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PROTOCOL

Cerebral Palsy: Ankle Foot Orthoses - Footwear Combinations

August 7, 2018

Study Protocol

Version: 1.0 August 7, 2018

Ankle Foot Orthoses – Footwear Combinations (AFO-FC): Biomechanics and Walking Activity in Cerebral Palsy

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Study site:

Orthocare Innovations- Biomechanics Laboratory

Contents

List of Abbreviations

AFO-	Ankle foot orthoses
AFO-FC	Ankle foot orthoses- footwear combinations
CP	Cerebral Palsy
ROM	Range of motion
GPS	Global Position System
ASKp	Activities Scale for Kids – Performance
LifeH	Assessment of Life Habits
OPUS	Orthotics and Prosthetics Users Survey
GMFCS	Gross Motor Function Classification System
MACS	Manual Ability Classification System
SW	StepWatch accelerometer

Research Synopsis

Study Title: Ankle Foot Orthoses – Footwear Combinations: Biomechanics and Walking Activity in Cerebral Palsy

Study Population: Children ages 4 – 14 years, inclusive, with ambulatory unilateral or bilateral cerebral palsy (CP).

Study Design: A prospective pre/post intervention study with 10 ambulatory children with CP will compare their current AFO to the AFO-FC. Participants will be recruited from the Rehabilitation clinic and Physical Therapy patient caseloads of the investigators. Maximal knee extension in stance as well as gait speed (aim 1) will be captured by gait analysis at the Orthocare Innovations biomechanics laboratory in Mountlake Terrace. Community walking activity will be captured with the ankle-worn StepWatch accelerometer (aim 2). Mobility based participation in day to day life will be documented by parental report of the Assessment of Life Habits for Children (Life-H). Physical activity will be sampled with the Activity Scale for Kids – Performance (ASKp) and satisfaction with the respective devices will be examined with parental report of the Orthotic and Prosthetic Users' Survey (OPUS).

Two outpatient study visits will be carried out before (baseline) and after (follow-up) the standard of care clinical visits to cast/fabricate and fit the participants' new AFO-FC devices. At the baseline study visit, informed consent/assent, three dimensional gait analysis, parental report of mobility-based community participation, physical activity and satisfaction with device will be carried out while wearing their current orthoses. At the end of that visit, the participant will go home wearing the StepWatch accelerometer and GPS monitors for 2 weeks. The accelerometer will be returned to study staff by postage paid envelope. The child then has the appropriate clinical visits to cast, fabricate, fit and tune their new AFO-FC with a home walking program as appropriate. Consistency of clinical AFO-FC prescription will be addressed by the use of the published algorithm,[1] (Appendix) currently utilized clinically by the investigators here at Seattle Children's Hospital (SCH). All the AFO (plastic brace) portions of the AFO-FC devices will be casted at SCH and fabricated at Cascade DAFO (Dynamic Ankle Foot Orthoses), Inc.. The family of the participant will supply the footwear (shoes). The footwear portion of the AFO-FC will be modified, fitted and tuned along with the AFO portion by the SCH orthotists and Dr Bjornson. Three months after the AFO-FC is tuned and finalized, they will return for the second study visit (follow-up) where all outcomes are collected again.

These results will provide the preliminary data essential for development and federal funding of a randomized clinical trial comparing current standard of practice "traditional' AFO to the AFO-FC approach. Study participation takes 12-16 weeks within clinical orthotic management.

Primary Objective: Examine the effect of AFO-FC on the primary outcomes of maximal knee extension during stance and gait speed as compared to current AFO prescription.

Secondary Objectives: Examine the effect of AFO-FC on daily walking activity, intensity and mobility-based participation and satisfaction as compared to current AFO prescription.

Sample Size: 10 children.

Study Duration: 12 months ending Sept 30, 2015.

Background and Significance

Cerebral palsy (CP) is the most common and costly neuromuscular condition among children in the US [2, 3], with a prevalence of 3.3-3.8/1000 [4] The clinical definition of CP is a group of disorders of movement and postural development which result in physical activity limitations. [5] A novel and comprehensive strategy has been articulated in the AFO-FC approach[11], but neither the previous strategy (AFO type)[12] nor the new strategy (AFO-FC)[11] has strong published evidence of efficacy.(Fig 1)

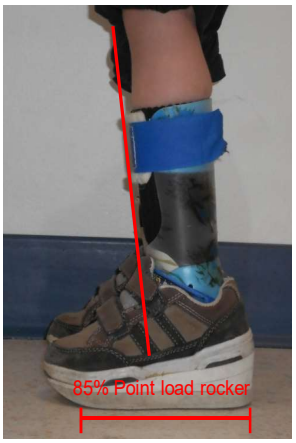
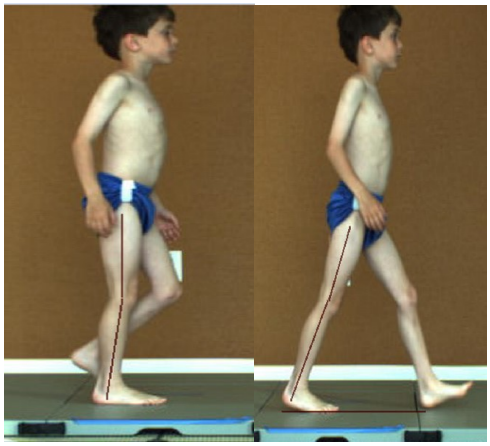


Figure 1 AFO-FC.

As typically developing children walk, the lower extremity segments (femur, tibia and foot) align such that the knee extended (straight) during midstance. This allows support of body weight transfer during single limb support and swing through of the opposite leg while walking.(See Figure 2) During terminal stance when the heel is leaving the ground, the segments of the leg demonstrate a straight knee allowing an adequate step length and weight transfer as the opposite foot contacts the surface.[13]

In contrast, ambulatory children with CP present with crouch gait characterized by misalignment of the segments of the lower extremity (femur, tibia and foot). This misalignment of lower leg segments does not adequately support the transfer of weight with a resulting inefficient walking pattern.[14] (Figures 3-5) During midstance when the foot should be flat on the surface, youth with CP present with either excessive or insufficient lower limb inclination (tibia) from vertical to support weight on one leg. For example crouch gait (Figure 3 & 4) is defined as excessive knee flexion in single limb stance. Excessive knee flexion during stance requires additional effort to walk,[15] causing fatigue and reducing walking behavior in children with CP. It can be observed visually, but only computerized gait analysis has sufficient accuracy to inform clinical decisions. This heterogeneity of walking patterns in CP requires an individualized approach to orthotic prescription as well as motor training to optimize walking skills.[13]

Fig. 2. TYPICALLY DEVELOPING GAIT:
MIDSTANCE **TERMINAL STANCE**



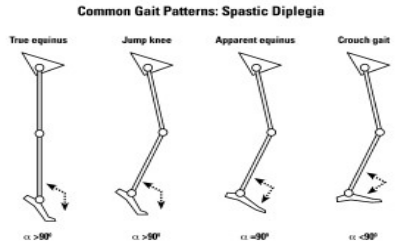


Fig 3. Abnormal leg segment alignment in CP

The current regional (Pacific Northwest) standard of care for orthotic prescription in ambulatory CP is usually an AFO that allows ankle movement (See Figure 4). This approach does not provide adequate alignment of the segments of the leg (knee is flexed) during midstance and terminal stance), which is due to insufficient control and weakness of the muscles about the ankle joint. A crouch gait walking pattern creates excessive demand on the knee extensors, results in shorter strides and an inefficient walking pattern. The habitual use of a crouch gait pattern significantly increases the energy cost of walking. [16] In fact, a crouch gait pattern is associated with the need for future orthopedic surgery [15] and an overall decrease in physical activity into adulthood.[17] In contrast, the AFO-FC approach with individualized segment alignment and shoe modifications limits ankle movement and appears to enhance knee extension during mid and terminal stance. (See Figure 5)

As compared to typically developing children, youth with CP take significantly fewer steps per day and spend less time walking and engaging in activities of high intensity.[18] van den Berg-Emons et al. reported that school children with spastic diplegic CP were less physically active than a healthy control group and that a typical child with CP would need to exercise 2.5 hr/day to reach the activity level of peers.[19] Children with CP have also been described as having one of the most sedentary lifestyles among pediatric disabilities.[20]. In a study of school-based activity performance and participation in Israel, youth with CP had significantly lower physical activity performance as measured by the School Function Assessment (SFA). The youth with CP participated significantly less often than their typically developing peers in daily school activities (i.e., playground games and moving to other areas of the school).[21] Walking mobility has also been shown to be predictive of restrictive participation in mobility, education, and social relations for children with CP.[22]

It is important to consider the implications of walking activity across the life span. In a California Developmental Disabilities Database study, Strauss, and colleagues (2004) reported the longitudinal functional skills of adults with CP at the ages of 20, 40 and 60 years. A marked decline in walking ability especially in late adulthood (age 60), was documented.[23] Self-reported functional walking in the community setting in late adulthood was associated with a longer life expectancy. CP leads to serious health problems that persist into adulthood[2, 24], and interventions to improve mobility are common although

Fig. 4. CEREBRAL PALSY-CROUCH GAIT AFO ALLOWING ANKLE MOVEMENT:
MIDSTANCE TERMINAL STANCE

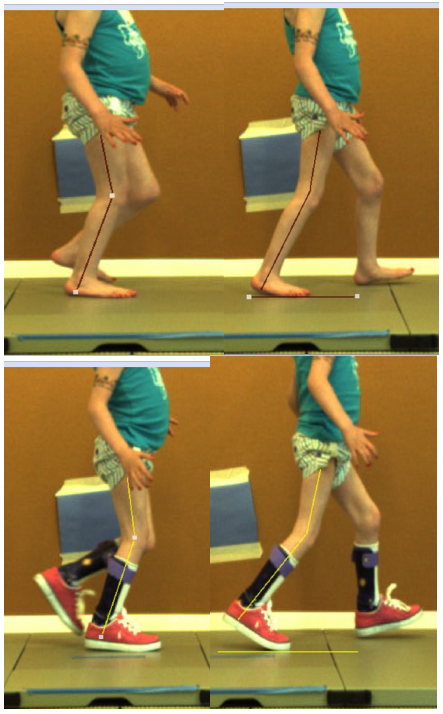
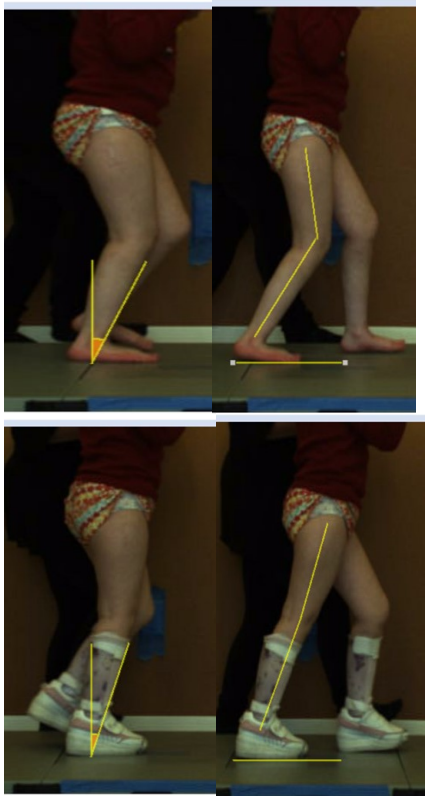


Fig 5. CEREBRAL PALSY-CROUCH GAIT AFO-FC - NO ANKLE MOVEMENT
MIDSTANCE TERMINAL STANCE



only partially effective in altering the progression of the musculoskeletal consequences of the condition.

We have documented improvement in community walking activity with the StepWatch accelerometer in a clinical cohort of 8 children with bilateral CP comparing their current AFO with the AFO-FC approach.[25] The children represented the following gait patterns: 3 equinus, 4 crouch and 1 jump gait (See Figure 6). Current AFO prescriptions all allowed full or partial ankle movement except for one child with a solid ankle without individualized leg segment alignment or shoe modifications. Average strides per day increased for all participants wearing the AFO-FC with an average group increase of 2,611 strides/day and a range increase from 387 to 3020. A minimal clinical important difference (MCID) in daily walking activity of 2,478 stride/day has been calculated from 37 children with CP for the average difference in strides/day walking with an assistive device to without.[26] Thus, our clinical experience with the AFO-FC approach suggests positive influence on community walking activity.

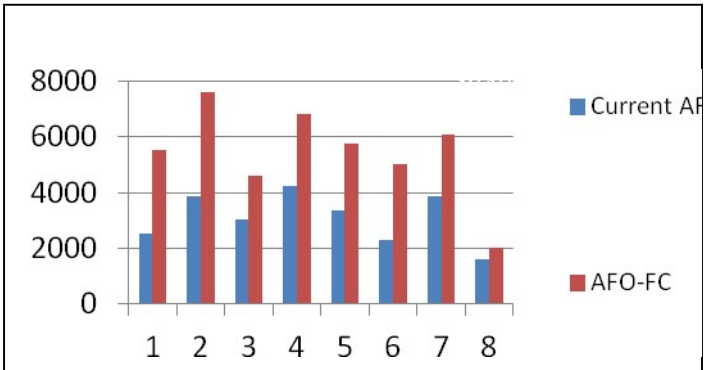


Fig .6 Average strides/day current AFO versus AFO-FC

Summary

The proposed protocol will help to substantiate our clinical experience with this novel approach to orthotic management in ambulatory children with CP. Currently there is no standardized approach for the orthotic management of this heterogenous population. Knowledge generated will lay the foundation for examining the proposed biomechanical mechanisms as well as translation to improved walking in day-to-day life. This work will document the effect of the AFO-FC approach on maximal knee extension in stance and walking speed (Aim 1). We hypothesize that improved knee extension in stance will produce increased walking activity in the community and parental report of mobility-based participation, physical activity and satisfaction with the devices. (Aim 2)

Objectives

Primary Objective

- **Aim 1: Examine the effect of AFO-FC on the primary outcomes of maximal knee extension during stance and gait speed as compared to current AFO prescription.** We hypothesize that 1) the ability to generate adequate knee extension in stance is impaired in their current AFO and contributes to limitations in gait speed and subsequent daily walking levels and intensity, and 2) the individualized leg segment alignment of the AFO-FC will produce positive improvements in knee extension during stance. Increased knee extension during stance will enhance the stability of stance phase, facilitate longer strides lengths and increased gait speed.
- Knee extension during stance and gait speed will be measured by computerized three dimensional gait analyses.
- Walking performance will be measured with the StepWatch accelerometer in each participant's daily environment (39).

Secondary Objectives

- **Aim 2: Examine the effect of AFO-FC on daily walking activity, intensity and mobility-based participation and satisfaction as compared to current AFO prescription.** We hypothesize that AFO-FC through improved knee extension during stance will result in faster walking speed facilitating a positive effect on community walking activity levels, intensity, mobility based day to day participation and satisfaction with device. Walking activity will be captured by the StepWatch accelerometer with participation and satisfaction assessed using parental report questionnaires
- Mobility based participation in day to day life will be documented by parental report of the Assessment of Life Habits for Children (Life-H).
- Physical activity will be sampled with the Activity Scale for Kids – Performance (ASKp)
- Satisfaction with the respective devices will be examined with parental report of the Orthotic and Prosthetic Users' Survey (OPUS).

Study Design and Methodology

We will conduct a prospective pre/post intervention study with 10 ambulatory children with unilateral (hemiplegia) or bilateral (diplegia) CP between the ages of 4 to 14 years. Participants will be recruited from the Rehabilitation clinic and Physical Therapy patient caseloads of the investigators. Two outpatient study visits will be carried out before (baseline) and after (follow-up) the standard of care clinical visits to cast/fabricate and fit the participants' new AFO-FC devices.

Outcomes –Maximal knee extension in stance as well as gait speed (aim 1) will be captured by 3 dimensional gait analysis at the Orthocare Innovations biomechanics laboratory in Mountlake Terrace. Community walking activity will be captured with the ankle-worn StepWatch accelerometer (aim2). Mobility based participation in day to day life will be documented by parental report of the Assessment of Life Habits for Children (Life-H). Physical activity will be sampled with the Activity Scale for Kids – Performance (ASKp) and satisfaction with the respective devices will be examined with parental report of the Orthotic and Prosthetic Users' Survey (OPUS).

Gait Analyses: Two gait analyses at self-selected walking speed will be conducted. At the baseline visit, gait will be recorded barefoot (to characterize gait pattern, Figure 3) and with current orthoses and shoes. Three months later, at Visit 2, gait analysis barefoot and with the AFO-FCs will be performed. To ensure consistency of motion data, markers will be attached by the same experienced lab personnel using the Plug In Gait model. Post-processing of all gait lab data will carried out by one individual. Markers will be placed on the

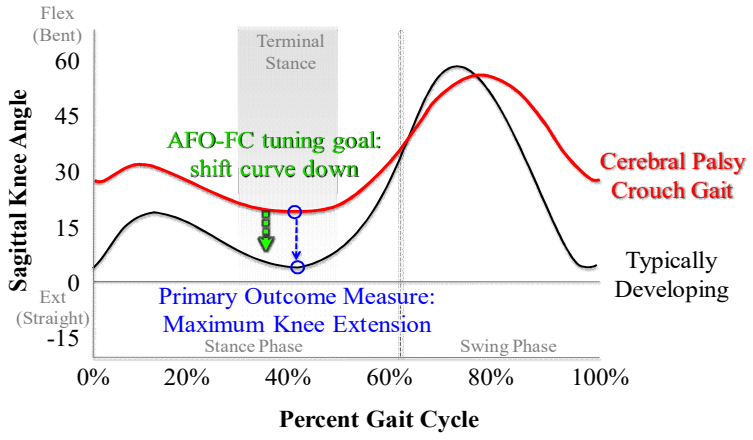


Figure 7. Knee extension output from gait analysis

child to accurately collect the three dimensional joint motions and forces using an 8-camera Vicon MX system with two integrated AMTI force platforms. Primary outcome variable: Maximal knee extension in terminal stance will be extracted from the data to quantify crouch gait in the current AFO vs. the AFO-FC. (Figure 7) Additional joint motion and force data will also be reviewed to understand the interactions of possible gait adaptations displayed by the participants.

StepWatch (SW): Accelerometers will be used to determine how much participants actually walk on a daily basis. The StepWatch (SW) is a small, lightweight device that looks like a pager and is strapped around the ankle. The SW measures the number of steps taken during a day at low, medium and high intensities. Participants will take this device home and wear it during walking hours for two weeks. Participants will return the SW by mail using a stamped mailing envelope supplied to them. The walking activity in average number of steps per day as well as number of steps in each intensity level per day will be obtained. These variables will be averaged for a total week of activity, weekday activity, and weekend activity to be used in the analysis.

Activity Scale for Kids-Performance Version (ASKp): The ASKp, a child self-report questionnaire measures what the child "did do" during the previous week. It will be used to measure activity performance in this study. Validity, reliability and sensitivity of this measure have been established for the population in this study.[27] There are 7 sub-domains represented within the ASKp including: personal care (3 items), dressing (4 items), other skills (4 items), locomotion (7 items), play (2 items), standing skills (5 items), and transfers (5 items). Child report will be used. The 30 items aggregate will be used to obtain one overall summary score for analysis.

Assessment of Life Habits (Life-H): The LIFE-H questionnaire will be used to sample mobility-based l life habits carried out in the participant's natural environment (home, school, neighborhood). For the purpose of this study the LIFE-H short form for children 5-13 years will be used, which, per developer is appropriate for 4 year-olds as well. The domains of housing, mobility and recreation will be the focus of this study. The LIFE-H produces a continuous score ranging from 0 to 9, which are developed by combining the results of the sub-score related to the degree of difficulty and type of assistance. The instrument also has a separate satisfaction scale that provides the individual's assessment regarding accomplishment of life habits (5-point Likert scale). Parental report will be used in this study. The mean of each category (mean of items) for accomplishment and satisfaction will be used in the analysis.

Orthotic and Prosthetic Users' Survey (OPUS): The OPUS is a self-report instrument that was developed to assess patient outcome in the areas of functional status, quality of life, and satisfaction with devices and services. [28] For the purpose of this study only the satisfaction with device scale will be used. It consists of 11 questions addressing orthotic comfort, fit, and wearability and uses one rating scale with four "extent of agreement" response categories. Child report will be used as feasible and if not then parental report will be collected. Data will be converted to ordinal or nominal data categories for analysis.

Study Population

Sample Size

Our long-range plans are to carry out a multi-site randomized trial comparing AFO-FC with AFO. Feedback from the NIH regarding these plans has indicated that we should first collect preliminary data on effect sizes and variability, in order to inform sample size and power calculations for such a study. Our TRIPP proposal is designed to achieve this goal within the time and budget limitations. Therefore, the proposed study is neither designed nor powered for inference on the intervention's efficacy. Sample size of 10 is proposed logistically feasible given the 12 months of funding and clinical caseloads of the investigators. This data will be used to

calculate effect size and standard-deviation estimates for the endpoints described above. These estimates will be reported together with graphical and table summaries of the raw data, as relevant."

Inclusion /Exclusion Criteria

Inclusion Criteria

1. Male or female, ages 4 to 14 years old, inclusive.
2. Has a diagnosis of cerebral palsy, of a diplegic, unilateral or bilateral distribution
3. Uses walking as primary method of mobility at school, home, and the community, and has a GMFCS level of 1, 2 or 3.
4. Barefoot gait pattern demonstrating leg segment misalignment consistent with the patterns in Figure 3.
5. Family has resources to attend all study sessions (i.e. transportation/schedule).
6. Currently wearing orthoses or clinically appropriate to wear orthoses to enhance walking activity.
7. Clinically deemed appropriate for a trial of the AFO-FC approach by the investigators

Exclusion Criteria

1. Non – English speaking.
2. Foster children or wards of the state.
3. Uses wheelchair or stroller mobility as a primary method of mobility, and uses walking either only at home, or only in therapy sessions.
4. Severe visual impairment, such that the visual impairment itself functionally limits mobility.
5. Any Orthopedic or Neurosurgery surgeries in the last 3 months.
6. Any Phenol or Botox injections to the legs in the last 3 months.
7. Uncontrolled seizure disorder, as defined as any seizure in the last 3 months which impacted their mobility skills and function. Seizures which did not affect their mobility are acceptable.
8. Unable to understand directions sufficiently to complete the study assessments.
9. Lower extremity fracture in the last 3 months.
10. Planned surgery or changes to medication during the study period.

Restrictions during the study:

1. Any medications which affect muscle tone or movement disorders are at a stable dose for 30 days prior to Baseline, and agree to maintain a stable dose during the protocol. If a dose change is needed, this will be recorded, and the child will stay on the study if the family still wishes to participate.
2. Participants' current physical therapy program will be continued throughout the protocol.

Study Duration and Timeline

	Study Period Months				
Study Task	1	2-9	10	11	12
IRB					
Train Intervention/Assessment staff					
Recruitment/Enrollment					
Assessment/Intervention					
Post Treatment Follow up Assessments					
Data Analysis and Manuscript preparation					

The project will begin Oct 30, 2014 and end Sept 30, 2015 per published call for submission guidelines

Study Visits and Procedures

	Baseline Visit	**Post Treatment Visit**
Study Week	Occurs after 1) Deemed clinically appropriate for AFO-FC 2) Family expresses interest in participation 3) Prior to fitting of new AFO-FC prescription appointment	3 months post clinical fitting of new AFO-FC prescription appointment (+/- 2 weeks)
Visit Number	1	2
Informed Consent	X	
Demographics	X	
Medical and Surgical History	X	
Gait Lab Assessment – Orthocare Innovations Biomechanics Lab	X (Barefoot & with current AFO prescription/shoes)	X (Barefoot & with AFO-FC)
Height	X	
GMFCS	X	
CFCS	X	
MACS	X	
ASKp	X	X
Life-H	X	X
OPUS	X	X
Concomitant Medications	X	X
Adverse Events		X
StepWatch Calibration/ Monitoring	X	X
GPS Monitoring	X	X

*ASKp is given to family to take home and complete on the day their monitors are returned.

Recruitment and Pre – Screening

Participants will be approached regarding interest in the study, once deemed clinically appropriate for the AFO-FC prescription by Drs. Bjornson and Apkon. The investigators (Drs. Bjornson and Apkon) will ask family if they are interested in hearing about the study. They will then be contacted by the study CRA or Dr Bjornson to describe the study and answer questions. Dr Bjornson will coordinate and schedule baseline visit.

Baseline Visit

A Baseline visit will be scheduled after 1) deemed clinically appropriate for the AFO-FC prescription, 2) family expresses desire to participate and 3) before the final fitting of the new AFO-FC prescription.

- Informed consent and assent and HIPAA authorization
- Demographic and medical history questionnaire, include current medications, prior surgeries, and outside physical therapy. Questionnaire includes maternal level of education, whether the family owns or rents their home, type of orthotics used, and contact information for any community therapist caring for the child.
- Gross Motor Classification System (GMFCS) scoring
- Communication Function Classification system (CFCS) scoring
- Manual Ability Classification system (MACS) scoring
- Gait Lab Assessment – Orthocare Innovations Biomechanics Lab-barefoot & with current AFO/shoe prescription.
- LIFE – H survey (completed by parent during visit)
- OPUS Survey (completed by parent during visit)
- Activity Scale for Kids (ASKp) (sent home for parent to complete at end of wearing of monitors)
- StepWatch: Calibration and fitting of the StepWatch activity monitor in a knit cuff on the left ankle. Children will be instructed to wear the StepWatch for the next 7 days while awake and not in the water, and to return it at their first treadmill training program session. Parents will be instructed to complete the ASKP on the 7th day of wearing the monitor and return by postage paid envelope..
- GPS**:** Children will be instructed in the use of the Global Positioning System (GPS) monitor at this visit with the same wearing and return protocol as the StepWatch. This device will be worn in a knit cuff on the right ankle.

Clinical Intervention

The child then has the appropriate clinical visits to cast, fabricate, fit and tune their new AFO-FC with a home walking program as appropriate. Consistency of clinical AFO-FC prescription will be addressed by the use of the published algorithm,[1] (Appendix) currently utilized clinically by the investigators here at Seattle Children's Hospital (SCH). All AFO portions of the AFO-FC devices will be casted at SCH and fabricated at Cascade DAFO (Dynamic Ankle Foot Orthoses), Inc., Ferndale WA. Families supply the shoes or footwear. The combined AFO with the footwear combinations FC will be fitted and tuned by the SCH orthotists and Dr Bjornson consistent with the published algorithm.

Post Treatment Visit

The single follow up visit will be conducted 3 months post clinical fitting of new AFO-FC prescription appointment (+/- 2 weeks).

- Record any adverse events, and update the concomitant medications and concomitant therapy form.
- Gait Lab Assessment – Orthocare Innovations Biomechanics Laboratory-barefoot & with AFO-FC prescription.
- LIFE – H survey (completed by parent during visit)
- OPUS Survey (completed by parent during visit)
- Activity Scale for Kids (ASKp) (sent home for parent to complete at end of wearing of monitors)
- StepWatch: Calibration and fitting of the StepWatch activity monitor in a knit cuff on the left ankle. Children will be instructed to wear the StepWatch for the next 7 days while awake and not in the water, and to return it at their first treadmill training program session. Parents will be instructed to complete the ASKP on the 7th day of wearing the monitor, and return by postage paid envelope.
- GPS**:** Children will be instructed in the use of the Global Positioning System (GPS) monitor at this visit with the same wearing and return protocol as the StepWatch. This device will be worn in a knit cuff on the right ankle.

Statistical Analysis Plan (See sample size above)

The primary analysis for both aims will be descriptive for direction of effect and to generate effect size and power analysis for future multi-center R01 grants.

Informed Consent Process

The child's parent/legal guardian will be approached for informed consent at the baseline visit. The study staff will review the consent form with the parent to explain study procedures, study purpose, voluntary nature of the study, and possible risks and/or benefits to the child and guardian. If the child is 7 years old or older and thinks and makes decisions at least as well as a 7 year old, then the child will complete an informed assent process with the study staff. This may include drawing pictures, verbal explanations, reading portions of the assent form out loud, and other methods, to ensure that the child understands the study purpose, procedures, and voluntary nature of the study. If the child agrees, he/she will sign an assent form, and have the researcher co – sign as indicated. Non – English speaking children will not be eligible, as there is not adequate interpreter support at the study locations. In addition, the activity surveys have not been validated in other languages.

Privacy and Confidentiality

Study data will be recorded on case report forms without any identifiers, coded with a study code, and stored in locked drawers in secure offices at Seattle Children's Research Institute. Study data will also be stored electronically in secure computer files and drives at Seattle Children's Research Institute and through REDCap at SCRI accessible only by study staff Gait lab data containing only the study ID will be stored electronically in secure computer files and drives at Orthocare Innovations. Anthropometric data collected as part of the gait analysis will be stored in locked file cabinets, by study ID.

Risk/Benefit

Risk to participants

Falling: There is a less likely, mild risk of falling during gait study assessments and treadmill training. All walking tests will be conducted on indoor, on non-skid surfaces designed for gait analysis, to reduce the risk of injury resulting from falls.

Muscle soreness and fatigue: There is a likely, mild risk of muscle soreness, and fatigue resulting from the exertion involved in the walk tests.

Skin irritation: There is a rare, mild risk of skin irritation due to wearing the StepWatch monitor on the left leg and the GPS on the right ankle. These monitors are worn with soft knit cuffs, similar to a sock, thus risk of irritation if rare. Families will be instructed to check the skin for any problems periodically, and to take a break if needed.

Emotional distress or embarrassment: There is a rare, mild, risk of emotional distress or embarrassment due to completing the research surveys. Parents will be informed that they can take a break or skip questions if they need to.

Loss of privacy*:* We were concerned about the possible loss of privacy for children who complete the GPS monitoring. To prevent this, all GPS data will be analyzed together, after the last child has completed study participation. The GPS maps will not be available to children or their parents.

Benefits to participants

Participants will likely benefit from information collected within the study protocol (gait lab, walking activity and parent surveys). This information has potential to inform the clinical orthotic management of the participant.

Data Safety Monitoring

The principal investigator will review any adverse events as they occur, and will report any possibly or definitely related adverse events to the IRB in accordance with their policies.

Conflict of Interest

None

Publication and Presentation

Results from this pilot study will be presented at appropriate professional conferences and submitted to appropriate journals.

Data and/or Sample Sharing

Data will not be shared with parties outside of the research team.

APPENDIX

A CLINICAL ALGORITHM FOR THE DESIGN AND TUNING OF ANKLE-FOOT ORTHOSIS FOOTWEAR COMBINATIONS (AFOFCs) BASED ON SHANK KINEMATICS

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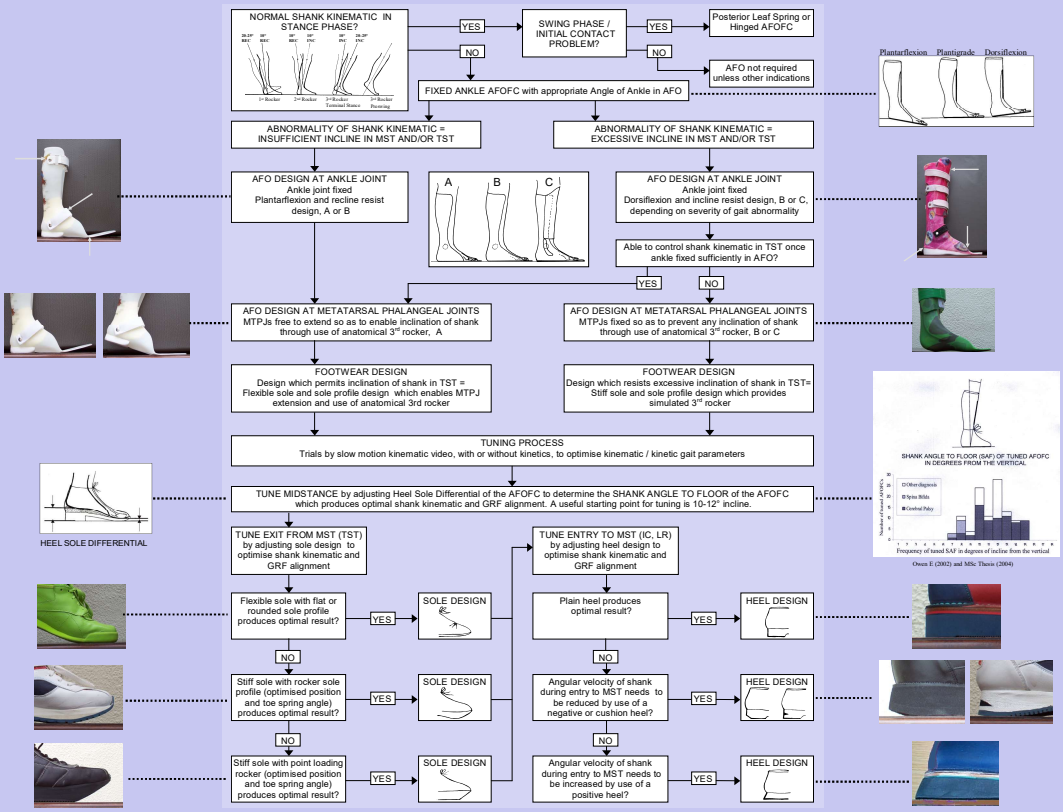
Eight years experience of designing and tuning AFOFCs for a population of children with cerebral palsy, spina bifida and other conditions (n=141) on the ORLAU Transportable Video Vector Generator Gait Laboratory, which provides combined kinematic and kinetic analysis, has enabled the formulation of an algorithm which will facilitate the design and kinetic and/or kinematic tuning of AFOFCs.



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