Date: 03092013 Version 0.2

Title of Project:

Effectiveness of Ankle-7 orthosis vs AFO orthosis on gait performance in diplegic cerebral palsied children.

Protocol ID: UDGEE_2012_OTTObock

BACKGROUND (knowledge already available on the effectiveness of the intervention)

The hypertonic muscle is a major cause of disability in children with cerebral palsy (PCI). A typical clinical manifestation of PCI is represented by spastic diplegia, affecting about 40% of this population. The movement disorder in children with CP results from the involvement of structures belonging to the central nervous system (top-down components) associated with variable involvement of structures belonging to the musculoskeletal system (bottom-up components). Both top-down and bottom-up components may provide clinical variables, the direct consequence of this phenomenon is that children with diplegia and PCI express more than one pattern of walking, different from the physiological one, each of which is characterized by more or less marked involvement of different muscles of the lower limbs.
The orthoses are frequently used to improve the ability of children with CP although, to date, the level of scientific evidence in support of their use is still limited. Improving the way through the most appropriate use of the orthoses requires the clinician with an understanding of spontaneous motor pattern and strategies adopted by the child during walking. To make a successful prescription, pathophysiology and pathological elements in the biomechanics of gait kinematics should be carefully considered and put into relation with the biomechanical characteristics of orthosis you have.
In recent years, we proposed a classification of spastic diplegia in childhood that can distinguish four different forms, according to the pattern of walking. (Ferrari et al, 2005) The second of these forms affects approximately 35% of children with diplegia and PCI and is characterized by knee flexing in mid-stance and sagittal swinging of pelvis.
The classification of the forms of diplegia has already been tested for its inter-operator reliability (Ferrari et al, 2008) and the criterion validity (Ferrari et al, 2008). In choosing the most suitable orthosis, the clinician should try to integrate its objectives, in terms of improved kinematics and kinetics of the way, with the priority functional needs expressed by the child and the family, taking into account technical and economic constraints. The Ankle Foot Orthosis (AFO) is the most commonly used orthosis in diplegic PCI children. However, recently it has been proposed an orthosis of new design that contains a carbon fiber component whose purpose is to store and return energy during the succession of phases of the gait cycle. The effects of this orthosis in children with diplegia and PCI have never been studied nor compared with the effects of AFO in this population.

OBJECTIVES OF THE STUDY
- What the study aims to demonstrate:

The aim of this work is to verify the superiority of the ankle-7 orthosis compared to the more widespread AFO, to improve the functionality and walking function of children with spastic diplegia and PCI. The effectiveness of the orthosis will be evaluated objectively using gait analysis and the use of the Goal Attainment Scale.

- What the study helps to add to current knowledge:

To date, there are no studies demonstrating the efficacy of ankle-7 orthosis on the walking function in this patient population. Furthermore, the level of scientific evidence to support the use of orthoses in spastic diplegia resulting from PCI, to date, is still limited. However, the use of orthoses in this population is widespread.

STUDY DESIGN

Monocentric	√	Complex Structure of Rehabilitation of Severe Developmental Disabilities - ASMN of Reggio Emilia (Italy)
Sponsored		Proposer: UOC Rehabilitation of severe developmental
Independent	√	disabilities, Department of Obstetrics - Gynecology - Pediatric ASMN Reggio Emilia The study is funded by the Company OttoBock The data are owned by the applicant and the structure of its affiliation

Study population

Children with PCI belonging to the 2nd form of spastic diplegia, afferent to the 3rd level for Severe Developmental Disabilities at Hospital Santa Maria Nuova, Reggio Emilia, aged between 6 and 18 years. To be included in the study, children must have a clinical and instrumental diagnosis of PCI, consisting of a complete medical history and results of magnetic resonance imaging.

According to our a hypothesis, the use of the ANKLE-7 orthosis will improve the power generated by the ankle joint during the push off. The data in our possession allows us to hypothesize that a minimum of 22 cases must be selected to meet inclusion and exclusion criteria for a study power of 80% with a Type I error of 5%. However, this calculation is based on very few cases followed very heterogeneous amongst themselves. For this reason, we intend to proceed to recruitment in two phases.

In the first phase of "pilot" study, 5 children will be selected to meet the eligibility criteria for the study in order to more accurately identify the expected gain with the use of ANKLE-7 orthosis compared to the most common AFO articulated, on the outcome measure we consider to be our main and secondary measures.

In the second phase, after verification of the power and feasibility of the study, we will proceed to the completion of the sample.

N° of people involved in the center: 22
first phase 5, second phase to be verified, according to our initial hypothesis 17

Duration of the study: from May 2012 to May 2014.

Criteria for inclusion

- Clinical indication to the use of orthoses to improve the walking function confirmed by instrumental parameters obtained from analysis of the path (dynamic electromyography, optoelectronic stereophotogrammetry analysis);
- Patients who already have AFO orthoses (or ankle-7) that need to be renewed;
- Patients with new clinical indication to the use of orthoses but not yet in possession of the same;
- Informed consent from parents / guardians of the child.

Criteria for exclusion

- Cognitive disabilities that may affect the child's participation in the activities related to this study, in the opinion of the investigators;
- Lower limbs sensory disability that may affect any beneficial effects of the use of the orthoses, in the opinion of the investigators;
- Other diseases associated or not associated with PCI that, according to investigators, could affect the child's participation in the activities related to this study (eg: drug-resistant epilepsy);
- Administration of antispasmodic drugs in the last 6 months;
- Functional surgery of the lower limbs in the last 6 months;
- Indication for surgical treatment to be carried out within 6 months after the date of inclusion in the study.

Outcome measures:

1_ power generated from the right and left ankle joints in the boost phase, measured by instrumental gait analysis

2_level of the knee joint kinematics: average extension in degrees of the right and left knees during initial contact, loading response and mid-stance calculated on a minimum of three walks or 15 steps, measured by instrumental gait analysis;

3_ stride length sn and dx, measured by instrumental gait analysis;

4_ walking speed measured by instrumental gait analysis;

5_ energy expressed during the walking;

7_ preference of use of AFO or Ankle_7, determined from the diary;

8_ clinical evaluation of the walking function, through the video-recording of the same and the Visual Gait Assessment Scale (OGS). (Boyd R, Graham HK. 1999; Eur J Neurol 6: S23-S35)

An independent observer, with at least ten years of clinical experience in the field of PCI, blinded to the allocation of children in the two groups, observe the videotapes of each child while walking using O_1 or O_2 covered with gaiters and will give an assessment of clinical improvement or worsening of the second situation compared to the first. For this purpose we will use the OGS, a validated observational assessment scale of gait.

An independent observer, with at least ten years of clinical experience in the field of PCI, blinded to the allocation of children in the two groups, observe the graphical reports of instrumental gait analysis of every child while using O_1 or O_2 and will give an assessment of clinical improvement or worsening of the second situation compared to the first.

Proposed intervention

The study is experimental and prospective, with a cross-over design.

The project is divided into the following phases:

T0 – at the beginning of the study children included will be subject to the following procedures and assessments:

1) demographic and anthropometric data collection;

2) randomization by concealed allocation to one of the following two groups:

- AFO - Ankle_7 group
- Ankle-7 – AFO group

Both, AFO and ankle-7, will be tailored to the patient

The two groups are distinguished by the order of the assignment of the two orthoses, respectively defined as the first assignment orthosis (O_1) and second assignment orthosis (O_2). The first group will use the hinged AFO orthosis (**tailor-made with range of motion of about 20 ° (-5 - + 15) from the indifferent position with ankle joint at 90 °)** as a first assignment and then the orthoses Ankle_7, while the second group will use the two orthoses according to the reverse order. The two will be used with the same orthotic footwear, with the exception of the cases where it will be necessary to change it due to accretion.

3) collection of the measures necessary for making the two orthotic devices at OttoBock of Reggio Emilia

4) training in the use of the orthoses according to a standardized protocol;

5) try on the patient's in-process first assignment orthoses (O_1) and subsequent delivery of them (see Annex A);

Subsequently, the patient will use O_1 for a period of 4-6 weeks.

T1 - patients will receive the following procedures and assessments:

1. try on the patient's in-process second assignment orthoses (O_2)
2. instrumental gait analysis and video recording of the walking while using O_1 (covered by elastic gaiters);
3. withdrawal of O_1
4. delivery of O_2 to the patient

Subsequently, the patient will use O_2 for a period of 4-6 weeks.

T2 - patients will undergo the following procedures and evaluations:

1. instrumental gait analysis and video recording of the walking while using O_2 (covered by elastic gaiters);
2. return of O_1 to the patient;
3. Delivery of the diaries and directions for completing and mailing back them at the end of the

follow-up period;

T3 - three months follow-up to detect the preference of use of AFO or Ankle-7 (by the child/parent)

Hypothesis	**Superiority**
Randomization	**YES** **Concealed allocation**
Blinding	**Single blind (assessor)**
Study monitoring	**Promoter**