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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.

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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

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

assessment also involved classifying the participant's baseline functional ability using the MACS, Gross Motor Functional Classification System, and House Thumb Classification.

The BBT is a brief assessment of hand function, specifically speed and accuracy of grasp and release, in which the participant is required to use one hand to move individual blocks of identical size and weight from one box to an adjacent box (crossing over a partition). After a 15-second trial period, the participant is given 60 seconds to move as many blocks as possible.¹⁶ The final score is the total number of blocks the participant successfully moves to the second box, in whole numbers (range, 0–150). For the purpose of this study, only the hand prescribed the orthosis was measured. The BBT has been shown to have strong test-retest and inter-rater reliability in typically developing children.^{16,17} Although no studies have specifically investigated the validity and reliability of the BBT for children with cerebral palsy and brain injury, a strong correlation has been found between BBT and MACS,¹⁸ a classification scale used to describe hand function in cerebral palsy. A number of previous studies have used the BBT as an outcome measure in the cerebral palsy population,^{18–22} and prior adult studies suggest that a change score of 4 blocks may represent a clinically significant improvement during a treatment period.²³

Statistical analysis

Participant attributes were analyzed in SPSS (version 23, IBM corporation, Armonk, New York) software using descriptive

statistics to determine baseline variability between the 2 groups. Comparison of differences between the 2 groups on the BBT was analyzed using an independent-samples *t* test, with statistical significance set at $<.05$. Gain score analysis was run using analysis of variance. Levene's test of variability was used to determine equality of variances between the 2 groups. Intention to treat was used.

Results

The flow of participants is shown in Figure 1. Participant baseline characteristics are shown in Table 1. There were no significant differences between the groups at baseline. All participants in the orthosis-only group were provided with a volar wrist orthosis. Most participants ($n = 12$, 80%) wore an orthosis that supported the wrist only, whereas 3 (20%) participants wore an orthosis that supported the wrist and thumb. No orthosis included a supination strap.

Results are shown in Table 2. An independent-samples *t* test showed that there were no significant differences between the orthosis group on the BBT (mean [M], 10.13; standard deviation [SD], 11.476) and the no orthosis group after treatment (M, 14.07; SD, 11.106; $t[28]$, -0.954 ; $P = .348$; 95% confidence interval [CI], -12.380 to 4.513).

Figure 2 shows the mean pre and post BBT scores for each treatment group. Figure 3 shows the pre and post BBT scores for each individual within the treatment and control groups. Levene's

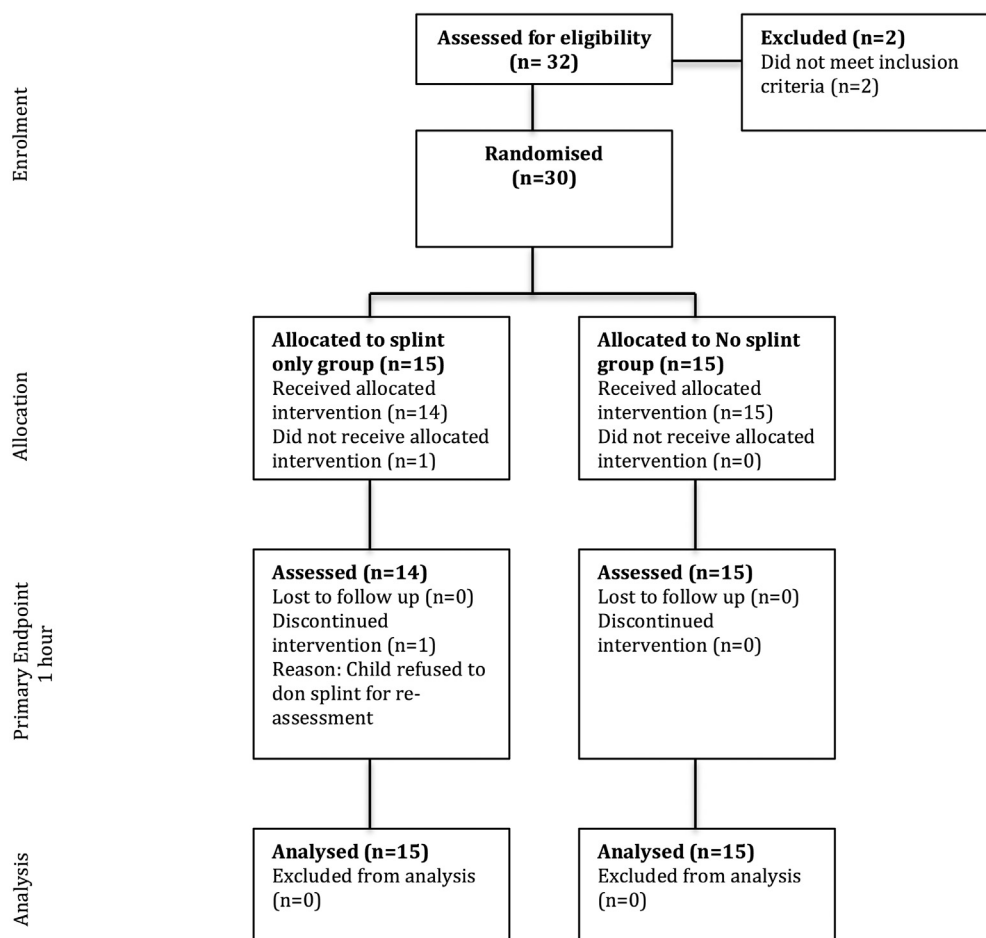


Fig. 1. Consolidated Standards of Reporting Trials (CONSORT) flow of participants through trial.

Table 1
Baseline participant characteristics

Participant information	Whole sample (n = 30)	Group 1 (orthosis), n = 15	Group 2 (no orthosis), n = 15
Age, y; M (SD)	8.2 (2.6)	8.3 (2.9)	8.1 (2.3)
Gender, n (%)			
Male	16 (53)	8 (53)	8 (53)
Female	14 (47)	7 (47)	7 (47)
Diagnosis, n (%)			
Cerebral palsy	28 (93)	13 (87)	15 (100)
Brain injury	2 (7)	2 (13)	0
Diagnosis, n (%)			
Unilateral	25 (83)	14 (93)	11 (73)
Bilateral	5 (17)	1 (7)	4 (27)
Motor type, n (%)			
Spastic	20 (67)	9 (60)	11 (73)
Dystonic	2 (7)	2 (13)	0
Mixed	7 (23)	4 (27)	3 (20)
Ataxic	1 (3)	0	1 (7)
MACS, n (%)			
I	4 (13)	3 (20)	1 (7)
II	20 (67)	10 (67)	10 (67)
III	5 (17)	2 (13)	3 (20)
IV	1 (3)	0	1 (7)
GMFCS, n (%)			
I	17 (57)	9 (60)	8 (53)
II	8 (27)	4 (27)	4 (27)
III	1 (3)	1 (7)	0
IV	4 (13)	1 (7)	3 (20)
House, n (%)			
1	13 (43)	6 (40)	7 (47)
2	2 (7)	2 (13)	0
3	11 (37)	4 (27)	7 (47)
4	1 (3)	1 (7)	0
No contracture	3 (10)	2 (13)	1 (7)
Type of orthosis			
Wrist only	NA	12 (80%)	NA
Wrist + thumb	NA	3 (20%)	NA

M = mean; SD = standard deviation; MACS = Manual Abilities Classification System; GMFCS = Gross Motor Functional Classification System; House = House Thumb Classification; NA = not applicable.

test of equality of variances showed no significant differences between the groups ($P = .587$). A paired-samples t test was also run for all participants to compare before and after prescription of hand orthosis. There were no significant differences in the scores for each case before (M, 12.233; SD, 10.2341) and after (M, 12.10; SD, 11.275; $t[29]$, 0.179; $P = .859$). So even when individual cases were analyzed, none of the participants improved significantly on the BBT.

There was 1 participant in each of the groups whose scores had a much greater change than most of the groups (participant 25 [no orthosis group] and participant 32 [orthosis group]). Post hoc, we removed the outliers from the analyses to confirm the result. The independent-samples t test was re-run with outliers removed with no significant differences between the orthosis group (M, 10.86; SD, 11.548) and the no orthosis group (M, 13.50; SD, 11.298; $t[26]$, -0.612 ; $P = .546$; 95% CI, -11.518 to 6.233).

BBT gain scores (posttest-pretest) were analyzed in an analysis of variance with orthosis group (orthosis vs no orthosis) as the independent variable. The increase in BBT was less for participants in the orthosis group (M, -0.93 ; SD, 2.269) than for those in the no orthosis group (M, 1.14; standard error, 1.916; $F[1, 26] = 6.812$; and $P < .05$).

Discussion

This study investigated the immediate effect of a hand orthosis. It did not measure the effect of the orthosis combined with treatment beyond this immediate time frame. Findings in our study

showed that children who wore a functional wrist orthosis did not immediately improve in their ability to grasp and release blocks when compared with children who did not wear a hand orthosis, although long-term effect was not measured. It is important that clinicians consider evidence-based interventions that may be used concurrently when prescribing orthoses, such as task-specific training. Clinicians should also follow-up to ensure that an orthosis is of benefit to the individual for whom it has been prescribed.

Therapists have traditionally fabricated hand orthoses for children with brain injury or cerebral palsy with the aim of assisting the child to grasp and release. Our hypotheses were that a hand orthosis would facilitate immediate improvements in hand function by supporting the joints; however, this hypothesis was incorrect. In our study, our gain scores suggest a trend toward wearing a hand orthosis having a negative impact on the ability to grasp and release in children (Fig. 2) although it is important to note that this study did not investigate the long-term effect of the orthosis.

Rehabilitation is now focused on directly addressing the child's activities and participation.²⁴ Although the premise is that improving underlying body structures and functions deficit will lead to greater activity use, our study findings do not support this premise for hand orthoses. This finding may be unsurprising—research beyond hand orthosis evidence has shown that if the goal of the therapy is to improve in a functional task, the child needs to actively practice that task to improve.²⁴ Providing a functional hand orthosis that addresses limitations in body structures, therefore, without concurrent task-specific training, is unlikely to improve immediate activity performance such as grasp and release. Clinical best practice is no longer to provide a child with an upper limb orthosis without training but rather to provide an orthosis in combination with other evidence-based interventions.^{4,25} More research is needed to empirically examine the effects of these interventions when provided in combination and during a longer period, and the larger RCT run concurrently with this study aims to do this.¹⁵

The results of our study are not consistent with previous studies regarding the benefits of functional orthoses^{7–10} in children. The study by Keklice and Uygur¹⁰ found an immediate benefit when a thumb abduction orthosis was applied to the hand. The reason for these differing results is unclear but may be because our study targeted a different joint or measured the effect using an activity outcome (BBT). Our study provided an orthosis to children, which supported their wrist in a neutral (functional) position, with the aim of stabilizing the wrist to improve hand function. It may be important in clinical practice not to assume that an orthosis designed to position the hand in a typical position will assist hand function and to ensure that the effect of the orthosis is measured immediately and beyond orthotic wear.

If prescribing a functional orthosis, therapists should prescribe the orthosis for a specific goal or task and ensure that the orthosis is assisting with that task by reviewing set goals and measuring outcomes, after both short- and long-term use of the orthosis. If

Table 2
Immediate follow-up results of pre- and post-BBT scores

Outcome score	Orthosis group (n = 15)	No orthosis group (n = 15)	Significance of between-group differences (P)
Baseline, M (SD)	12.067 (10.2083)	12.400 (10.6154)	.931
End point, M (SD)	10.13 (11.476)	14.07 (11.106)	.348
Gain scores	n = 14	n = 14	
M (SD)	-0.93 (2.269)	1.14 (1.916)	.015

BBT = box and blocks test; M = mean; SD = standard deviation.

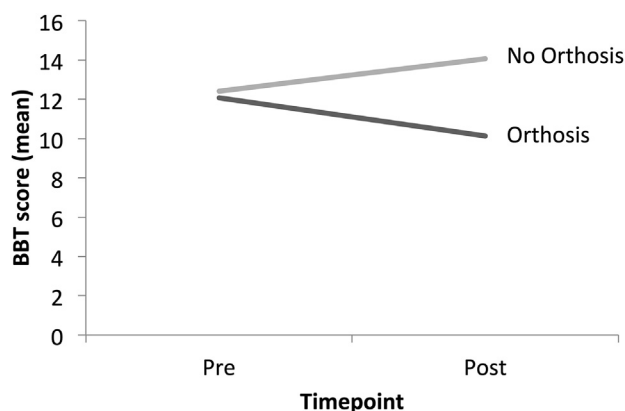


Fig. 2. Box and blocks test results, shown as the group mean for orthosis group compared with no orthosis group.

there is a functional goal, we now know that the child needs to practice that specific goal to actually improve,²⁴ which again highlights the importance of adjunctive task-specific training being included in therapeutic recommendations when prescribing an orthosis.

It is plausible that the lack of improvement on our primary outcome measure was because performance on the measure was unreliable. The reliability of the BBT as a short-term outcome measure in this population remains unclear. A study investigating BBT norms in a small sample of 3–10-year-old children suggested that there may be a practice effect of 4 blocks when retested 1 week after baseline.¹⁷ This study recommended repeating the assessment immediately at baseline and using the participant's best score;¹⁷ however, data collection for the present trial had begun before this recommendation being published. Therefore, it is unclear whether there is likely to be a practice effect when retested 1 hour after baseline, as was the protocol in the present study. That said, findings suggest that even with a potential risk of a practice effect, we still did not find an improvement in scores with orthotic wear.

Future directions

The type of child who may benefit immediately from wearing a functional orthosis remains unclear with regard to diagnosis, motor type, and typography. The relationship between functional hand orthoses and task-specific training also remains unclear. Therefore, further research of longer duration using reliable outcome measures is needed to guide prescription of functional hand orthoses for children with cerebral palsy or brain injury. Research is currently underway investigating the use of functional hand orthoses combined with the cognitive orientation to daily occupational performance (CO-OP) approach for this population.¹⁵ In clinical practice, it is vital that when clinicians are prescribing a functional hand orthosis that (1) a specific goal is set, (2) children are given the opportunity to practice the goal with and without the orthosis, and (3) outcome measures are collected to ensure that the orthosis is of functional benefit to the child.

Limitations

This was a small but adequately powered study as suggested by the narrow CI around estimates of the between-group differences. The primary outcome measure was a basic measure of hand function, specifically speed and accuracy of grasp and release of blocks. The orthoses used in this study were not designed specifically to assist with the BBT, but rather, designed to assist with the child's individual goals. In this context, the BBT may not be sensitive to change, and qualitative data from participants may have been valuable, however were not formally collected. The study included a heterogeneous sample with regard to diagnosis and hand function. This study was specifically designed to measure the immediate effect of a hand orthosis, although some may argue that long-term measures are needed, which were the purpose of a concurrent study.¹⁵ Some may argue that this study was flawed by the type of orthosis used, but a number of measures were put in place to ensure appropriateness of the orthosis. All prescribers were experienced therapists, and the orthosis had the flexibility to meet the individual needs of the child and maximize acceptance of

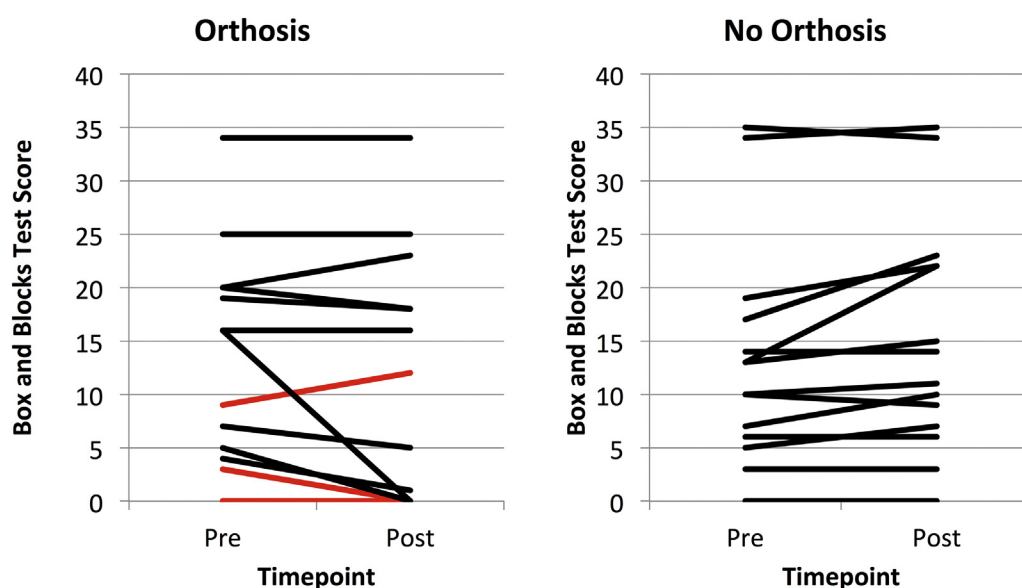


Fig. 3. Individual participants' before and after box and blocks raw scores (each line represents 1 individual participant). Participants who wore an orthosis supporting the thumb in addition to the wrist are shown in red. All other participants wore an orthosis supporting the wrist only. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

the orthosis. No adverse events were reported as a result of the orthoses.

Conclusions

For children with cerebral palsy or brain injury in this study, prescription of a functional wrist orthosis, supporting the wrist in a neutral position, did not immediately improve the ability to grasp and release. If prescribing hand orthoses, clinicians should set a clear goal, consider what long-term effect the orthosis may have on function and follow-up to ensure that the orthosis is assisting with the goal set for the child. Further research is needed to investigate whether providing task-specific training concurrently with orthosis wear during a longer period improves the outcome.

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Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jht.2017.09.006>.

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Quiz: # 584

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- # 1. The study design was
 - a. qualitative
 - b. a case series
 - c. RCTs
 - d. retrospective cohort
- # 2. The primary outcome measure was
 - a. improved hand function
 - b. patient satisfaction
 - c. reduced spasticity
 - d. improved ROM
- # 3. The control group received
 - a. only home program instruction
 - b. massage and exercise
 - c. the customized orthotic
 - d. no orthotic
- # 4. Results suggested that
 - a. no further research is needed to answer the investigators' questions
 - b. wearing the custom designed orthotic actually decreased grasp and release function
 - c. there was no significant improvement by wearing the custom designed orthotic
 - d. there was demonstrable improvement by wearing the custom designed orthotic
- # 5. Prior to the study there was strong data in support of the orthotic being investigated
 - a. true
 - b. false

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