

A systematic review of the effects of soft splinting on upper limb function in people
with cerebral palsy

An AACPDM Evidence Report

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Written by

A.M. Blackmore PhD*, S.A. Garbellini BSc(OT), M(Pub Hlth),
P. Buttigieg BAppSc(OT Hons), and J. Wells BAppSc(OT)

Approved by

AACPDM Treatment Outcomes Committee Review Panel: American Academy for
Cerebral Palsy and Developmental Medicine

Lisa Samson-Fang, MD
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Alexander Hoon, MD
Meg Barry-Michaels PhD, PT, PCS
Robbin Hickman PT MHS PCS

John McLaughlin, MD
Michael Msall MD

*Corresponding author:

Dr Marie Blackmore
Senior Research Therapist
The Centre for Cerebral Palsy
PO Box 61
Mount Lawley 6929
Western Australia
AUSTRALIA
Phone: +61 8 9443 0395
Fax: +61 8 9444 7299
Email: Marie.Blackmore@tccp.com.au

Summary

Objective: The objective of this systematic review was to describe the existing evidence about the effects of soft splinting on upper limb function in people with cerebral palsy.

Methods: The following databases were searched: PUBMED, CINAHL, Proquest Health and Medical Complete), Cochrane Database of Systematic reviews, OTseeker, Physiotherapy Evidence Database (PEDro), and Database of Reviews of Effectiveness (DARE). The selection criteria were: (a) that the effects of soft splinting on upper limb function were reported, (b) that participants had cerebral palsy, (c) that the article appeared in a peer-reviewed journal, and (d) that the article was in English. Articles were excluded if: (a) they were reviews, letters, editorials, surveys or anecdote, (b) the soft splinting intervention included surgery or electrical stimulation, or (c) the intervention included dynamic or static splinting with rigid components.

Results: Of the five articles identified in this review, three were case series designs, one was a single-subject design, and one was a mixed design, which we divided into a case series design and a randomized controlled trial (RCT). This RCT found no significant differences between children who had and had not worn soft splints in their muscle strength (grip strength and abdominal muscle strength). Other expected effects of soft splinting on body structures and function, such as spasticity, range and quality of movement, postural control, sensory and proprioceptive awareness, and proximal stability have not been examined in any RCT.

Conclusions: There is no evidence at present to support the use of upper limb soft splinting for people with cerebral palsy. Some adverse effects have been identified in body suits.

High quality RCTs are required on upper limb soft splinting to determine its effects.

(276 words)

The AACPDm has undertaken the development of systematic reviews to summarize the literature about specific intervention strategies used to assist children with developmental disabilities. These reviews are not best practice documents or practice guidelines, but rather they gather and present the best evidence – for and against – the effectiveness of an intervention. Their goal is to present the evidence about interventions in an organized fashion to identify gaps in evidence and help address new research that is needed. The Academy is neither endorsing nor disapproving of an intervention in these reviews. Every effort has been made to assure that AACPDm systematic reviews are free from real or perceived bias. Details of the disclosure and consensus process for AACPDm outcomes reports can be viewed at www.AACPDm.com. Nevertheless, the data in an AACPDm Systematic Review can be interpreted differently, depending on people's perspectives. Please consider the conclusions presented carefully.

Introduction

Sensory and motor impairments are common among people with cerebral palsy (CP) (1). They demonstrate reduced manual dexterity and pinch strength (2) and a lack of spontaneous manipulation (3). In the long term, spasticity can lead to reduced range of motion and muscle contractures (4, 5). In a study of hand function, 169 children with hemiplegic CP were tested on eight hand-grips used in activities of daily living. Of these children, 47% had “good” hand function, 39% had “moderately impaired” hand function, and 14% had “poor” hand function (1).

Splinting is based upon two widely used approaches to the management of spasticity: the biomechanical approach, which aims to prevent deformity by aligning, mobilizing and stabilizing joints, and the neurophysiological approach, which aims to reduce spasticity by sustained stretch and reflex-inhibiting positions (6, 7). Soft

splints are customized splints that conform to the shape of the wearer, and are made with soft pliable material (such as neoprene and lycra). They do not include any rigid, static or hinged components that limit movement, though they may include semi-rigid components for stability and postural support. Soft splints include garments worn on the trunk or body surface as well as those worn only on the upper limb. They are believed to: enhance sensory and proprioceptive awareness, leading to a better more secure exploration of the environment; increase proximal stability; enhance function; and improve grasping and feeding ability (8, 9), though evidence for these benefits is mainly anecdotal.

Several mechanisms have been proposed as the means by which soft splints achieve their effects: they oppose spastic muscle action (6); they apply a line of mechanical pull to favour rotation and decrease spasticity by prolonged stretch and cutaneous stimulation from tight skin contact (10); they stimulate mechanoreceptors to enhance joint positioning sense and body awareness (8, 11, 12).

Although soft splints have been used for at least a decade in several countries, there has never been a systematic review examining their effects. Therefore, the objective of the present systematic review was to describe the existing evidence about the effects of soft splinting on upper limb function in people with CP.

Method

SEARCH STRATEGY

The search terms used in this review were wide-ranging in order to ensure that all possible relevant articles were identified: “dynamic splint OR dynamic splinting OR dynamic splints OR soft splint OR soft splinting OR soft splints OR lycra OR neoprene OR hand splint OR hand splinting OR hand splints OR hand orthosis OR hand orthoses OR wrist orthosis OR wrist orthoses OR upper limb orthosis OR upper limb orthoses”. The following databases were searched: PUBMED, CINAHL,

Proquest Health and Medical Complete, Cochrane Database of Systematic reviews, OTseeker, Physiotherapy Evidence Database (PEDro), and Database of Reviews of Effectiveness (DARE).

SELECTION OF ARTICLES

The selection criteria were: (a) that the effects of soft splinting on upper limb function were reported, (b) that participants had CP (with separate results for the participants with CP if the sample included participants without CP), (c) that the article appeared in a peer-reviewed journal, and (d) that the article was in English. Articles were excluded if: (a) they were reviews, letters, editorials, surveys or anecdote, (b) the soft splinting intervention included surgery or electrical stimulation, or (c) the intervention included dynamic or static splinting with rigid components. Most studies did not mention whether the participants had received Botulinum Toxin A (BtA); only one study (13) mentioned that none of the participants had received BtA.

This search yielded 966 articles. Two of the authors independently reviewed the articles' titles and abstracts using these criteria, and excluded 962 articles: 477 because they did not report the effects of soft splinting on upper limb function; 248 because they did not include participants with CP; 115 because they were not in English; 25 because they were reviews, letters, editorials, surveys or anecdote; 34 because the interventions included surgery or electrical stimulation; and 63 because the interventions included dynamic or static splinting with rigid components.

Four articles were selected for inclusion in the systematic review. Any disagreements between the two authors were resolved by discussion between themselves and a third author. The reference lists of all selected articles were also reviewed independently by two authors, and any articles that met the selection criteria were included. This process yielded a fifth article.

DATA EXTRACTION

The American Academy of Cerebral Palsy and Developmental Medicine's (AACPD) Methodology to develop systematic reviews of treatment interventions (Revision 1.1) (14) was used for extracting data from the articles. Each article was coded independently by all authors and any disagreements were resolved by discussion. Methodological data were extracted to describe the population, sample size, and interventions. The outcomes in the articles with levels I, II or III of evidence were coded according to the International Classification of Function (ICF) components shown in Table 1. Level of evidence was rated from I to V according to the rating system presented in Table 2.

Insert Tables 1 and 2 about here

Descriptions of the samples and interventions used in each study, their research designs and ratings of their levels and quality, are shown in Table 3.

Insert Table 3 about here

QUALITY ASSESSMENT

The AACPD conduct questions were used to rate the quality of studies. Table 4 shows the ratings for each of these questions for the only study found at level I, II or III of evidence.

Insert Table 4 about here

OUTCOMES

The outcomes of the only study at level I, II or III of evidence is summarized under the three ICF components in Table 5.

Insert Table 5 about here

COMPLIANCE AND ADVERSE EFFECTS

All articles were reviewed for compliance and adverse effects and the results are shown in Table 6.

Insert Table 6 about here

Results and Discussion

1. WHAT EVIDENCE EXISTS ABOUT THE EFFECTS OF THE INTERVENTION IN THE COMPONENTS OF ICF IN WHICH IT WAS EXPECTED TO WORK?

There were no significant differences between groups of children who had and had not worn soft splints in their muscle strength (grip strength and abdominal muscle strength) (15). Other expected effects of soft splinting on body structures and function, such as spasticity, range and quality of movement, postural control, sensory and proprioceptive awareness, and proximal stability have not been examined in any RCT.

2. WHAT EVIDENCE EXISTS ABOUT THE EFFECTS OF THE INTERVENTION IN THE OTHER COMPONENTS OF ICF?

Currently there is no evidence from any RCT on the other components of ICF, namely activities and participation (such as upper limb function in activities of daily living) and contextual factors.

3. WHAT EVIDENCE EXISTS FOR LINKAGES OF EFFECTS WITHIN AND BETWEEN THESE COMPONENTS?

There is no current evidence for linkages between components of the ICF because few measures of body structures and function and no measures of activities and participation or contextual factors have been used in any RCTs of soft splinting.

4. WHAT KINDS OF MAGNITUDE OF COMPLICATIONS HAVE BEEN DOCUMENTED?

Table 6 shows that many adverse effects have been reported in association with soft splinting when body suits are worn. Several studies also report discomfort and inconvenience. These problems were significant enough to reduce compliance in up to 50% of children.

5. WHAT IS THE STRENGTH OF THE EVIDENCE?

The evidence regarding soft splinting is very weak, with only one RCT published (Level of Evidence II). As indicated in Table 5, this study was methodologically weak. It used a small sample size, a heterogeneous population (with no distinctions between diagnostic groups of CP such as spastic or dyskinetic or between levels of severity), and it failed to include the outcome measures that would be expected (anecdotally and clinically) to be affected by soft splinting. Generalization from the research to clinical practice is not possible at this stage because of insufficient studies.

Conclusions

IMPLICATIONS FOR PRACTICE

There is no evidence at present to support the use of upper limb soft splinting for people with CP. Some adverse effects have been associated with use of body suits, and so clinicians who decide to use soft splinting need to monitor these effects.

IMPLICATIONS FOR RESEARCH

High quality RCTs (with more homogeneous samples and adequate power) are required on soft splinting to determine its effects, not only on the expected outcomes in the areas of body structure and functions, but also on the other components of ICF. As there is no strong evidence to suggest that soft splinting is either beneficial or harmful, an RCT comparing soft splints with a control group could be conducted.

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Table 1. ICF Components and Definitions

ICF Component	Definition
Body Function	Body functions are the physiological functions of body systems including psychological functions
Body Structure	Body structures are the anatomical parts of the body such as organs, limbs, and their components
Activity	Activity is the execution of a task or action by an individual
Participation	Participation is involvement in a life situation
Context/Environmental Factors	Environmental factors make up the physical, social and attitudinal environment in which people live and conduct their lives

Table 2. Levels of Evidence used in AACPDM reviews

Level	Intervention (Group) studies
I	Systematic Review of randomized controlled trials (RCT's) Large RCT (with narrow confidence intervals) (n>100)
II	Smaller RCT's (with wider confidence intervals) (N<100) Systematic Reviews of cohort studies "Outcomes research" (very large ecologic studies)
III	Cohort studies (must have concurrent control group) Systematic reviews of Case Control Studies
IV	Case series Cohort study without concurrent control group (e.g. with historic control group) Case-control Study
V	Expert Opinion Case Study or report Bench research Expert opinion based on theory or physiologic research Common sense/anecdotes

Table 3. Summary of studies – interventions and participants

Study	Level of evidence	<i>Soft splinting intervention</i>	<i>Control Intervention</i>	<i>Population</i>	<i>Total n</i>	<i>Ages</i>
Research design						
Blair et al. 1995 (15)	IV Case series	Lycra UPSuits worn for mean of 6.5 h/d for mean of 53d (4w wear, 3w nonwear, 6w wear).	No control group	Tone abnormalities; spasticity (9), Athetosis (7), Dystonia (10), Ataxia (5), Hypotonia (1), Motor impairment profound (6), severe (9), moderate (5), mild (4) on GMFM; no previous UPSuit use.	24	<4.5 - >8y
Blair et al. 1995 (15)	II-W RCT	4w daytime wear of Lycra UPSuits, 3w nonwear, 6w wear.	No UPSuit	Tone abnormalities; UPSuit: Spasticity (2), athetosis (2), dystonia (3), ataxia (1); Ctl: spasticity (4), athetosis (1), dystonia (2), ataxia (1).	16 Rx=8* Ctl=8	<4.5 - >8y

Edmondson et al. 1999 (16)	IV Case series	Camp lycra body suit without boning worn for at least 6h/d for 12 mo	No control group	CP; spastic athetosis (6), spastic diplegia (4), spastic quadriplegia (2), hypotonia (2), hemiplegia with ataxia (1).	15	2 – 12y (M=6.8)
Nicholson et al. 2001 (13)	IV Case series	Individually tailored lycra garments: either full-body garment with long sleeves (6), vest with full sleeve and gloves (3), or full suits with at least one glove (3) worn at least 6h/d for 6w; plus usual therapy.	No control group	CP with significant impairment of upper limb function on Erhardt scale; no previous lycra use, BtA or surgery; spastic diplegia (3), spastic quadriplegia (1), spastic hemiplegia (1), athetosis (3), athetoid hemiplegia (2), ataxia (1), severe quadriplegia (1).	12	2-17y (M=6.8)

Knox 2003 (17)	IV Case series	Camp lycra garments without boning worn >4h/d for 4w; either total body (5), total body and gloves (1), long-sleeved vest (1), shorts (1); plus usual therapy.	No control group	no previous lycra use; spastic diplegia (2), spastic quadriplegia (2), choreoathetosis (2), dystonic quadriplegia (2).	8	3;5-13y (M=8.9)
Corn et al. 2003 (18)	Single subject AB design	Second skin upper limb splints for 6h/d at school for several weeks	No splint	CP (asymmetric spastic quadriplegia and spastic quadriplegia); ABI (ataxic hemiplegia and spastic quadriplegia); CP had worn splints for at least 12 mo; ABI had not worn splints; all with functional limitations due to spasticity**	4	CP: 8 & 16y ABI: 11 & 13y

ABI acquired brain injury; Ctl Control Group; d days; GMFM Gross Motor Function Measure; h hours; M mean; mo months; Rx Treatment Group; w weeks; y years.

*Note: These are 8 of the 24 children in the case series.

** Separate results given for participants with CP.

Table 4. Conduct of study (Levels I, II and III evidence only).

Study	Level/Quality	1	2	3	4	5	6	7
Blair et al. 1995 (15)	II-W (0/7)							

Conduct of the study is rated as “strong” (6-7 ticks), “moderate” (4-5 ticks) or “weak” (0-3 ticks).

1. Were inclusion and exclusion criteria of the study population well described and followed? 2. Was the intervention well described and was there adherence to the intervention assignment? (for two-group designs, was the control exposure also well described?) 3. Were the measures used clearly described, valid and reliable for measuring the outcomes of interest? 4. Was the outcome assessor unaware of the intervention status of the participants (i.e. were there blind assessments)? 5. Did the authors conduct and report appropriate statistical evaluation including power calculations? 6. Were dropouts/loss to follow-up reported and less than 20%? For two-group designs, was dropout balanced? 7. Considering the potential within the study design, were appropriate methods for controlling confounding variables and limiting potential biases used?

Table 5. Summary of studies: outcomes, measures, and results (Levels I, II and III evidence only).

<i>Study</i>	<i>Outcome of interest</i>	<i>Measure</i>	<i>Components of Health</i>		
			<i>Body Structure/s</i>	<i>Activities and</i>	<i>Contextual</i>
			<i>Body Functions</i>	<i>Participation</i>	<i>Factors</i>
Blair et al. 1995 (15) LOE II-W	Respiratory capacity	Spirometry: Forced expiratory volume in 1 minute	ns		
		Force vital capacity	ns		
	Muscle strength	Grip strength (vigrometer)	ns		
		Abdominal muscle strength (crunches number and duration)	ns		

LOE Level of evidence; ns not significant

Table 6. Compliance and adverse effects associated with soft splinting.

Study	Type of splinting	Compliance	Adverse effects
Blair et al. 1995 (15)	Lycra UPSuit	6/24 showed poor compliance which contributed to the decision to discontinue wear. UPSuits worn 60.2% days intended	Vomiting, upper extremity cyanosis, hyperthermia, induced muscle weakness, inhibition of voluntary movement, respiratory compromise*, intractable peripheral cyanosis associated with hypo-activity*
Edmondson et al. 1999 (16)	Camp lycra body suit	14/15 children tolerated body suit well after 1 week for at least 6h/d	Erythema in the axilla
Nicholson et al. 2001 (13)	Individually tailored lycra garments: some full-body, some vests	All children complied with wearing garment 6h/d for 6w.	Eczema irritated (1), rubbing (1), child didn't urinate while wearing suit (1); constipation while wearing suit (3); circulation difficulties (3); friction sores between legs and at zip sites (3)
Knox 2003 (17)	Camp lycra garments: some full-body, some vests, some shorts	4/8 children achieved wearing time for > 4h/d for 4w.	Restricted UL function

*Contra-indications to UPSuit prescription

h hours, d days, w weeks

Numbers in parenthesis show numbers of children