Spasticity in children and young people with non-progressive brain disorders: management of spasticity, co-existing motor disorders and their early musculoskeletal complications

Orthoses

Bibliographic details	Number of Participants Characteristics	Intervention characteristics	Outcome measures and results	Quality assessment	Reviewer comment
Periodical Developmental Medicine and Child Neurology **Authors** Buckon,C.E., Thomas,S.S., Jakobson-Huston,S., Moor,M., Sussman,M., Aiona,M. **Year of publication** 2004 **Study location** USA **Ref ID** 75791 **Type of study** Randomised controlled study **Aim of study** To determine how three commonly prescribed AFO configurations (HAFO, PLS, SAFO), with varying amounts of ankle motion, influenced proximal joint dynamics, energy expenditure, and functional skill performance in ambulatory children with spastic diplegia.	**Inclusion Criteria** 1) Aged from 4 to 18 years 2) capable of independent ambulation without assistive devices 3) using an AFO at the time of enrollment or with AFO use indicated 4) no orthopedic or neurosurgical intervention in the preceding year **Exclusion Criteria** not stated **Baseline characteristics** Sixteen children with spastic diplegia males: 10, females : 6 Mean age : 8 years 4 months, SD 2 years 4 months Age range : 4 years 4 months to 11 years 6 months 4 children were classified at GMFCS level I 12 were at classified at GMFCS level II. None of the children was	Procedures An ankle mold was made for each child upon initiation into the study by a single orthotist and the original mold was used to fabricate all three AFO configurations. Each AFO was worn daily for 6 to 12 hours and removed at night over a period of 3 months.Each child walked at a self-selected speed along a 7.5 meter walkway. A total of 10 to 20 walking trials were performed in order to obtain five right and five left trials with useful forceplate data. Data from three representative trials for each side were averaged and mean values were used for analysis. Each child's participation in the study lasted 1 year and comprised 4 visits : a baseline assessment after 3m of no AFO wear, and an assessment at the end of each AFO 3 month wearing period.	Outcomes:Kinematic analysis and energy expenditure. BOTMP, GMFM, GMPM and PEDI Baseline assessments were performed barefoot (BF), except for energy expenditure which was performed with shoes on and no AFO. a Mean of this condition differed significantly from mean of BF condition b Mean of HAFO differed significantly from mean of SAFO c Mean of HAFO differed significantly from mean of the PLS Ankle dorsiflexion ($p \leq 0.01$) Initial contact Barefoot = –7.2 (13) HAFO = 5.4 (3.9)a PLS = 4.8 (4.6)a SAFO = 5.0 (4.5)a Peak dorsiflexion stance Barefoot = 5.7 (12.9)	Prospective or retrospective : Prospective Cross-sectional or longitudinal : Cross sectional - group means are presented (not change scores) Design : experimental Randomised : All children randomly assigned to 1 of 3 sequences of AFO use following a 3 month baseline period of no AFO use. Allocation concealment: unclear Similar prognosis at baseline : unclear Blinded subjects : n Blinded therapists : n Blinded assessors : n >85% follow up : y ITT analysis : y Because of the number of variables analyzed using ANOVA, Bonferonni corrections were used to set the level of significance for	Funding : Shriners Hospitals for Children Consent : Informed consent was obtained for each child Ethical approval : Shriners Hospitals for Children and the Institutional Review Board of the Oregon Health Sciences University, Portland

	involved in ongoing PT during their participation	AFO movement details : complete Orthotic Aim : not given AFO ankle angle details : complete toe plate length details :full length materials details : complete alignment details : not given prefab or custom : custom randomised testing order : y acclimatisation time : >4wks	HAFO = 18.6 (8.3)a,b PLS = 14.8 (7.3)a SAFO = 12.5 (5.3)a Peak dorsiflexion time, % Barefoot = 27 (14) HAFO = 46 (5)a,b PLS = 38 (13)a SAFO = 36 (13)a Peak dorsiflexion swing Barefoot = –3.6 (13.9) HAFO = 8.3 (5.5)a PLS = 6.9 (4.6)a SAFO = 7.2 (5.6)a Range Barefoot = 29.7 (14.8) HAFO = 16.5 (5.7)a PLS = 14.6 (4.5)a SAFO = 10.6 (3.8)a Velocity, m/s Barefoot = 1.08 (0.22) HAFO = 0.98 (0.21)b PLS = 1.11 (0.19) SAFO = 1.04 (0.18) Ankle range (p≤0.025) Dorsiflexion knee extension, degrees Barefoot = 8 (5) HAFO = 10 (7) PLS = 8 (6) SAFO = 8 (5) Dorsiflexion knee flexion, degrees Barefoot = 17 (9)	each variable category. Owing to the lack of a significant difference between the right and left lower extremity variables (paired t-tests), the right extremity values were randomly selected for analysis. In the three participants who were braced unilaterally, the braced lower extremity was analyzed. This approach to data analysis was preferred to combining data from both lower extremities into one database, as the latter approach falsely represents the number of participants	

			HAFO = 19 (8) PLS = 18 (9) SAFO = 15 (6) GMFM (p≤0.025) Standing Barefoot = 35.4 (2.7) HAFO = 35.5 (3.0) PLS = 35.6 (3.1) SAFO = 35.8 (2.8) Walking/Running/Jumping Barefoot = 57.1 (12) HAFO = 61.0 (10.9)a PLS = 60.8 (10.3)a SAFO = 60.6 (10.5)a PEDI (p≤0.025) Mobility Functional skills Shoes on/No AFO = 51.2 (2.7) HAFO = 51.9 (2.8) PLS = 52.9 (2.6) SAFO = 52.6 (3.2) Caregiver assistance Shoes on/No AFO = 34.1 (1.4) HAFO = 34.5(1.1) PLS = 34.3 (1.8) SAFO = 34.4(1.3) Percentage of children able to master item (i.e. keep up with peers) Item 31: walk between rooms Shoes on/No AFO = 31		

			HAFO = 25 PLS = 38 SAFO = 44 Item 44: walk more than 150 feet Shoes on/No AFO = 13 HAFO = 0 PLS = 0 SAFO = 13		

Bibliographic details	Number of Participants Characteristics	Intervention characteristics	Outcome measures and results	Quality assessment	Reviewer comment
Periodical Journal of Pediatric Orthopaedics **Authors** Rethlefsen,S., Kay,R., Dennis,S., Forstein,M., Tolo,V. **Year of publication** 1999 **Study location** USA **Ref ID** 76781 **Type of study** Randomised controlled study **Aim of study** To quantify the effects of fixed and articulated AFOs on gait in children with CP and determine whether one type results in improved mechanics. Secondarily, to determine patient criteria for use of fixed and articulated AFOs	**Inclusion Criteria** 1) No more than 15 degrees hip flexion contractures 2) Popliteal angles of <45 degrees 3) 5 degrees or more dorsiflexion range of motion available with the knee extended 4) Independent ambulation without assistive devices 5) No orthopaedic or neurosurgery in the preceding year **Exclusion Criteria** Not stated **Baseline characteristics** 21 children with diplegia Mean age 9.1 SD 2.2 yrs (range 5.3 - 13.5 yrs) All participants used fixed or articulated AFOs at the time of enrollment or were in need of orthoses.	Intervention : SAFO(fixed) or HAFO (articulated) Control : shoes Procedures 18/21 sparticipants had both a pair of SAFOs (fixed) and a pair of HAFOs (articulated) made from the same mold by the orthotist involved in the project. A pair of SAFOs (fixed) were made for each of the remaining 3 participants who already had HAFOs (articulated) that fit and functioned appropriately. Subjects followed individualised schedules alternating between the 3 footwear conditions (shoes, SAFO, HAFO) every 3 days for 4-6 weeks. The order was determined randomly for each child. The order of gait assessment with the 3 footwear conditions (shoes, SAFO, HAFO) was also randomly determined. Subjects were asked to walk at a self-selected speed making several passes through the laboratory under each footwear condition, with surface EMG electrodes, until 3 clean foot-plate strikes were achieved for both sides.	Outcomes : level walking Ankle dorsiflexion, Initial contact n=42 No AFO (shoes on) = -0.6±6 HAFO = 4±5 SAFO = 3±4 Ankle dorsiflexion,terminal stance n=42 No AFO (shoes on) = 8 ± 8 HAFO = 13 ± 6 SAFO = 8 ± 4 Knee, initial contact (degrees) n=42 No AFO (shoes on) = 27 ± 13 HAFO = 28 ± 12 SAFO = 26 ± 11 Knee, terminal stance (degrees) n=42 No AFO (shoes on) = 12 ± 10 HAFO = 13 ± 10 SAFO = 11 ± 10 Velocity (m/min) n=40 No AFO (shoes on) = 63.2 ± 8.4 HAFO = 64.5 ± 9 SAFO = 63.6 ± 12	Prospective or retrospective : Prospective Cross-sectional or longitudinal : Cross sectional Design : experimental Randomised : random allocation to sequence of tx with FAFO, DAFO or shoes Allocation concealment: No Similar prognosis at baseline : unclear Blinded subjects : No Blinded therapists : No Blinded assessors : No >85% follow up? : Yes ITT analysis : Yes	Funding : United Cerebral Palsy Research and Educational Foundation Ethical approval : not stated Consent : not stated

		AFO movement details : complete Orthotic Aim : ambiguous AFO ankle angle details : unclear toe plate length details :not given materials details : not given alignment details : not given prefab or custom : custom acclimatisation time : alternating 3 days wear for 3 footwear conditions over 4-6 weeks			

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Periodical Developmental Medicine and Child Neurology **Authors** Buckon,C.E., Thomas,S.S., Jakobson-Huston,S., Sussman,M., Aiona,M. **Year of publication** 2001 **Study location** **Ref ID** 76476 **Type of study** Randomised controlled study **Aim of study** To examine the effectiveness of the hinged ankle–foot orthosis (HAFO), posterior leaf spring (PLS), and solid ankle–foot orthosis (SAFO), in preventing contracture, improving efficiency of gait, and enhancing performance of functional motor skills in children with spastic hemiplegia	**Inclusion Criteria** 1) Aged from 4 to 18 years 2) capable of independent ambulation without assistive devices 3) using an AFO at the time of enrollment or with AFO use indicated 4) no orthopedic or neurosurgical intervention in the preceding year 5) Diagnosis of hemiplegia **Exclusion Criteria** not stated **Baseline characteristics** 30 children with hemiplegia were recruited Male :21 Female : 9 Left hemiplegia : 16 Right hemiplegia : 14 Mean age : 9y 4m (range =5y3m - 15y3m) At baseline each child was assessed barefoot. Two older children had a history of tendo-achilles lengthening 6-7 years before their participation in the study. One child dropped out of the study after the baseline assessment due to refusal to wear an AFO during the day	Intervention : hinged AFO (with plantarflexion stop), solid AFOs and PLS Control : barefoot or shoes Procedures An ankle mold was made for each child upon initiation intothe study by a single orthotist and the original mold was used to fabricate all three AFO configurations. Each AFO was worn daily for 6 to 12 hours and removed at night over a period of 3 months.Each child walked at a self-selected speed along a 7.5 meter walkway. A total of 10 to 20 walking trials were performed in order to obtain five right and five left trials with useful forceplate data. Data from three representative trials for each side were averaged and mean values were used for analysis. AFO movement details : complete Orthotic Aim : not given AFO ankle angle details : complete toe plate length details :full length materials details : complete alignment details : not given	Outcomes: Passive ankle ROM, gait analysis and energy expenditure. GMFM, GMPM and PEDI All assessments were performed by one of two clinicians with each child's clinician remaining constant throughout the study.Assessments were performed at baseline and at the end of each 3 m period, and therefore consisted of 4 assessments during 1 year Due to the number of variables analyzed using ANOVAs, Bonferonni corrections were used to set a level of significance for each variable category. Significance levels were set as follows: p <0.05 for gait kinetics; p<0.025 for ankle range of motion, GMFM, and PEDI; p <0.017 for ankle and knee kinematics and energy consumption; p <0.0125 for gait parameters, and p<0.007 for the GMPM. Ankle dorsiflexion,°Knee extended Barefoot = 5 (6) HAFO = 7 (5) PLS = 7 (4)	Prospective or retrospective : Prospective Cross-sectional or longitudinal : Cross sectional - group means are presented (not change scores) Design : experimental Randomised : All children randomly assigned to 1 of 3 sequences of AFO use following a 3 month baseline period of no AFO use. . Allocation concealment: unclear Similar prognosis at baseline : unclear Blinded subjects : n Blinded therapists : n Blinded assessors : n >85% follow up : y ITT analysis : y Between group statistical analysis : n	Funding : Shriners Hospitals for Children Consent : Informed consent was obtained for each child Ethical approval : Shriners Hospitals for Children and the Institutional Review Board of the Oregon Health Sciences University, Portland

		prefab or custom : custom randomised testing order : y acclimatisation time : >4wks	SAFO = 6 (4) Ankle dorsiflexion,°Knee flexed Barefoot = 12 (6) HAFO = 14 (6) PLS = 14 (6) SAFO = 13 (4) Ankle dorsiflexion, Initial contact Barefoot = –11 (6) HAFO = 3 (4) PLS = –0.2 (5) SAFO = 2 (4) Ankle dorsiflexion, Peak stance Barefoot = 6 (5) HAFO = 16 (6) PLS = 13 (7) SAFO = 11 (5) Ankle dorsiflexion, Dynamic range Barefoot = 26 (7) HAFO = 16 (4) PLS = 15 (4) SAFO = 11 (3) Group mean (SD) for Velocity (m/s) No AFO (barefoot) = 1.07 (0.22) HAFO = 1.14 (0.16) PLS = 1.18 (0.17) SAFO = 1.11 (0.17)		

			Group mean (SD) for GMFM GMFM dimension Stand No AFO (barefoot) = 37.6 (2) HAFO = 37.9 (1) PLS = 37.8 (1) SAFO = 38.0 (1) GMFM dimension Walk/Run/Jump No AFO (barefoot) = 67.1 (5) HAFO = 68.1 (3) PLS = 68.1 (3) SAFO = 67.6 (4) Group mean (SD) for number of children able to master select PEDI items No AFO (shoes on) = HAFO = PLS = SAFO = PEDI Mobility dimension Functional Skills No AFO (shoes on) = 55.4 (2) HAFO = 56.7 (2) PLS = 56.6 (2) SAFO = 56.8 (2) Indoor/Outdoor Locomotion Distance/Speed Item 31 : moves between rooms – no difficulty No AFO (shoes on) = 24/30 HAFO = 23/30 PLS = 27/30 SAFO = 23/30		

			Item 44 : moves 150 feet or longer – no difficulty No AFO (shoes on) = 8/30 HAFO = 15/30 PLS = 18/30 SAFO = 11/30		

Bibliographic details	Number of Participants Characteristics	Intervention characteristics	Outcome measures and results	Quality assessment	Reviewer comment
Periodical Gait and Posture **Authors** Sienko,Thomas S., Buckon,C.E., Jakobson-Huston,S., Sussman,M.D., Aiona,M.D. **Year of publication** 2002 **Study location** USA **Ref ID** 98325 **Type of study** Randomised controlled study **Aim of study** To determine whether different AFO configurations have a detrimental effect on both funtion and kinematics during stair locomotion in children with spastic hemiplegia	**Inclusion Criteria** Patients recruited from larger study of children with cerebral palsy. Inclusion criteria were 1) 4 - 18 years of age 2) no ankle or foot surgery 1 year prior to enrollment 3) independent ambulation 4) Require AFO useas indicated by a physician **Exclusion Criteria** Not stated **Baseline characteristics** 19 children with hemiplegia were included in the analysis. They were able to ascend and descend the stairs reciprocally during the barefoot assessment with or without the use of a handrail. Mean Age : 9±3 yrs (range : 6-15 years) Mean height : 138.7 cm (range : 122-173cm) Mean weight : 34.7kg (range 19-75kg)	Intervention : SAFO, HAFO, PLS with child's own shoes (for each evaluation and with attempt made to keep the shoes constant throughout the study) AFO movement details :incomplete Orthotic Aim : incomplete AFO ankle angle details : not given toe plate length details : not given materials details : not given alignment details : not given prefab or custom : custom randomised testing order : yes acclimatisation time : 3 months for each condition Control : barefoot Comparisons relevant to this review : 1) Barefoot vs SAFO 2) SAFO vs HAFO 3) SAFO vs PLS Procedure Each child participated in the study for a year. After 3 months of no AFO wear children then followed 3 months of SAFO, HAFO and PLS wear according to a	Gait parameters : Velocity = the amount of time required for the limb to move the distance from stair one to stair three with an average of three trials from each limb used in the analysis. Between group statistical analysis : yes - ANOVA, significance set at p=0.025 for gait parameters Velocity ascent (time for distance stair 1 to stair 3) 1) Barefoot vs SAFO Barefoot = 0.280 ± 0.06 SAFO = 0.270 ± 0.07 P= No significant difference (reported) 2) SAFO vs HAFO SAFO = 0.270 ± 0.07 HAFO = 0.281 ± 0.07 P= No significant difference (reported) 3) SAFO vs PLS SAFO = 0.270 ± 0.07 PLS = 0.304 ± 0.07 P= No significant difference (reported) Velocity descent (time for distance stair 3 to stair 1) 1) Barefoot vs SAFO Barefoot = 0.259 ± 0.06 SAFO = 0.296 ± 0.10	Prospective or retrospective Prospective Cross-sectional or longitudinal Cross sectional Design : Experimental Randomised : random allocation to order of treatment with SAFO, HAFO or PLS Allocation concealment : no details Similar prognosis at baseline : unclear Blinded subjects : no Blinded therapists : no Blinded assessors : no >85% follow up? : yes ITT analysis : yes	Funding : Shriners Hospitals for Children Consent : Participants gave written consent Ethical approval : Institutional Review Board

		randomised treatment order. Assessments were performed at the end of each condition's period. Each child reciprocally ascended and descended 4 stairs (rise = 15.2cm, run = 24.1cm, slope = 32 degrees) which were smaller and less steep than those found in the community (slope = 36.8 degrees) Stair ascent cycle = foot contact (involved or uninvolved) on stair one to foot contact with the same foot on stair three. Stair descent cycle = foot contact (involved or uninvolved) on stair three to foot contact with the same foot on stair one. The average of three trials for both the involved and uninvolved limbs were used for the analysis of stair ascent and descent.	P= No significant difference (reported) 2) SAFO vs HAFO SAFO = 0.296 ± 0.10 HAFO = 0.280 ± 0.08 P= No significant difference (reported) 3) SAFO vs PLS SAFO = 0.296 ± 0.10 PLS = 0.323 ± 0.11 P= No significant difference (reported) Kinematic data for stair locomotion : No relevant kinematic data (in stance and swing) Functional impact of AFO configurations on stair locomotion assessed by structured interviews with parents, using stair specific outomes from PEDI % of children capable of performing (defn keeping up with peers) Item 54 (walks up entire flight without difficulty) and Item 59 (walks down entire flight without difficulty). Between group statistical analysis : yes - Cochran Q-test, significance set at p<0.05 Ascent PEDI Item 54 (keeps		

			up with peers) 1) Barefoot vs SAFO Barefoot = 6/19 SAFO = 9/19 P= No significant difference (reported) 2) SAFO vs HAFO SAFO = 9/19 HAFO = 12/19 P= No significant difference (reported) 3) SAFO vs PLS SAFO = 9/19 PLS = 8/19 P= No significant difference (reported) Descent PEDI Item 59 (keeps up with peers) 1) Barefoot vs SAFO Barefoot = 5/19 SAFO = 7/19 P= No significant difference (reported) 2) SAFO vs HAFO SAFO = 7/19 HAFO = 10/19 P= No significant difference (reported) 3) SAFO vs PLS SAFO = 7/19 PLS = 6/19 P= No significant difference (reported)		

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Periodical Gait and Posture **Authors** Radtka,S.A., Skinner,S.R., Johanson,M.E. **Year of publication** 2005 **Study location** USA **Ref ID** 98326 **Type of study** **Aim of study** To compare the effects of solid and hinged ankle foot orthoses on the gait of children with s[astic diplegic cerebral palsy who ambulate with excessive ankle plantar flexion during stance	**Inclusion Criteria** Patients recruited from regular outpatients clinical for children with cerebral palsy. Inclusion criteria were each child 1) ankle dorsiflexion to 0 degrees in weightbearing during static standing 2) excessive ankle plantarflexion of 5 degrees or more during stance in gait 3) passive ankle dorsiflexion of 5 degrees with knee extended 4) passive hip extension to -10 degrees or less as measured by the Thomas test 5) passive hamstring length of 50 degrees or more as measured by a straight leg raise 6) mild spasticity of the triceps surae, hamstring and quadriceps or a score of 1 (Ashworth) mild resistance at the end range of passive motion. **Exclusion Criteria** Not stated **Baseline characteristics** 12 children with diplegia who ambulate with excessive ankle plantar flexion during stance Mean age 7.5 SD 3.83 yrs (range 4-16 yrs) None of the subjects had ever undergone Achilles tendon or	Intervention : Solid and hinged AFO (with shoes) AFO movement details : clear Orthotic Aim : complete AFO ankle angle details : complete toe plate length details : full length materials details : complete alignment details : not given prefab or custom : custom randomised testing order : y acclimatisation time : 1 month Control : barefoot Comparisons relevant to this review : 1) Barefoot vs SAFO 2) SAFO vs HAFO Procedures : Each child wore no orthoses for an initial 2 wks baseline period, solid or hinged AFOs for 1 month, no orthoses for 2 wks, and solid or hinged AFOs AFO for 1 mth. The order was randomly assigned. Children were asked to walk on a 10m walkway at a self-selected speed without being informed of the position of footplates and with active surface electrode pairs on lower limbs and footswitches	Outcomes : EMG, 3 dimensional motion analysis and temporal-distance characteristics, knee and ankle sagittal joint moments and powers during the stance phase Outcomes were assessed at the end of the initial 2 week period with no orthoses for a baseline measurement, the 1 month period wearing solid AFOs and the 1 month period wearing hinged AFOs (NB not at the end of the second 2 week period with no orthoses) Group means with standard deviations were calculated for outcomes. ANOVA with repeated measures was used to examaine the barefoot and AFO configurations on these coutomes at an alpha level of 0.05. For signicicant ANOVA tests, three post-hoc pairwise comparisons (SAFO vs HAFO, No AFO vs SAFO and No AFO vs HAFO) were conducted using Tukey's Honestly Significant Difference Test to determine significant differences at an alpha level of 0.05. Temporal-distance gait	Prospective or retrospective : Prospective Cross-sectional or longitudinal : Cross sectional Design : Experimental Randomised : random allocation to order of treatment with SAFO or HAFO Allocation concealment : n Similar prognosis at baseline : n Blinded subjects : n Blinded therapists : n Blinded assessors : n >85% follow up : y ITT analysis : y	Funding : Shriners Hospitals for Children Consent : Parents or participants aged over 12 gave written consent Ethical approval : Institutional Review Board, University of California

	gastrocnemius lengthening surgical procedures in the past or any other orthopaedic surgery during preceding year. 10 subjects ambulated without assistive devices. 9 subjects wore rigid AFO and 3 subjects used hinged AFO for at least 1 year prior to participation.	alone the entire plantar surface of both feet for the barefoot baseline test and on the shoes for tests with both orthoses. 2 trials with 4 -6 gait cycles per condition were averaged for each subject.	characteristics : Velocity (cm/sec) 1) Barefoot vs SAFO Barefoot = 90.62 ± 23.02 SAFO = 94.70 ± 22.07 P = No significant difference (reported) 2) SAFO vs HAFO SAFO = 94.70 ± 22.07 HAFO = 99.63 ± 20.53 P = No significant difference (reported) Ankle dorsi/plantarflexion at initial contact - post hoc analysis 1) Barefoot vs SAFO Barefoot = -8.14 ± 5.46 SAFO = 7.09 ± 5.06 P < 0.05 (reported) 2) SAFO vs HAFO SAFO = 7.09 ± 5.06 HAFO = 5.37 ± 7.00 P = No significant difference (reported) Ankle dorsi/plantarflexion at terminal stance - post hoc analysis 1) Barefoot vs SAFO Barefoot = -1.30 ± 6.59 SAFO = 11.50 ± 4.28 P < 0.05 (reported) 2) SAFO vs HAFO SAFO = 11.50 ± 4.28		
			HAFO = 16.13 ± 6.17 P < 0.05 (reported)		

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Periodical American Journal of Physical Medicine and Rehabilitation **Authors** Carlson,W.E., Vaughan,C.L., Damiano,D.L., Abel,M.F. **Year of publication** 1997 **Study location** USA **Ref ID** 76482 **Type of study** Randomised controlled study **Aim of study** To compare the effects of a fixed AO, a SMO and a no brace condition, but including shoes	**Inclusion Criteria** Patients recruited from regular outpatients clinical for children with cerebral palsy. Inclusion criteria were each child 1) had to be ambulatory 2) have no fixed joint contractures requiring surgery 3) had to exhibit a dynamic equinus or crouch gait 4) have no varus or valgus hindfoot instability **Exclusion Criteria** Not stated **Baseline characteristics** 11 children with diplegia and spastic equinus rigid hindfoot Mean age 6.9y Age range 4-11yrs Males n=6, Females n=5 9 children had no history of surgery, 2 children had a history of adductor and tendo-achilles lengthening on both sides 9 children were independent walkers, 1 child was an independent walker with AFOs and one ambulated aroundthe house with a walker Prior bracing : 5 children had had AFOs, 5 children had had AFOs and SMOs and one child had previously had SMOs only	Intervention : rigid AFO, SMO with no plantar flexion stop Control : shoes only AFO movement details : clear Orthotic Aim : complete AFO ankle angle details : not given toe plate length details : not given materials details : not given alignment details : not given prefab or custom : not given randomised testing order : y acclimatisation time : one month Procedures : Subjects were bought a pair of shoes at the start of the protocol and were required to wear them during the 4 months of the experiment and throughout the gait studies. Each subject made 4 difference visits to the gait lab with visits spaced one month apart. Month 1 : after wearing no brace for one month a baseline test of walking with shoes but no orthosis was performed Month 2 : the child wore an AFO or SMO (as randomised) inside the shoes for one month	Outcomes : Temporal-distance, kinematic and kinetic parameters were assessed using data averaged from three walking trials for each or the right and left sides. There were no statisitically significant differences between the left and right sides (from preliminary data) therefore the two sides were averaged for each patient before making comparisons among the baseline, AFO and SMO conditions. Velocity (m/s) - group mean SAFO = 1.00 ± 0.19 SMO = 1.00 ± 0.20 P= No significant difference (reported) Ankle dorsiflexion angle at foot strike (degrees) - group mean SAFO = 10.0 ± 6.0 SMO = 3.3 ± 7.0 P < 0.05 (reported)	Prospective or retrospective : Prospective Cross-sectional or longitudinal:Cross sectional Design : experimental Randomised : random allocation to order of treatment with SAFO or SMO Follow up length : 4 months Allocation concealment: No Similar prognosis at baseline : unclear Blinded subjects : No Blinded therapists : Unclear Blinded assessors : unclear >85% follow up? : Yes ITT analysis : Yes	Funding : supported in part by a grant NIH HD30134 from the US Public Health Service and grant H133P10006 from the US Dept of Education Ethical approval : Approved by the authors institution's Human' Subjects Committee Consent : All subjects (or their families) signed a consent form

	In most cases clinic notes indicated that there was only mild involvement of both sides and all children were considered to be community ambulators	and returned for testing Month 3 : after wearing no brace for one month a 2nd baseline test of walking with shoes but no orthosis was performed Month 4 : the child wore an AFO or SMO (as randomised) inside the shoes for one month and returned for testing Subjects walked at their freely selected speed during each gait testing session where they were asked to perform between 10-20 walking trials (usually) before the desired minimum of 3 clean strikes for each foot were obtained on force plates. The subjects had no difficulty in performing this amount of walking Temporal-distance, kinematic and kinetic parameters were assessed using data averaged from three walking trials for each or the right and left sides.			

Bibliographic details	Number of Participants Characteristics	Intervention characteristics	Outcome measures and results	Quality assessment	Reviewer comment
Periodical Neurorehabilitation **Authors** Elliott,C.M., Reid,S.L., Alderson,J.A., Elliott,B.C. **Year of publication** 2011 **Study location** Australia **Ref ID** 132638 **Type of study** Randomised controlled study **Aim of study** To investigate the effects of lycra arm splint wear on goal attainment and three dimensional kinematics of the upper limb and trunk in children with cerebral palsy (CP)	**Inclusion Criteria** Children diagnosed with hypertonic CP **Exclusion Criteria** Not reported **Baseline characteristics** n=16 Age / years (mean±SD, range): 11.5±2.2, 8 - 15 Sex (n) Male: 8 Female: 8 3 children had quadriplegia and 13 had hemiplegia Hypertonic responses (n): - Spastic: 10 - Dystonic: 5 - Rigid: 1 Functional ability of the affected upper limb ranged from 27 - 85 on the Melbourne Assessment of Unilateral Upper Limb Function. No significant difference was identified between the two groups in Melbourne assessment score, maximum elbow extension, and maximum supination. No children had Botulinum	Randomisation The study used a randomised parallel group trial with waiting list control design. Participants were randomised to two groups. Group 1 completed a splint-wearing regime combined with goal directed training for three months. Group 2 completed goal directed training only, therefore acting as a control population. Subsequently, group 2 then completed the splint-wearing regime combined with goal directed training for three months. Intervention: The intervention consisted of three months of lycra arm splint wear, combined with goal directed training. The Second Skin lycra splints were individually custom designed, and consist of sections of lycra stitched or under tension with a specific direction of pull. The arm splint extends from the wrist to the axilla, and is designed to promote better hand and arm function by	GAS-T scores at 3 months Group 1 Mean change ± SD = 53 ± 5.0 Group 2 Mean change ± SD = 35 ± 6.8 The authors note that a change score ≥50 represented the expected change in goal attainment over the 3 month period.	Prospective or retrospective: prospective Cross-sectional or longitudinal: longitudinal Design: experimental Randomised: method of randomisation not reported Allocation concealment: unclear Similar prognosis at baseline: yes - no significant difference in Melbourne Assessment Blinded subjects: no Blinded therapists: unclear Blinded assessors: unclear, also not reported who measured RoM. >85% follow up: yes ITT analysis: yes	Further details of methodology can be found in an excluded study, Elliott et al. 2011, which did not report any outcomes relevant to the review, but describes methodology in more detail. Funding: All splints were provided by Second Skin, but the company had no involvement in study design, data collection, analysis or interpretation, or preparation of the manuscript. Consent: Written informed consent was attained from each participating family Ethical approval: From University of Western Australia

	Neurotoxin-A or lycra splinting within previous two years.	addressing postural and tonal issues impacting on the elbow, by addressing either pronation-flexion or supination-extension. The pronation-flexion splint is designed for children whose functional performance is limited by strong elbow extension and supination. The supination-extension splint is designed for those whose performance is limited by strong elbow flexion and pronation. - The participants wore their arm splints during school hours, approximately 6 hours per day, 5 days per week. The goal directed training consisted of active practice of task-specific activities related to the child's functional goals. Active practice was incorporated into the child's daily routine taking approximately 25 minutes to complete. <u>Assessment</u> - The children were assessed at baseline and then at 3 months. All baseline assessments were completed with the splint off. The three months condition was performed wearing the splint,			

		following three months of the splinting intervention. <u>Data analysis</u> To determine the effect of the splint on variables, repeated measures ANOVAs were conducted to analyse differences between the splinting conditions for the entire cohort of participants. Each independent variable had four levels (k=4). The assumptions of normality, homogeneity of variance and sphericity were met for all variables. A medium effect size of 0.5 was used to establish functional differences between changes over time that were shown to be significantly different.			