to the sensation of the electrical stimulation. The electrically elicited contractions were dosed to achieve a maximum tolerated contraction force by adjusting the stimulus pulse

duration between 5 and 200 μs while using a current amplitude of 20 mA and a pulse frequency of 50 pps (StIM System, NeuroControl Corporation). The training dose of the NMES was measured as the peak force of the maximum tolerated electrical contraction divided by the maximum voluntary isometric contraction (MVIC) force as measured on a computer-controlled dynamometer (see below for position and device description). The targeted stimulation dose was to elicit a force ≥ 50% of the patients' MVIC.

The children in the NMES group performed the electrically elicited contractions without voluntary effort on a custom-built exercise board that held the hip joints in 50 degrees of flexion, the knees in 60 degrees of flexion, and the ankles in neutral (Figure 1). The children were instructed to relax during stimulation. Only one muscle group was exercised at a time. An isometric contraction was 15 seconds in duration, which included a 3-second ramp-up time. The stimulator was programmed to perform 1 set of 15 contractions for each side such that the contractions alternated from right to left. The left-side contraction was initiated 15 seconds after the right-side contraction terminated, and each side was allowed 45 seconds of rest before its subsequent contraction. Thus, each muscle contracted with a 15-second on and 45-second off duty cycle, and the right and left sides were out of phase by 30 seconds. A total of 15 minutes of exercise were required to train each muscle group. The children performed this training 3 times per week for 12 weeks for both quadriceps and triceps surae muscles. Subject compliance was monitored with a handwritten logbook and a compliance meter within the stimulator. The parents or guardians and children were instructed in the setup procedures and were given written instructions with illustrations for NMES strength training. After 6 weeks of training, the children returned for an interim assessment. During this session, the pulse duration was increased as tolerated to further increase the force produced by the stimulation, the training dose was remeasured, and compliance data were recorded from the stimulator and logbook. In addition, the stimulator's compliance meter and the hand-written logbook were also recorded. After the second 6 weeks of training, the training dose and compliance data were each recorded again.

Volitional Strength Training

Children with CP who were in the volitional training group were taught to perform 1 set of 15 MVICs 3 times per week for 12 weeks for the quadriceps and triceps surae muscles. The children in the volitional training group performed the isometric contractions on a custom-built exercise board as described above for the children in the NMES group. Contractions were performed to mimic NMES training, with each contraction lasting 15 seconds in duration. Contractions were timed by the child, parent, or guardian on an electronic timer. The parents or guardians were also trained to provide verbal encouragement for maximum effort during the length of each contraction. Additionally, parents/guardians and children were instructed in the setup procedures and were given a logbook to document their training along with written and illustrated instructions for volitional strength training. After 6 weeks of training, children were brought back to record their logbooks and to allow one of the investigators to observe a strength-training session to ensure that training was being performed properly.

MVIC Force and Voluntary Muscle Activation Testing

All MVIC force and voluntary activation testing was performed on a computer-controlled dynamometer (Kin-Com II, Chattecx Corp, Chattanooga, TN, USA) and performed in the same test. Patients were encouraged to perform MVICs, and when force reached a plateau, a maximal brief electrical stimulus was superimposed on the volitional effort to assess the extent of motor unit recruitment (Figure 2). For the quadriceps femoris, patients were seated with their right leg, thigh, pelvis, and shoulders stabilized with inelastic straps and seat belts. Hips were flexed to approximately 85 degrees, knees flexed to 60 degrees, and participants

were instructed to keep their arms folded across their chest or lap. The axis of the dynamometer was aligned to the lateral femoral condyle, and the force transducer pad was 2 finger widths (~3.5 cm) above the apex of the lateral malleolus. For the triceps surae, patients were supine with their right foot placed in the dynamometer's foot apparatus with the axis of the dynamometer aligned bisecting the lateral and medial malleoli. The patient's heel was secured in the heel counter with athletic tape, and the foot, heel, and lower leg were additionally stabilized with Velcro straps. The ankle was flexed to neutral for isometric testing. Each patient's position while on the dynamometer was measured and recorded for future testing.

MVIC force and voluntary muscle activation testing was performed immediately before and after the 12-week strength-training program. For all patients, voluntary muscle activation testing used surface electrical stimulation with self-adhesive electrodes covering the width of the muscle. Depending on the size of the individual, electrodes ranged from 3.8 × 6.35 cm to 7.6 × 12.7 cm (Axelgaard Manufacturing Company, LTD, Fallbrook, CA, USA; ConMed Corporation, Utica, NY, USA). Two hours before testing was to begin, the electrode size was selected and an area slightly larger than the electrode was marked with a permanent marker. An anesthetic cream (EMLA, Astra-Zeneca Pharmaceuticals, LP, Wilmington, DE, USA) was applied to the area and covered with a self-adhesive occlusive dressing. This cream was used to reduce the cutaneous sensation during the electrical stimulation and to reduce the possibility of reflex responses due to the electrical stimulation. The cream was left on the skin for approximately 2 hours, after which the cream was removed and the skin cleansed with alcohol before electrode placement. For the quadriceps, electrodes were placed across the width of the proximal and distal musculature. For the triceps surae, electrodes were placed across the width of the proximal portion of the medial and lateral gastrocnemius muscles just below the knee joint line and longitudinally across the distal portion of the soleus superior to the Achilles tendon. The quadriceps and triceps surae muscles were stimulated with a Grass Instruments S88 stimulator with a Grass model SIU8T stimulus isolation unit (Astromed, Inc, West Warwick, RI, USA). Force data during MVIC testing were sampled at 2000 Hz and analyzed with custom written software (Labview; 4.0.1, National Instruments, Austin, TX, USA).

Once positioned on the dynamometer patients performed a submaximal knee extension or ankle plan-tarflexion isometric contraction and then performed a practice MVIC after approximately 2 minutes of rest. Next, the electrical stimulation intensity used for testing voluntary muscle activation was set by gradually increasing the voltage output in 5- to 10-volt increments, until a force plateau was achieved using a 13-pulse, 100-pps electrical train in which each puke was 600 μS in duration. We termed this stimulus the *maximum burst*. On the dynamometer's feedback monitor, visual force targets were set approximately 10% higher than the force produced during the practice MVIC trial. After a 5-minute rest, 2 to 3 attempts at knee extension or ankle plan-tarflexion MVICs were performed to quantify peak voluntary force production and volitional activation. A 5-minute rest was allowed between each attempt. Peak forces were normalized to each participant's body weight. Voluntary activation of the quadriceps and triceps surae muscles was assessed by delivering die maximum burst during an MVIC and again immediately after the MVIC attempt when the force returned to baseline.[2] A ratio that represents the degree of voluntary activation was calculated as follows:

$$\text{Vol. Activation} = 1 - \frac{\text{Force Augmentation from Maximum Burst}}{\text{Force of Maximum Burst at Baseline}}$$

where 1.0 represents full voluntary activation and anything < 1.0 represents incomplete activation.[2]

MRI of Quadriceps Femoris and Triceps Surae Muscle Morphology

Magnetic resonance imaging (MRI) was used to assess changes in muscle morphology quantitatively and to determine the interaction between changes in muscle cross-sectional area (CSA) and gains in muscle strength over the 12-week training program. Patients went through an MRI training program in which a recreational therapist from Shriners Hospitals for Children instructed the child on what to expect during an MRI. The M RI scan was simulated by having the patient don earplugs and lie supine inside a “play tunnel.” Patients listened to an audio-tape of an actual MRI scan and were instructed to lie still for the duration of the recording. Patients were also given the opportunity to tour the MRI facility and observe a scan in progress. If a child became severely anxious about having the MRI, the child and parent/guardian were given the option to schedule the MRI session with light sedation from an anesthesiologist from Temple University Hospital (Philadelphia, PA). The anesthesiologist obtained separate parental/guardian consent and child assent if sedation was chosen.

All imaging procedures were performed in a clinical 1.5 Tesla magnet (GE Medical Systems, Waukesha, WI, USA) located at Temple University Hospital. Prior to initiating any images of study patients, MRI personnel reviewed provided safety documentation regarding MRI imaging with internal Memberg electrode implants. The proposed procedures were determined safe, and the documentation was kept on file. Images of the right leg were acquired using a standard thoracic coil. Patients were placed supine, and padded supports were used to help maintain the leg in a fixed and relaxed position. Sequential scans acquired 3D data from the most proximal to the most distal part of the quadriceps femoris or triceps surae muscles, using a standard spoiled gradient-echo sequence. The imaging protocol was conducted as follows: (1) Coronal T1-weighted (TR/TE = 500/20) spin-echo localizing scans were obtained with a field of view of 24 cm and a slice thickness of 5 mm and (2) transverse 3D spoiled gradient-echo images (flip angle = 30) were obtained with a TR of 22.5 ms, and minimum TE was automatically determined by the imaging software (typically 1.7 ms). The images were acquired with an encoding matrix of 256 × 256 × 28. A field of view of 12 to 27 cm was used depending on the size of the patient’s leg, and slice thickness was 7 mm. Chemically selective fat suppression was used to enhance definition between muscle groups. The image slice that contained maximum fat-free CSA of the quadriceps and triceps surae muscles was determined using an interactive computer program, EXTRACTOR, and a correction algorithm.[34]

Instrumented gait analysis—Gait data were collected using a 7-camera motion analysis system and processed using Vicon Clinical Manager software (Vicon, Oxford Metrics, Lake Forest, CA, USA). The participants walked barefoot along a 6-m walkway at a self-selected walking speed with their usual assistive device if they used one. Walking speed was calculated from the average of 3 gait cycles. Gait cycles were obtained after the participant reached a steady-state walking speed.

Statistical Analysis

All raw data files were gathered by the lead investigator (SL) and assigned randomly generated, nonrepetitive numerical filenames for analysis. Using this method, the data analyzers were blinded to whom the data belonged (SL did not participate in data analysis). The mean difference scores between baseline and post-12-week strength-training measures of MVIC peak force normalized to body weight, voluntary muscle activation, and maximum CSA for the quadriceps and triceps surae muscles of the right lower extremity were each

compared between NMES and volitional groups using independent *t* tests with alpha set to .10. An alpha level of .10 was chosen because this report represents preliminary data from an ongoing study, and we wanted to guard against committing a type II error,[35] If no between-group differences were found within-group *t* tests (alpha set to .10) were used to examine for pre-post training differences. Because all of our hypotheses were directional, all *t* tests were 1-tailed. For each treatment group (NMES and volitional), the data for the quadriceps femoris and triceps surae muscles were combined and linear regressions were performed to determine which variables (percentage change in voluntary muscle activation or maximum CSA) were most important in determining the degree of change in force production. Lastly, the relationship between the NMES training dose and the percentage change in CSA area was examined across muscle groups using linear regression.

RESULTS

Five out of 6 patients completed strength training as prescribed for the NMES group. All 5 patients completed training as prescribed in the volitional group. The dam from 1 NMES patient were excluded from final analysis because of a localized irritation at the lead passing site of the left medial gastrocnemius electrode; this patient did not complete the NMES strength training as structured on the training calendar. This patient, on multiple occasions during the last week, performed 2 sets of 15 repetitions for each muscle group to obtain the goal number of training sessions. This made the patient sore and most likely impaired her force-generating ability.

There were no differences in initial body mass (NMES = 40.12 [SD, 10.68] kg, volitional = 34.04 [SD, 8.88] kg; $t = 0.88$; $P = 20$) or change in body mass between the 2 groups over the 12-week intervention (NMES = 0.48 [SD, 1.24] kg, volitional = 0.74 [SD, 1.93] kg; $t = -0.22$; $P = .414$). The quadriceps and triceps surae NMES training dose was measured relative to the patient's MVIC obtained at 3 time points: pretraining, after 6 weeks of training, and posttraining. The quadriceps NMES training dose increased from 81.8% to 118.9% of the MVIC after 6 weeks of training (Table 1). We were not, however, on average able to increase the NMES training dose for the triceps surae muscles at the 6-week time point owing to suboptimal electrode placement at implantation or owing to patient tolerance (Table 1).

The quadriceps lemons MVIC force normalized to body weight increased more over the 12-week strength-training intervention for the NMES group compared to the volitional group (Figure 3A; NMES +1.61 N/kg, volitional +0.52 N/kg; $t = 1.69$; $P = .065$). A similar pattern of change in normalized force production occurred for the triceps surae muscles with the NMES group increasing force generation more than the volitional group (Figure 3B; NMES +0.80 N/kg, volitional −0.29 N/kg; $t = 1.88$; $P = .049$).

In an attempt to explain the changes in force production, we examined the changes in voluntary muscle activation and muscle CSA. We had hypothesized that the volitional group would experience a greater increase in voluntary muscle activation because of a practice effect from their training; however, no between-group differences were observed for the quadriceps (Figure 3C; $t = 1.20$; $P = .13$) or triceps surae (Figure 3D; $t = -1.25$; $P = .12$). Both groups, however, had significant gains in voluntary activation of the quadriceps (NMES +0.057, $t = -1.678$, $P = .084$; volitional +0.134, $t = -2.478$, $P = .034$) but not in voluntary activation of the triceps surae (NMES +0.104, $t = -1.136$, $P = 160$; volitional −0.098, $t = 0.732$, $P = .252$). For muscle CSA, we had hypothesized that the NMES group would show greater increases in CSA than the volitional group because we predicted that we would produce greater training forces with NMES. We found that training with NMES produced greater changes in quadriceps CSA than volitional training (Figure 3E; NMES

+4.42 cm^2, volitional +2.36 cm^2; $t = 2.52$, $P = .023$), but not in triceps surae CSA (Figure 3F; NMES +1.28 cm^2, volitional +0.35 cm^2; $t = .77$, $P = .232$). For the triceps surae, neither group showed significant muscle hypertrophy following training (NMES $t = -1.223$, $P = .144$; volitional $t = -1.368$, $P = .132$).

To gain a better sense of the contribution that voluntary activation and muscle CSA made toward changes in force production, linear regressions were used to compare the percentage change in voluntary activation or muscle CSA to the percentage change in MVIC force pooled across both muscle groups for each treatment group. The variability in voluntary activation of the agonists explained approximately 67% of the variability in the MVIC force for the NMES group (Figure 4A; $r^2 = .67$; $F = 15.944$; $P = .004$) and approximately 37% of the variability in MVIC force in the volitional group (Figure 4B; $r^2 = .37$, $F = 4.737$, $P = .061$). No relationship was seen, however, between the percent change in maximum CSA and the percentage change in MVIC force for either the NMES ($r^2 = .001$, $F = 0{,}007$, $P = .933$) or volitional groups ($r^2 = .074$, $F = 0.481$, $P = .514$).

Walking speed was used to examine if either NMES or volitional training had an impact on gait performance (Figure 5). There was no pre-post intervention difference between the NMES and volitional groups ($t = 1.149$; $P = .142$). The NMES group, however, showed a within-group increase in walking speed from 80.47 (SD, 16.80) cm/s at baseline to 96.37 (SD, 25.78) cm/s after 12 weeks of training ($t = 2{,}671$; $P = .028$), whereas the volitional group did not (85.57 [SD, 27.85] cm/s to 89.99 [SD, 23.14] cm/s; $t = 0.551$; $P = .306$).

DISCUSSION

The results of this preliminary study support the concept that children with spastic diplegic CP can use percutaneously implanted electrodes for NMES strength training of the quadriceps femoris and triceps surae. To our knowledge, this is the first use of high-force, low-repetition NMES strength training in these children. High training doses for the quadriceps (~130% of MVIC) and triceps surae (~60% of MVIC) were achieved by using a percutaneously implanted electrode system that was well tolerated, in part because the implanted electrodes avoided the sensory receptors in the skin and subcutaneous tissue.[36]

Force production improved by approximately 32% and 33% in the NMES group for the quadriceps femoris and triceps surae muscles, respectively (Figure 4A and B). These percentage gains in force production are very similar in magnitude to the 13.1% to 47.8% gains in knee extensor force reported after resistance training in healthy, prepubescent children[37–41] and to the 16.5% to 48.5% gains reported for children with CP.[14,15,18,42,43] High-force strength training in children can be performed safely and effectively under the proper supervision where good technique is emphasized.[37,38,40,44] Despite having the children train at home with very high contraction intensities (up to 160% MVIC), none of the children experienced any negative responses other than short-term muscular soreness lasting several days after the initiation of training and after the dose was increased at midtraining. We believe that we were able to train safely because we made sure that the contraction was not causing any joint pain (eg, anterior knee pain) and we trained the parents or guardians to stabilize their child appropriately on the customized exercise boards so that the contractions would be isometric.

Several possibilities may explain why we observed greater increases in normalized force production for the NMES compared to the volitional trained group. One reason may be related to the NMES group training at force levels beyond what they were able to produce volitionally from the quadriceps femoris (~118% of MVIC). Thus, the NMES group loaded the musculotendon unit to a greater degree than the children training with MVICs. This

higher loading may have exceeded the threshold required to induce a training response. This theory seems especially plausible because we previously demonstrated that children with CP are not able to activate their muscles fully and, therefore, might not be able to attain training forces that are sufficient to induce an effect.[2] When the dose-response relationship was examined for the NMES group, however we saw no clear relationship (r^2 = .139; P > .05). Other possibilities may be that the NMES may provide a more consistent training force because each contraction is not susceptible to variations in voluntary activation (Figure 6). Additionally; NMES may be facilitating neural factors that are associated with early changes in force production during strength training.[45–48]

Mechanistically our results indicate that voluntary muscle activation is the primary factor that accounts for changes in force production in children with spastic diplegia after 12 weeks of training (Figure 3A and B). This finding is supported in the strength-training literature for typically developing preadolescent children.[39,40] Ozmun and colleagues[39] studied the neuromuscular adaptations to an 8-week volitional training program for the elbow flexors using integrated EMG amplitudes. Children in the trained group experienced a 27.8% increase in force production and a 16.8% increase in integrated EMG amplitude. Ramsay and colleagues[40] assessed voluntary activation using twitch-interpolation, a technique similar to what we described in this study, during which a single stimuli is delivered during the contraction and again while at rest. Training was performed for 20 weeks for the elbow flexors and knee extensors. Voluntary muscle activation increased by 13.2% and 17.4% in the elbow-flexors and knee extensors after training, respectively, but these increases only represented a trend due to high variability in the data.

We hypothesized that we would see a larger increase in voluntary activation in the group that trained with volitional contractions because they would have practiced MVICs for 12 weeks. Our preliminary study shows that both NMES and volitional groups increased their quadriceps femoris volitional activation, but there was no difference in magnitude between the groups. We, however, observed no significant increases in triceps surae volitional activation, but 4 out of 5 patients in the NMES group increased their volitional activation, whereas increased volitional activation was evident for only 2 out of 5 patients in the volitional group. Our combined volitional activation data from the quadriceps femoris and triceps surae demonstrate a linear relationship between the change in force and the change in voluntary activation that was nearly twice as strong in the NMES group (r^2 = .67 vs .37). In case studies, people poststroke were able to volitionally perform ankle dorsiflexion immediately after electrical stimulation was delivered to the tibialis anterior.[49] More recently, increases in voluntary activation[50] and fMRI voxel intensity of the involved motor cortex[51] after several weeks of treatment with NMES were found in patients with stroke compared to a control group.

Another mechanism for increasing force generation that we examined was muscle hypertrophy. We measured the maximum fat-free CSA of the quadriceps femoris and triceps surae muscles using MRI and found a significant increase in CSA in the quadriceps femoris muscles in the NMES group (10.87%) and a nonsignificant change in the volitional group (4.34%). No differences were observed in hypertrophy for the triceps surae muscles. The average percentage increase in quadriceps maximum CSA in the NMES group is within the reported range of 4.9% to 19.3% increases for young adults following strength training.[52–57] The increase in quadriceps maximum CSA seen in the volitional group was at the low end of the reported range for young adults.[52–57] The more robust increase in CSA seen in the quadriceps of the NMES group could have resulted from the substantially higher relative forces produced versus the triceps surae (Table 1). However, we did not see a relationship between the percentage change in MVIC force and the percentage change in CSA. The lack of a linear relationship between the percentage change in MVIC force and percentage

change in CSA could be the result of only a modest increase in CSA and limited variability in the data. Therefore, more patients will be necessary to make any conclusions regarding the relationship between changes in muscle CSA and MVIC force.

Our inability to achieve equivalent forces when stimulating the triceps surae was due to either electrode placement or discomfort. Of the 5 individuals on whom we report dosing information, 2 patients only had 1 electrode placed to activate the entire triceps surae. Subsequent to finding out that the triceps surae stimulation doses were not as high as the quadriceps femoris, we changed our implantation procedure to include electrodes in both the medial and lateral heads of the gastrocnemius. This change helped to produce greater forces; however, we found for this smaller muscle group, subject tolerance is lower than for quadriceps femoris muscle stimulation. Another important clinical difference between the 2 muscle groups is that children in this study wore molded ankle foot orthoses for ambulation, which discouraged their use of die triceps surae muscles during weight bearing. Thus, the use of orthoses may have blunted any potential hypertrophic effect of the stimulation training.

In this preliminary study, we did not observe group differences in the magnitude of pre-post intervention walking speed. However, a within-group increase in speed was observed for the NMES group. This gain in walking speed was approximately twice the magnitude observed by another strength-training study in children with spastic diplegia.[13] We believe, therefore, that NMES has great potential for use in conjunction with volitional strength training and motor learning therapies to achieve the goal of increased function for children with CP.

To our knowledge, this is the first study to show strength gains using electrically elicited high-force, low-repetition contractions of the quadriceps femoris and triceps surae muscles for strength training in children with CP. These preliminary findings will be further tested in the course of the larger randomized clinical trial involving nonexercised control, NMES, and volitional groups with spastic diplegia from CP.

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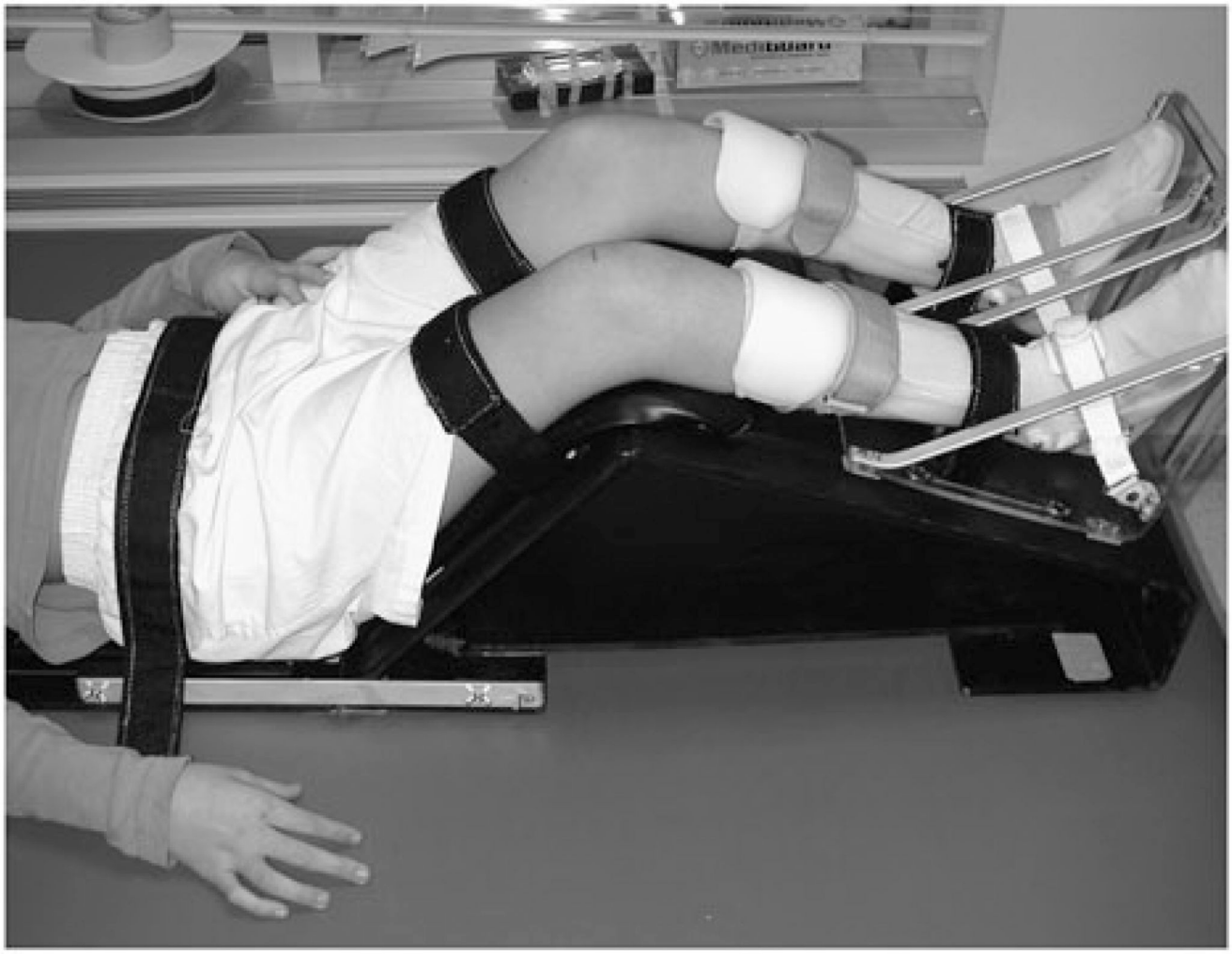

Figure 1.
Custom-built exercise board used for neuromuscular electrical simulation and volitional strength-training programs. The hips are positioned in 50 degrees of flexion, knees in 60 degrees of flexion, and the ankles in neutral.

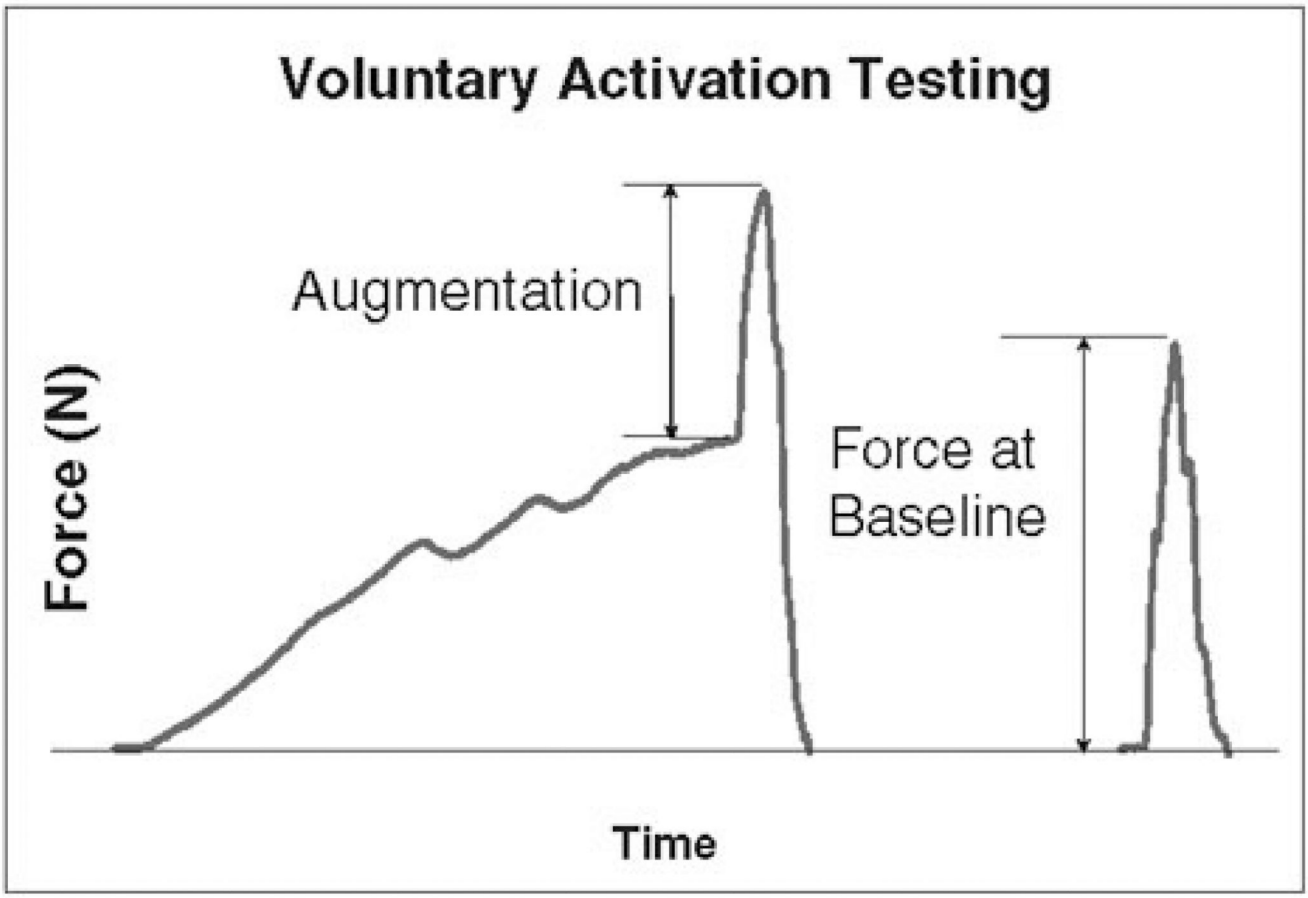

Figure 2.
Raw force trace during maximum voluntary isometric contraction (MVIC) and voluntary activation testing. A maximal burst of electrical stimulation is delivered during the MVIC when the force plateaus (force augmentation from maximum burst) and again when the force returns to baseline and the patient is at rest (force of maximum burst at baseline).

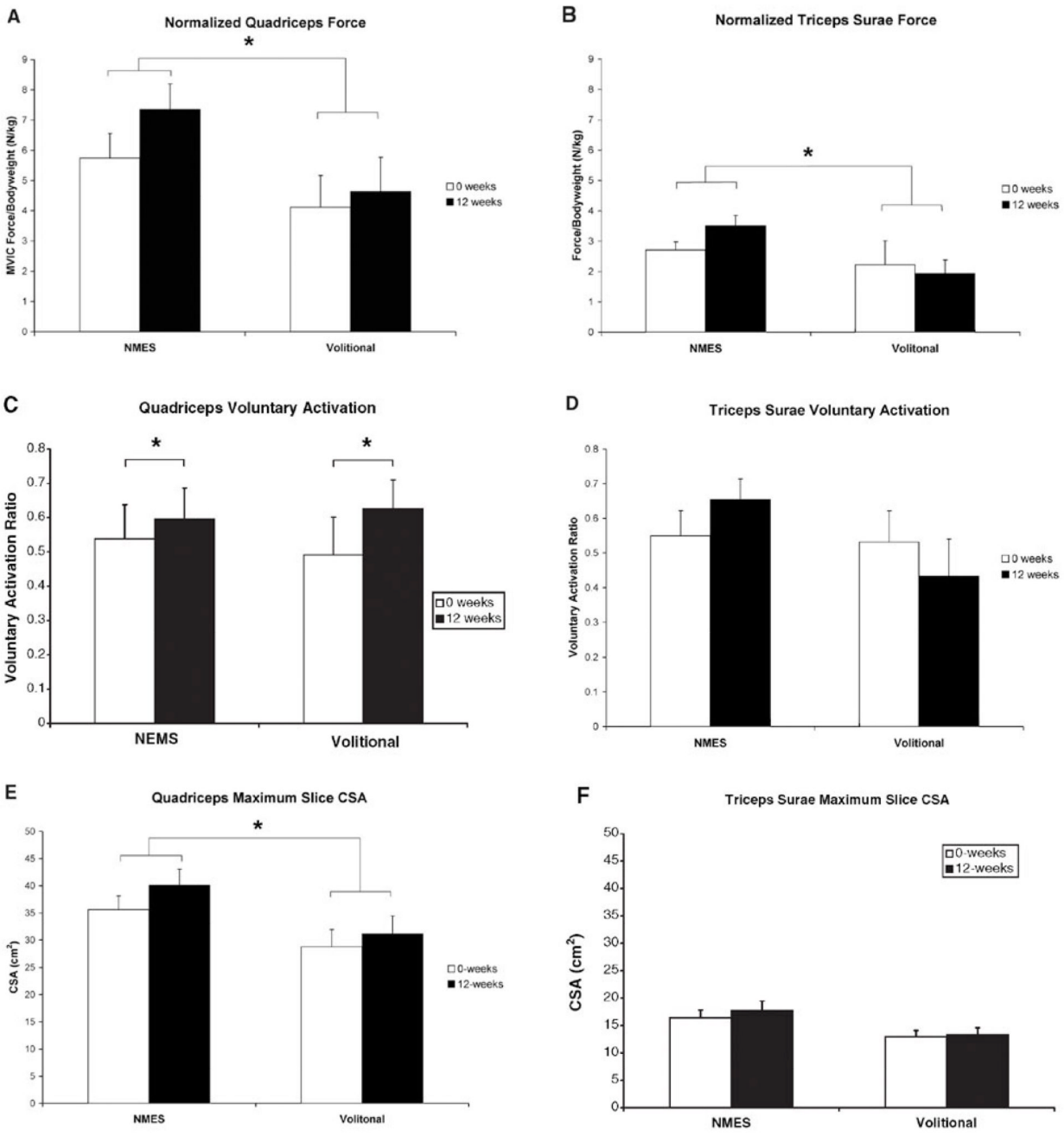

Figure 3.

Quadriceps femoris (A) and triceps surae (B) force production normalized to body weight (N/kg) before (open bars) and after (solid bars) neuromuscular electrical stimulation (NMES; n = 5) and volitional (n = 5) 12-week strength-training programs in children with spastic diplegic cerebral palsy. The amount of voluntary muscle activation before (open bars) and after (solid bars) NMES and volitional strength training in the (C) quadriceps femoris and (D) triceps surae muscles. The maximum cross-sectional area (CSA) before (open bars) and after (solid bars) strength training using NMES or volitional exercise in the (E) quadriceps femoris and (F) triceps surae muscles. MVIC = maximum voluntary isometric contraction, **P* < .1.

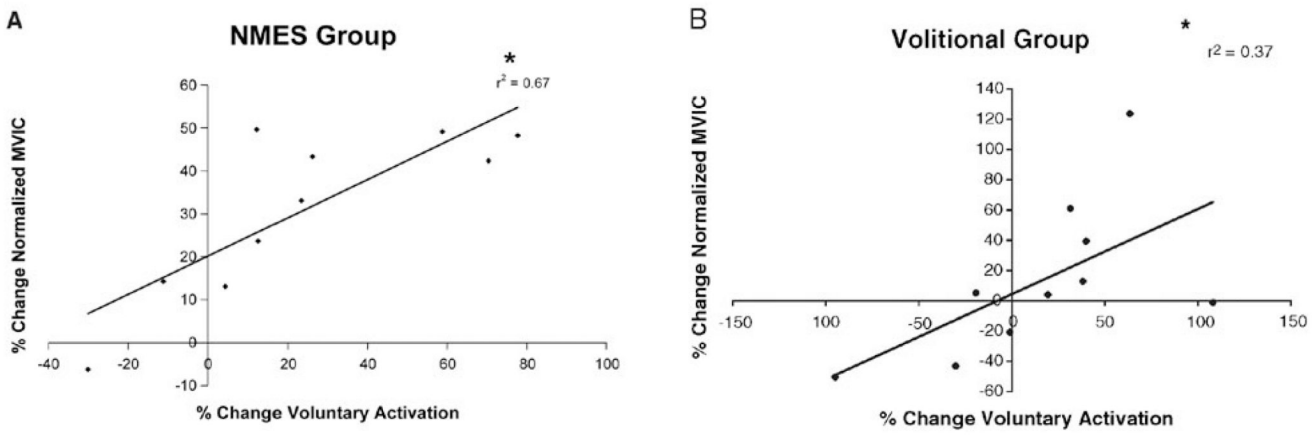

Figure 4.

The relationship between the percentage change in voluntary activation and the percentage change in maximum voluntary isometric contraction force in the (A) neuromuscular electrical stimulation (NMES) and (B) volitional strength-training groups after pooling the data for the quadriceps and triceps surae. MVIC = maximum voluntary isometric contraction. * indicates a significant positive linear relationship, $P < .1$.

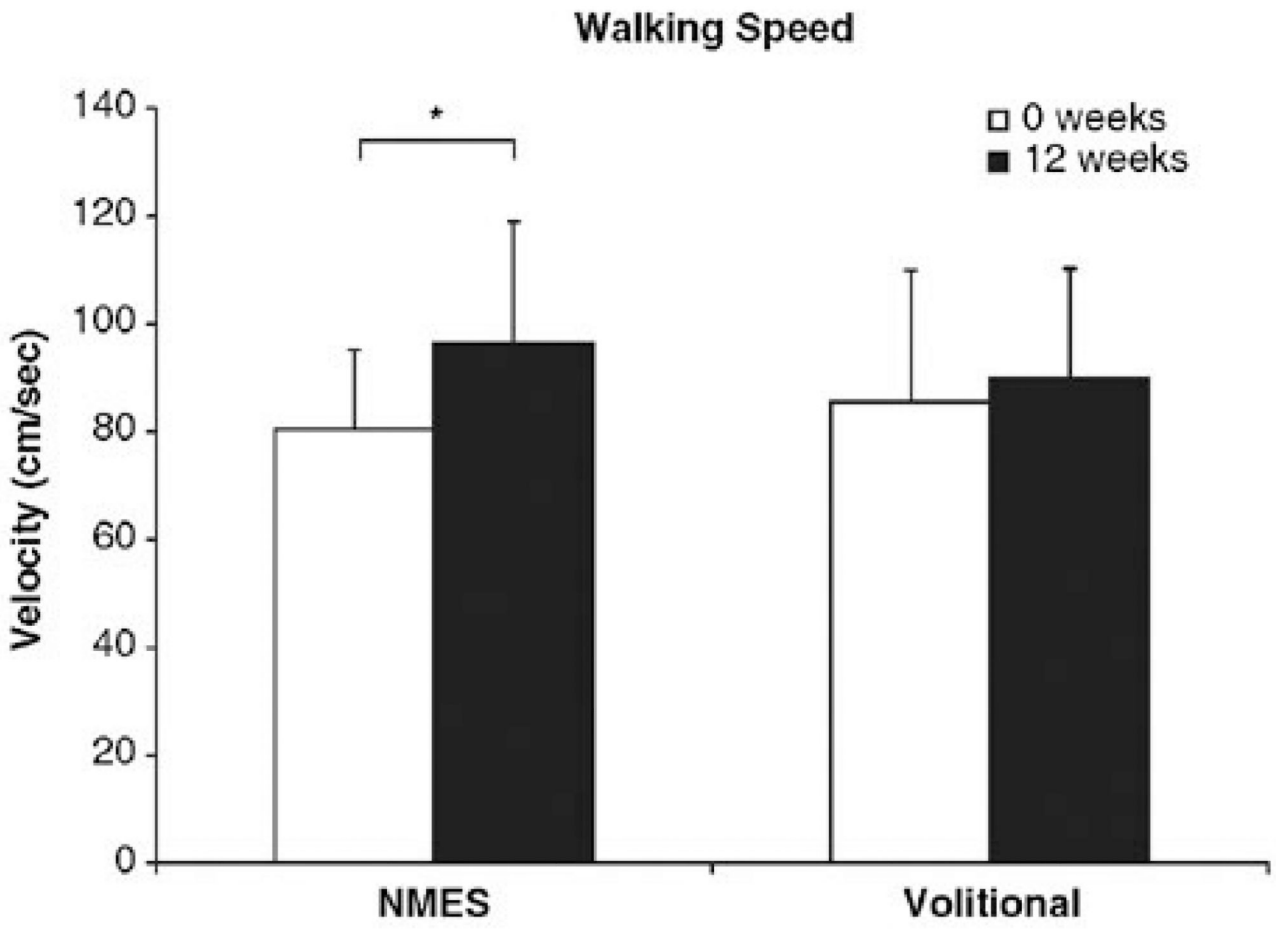

Figure 5.
Self-selected walking speed before (open bars) and after (solid bars) a 12-week strength-training program that uses either neuromuscular electrical stimulation (NMES) or volitional isometric contractions. * $P < .1$.

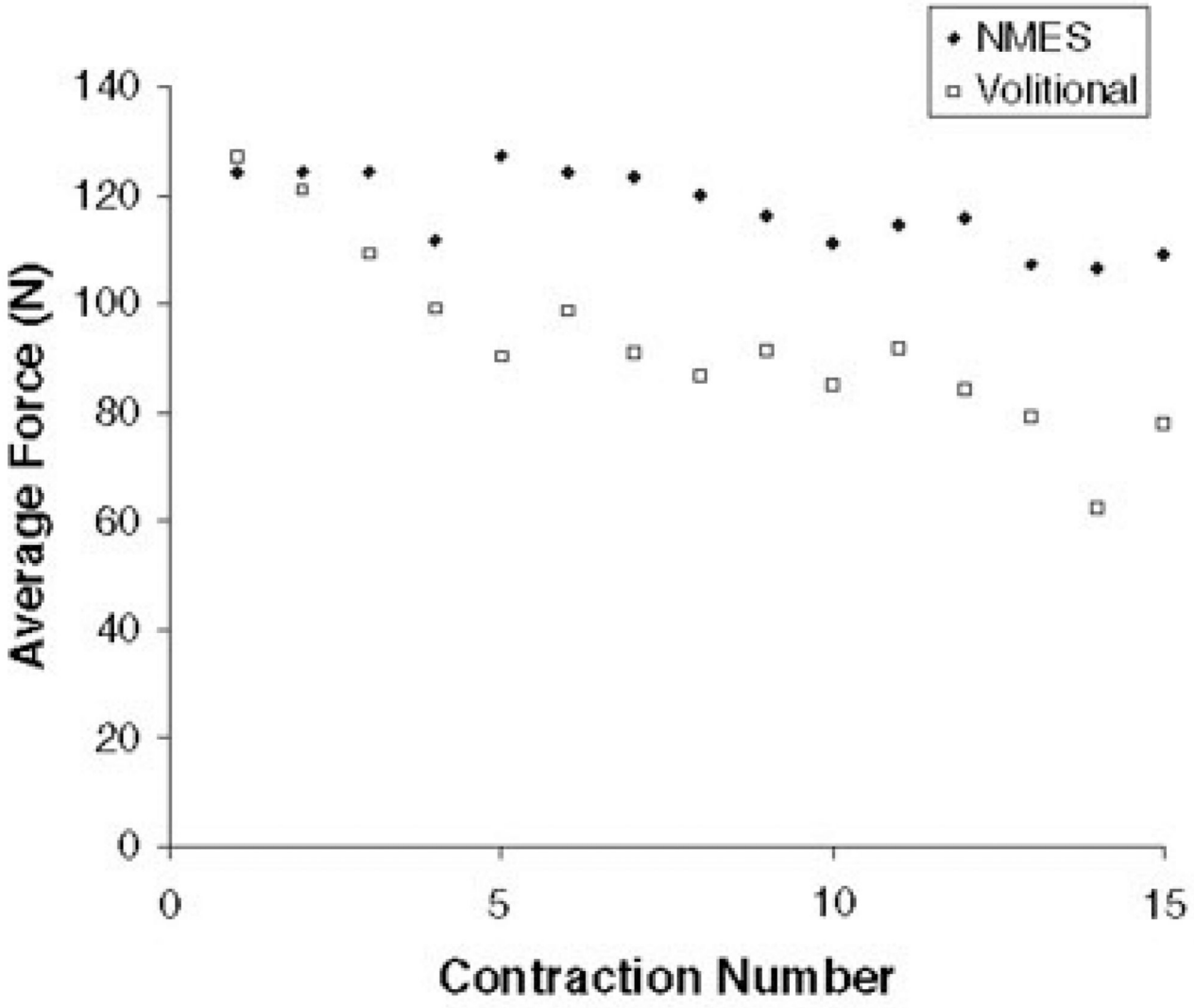

Figure 6.
Example of the average forces of one child with cerebral palsy performing knee extension training using only neuromuscular electrical stimulation (NMES; solid symbols) or volitional contractions (open symbols) while being recorded on a dynamometer. This child was in the volitional training group and later had electrodes implanted for NMES strength training (NMES data not included in this report).

Table 1

Neuromuscular Electrical Stimulation Training Doses (% maximum voluntary isometric contraction force)

	Right Quadriceps			Right Triceps Surae		
Subject	**Pre**	**6 Weeks**	**Post**	**Pre**	**6 Weeks**	**Post**
1	152.0	157.0	160.9	64.7	57.4	66.2
2	98.4	154.0	143.6	53.0	51.2	67.9
3	53.4	60.5	—	74.5	32.1	—
4	61.5	128.0	112.4	57.6	62.6	74.3
5	43.5	95.1	105.1	33.8	38.7	35.0
Mean (SD)	81.8(39.7)	118.9(36.7)	130.5(22.7)	56.7(13.6)	48.4(11.4)	60.9(15.2)