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Scientific/Clinical Article

Immediate effect of a functional wrist orthosis for children with cerebral palsy or brain injury: A randomized controlled trial

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ABSTRACT

Study Design: Two-group randomized controlled trial.
Introduction: Upper limb orthoses worn during functional tasks are commonly used in pediatric neurologic rehabilitation, despite a paucity of high-level evidence.
Purpose of the Study: The purpose of this study was to investigate if a customized functional wrist orthosis, when placed on the limb, leads to an immediate improvement in hand function for children with cerebral palsy or brain injury.
Methods: A 2-group randomized controlled trial involving 30 children was conducted. Participants were randomized to either receive a customized functional wrist orthosis (experimental, $n = 15$) or not receive an orthosis (control, $n = 15$). The box and blocks test was administered at baseline and repeated 1 hour after experimental intervention, with the orthosis on if randomized to the orthotic group.
Results: After intervention, there were no significant differences on the box and blocks test between the orthotic group (mean, 10.13; standard deviation, 11.476) and the no orthotic group (mean, 14.07; standard deviation, 11.106; $t[28]$, −0.954; $P = .348$; and 95% confidence interval, −12.380 to 4.513).
Discussion: In contrast to the findings of previous studies, our results suggest that a functional wrist orthosis, when supporting the joint in a 'typical' position, may not lead to an immediate improvement in hand function.
Conclusions: Wearing a functional wrist orthosis did not lead to an immediate improvement in the ability of children with cerebral palsy or brain injury to grasp and release. Further research is needed combining upper limb orthoses with task-specific training and measuring outcomes over the medium to long term.

Introduction

Upper limb orthoses have been a therapeutic intervention used by physical and occupational therapists for children with cerebral palsy and brain injury for many years.[1-3]

Functional hand orthoses are orthoses that are worn during a task, with the purpose of facilitating achievement of that task. Examples of a functional hand orthosis may be a wrist cock-up orthosis with the aim of optimizing wrist position for grasp and release, thumb spica with the aim of optimizing thumb opposition for a task requiring manipulation, or supination orthosis that aims to assist active supination of the forearm and hand to facilitate play in infants.[3] The purpose of functional orthoses differs from nonfunctional orthoses that address underlying body structures, such as a resting orthosis prescribed to stretch soft tissue or a

Consent and ethical approval: Written informed consent was obtained from the parents and/or carers of all participants for publication of this trial. A copy of the written consent is available for review by the editor of this journal. Ethical approval was granted by the following Human Research Ethics Committees: The University of Notre Dame (012042S), Hunter New England Local Health District (11/11/16/4.03), Cerebral Palsy Alliance (2012-02-01), Monash Health (14232B), and Children's Health Queensland (HREC/15/QRCH/122).

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compression garment to manage scar tissue. Despite functional hand orthoses being used commonly, there is a lack of high-level evidence to support this type of orthosis in clinical practice.[4]

The International Classification of Functioning, Disability and Health (ICF) focusses on activities and participation, rather than body structures and functions. Critics of functional hand orthoses argue that an orthotic aims to normalize joint position (body structures intervention), which may in fact hinder a child's ability to carry out a task or participate in an activity. Given what we now know about neural plasticity resulting from the active use of a limb,[5] it is conceivable that a functional orthosis that passively positions a joint may inadvertently impede the active use of the limb and limit neural change. Advocates of orthoses may argue that positioning the hand or limb in a functional position during activity may allow successful use of the limb, which in turn may have a carryover effect during that task even when the orthosis is removed. The empirical evidence to support either of these theories regarding functional hand orthoses remains unclear.

Although there are 4 published randomized controlled trials (RCTs) investigating functional hand orthoses,[6-10] the efficacy of this intervention remains unclear. Existing RCTs differ with regard to the type of orthosis used, duration of intervention, and outcome measure collected.[11] These studies generally reported that children who received a functional hand orthosis had better outcomes than those who did not receive an orthosis. In addition to these RCTs, there exist lower levels of evidence, which also support the potential benefits of functional hand orthoses.[12-14]

It is generally accepted that a functional hand orthosis, worn during activity, be prescribed concurrently with task-specific training, although this theory is unproven. It is feasible that, due to limited resources, clinicians may, under some circumstances, provide an orthosis in isolation. The purpose of this study was to investigate if prescribing an orthosis to support the wrist in a neutral position, without any functional practice or follow-up, leads to an immediate improvement in hand function.

Purpose of the study

The purpose of this trial was to investigate whether a functional wrist orthosis leads to an immediate improvement in hand function, assessed using the box and blocks test (BBT), in children with cerebral palsy or brain injury. It was hypothesized that children who received a functional hand orthosis would achieve greater improvements on the BBT compared with children who did not receive an orthosis.

Methods

Design and sample size

Our RCT was registered with the Australian New Zealand Clinical Trials Register (ACTRN12613000690752). Detailed study procedures have been previously published.[15] Sample size calculations were based on our calculation for a later, larger, and long-term RCT, for which the study participants in the present study were also enrolled.

Participants

Children were eligible to participate if they met the following inclusion criteria: (1) age 4-15 years; (2) diagnosis of cerebral palsy or brain injury (minimum 12 months after injury), (3) Manual Abilities Classification System (MACS) I-IV, (4) impaired hand function as a result of the neurologic condition, (5) goals related to improving hand function, (6) sufficient language as well as cognitive and behavioral skills to set goals and interact with the therapist. Exclusion criteria include (1) impaired hand function resulting from secondary condition (eg, fracture), (2) significant intellectual or language impairment, or (3) known allergy to orthotic materials.

Procedures

Ethical approval for this study was given by each participating organization and the University of Notre Dame, Australia (012042S). Participants were recruited to this multicenter study in 3 states of Australia, from September 2013 to January 2016. Potential participants were assessed for eligibility, and written consent was obtained from the carers of all participants. Participants were randomized immediately after baseline assessment. Randomized sequence was generated using a computer random number generator, and allocation concealment was achieved using sequentially numbered opaque sealed envelopes, opened by an offsite officer not involved in the study. Blinding of participants, therapists, and assessors was unable to be achieved due to the visible nature of the intervention (the orthosis needed to be worn during assessment to determine its effectiveness). Assessors were blinded for all the baseline assessments (before randomization), and participants were not aware of the study hypotheses to minimize study bias.

Intervention

After baseline assessment, participants were randomly allocated to 1 of 2 study groups, experimental functional wrist orthosis group or control (no orthosis intervention) group.

Functional hand orthosis

The functional hand orthosis was a volar wrist cock-up orthosis, with the option of an additional thumb support or a supination strap. The orthosis aimed to position the wrist in a functional position, ideally in 20°-30° of extension; however, the orthosis was customized according to the individual participant's finger flexion and extension status. Orthoses were prescribed and manufactured by experienced pediatric occupational therapists with advanced orthotic skills. Orthoses were customized for each participant according to individual needs; however, a static support on the volar surface of the wrist (either thermoplastic or aluminum) was consistent across all orthoses to standardize orthosis fidelity. Orthoses were made from neoprene, thermoplastic/aluminum, or a combination of these materials. The child's goals, amount of support required at the wrist, and child and families preference were all taken into consideration when deciding what type of orthosis to prescribe. Examples of common goals chosen by participants included self-care activities (cutlery use, opening packets and containers, and grooming), productivity (typing/handwriting), and leisure (ball skills).

Control

Participants in the control group did not receive any intervention between baseline and 1-hour follow-up measures.

Outcome measures

Outcome measures were taken on 2 occasions: (1) at baseline and (2) at the primary end point, which was an immediate follow-up assessment after 1 hour of experimental orthosis wearing (or 1 hour of the controlled condition). Participants in the orthosis group wore their functional orthosis during post-treatment measurement. The primary outcome measure was the BBT.[16] Baseline