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Technical innovations for the diagnosis and the rehabilitation of motor and perceptive impairments of the child with Cerebral Palsy

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Contents

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PART I

General introduction

General introduction

The treatment of the Cerebral Palsy (CP) is considered as the “core problem” for the whole field of the pediatric rehabilitation. The reason why this pathology has such a primary role, can be ascribed to two main aspects. First of all CP is the form of disability most frequent in childhood (one new case per 500 birth alive, (1)), secondarily the functional recovery of the “spastic” child is, historically, the clinical field in which the majority of the therapeutic methods and techniques (physiotherapy, orthotic, pharmacologic, orthopedic-surgical, neurosurgical) were first applied and tested. The currently accepted definition of CP – *Group of disorders of the development of movement and posture causing activity limitation* (2) – is the result of a recent update by the World Health Organization to the language of the International Classification of Functioning Disability and Health, from the original proposal of Ingram – *A persistent but not unchangeable disorder of posture and movement* – dated 1955 (3). This definition considers CP as a permanent ailment, i.e. a “fixed” condition, that however can be modified both functionally and structurally by means of child spontaneous evolution and treatments carried out during childhood. The lesion that causes the palsy, happens in a structurally immature brain in the pre-, peri- or post-birth period (but only during the firsts months of life).

The most frequent causes of CP are: prematurity, insufficient cerebral perfusion, arterial haemorrhage, venous infarction, hypoxia caused by various origin (for example from the ingestion of amniotic liquid), malnutrition, infection and maternal or fetal poisoning. In addition to these causes, traumas and malformations have to be included. The lesion, whether focused or spread over the nervous system, impairs the whole functioning of the Central Nervous System (CNS). As a consequence, they affect the construction of the *adaptive functions* (4), first of all posture control, locomotion and manipulation. The palsy itself does not vary over time, however it assumes an unavoidable “evolutionary” feature when during growth the child is requested to meet new and different needs through the construction of new and different functions.

It is essential to consider that clinically CP is not only a direct expression of structural impairment, that is of etiology, pathogenesis and lesion timing, but it is mainly the manifestation of the path followed by the CNS to “re”-construct the adaptive functions “despite” the presence of the damage. “Palsy” is “*the form of the function that is implemented by an individual whose CNS has been damaged in order to satisfy the demands coming from the environment*” (4). Therefore it is only possible to establish general relations between lesion site, nature and size, and palsy and recovery processes. It is quite common to observe that children with very similar neuroimaging can have very different clinical manifestations of CP and, on the other hand, children with very similar motor behaviors can have completely different lesion histories. A very clear example of this is represented by hemiplegic forms, which show bilateral hemispheric lesions in a high percentage of cases.

The first section of this thesis is aimed at guiding the interpretation of CP. First of all the issue of the detection of the palsy is treated from historical viewpoint. Consequently, an extended analysis of the current definition of CP, as internationally accepted, is provided. The definition is then outlined in terms of a *space* dimension and then of a *time* dimension, hence it is highlighted where this definition is unacceptably lacking. The last part of the first section further stresses the importance of shifting from the traditional concept of CP as a *palsy of development* (defect analysis) towards the notion of *development of palsy*, i.e., as the product of the relationship that the individual however tries to dynamically build with the surrounding environment (resource semeiotics) starting and growing from a different availability of resources, needs, dreams, rights and duties (4).

In the scientific and clinic community no common classification system of CP has so far been universally accepted. Besides, no standard operative method or technique have been acknowledged to effectively assess the different disabilities and impairments exhibited by children with CP. CP is still “an artificial concept, comprising several causes and clinical syndromes that have been grouped together for a convenience of management” (5). The lack of standard and common protocols able to effectively diagnose the palsy, and as a consequence to establish specific treatments and prognosis, is mainly because of the difficulty to elevate this field to a level based on scientific evidence.

A solution aimed at overcoming the current incomplete treatment of CP children is represented by the clinical systematic adoption of objective tools able to measure motor defects and movement impairments. A widespread application of reliable instruments and techniques able to objectively evaluate both the form of the palsy (diagnosis) and the efficacy of the treatments provided (prognosis), constitutes a valuable method able to validate care protocols, establish the efficacy of classification systems and assess the validity of definitions.

Since the ‘80s, instruments specifically oriented to the analysis of the human movement have been advantageously designed and applied in the context of CP with the aim of measuring motor deficits and, especially, gait deviations. The *gait analysis* (GA) technique has been increasingly used over the years to assess, analyze, classify, and support the process of clinical decisions making, allowing for a complete investigation of gait with an increased temporal and spatial resolution. GA has provided a basis for improving the outcome of surgical and nonsurgical treatments and for introducing a new modus operandi in the identification of defects and functional adaptations to the musculoskeletal disorders.

Historically, the first laboratories set up for gait analysis developed their own *protocol* (set of procedures for data collection and for data reduction) independently, according to performances of the technologies available at that time. In particular, the stereophotogrammetric systems mainly based on optoelectronic technology, soon became a gold-standard for motion analysis. They have been successfully applied especially for scientific purposes. Nowadays the optoelectronic systems have significantly improved their performances in term of spatial and temporal resolution, however many laboratories continue to use the protocols designed on the technology available in the '70s and now out-of-date. Furthermore, these protocols are not coherent both for the biomechanical models and for the adopted collection procedures. In spite of these differences, GA data are shared, exchanged and interpreted irrespectively to the adopted protocol without a full awareness to what extent these protocols are compatible and comparable with each other.

Following the extraordinary advances in computer science and electronics, new systems for GA no longer based on optoelectronic technology, are now becoming available. They are the Inertial and Magnetic Measurement Systems (IMMSs), based on miniature MEMS (Microelectromechanical systems) inertial sensor technology. These systems are cost effective, wearable and fully portable motion analysis systems, these features gives IMMSs the potential to be used both outside specialized laboratories and to consecutive collect series of tens of gait cycles. The recognition and selection of the most representative gait cycle is then easier and more reliable especially in CP children, considering their relevant gait cycle variability.

The second section of this thesis is focused on GA. In particular, it is firstly aimed at examining the differences among five most representative GA protocols in order to assess the state of the art with respect to the inter-protocol variability. The design of a new protocol is then proposed and presented with the aim of achieving gait analysis on CP children by means of IMMS. The protocol, named *'Outwalk'*, contains original and innovative solutions oriented at obtaining joint kinematic with calibration procedures extremely comfortable for the patients. The results of a first in-vivo validation of Outwalk on healthy subjects are then provided. In particular, this study was carried out by comparing Outwalk used in combination with an IMMS with respect to a reference protocol and an optoelectronic system. In order to set a more accurate and precise comparison of the systems and the protocols, ad hoc methods were designed and an original formulation of the statistical parameter coefficient of multiple correlation was developed and effectively applied. On the basis of the experimental design proposed for the validation on healthy subjects, a first assessment of Outwalk, together with an IMMS, was also carried out on CP children.

The third section of this thesis is dedicated to the treatment of walking in CP children.

Commonly prescribed treatments in addressing gait abnormalities in CP children include physical therapy, surgery (orthopedic and rhizotomy), and orthoses. The orthotic approach is conservative, being reversible, and widespread in many therapeutic regimes. Orthoses are used to improve the gait of children with CP, by preventing deformities, controlling joint position, and offering an effective lever for the ankle joint. Orthoses are prescribed for the additional aims of increasing walking speed, improving stability, preventing stumbling, and decreasing muscular fatigue. The ankle-foot orthosis (AFO), with a rigid ankle, are primarily designed to prevent equinus and other foot deformities with a positive effect also on more proximal joints. However, AFOs prevent the natural excursion of the tibio-tarsic joint during the second rocker, hence hampering the natural leaning progression of the whole body under the effect of the inertia (6). A new modular (submalleolar) astragalus-calcanear orthosis, named OMAC, has recently been proposed with the intention of substituting the prescription of AFOs in those CP children exhibiting a flat and valgus-pronated foot.

The aim of this section is thus to present the mechanical and technical features of the OMAC by means of an accurate description of the device. In particular, the integral document of the deposited Italian patent, is provided. A preliminary validation of OMAC with respect to AFO is also reported as resulted from an experimental campaign on diplegic CP children, during a three month period, aimed at quantitatively assessing the benefit provided by the two orthoses on walking and at qualitatively evaluating the changes in the quality of life and motor abilities.

As already stated, CP is universally considered as a persistent but not unchangeable disorder of posture and movement. Conversely to this definition, some clinicians (4) have recently pointed out that movement disorders may be primarily caused by the presence of *perceptive* disorders, where perception is not merely the acquisition of sensory information, but an active process aimed at guiding the execution of movements through the integration of sensory information properly representing the state of one's body and of the environment. Children with perceptive impairments show an overall fear of moving and the onset of strongly unnatural walking schemes directly caused by the presence of perceptive system disorders.

The fourth section of the thesis thus deals with accurately defining the perceptive impairment exhibited by diplegic CP children. A detailed description of the clinical signs revealing the presence of the perceptive impairment, and a classification scheme of the clinical aspects of perceptual disorders is provided. In the end, a functional reaching test is proposed as an instrumental test able to disclosure the perceptive impairment.

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PART II

Cerebral Palsy

Chapter 1

GUIDE TO THE INTERPRETATION OF CEREBRAL PALSY

Abstract

The term ‘Cerebral Palsy’ (CP) commonly designates a group of conditions characterized by chronic motor impairment due to an early occurrence of a stable lesion to the brain. The motor disability in CP commonly includes several aspects of organization and control of movement and posture. The motor impairment may lead to orthopedic complications that further restrict motor abilities. Other clinical problems may be associated with motor impairment because of lesions caused by the same pathological process or because of restricted motor development. Associated problems may include sensory and perceptual impairment, notably visual impairment, cognitive impairment, affective and behavioral disturbances. Given its inclusiveness the term implies a lot of heterogeneity in terms of etiology as well as types and severity of motor and associated disabilities. However, the designation has remained in universal use by clinicians, therapists, epidemiologists and researchers.

The aims of this chapter are to:

1. briefly introduce to the nature of the defect through an historical analysis of the diagnostic process of CP, starting from the identification of the motor defects up to the recognition of the perceptive impairments, underling the contribution provided by gait analysis;
2. present the main, universally accepted clinical definition for CP, thus proving why CP is not properly a disease and why it must be considered as an interaction problem between the individual and the environment that involves and acts on different levels of functioning, disability and health.

This chapter is largely based on the studies published in the book of Ferrari A. et al., “The spastic forms of cerebral palsy: a guide to the assessment of adaptive functions” published by Springer in 2009.

1. Cerebral Palsy detection: from John Little to the present

As for many essential aspects of human life, William Shakespeare wrote an outstanding description of a person affected by cerebral palsy (CP), through the words uttered by the Duke of Gloucester, future King Richard III, by which he hints at his condition as being related to prematurity and respiratory disorders.

"I, that am curtail'd of this fair proportion, cheated of feature by dissembling nature, deform'd, unfinish'd, sent before my time into this breathing world, scarce half made up, and that so lamely and unfashionable that dogs bark at me, as I halt by them" (William Shakespeare, Richard III).

Historical documents report how the existence of children with movement disorders was already known at the time of the Sumerians, and certainly Hippocrates was aware of this disease (1,2). However, the first detections and descriptions of CP certainly date back to the Victorian age.

Sir John Little was the first to describe this disease, even though he did not employ the term "cerebral palsy" in his famous work of 1861 (3). He especially investigated deformities developing in individuals with generalized spasticity. In 1861, he published a report of his experience based on 20 years of clinical investigations on this type of disorder, supported by a rich data collection on possible correlations between pregnancy or delivery disorders and the resulting alterations of the physical and psychological development of children presenting with articular deformities. Little maintained that both spasticity and deformities were caused by asphyxia and cerebral hemorrhage secondary to delivery distress. A new nosological entity was then defined and named "Little's Disease".

Sigmund Freud, in his "Die infantile Cerebrallahmung" (Infantile cerebral palsy), written in 1897 (4), investigated the causes of these motor disorders, ascribing, in contrast with Little, more importance to pre-term birth and to intrauterine development disorders than to distress suffered during delivery. It is interesting to notice how, in the same work, Freud points at the inadequacy of the nosological entity of "CP" as a purely clinical category, related neither to a precise and single etiology nor to a precise and single anatomopathological picture. He then concludes by incorrectly predicting that this definition would soon be abandoned and replaced by different and more precise ones.

In the first part of the 19th century until the Second World War, the interest in the investigation of spastic disorders in children remained quite low. Very few were also the attempts to establish rehabilitation programs, which were received with little enthusiasm.

Immediately after the Second World War, medical research revived the interest in this field, with the rapid creation of many specialties and a renewed focus on disabled children and their social and environmental context. Advances in obstetrician assistance techniques and more sophisticated instruments of neonatal intensive care significantly reduced overall mortality, but also allowed the survival of a larger number of individuals at risk. This rapidly led to the investigation of new and more appropriate working methods in different professional fields. Progress achieved in the investigation of genetic and metabolic diseases and their consequences on the central nervous system allowed a redefinition of many clinical pictures that were previously classified under the still nonspecific diagnostic label of CP. In this background, in 1947, the American Academy for Cerebral Palsy (AACP) was founded. Conceived as a multidisciplinary professional association aimed at promoting research in the field of infant disability, AACP gathered the most important clinical disciplines and their corresponding activities of motor therapy, psychopedagogy and psychology. The founders of AACP represented different clinical specializations, including neurology, pediatrics and psychiatry.

In 1957, driven by the need to clarify the terminology used in different parts of the world, but also aiming at raising consensus about the classification of CP, an AACP conference was held. A definition, which is still very popular today, resulted from the conference, according to which CP must be considered as “a permanent but not unchangeable disorder of posture and motion, due to a cerebral defect or non-progressive lesion, which took place before the brain had completed the main morphofunctional maturation processes; the motor disorder is prevalent but not exclusive, and may vary in type and severity”. With the same objective, in England, Ronnie Mac Keith and coworkers in 1964 published, edited by Martin Bax, a definition of CP which still has the widest international consensus, according to which “cerebral palsy is a posture and motion disorder, due to a defect or a lesion of the immature brain. For practical aims, we need to exclude from cerebral palsy those disorders of posture and motion which are 1) short-term, 2) due to a progressive disease, 3) exclusively due to mental retardation” (5). It is partly surprising that the definition of CP remained quite unchanged for 50 years, probably thanks to its simplicity and to the fact that it is function-based. However, this definition nowadays comprise important limitations, both theoretical and practical, and should probably be updated considering the enormous progress achieved in many detection techniques and in clinical nosography (6).

Initially conceived as an orthopedic deficiency of neurological origin, it was shortly recognized as a pathological condition involving more functional systems and, as such, requiring the concurrent attention of different specialists and care services. More recently, it has started to be more and more considered as a complex developmental disorder, a disability that becomes increasingly evident during the growth of the individual, which, for this reason, deserves to receive early detection and treatment. In such a way, this disease, initially considered as orthopedic by Little, has become today the prototype of infant developmental disability.

Coming nowadays, beside the motor impairments identified since the Victorian age, some authors, Ferrari among the firsts, established the presence of perceptual disturbances (7,6) as the main core of the disability. The clinical observation carried out by these authors, pointed out that a subgroup of CP children, among the diplegic and the tetraplegic forms, show motor impairment not related to structural conditions of the locomotion apparatus but rather to the failure of a complex neurological process that enables the individual to take in the spatial-temporal aspects of sensory information and on the base of their mutual coherence to produce organized motor behavior. In other words, the cognitive-perceptual-motor dysfunction that entails with the inability to adapt and to integrate environmental experiences is the main responsible for the activity limitations in a large subgroup of CP children. This impairment, defined Perceptive Impairment, beside the motor impairment should be considered in the nosological definition of CP as the primary syndrome responsible for the long-term prognosis.

Being the movement problems the main core of treatments, the quantitative measure of the movement by means of instrumental techniques covered a primary role in the CP context. Beside the improvements in the investigation of genetic and metabolic diseases, historically CP was the first rehabilitation subject receiving benefits from the application of the methods and techniques for the objective study of the human movement (7, 8). Since the ‘80s, the application of instruments specifically oriented to the acquisition and the analysis of the movements and especially the walk, has contributed substantially to the improvement in the treatment and in the diagnosis of the disorders provoked by CP. The "gait analysis" (GA) is increasingly used to assess, to analyze, classify, and to support the process of clinical decisions making, allowing a deep and complete investigation of the gait in augmented temporal and spatial resolution.

GA has became available for clinical use in the 80s after the engineers, Cappozzo among the firsts, provided robust and reliable theoretical background able to translate mathematical concepts into the clinical context. The development of biomechanical models customized on ad hoc measurement systems permitted to describe quantitatively the gait features according with the clinical language (9). Perry (10), Sutherland (11-13) Davis (14) and Kadaba (15), have been pioneers in the clinical application of gait analysis techniques to assist in the treatment of patients with CP. The work of Perry and Sutherland has provided a basis for improving the outcome of surgical and nonsurgical treatment of CP and for introducing a new modus operandi in the identification of the defects and the functional adaptations to musculoskeletal disorders in walking. Following the extraordinary evolutionary process of the computer science, measuring systems for GA are becoming more and more cheap, user-friendly and comfortable for patients (16). GA is therefore destined to become increasingly a widespread and acknowledge tool for clinical and research activity on CP children (17). Furthermore, offering an effective platform on which i) look at the impairments through a “magnifying glass” that are focused and particularized graphs, ii) quickly exchange patients information among clinical and research centers, and iii) monitor the state of the patient over the years, GA is also oriented to be used as an outstanding didactic tool.

An extremely challenging time in the field of CP is therefore underway, with the likely possibility to achieve with the aim of GA both the aim set out by Freud about overcoming the concept of CP as a vague entity in favor of precise clinical pictures and to refine the treatments from the surgery to the orthoses on the basis of the patient resources and defects.

2. Definition of Cerebral Palsy

Starting from the original work of Mac Keith and coworkers and edited by Bax (5), the definition with the current and widest international consensus states:

"Cerebral palsy describes a group of disorders of the development of movement and posture, causing activity limitation, that are attributed to non-progressive disturbances that occurred in the developing foetal or infant brain. The motor disorders of cerebral palsy are often accompanied by disturbances of sensation, cognition, communication, perception, and/or behavior, and/or by a seizure disorder" (Bax, Goldstein, Rosenbaum et al (18)).

The word disorder refers to a situation, i.e. a final state, and not to a disease, which instead can improve or worsen and in theory can also be overcome. So actually a CP child can be considered neither a sick person nor a healthy individual. The adjective persistent reinforces the concept of disorder as a stable and definitive situation, therefore not evolving (to express this concept, the term fixed encephalopathy is also used), while the expression not unchangeable partly weakens this concept by showing that motor and non-motor disorders provoked by CP can however improve or worsen, spontaneously by itself or through treatment (6). These changes can be related to the competence of the central nervous system (CNS) and to the structural conditions of the locomotion apparatus (LA). With regard to worsening, it is necessary to note that, although the damage does not itself evolve, environmental demands on the CNS become more and more challenging over time, consequently worsening the disability due to the deficiencies carried over from the past. The lack of a certain function in fact will subsequently hinder the acquisition of further functions related to it (14). The expression alteration of cerebral function underlines that palsy provokes the inability of the whole CNS, rather than the deficiency of one or more single organs that compose it. The word cerebral has to be interpreted, in a holistic way, as a synonym of CNS instead of a synonym of brain (a system, as an operating coalition among different organs, systems and structures, is always greater than and different from the sum of the singular individual parts that compose it). The lesion indeed can also affect and impair other structures (cerebellum, brainstem, etc.) and thus affect more than single areas of the brain, the whole functioning of central nervous system. It is well know that the lesion of an organ can be limited and isolated but it cannot be overcome. The lesion of a system can allow a different functioning modality of the system itself (concept of network), but it affects all the consisting parts.

The expression growth and development of the nervous system, which refers to the adjective "cerebral" rather than to the noun "function", means that palsy in children differs from palsy in adults, being characterized by a lack of function acquisition instead of the loss of already acquired functions. However, the expression remains ambiguous, since it does not define which functions it refers to, although it is usually attributed to motor functions (posture control, locomotion, and manipulation).

If, on the one hand, there can be alternative solutions, functional substitutions, and adjustments that make the individual able to build the function "despite" the lesion (plasticity), on the other hand we must recognize that no system function will remain undamaged by the consequences of the lesion. Therefore, CP rehabilitation cannot be anything but "global". It is important to highlight that the therapeutic project has to be all encompassing in itself and not just an intervention performed by a single therapist. Rehabilitation does not have to deal with the lesion as the loss of a more or less important or large part of an organ or system, which can be at least partially compensated by the activation of reserve or substitution structures. In CP, in fact, palsy means a different functioning of the entire system (computational error), due to a foreseeable internal coherence (self-organization), underlying the so-called "natural history" of any clinical form.

As every other asymptomatic child, a child affected by CP is a living system and each experience, event, and change will become a part of him and can never be canceled. The therapy will only be superimposed on the system to guide it to a better and more effective functioning (changeability, streamlining) but, in any case, without ever managing to achieve some degree of normality.

Defects analysis (lesions) will have to be countered by resources availability (functions). The traditional concept of CP as a palsy of development (defect analysis) theoretically has to be replaced with the notion of development of palsy (19), i.e., as the product of the relationship that the individual however tries to dynamically build with the surrounding environment (resource semeiotics). "Each individual, during his onthogenic development, through the interaction with the external world, builds his own representation of the world that is made up of facts and relations among facts, that are hierarchically organized according to an increasing complexity, corresponding to behavior strategies that allow him to survive in the best possible way" (20). Hence, development is the expression of a dynamic interaction between biological maturation and environment.

The term cerebral palsy does not only refer to an age, but it also describes the specificity of child palsy as a lack of function acquisition (compared to the usual age of appearance), as opposed to adult palsy as loss of already-acquired functions. During the construction of adaptive functions, precise development deadlines can be recognized. Within these deadlines the child has to become aware of his needs and of the rules related to the mechanisms and processes needed to comply with them. "Functional deadlines are dates within which different developmental competences, that are individual, neuromotor, cognitive, emotional, environmental, technical, family-related and social, must come together to develop those functions which are critical for the development, for example walking. The lack of even one of this requisites at its appointment deadline can be sufficient to block a motor competence that otherwise would be potentially ready" (6).

Growing up while respecting the deadlines means to be able to face and solve specific problems (needs, desires) once they become significant for the individual. In rehabilitation of CP children, some functions can be proposed to the child only within specific periods of time (in time) and that development is not just a sequence of chronological acquisitions, regardless of why (needs and desires), when (importance of the experience), and how (influence of models and environment).

"The intervention of gravity in motion organization occurs during particular development moments. For example, if the action of gravity is modified in young rats, a significant delay in locomotion development is observed. Therefore, there is a critical period for motricity, at around ten days after birth, during which the nervous system needs gravity as a reference to organize movement co-ordination" (21). Only those functions acquired within determined periods (met deadlines) become part of the individual's identity and therefore become impossible to renounce. In children with CP, identity development is not always necessarily simultaneous with motor development. This is why the rehabilitation of CP children requires a completely different approach from the rehabilitation of adults with neural damage and, in terms of methodology, justifies the existence of "windows of opportunity" beyond which the re-educational treatment of the function loses its intrinsic meaning. For example, walking is an important goal between 0 and 2 years of age and between 3 and 5 years, and it can still be so between 6 and 8 in some specific situations, while it is not so important later on (outside time limit). Conversely, being able to autonomously use a manual or electric wheelchair instead becomes a important developmental progress. This device can be proposed to patient already between 3 and 5 years of age, if walking prognosis reveals negative. The continuation of re-educational treatment is to be considered as unjustified if, after a reasonable period of time, no significant modification has occurred (outside time limit (7)).

In CP, together with the space dimension, defining the nature and size of the deficit (posture and gesture disorder, perceptive organization disturbance, conceptual deficiency, etc.), there is a time dimension that explains how and why the individual's ability to modify himself reduces according to age, while his adaptation to disability progressively increases. From a primary damage of organs, systems, and CNS structures directly related to the lesion site, there is a shift to a secondary damage represented by a missing acquisition of motor, cognitive, communicative, and relational competences (also from a morphological point of view: during the first stages of cortical development, the lesion of a cortical area provokes defects in the neuronal maturation of other areas, since they have no trophic support from the damaged area's connections), and then a third damage or locomotion apparatus pathology occurs (weakness, fatigue, instability, range of joint movements limitation, bone deformity, etc.), which further contributes to reducing the choice of freedom provided by CP to the individual's CNS (developmental disability).

3. From a neurological to a rehabilitative diagnosis

When detecting a new CP case, the first task of the rehabilitation physician is to translate to the parents the concept of lesion (loss of CNS anatomic and physiologic integrity) into the concept of palsy (alteration of produced functions). The therapeutic proposals to modify palsy (physiotherapy, antispastic drugs, orthosis and devices, functional surgery, etc.) will be accepted and agreed upon, and the achieved results will be evaluated and positively judged, in proportion to in what way and how much the idea of “palsy” has been conveyed and understood.

Neurological diagnosis considers palsy as the sum of the defects which are present in the child’s motor repertoire (spasticity, clonus, scissor pattern, etc.); however it does not sufficiently clarify their nature. It is therefore important to be able to assess, beside the repertoire of defects, also the resources that are still available, be they related to the individual or to the context he lives in, and their applicability, since rehabilitation treatment is precisely based on exploiting resources rather than eliminating defects. “Therapy” can neither cancel CP symptoms or signs nor hide or disguise them (inhibit pathological reflexes, making hemiparetic patients’ motricity symmetrical, etc.), nor can it solve the so-called “developmental delay”. Instead, it will have to bring out the capabilities of the person considering his specific defects and residual abilities within his living environment, i.e. his physical environment as well as the social and cultural context (6).

The easiest way to make parents understand the problem of palsy is to introduce it as a problem related to **muscles**. It could be a problem of weakness or of excessive power. However, it is difficult to explain how, in the same child, the same muscle can be simultaneously too weak at one end and too strong at the other: rectus femoris might be too weak as a knee extensor and too strong as a hip flexor, hamstrings might be too weak as thigh extensors and too strong as knee flexors and so on.

It could be more adequate to conceive palsy as a **movement** problem, but only by defining which elements alter it (measure, form or content). It might indeed be a problem of measure: on the one hand the “spastic” child who does not move enough, while on the other hand the “dyskinetic” one who moves too much. But it is difficult to explain how, in the same “spastic” child, besides the problem of not moving enough there is also inability to stop moving and stay still (postural control).

It could be a problem connected to motion pattern (22). In CP, the type of palsy can be recognized by competing patterns and its severity is indicated by their aggressiveness and stereotype. It could be a problem related to the content of motor activity, that is to say the relation between the chosen goal and the motor tool adopted to achieve it. Hence, palsy could involve not just tools but also aims (palsy as poverty of contents and rigidity of adopted strategies). It is not just an inability to move but more precisely an inability to act.

Time dimension does not fit into this interpretation: palsy is not just inability to act in space, but above all it is immobility in time, the unsurpassable delay and eternal promise of a future unachievable because it has already gone by. Time is the dimension of change, the true essence of growth. The lack of change measures palsy severity (time without change, (6)). Therefore, it becomes necessary to think more generally about the meaning of motion. Motion is the first and most important tool possessed by the child to adapt (that is to say to become adequate) to the environment in which he lives and, at the same time, to progressively be able to adapt this environment to meet his specific needs. In CP, palsy means being contemporarily inadequate for the surrounding environment and unable to act on this in order to adapt to it.

Interpreting palsy as an interaction problem between the individual and the environment rather than as a problem related to posture and motion represents to the author's opinion a more effective starting point while speaking about what is and concern Cerebral Palsy. In CP, palsy cannot be seen or interpreted as a loss, a limitation, a stop, a stiffening, an obstacle, or a constraint but as a response attempt to satisfy both the internal need to be adequate and the external need to adapt to the immediate environment, created by a child whose nervous system has been irremediably damaged.

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PART III

Gait analysis on CP children state of the art and proposal of a protocol based on new generation technology

Gait analysis on CP children state of the art and proposal of a protocol based on new generation technology

Abstract

Data collection and reduction procedures, coherently structured in protocols, are necessary in gait analysis in order to make kinematic and kinetic measurements clinically comprehensible. A protocol defines the biomechanical model and the procedures necessary for data collection, processing, analysis and reporting of results.

Historically, the first laboratories set up for gait analysis developed their own protocol independently, according to their specific clinical requirements and to the technologies available at that time. In particular, the stereophotogrammetric systems mainly based on optoelectronic technology, became a gold-standard for motion analysis. Nowadays, the first protocols designed on the first stereophotogrammetric systems are still currently used. However, they differ considerably for the marker-set and collection procedures, and for the implemented biomechanical model, i.e. measured variables, degrees of freedom assigned to the joints, anatomical and technical references, joint rotation conventions, and terminology. In spite of these differences, gait analysis data are shared, exchanged and interpreted irrespectively of the protocol adopted without a full awareness to what extent these different protocols can be compared to each other.

The first aim of this chapter is therefore to assess the state of art in the variability associated with the use of different protocols.

A comparison was made among five worldwide representative protocols by analyzing kinematics and kinetics of the trunk, pelvis and lower limbs contemporarily during the same gait cycles. A single comprehensive arrangement of markers was defined by merging the corresponding five marker-sets. Two healthy subjects and one patient who had a special two-degrees-of-freedom knee prosthesis, were analyzed. Five corresponding experts participated in the data collection and analyzed independently the data according to their own procedures.

Stereophotogrammetric systems present some relevant drawbacks as they are costly, difficult to move and have a restricted field of view. These features therefore limit their use to specifically dedicated laboratories and restrict the acquisition of a subject's walk to few strides per trial, under conditions which can be far from a steady state. In addition, the acquisition of gait in an unfamiliar and artificial environment, such as that of a laboratory, can psychologically condition the subject, who will over-perform with respect to his/her everyday life ability.

A possible solution to these problems is represented by the use of Inertial and Magnetic Measurement Systems (IMMSs). IMMSs are commercially available, cost effective and easily portable motion analysis systems. Owing to these features, the IMMSs might allow the user to execute and acquire movements in laboratory-free settings, in a continuous modality, for longer periods; therefore, allowing for the collection of a great number of consecutive gait cycles during *spontaneous* walking in daily life environments.

The second aim of this chapter is to introduce the general features of the Xsens system (Xsens Technologies, NL), presented here as a standard IMMS. In order to use IMMSs for movement analysis, ad hoc biomechanical models and collection procedures have to be designed. The critical part of this process is that, conversely from the stereophotogrammetric system, it is not yet possible to obtain information regarding the position of the sensors. This implies that models and protocols developed in the past are no longer applicable, and different techniques must therefore be conceived.

The third aim of this chapter is to present a novel protocol named 'Outwalk', designed to measure the joint kinematics during gait in every day environment, by means of the Xsens system. Outwalk presents original and innovative solutions oriented at obtaining joint kinematics, without referring to trajectories of anatomical landmarks. Furthermore, Outwalk was specifically developed to measure thorax–pelvis and lower-limb kinematics, in clinical settings, on CP children and on below/above knee amputees. For its use on CP children, special calibration procedures and models assumptions were set up.

In the fourth section of this chapter, the validation of the novel protocol is presented. In particular, Outwalk was validated on four healthy subjects when used in combination with an Xsens system, against a reference protocol (CAST) and an optoelectronic system, Vicon (Oxford Metrics Group, UK). For this purpose, an original approach based on three tests was developed in order to separately investigate:

1) the consequences on joint kinematics of the differences between protocols (Outwalk vs. CAST),
2) the accuracy of the hardware (Xsens vs. Vicon), and
3) the summation of protocols' differences and hardware accuracy (Outwalk + Xsens vs. CAST + Vicon).

Furthermore, in order to conclude that Outwalk is at the state of the art as a standard protocol for clinical measurement, it was compared with the performances collected from the other five protocols assessed in the first section of this chapter under the same experimental conditions.

In the fifth section a test of Outwalk on children affected by CP is reported. This experiment was aimed at investigating the validity of the Xsens system together with Outwalk, when used on a pediatric pathologic population. The children involved were firstly measured in combination with a reference system (Optotrak; Northern Digital Instruments, Canada) and protocol (CAST); then measured in a reserved area outside the laboratory, while wearing just the IMMS, in order to establish the influence of laboratory setting itself on gait patterns and to assess the Outwalk feasibility in measuring the gait during long distances.

Finally at the end of this chapter, a new formulation of the ‘Coefficient of Multiple Correlation’ (CMC) is presented and analyzed. CMC is hereby proposed as a synthetic parameter able to effectively measure the overall similarity of joint-angle waveforms acquired synchronously through different media (e.g. different protocols or measurement systems), when the effect of the media on waveforms similarity is the only relevant aspect. The new formulation of the CMC has already been used in the validation of Outwalk, and has been proposed in order to be particularly useful when comparing the outcomes of different protocols especially for pathologic populations, where the biological variability can be of a greater magnitude compared to healthy subjects.

Chapter 2

QUANTITATIVE COMPARISON OF FIVE CURRENT PROTOCOLS IN GAIT ANALYSIS

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Abstract

Data collection and reduction procedures, coherently structured in protocols, are necessary in gait analysis to make kinematic and kinetic measurements clinically comprehensible. The current protocols differ considerably for the marker-set and for the biomechanical model implemented. Nevertheless, conventional gait variables are compared without full awareness of these differences.

A comparison was made of five worldwide representative protocols by analysing kinematics and kinetics of the trunk, pelvis and lower limbs exactly over the same gait cycles. A single comprehensive arrangement of markers was defined by merging the corresponding five marker-sets. This resulted in 60 markers to be positioned either on the skin or on wands, and in 16 anatomical landmark calibrations to be performed with an instrumented pointer. Two healthy subjects and one patient who had a special two degrees of freedom knee prosthesis implanted were analysed. Data from up-right posture and at least three gait repetitions were collected. Five corresponding experts participated in the data collection and analysed independently the data according to their own procedures.

All five protocols showed good intra-protocol repeatability. Joint flexion/extension showed good correlations and a small bias among protocols. Out-of-sagittal plane rotations revealed worse correlations, and in particular knee abduction/adduction had opposite trends. Joint moments compared well, despite the very different methods implemented. The abduction/adduction at the prosthetic knee, which was fully restrained, revealed an erroneous rotation as large as 308 in one protocol. Higher correlations were observed between the protocols with similar biomechanical models, whereas little influence seems to be ascribed to the marker-set

1. Introduction

Protocols of gait analysis are intended to make kinematics and kinetics of pelvis and lower limbs clinically interpretable [1,2,3,4]. A protocol defines a biomechanical model and the procedures for data collection, processing, analysis and reporting of the results. Historically, probably because of the constraints implied in the pioneering technology, only few laboratories have developed their own protocol independently according to specific clinical requirements [5]. In addition to the different marker-sets and collection procedures, many important differences exist between the current protocols also in the biomechanical model, which includes the measured variables, degrees of freedom assigned to the joints, anatomical and technical references, joint rotation conventions, and terminology. In spite of these differences, gait analysis data are shared, exchanged and interpreted irrespectively of the protocol adopted. Recent international initiatives in clinical gait analysis, such as web-accessible services for data repository [6] or data processing [7], do not impose strict rules about the explicit indications of the protocol adopted. Although the considerable methodological differences are expected to produce inconsistent results, and therefore affect considerably the clinical interpretation, it is still unknown to what extent the different protocols used worldwide compare to each other.

The original 'Newington model' [8,9] is the pioneer and the most commonly used technique for gait data acquisition and reduction. It has been also the basis of many commercial software packages, the most recent being Plug-in Gait (PiG - Vicon Motion Systems, Oxford, UK). The protocol developed at the 'Servizio di Analisi della Funzione Locomotoria' (SAFLo - [10]) implemented different segmental anatomical references and external marker configurations. A little later, a distinction between internal anatomical landmarks and external technical markers was introduced [11]. This 'Calibration Anatomical System Technique' (CAST) was followed by definitions of the references [12] and a standard application [13]. Taking advantage of recently published recommendations [14,15], the protocols 'Laboratorio per l'Analisi del Movimento nel Bambino' (LAMB) [16] and 'Istituti Ortopedici Rizzoli Gait' [17] were also proposed. The latter was the basis of the software 'Total 3D Gait' (T3Dg – Aurion s.r.l., Milan, Italy).

The precision and accuracy of gait analysis experiments are certainly influenced by the instrumentation used [18] but particularly by the interposition of soft tissues between markers and bones, which have unpredictable effects [19,20]. In addition, there is natural intra-subject variability [21,22], particularly associated to different walking speeds. Furthermore, large differences have been observed among subjects [23-27], mainly associated to age, gender, body mass index, and probably to ethnic characteristics. Intra- [28] and inter-examiner [29] gait data variability, resulting from inconsistent bony landmark identification and marker positioning, has also been underlined. Inter-laboratory variability has also been analysed, before [5] and after [30] relevant instructions provided to the examiners. However, all of these studies were based on the 'Newington model' or its modifications, limiting the figures of variability to that single protocol. A quantification of inter-protocol variability is fundamental to separate the variability associated to the protocol in itself from that of all the other sources. Only a partial comparison between two software versions of the 'Newington model' has been reported [31]. Considerable differences were revealed in many variable peaks although the mean difference over the gait cycle was less than 1°.

The purpose of the present study was to assess the inter-protocol variability of five different protocols and this was achieved by analysing exactly the same gait acquisition. In order to remove the variability associated to repeated gait cycles and to focus on variability associated to more conceptual differences, a single comprehensive marker-set was devised from the union of the corresponding five. This would contribute to giving a quantitative picture of all the sources of variability, from the intra-subject to the inter-protocol. By looking at several repetitions of the gait cycle, we were aimed also at comparing intra- with inter-protocol variability. Finally, the performance of these protocols was compared also by analysing the errors implied in a special condition where one joint degree of freedom was known a priori.

2. Material and Methods

A single marker set was designed to implement the five protocols under analysis, i.e. T3Dg [17], PiG [8,9], SAFLo [10], CAST [13], LAMB [16], by limiting the total number of necessary markers. This ultimately included 60 markers (Figure 1): 22 on each leg, 5 on the pelvis and 11 on the trunk. The lateral and medial epicondyle markers were included in a special cluster of three markers clamped to the femoral condyles as required by SAFLo [10]. The two medial malleoli markers were removed after static up-right posture acquisition. As for the CAST, four technical markers were attached to each segment [13,19,32]. The great trochanter, medial and lateral epicondyles, medial and lateral malleoli, head of the fibula, and tibial tuberosity were also calibrated in each leg by using a pointer on which two markers were located at known distances from the tip [11-13]. All the other landmarks necessary for this protocol were calibrated by using corresponding markers in a single static up-right posture.

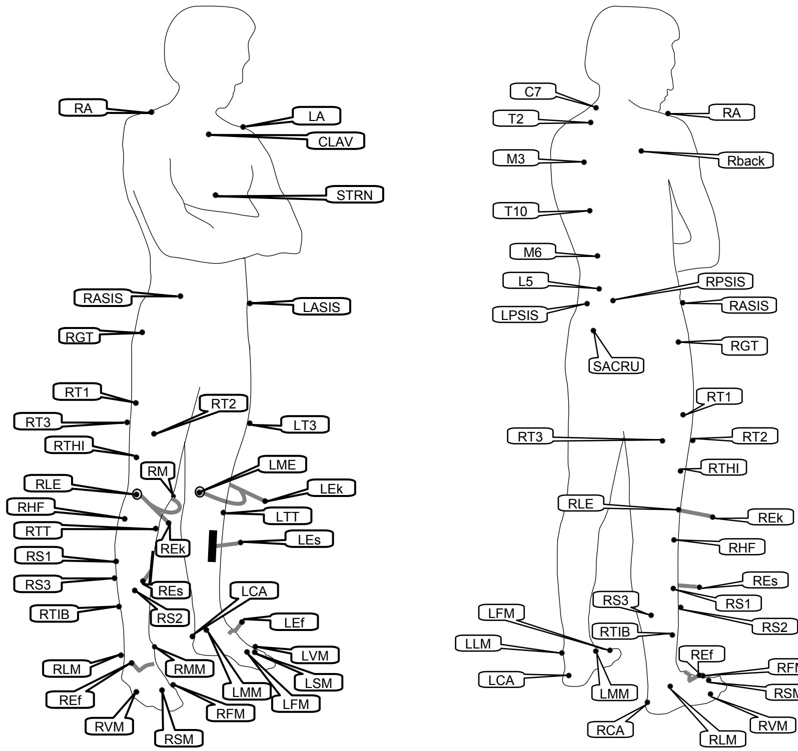

Fig 1: Diagram of the marker-set (antero-lateral – left and postero-lateral – right views) implemented for the experiments.

Two asymptomatic subjects (AF: 24 years, 188 cm, 74 Kg; BM: 24 years, 181 cm, 89 Kg) and one patient (SZM: 54 years, 177 cm, 95 Kg) were analysed. The latter had a special knee prosthesis (MRH Knee, Stryker Corporation) implanted, which allows rotations about the medio-lateral axis of the femur (flexion/extension) and about the longitudinal axis of the tibia (internal/external rotation), while preventing fully abduction/adduction.

Marker trajectories and ground reaction forces were collected respectively by an eight-camera motion capture system (Vicon 612, Vicon Motion Systems Ltd, Oxford, UK) and two force plates (Kistler Instrument AG, Switzerland) at 100 samples per second. Data acquisitions were carried out in the presence of experts for each protocol, who performed all together landmark identification and marker mounting. Each expert took the relevant anthropometric measures required by his own protocol independently. The subjects were asked to walk barefoot at their natural speed, and 5-6 walking trials were recorded.

After each acquisition session, 3D marker trajectories were reconstructed and the right and left stride phases were identified. At least three gait cycles for each limb were selected on the basis of good quality of the marker trajectories and ground reaction forces. For each selected gait cycle, the marker trajectories of each marker set were extracted from the data file and provided to the expert of each protocol together with relevant ground reaction forces. Distinct procedures for data filtering or smoothing, those characteristic of each protocol, were applied independently by each expert. Neither normalisation nor off-set subtraction was performed. Relevant gait analysis results from the five elaborations and from the repetitions were then superimposed in relevant plots, with a careful comprehension of the variable correspondences, regardless of the different terminology adopted. The variable units were unified, i.e. segment and joint rotations were expressed in degrees and joint moments in Newton per metre (Nm).

The mean absolute variability (MAV), i.e. maximum minus minimum values along each frame averaged over all samples of the gait cycle [5,17,29,30], was calculated for each variable. Once normalised by the range of the variable, the mean relative variability (MRV%) was obtained. As for the joint moments, MAV and MRV% applied only to the stance phase because CAST and T3Dg assume a zero value in the swing phase. In order to identify separately intra-subject variability, MAV and MRV% were also calculated for some variables that are independent from protocol-based processing, i.e. the vertical co-ordinate of markers and ground reaction force. Coefficients of correlation (Pearson moment) between any possible couple of protocols were calculated by standard statistical analysis (Matlab, Mathworks, USA), as used elsewhere [33]. The significance level of each correlation coefficient was obtained by computing the p-value. If the p-value was small, say less than 0.001, the correlation was statistically significant. The mean over trials of the correlation coefficients for each gait variable was calculated after a 'z-distribution' transformation [34].

3. Results

A very small intra-subject variability for both kinematic and kinetic results was observed in each subject. In subject AF, MRV% for the vertical co-ordinate of the sacrum, lateral epicondyle and lateral malleolus was 9.0%, 9.2%, and 4.9% respectively. MRV% of the vertical, medio-lateral and antero-posterior components of the ground reaction force was 4.7%, 11.3% and 5.6% respectively. For these six variables, the corresponding coefficients of correlations were 0.979, 0.979, 0.995, 0.973, 0.992 and 0.992, all with $p<0.001$. Because the variability over repetitions is much smaller than that over protocols (Figure 2), a single representative trial is reported from now on.

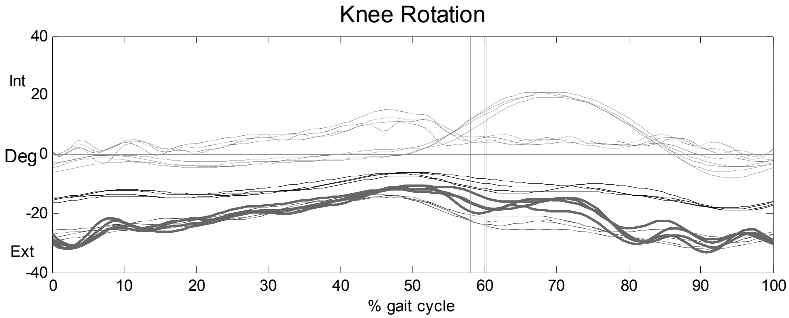

Fig 2: Internal/external rotation at the left knee of subject AF as calculated by T3Dg (dash), PIG (dot lines), SAFLo (dash-dot), CAST (black solid), and LAMB (grey thick-solid) for all four trial repetitions.

Intra-protocol repeatability was high and similar for each protocol (Table 1). Not a single protocol was found particularly sensible to subject variation over repetitions. In particular, MAV was confined to 5° for the pelvis rotations, 7° for all joint rotations and 18Nm for joint moments.

Protocols	T3Dg		PiG		SAFLo		CAST		LAMB	
Rotations [deg]	**right**	**left**	**right**	**left**	**right**	**left**	**right**	**left**	**right**	**left**
Pelvic Tilt	1.4		1.5		1.8		1.4		1.4	
Pelvic Obliquity	1.0		1.0		1.0		0.9		1.0	
Pelvic Rotation	4.8		4.8		4.8		4.9		4.1	
Hip Flexion/Extension	3.3	2.8	3.5	3.0	3.2	3.8	3.4	2.6	3.5	2.9
Hip Abduction/Adduction	1.7	2.5	1.9	2.7	2.3	2.4	1.7	2.6	1.9	2.7
Hip Internal/External Rotation	3.1	2.9	3.8	2.9	4.6	6.3	3.5	3.0	4.1	2.9
Knee Flexion/Extension	3.5	2.0	3.4	2.2	3.1	3.1	3.4	2.1	3.5	2.1
Knee Abduction/Adduction	1.3	1.2	1.5	1.3	1.8	1.6	1.0	0.8	1.0	1.0
Knee Internal/External Rotation	2.7	2.7	2.7	2.4	4.0	2.9	1.9	2.1	3.4	3.1
Ankle Dorsi/Plantarflexion	2.4	2.3	2.5	2.1	2.1	2.4	2.1	2.1	2.7	2.4
Ankle Eversion/Inversion	1.6	1.8			1.2	2.3	1.6	1.7	0.5	0.8
Ankle Abduction/Adduction	2.5	3.4			2.0	3.1	1.5	3.1	0.6	0.8
Moments [N*m]										
Hip Flexion/Extension	12.5	17.4	14.0	15.5	13.0	15.6	12.8	17.1	10.1	15.6
Hip Abduction/Adduction	7.9	10.0	7.3	7.9	8.0	9.6	8.2	10.2	5.5	7.3
Hip Internal/External	2.0	1.1	2.2	2.0			2.1	1.4	1.7	1.0
Knee Flexion/Extension	8.7	11.9	8.3	11.5	8.0	9.7	9.2	11.6	9.9	11.9
Knee Abduction/Adduction	4.0	6.8	3.6	5.7	3.7	6.1	4.4	6.4	3.6	5.7
Knee Internal/External	1.5	0.9	2.6	1.8			1.6	1.1	1.5	1.1
Ankle Dorsi/Plantarflexion	14.0	9.2	14.7	9.6	14.3	11.5	13.9	9.7	16.0	11.0
Ankle Eversion/Inversion	3.8	4.3			2.4	5.9	3.9	4.2	3.0	2.9
Ankle Abduction/Adduction	4.1	3.2					1.4	1.6	5.3	4.0

Table 1: Intra-protocol variability along the four trials across each joint rotation and moment variables for subject AF. The average value of the maximum minus minimum over each sample (MAV) is reported for the right and left leg for each protocol.

Overall, a general uniformity was found among the five protocols for most of the variables in all three subjects, a typical subject -AF- being reported in Figures 3 and 4. Good consistency was observed for all joint flexion/extensions, acceptable consistency was found for pelvic rotations, for hip out-of-sagittal plane rotations and for all joint moments. Poor consistency was found for trunk rotations and out-of-sagittal plane rotations in knee and ankle joints. In particular, though limited to the swing phase, abduction/adduction of the right knee (Figure 3) reveals large adductions in PiG, small adductions in T3Dg and LAMB, nearly no motion in SAFLo, and small abductions in CAST.

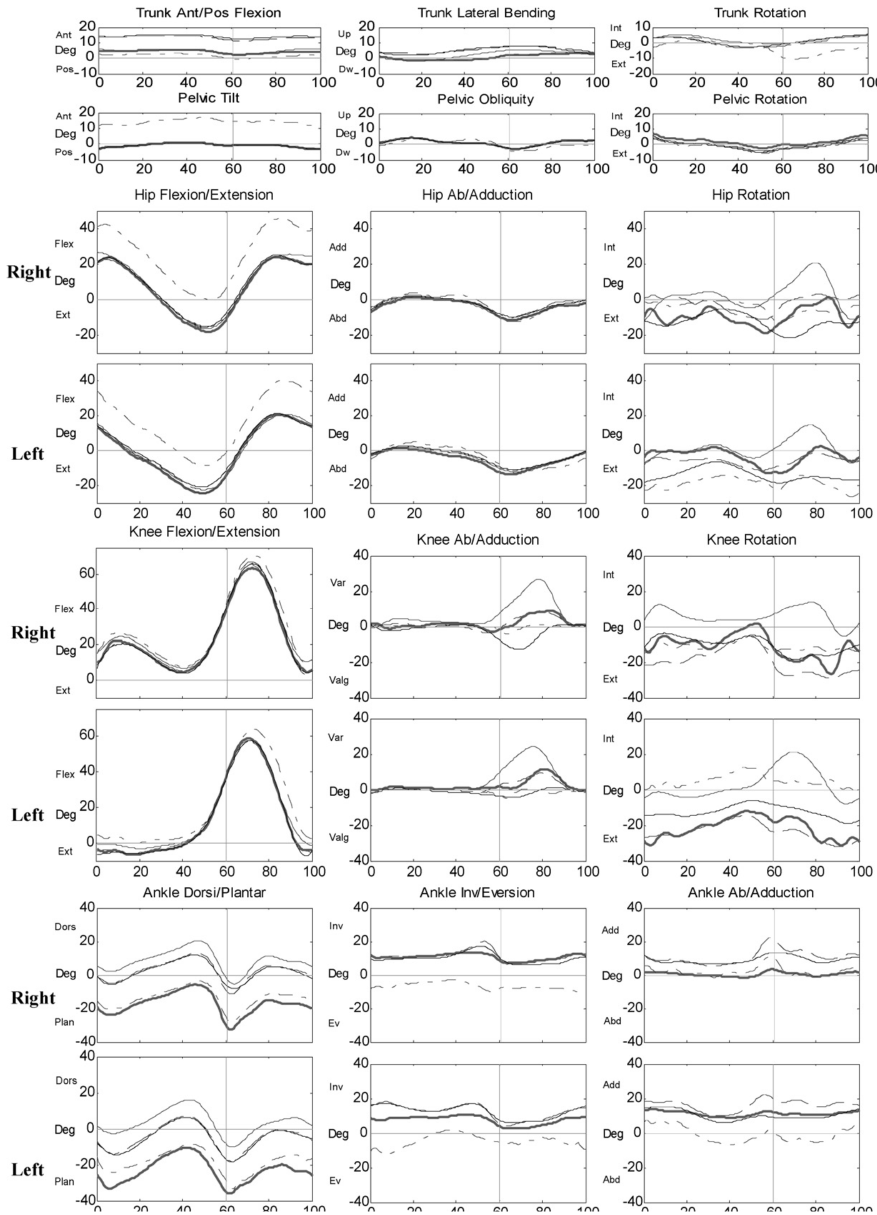

Fig 3: Kinematics variables as calculated by the 5 protocols (line styles as in Figure 2) and relative to only one complete gait cycle of subject AF. Trunk, pelvis, and right and left hips, knees, and ankles are reported over the rows; sagittal, frontal and transverse plane rotations over the columns. All five protocols reveal abnormal motion at the left knee (see Discussion for more details).

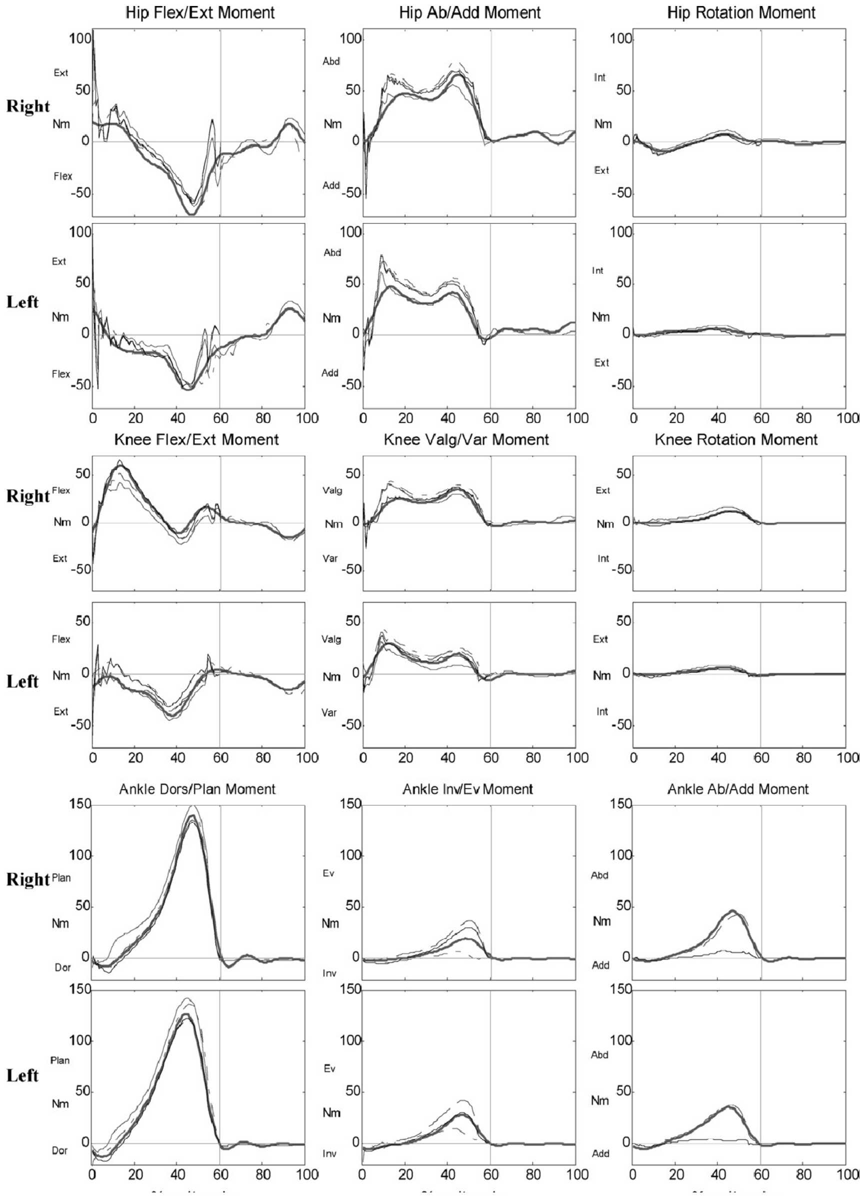

Fig 4: Kinetic variables of subject AF, line styles as in Figure 2. The convention adopted was that of the external moment, i.e. the resultant moment of the external forces.

Correspondingly, inter-protocol variability was obtained (Table 2), confining MAV to 21Nm for the joint moments, but with peaks of 31° and 27° respectively for knee internal/external rotation and ankle dorsi/plantarflexion. This was obtained with a full analysis of the trials for each variable, i.e. by joining the four repetitions in a single virtual trial composed of the sequential series of the four performed by subject AF. For a few variables, the results from the right and left legs were not fully consistent within this subject. Very similar results were found for the other two subjects analysed.

	MAV	**MAV**	**MRV%**	**MRV%**
Rotations [deg]	**right**	**left**	**right**	**left**
Pelvic Tilt	15.4		72.6	
Pelvic Obliquity	1.9		19.0	
Pelvic Rotation	3.6		16.6	
Hip Flexion/Extension	20.4	18.2	29.9	25.8
Hip Abduction/Adduction	6.1	8.2	30.4	32.4
Hip Internal/External Rotation	17.0	21.0	38.1	47.2
Knee Flexion/Extension	5.8	7.7	8.4	10.8
Knee Abduction/Adduction	11.9	7.5	27.2	23.7
Knee Internal/External Rotation	25.6	30.9	56.3	56.9
Ankle Dorsi/Plantarflexion	25.5	26.8	44.3	48.0
Ankle Eversion/Inversion	18.5	18.2	57.9	56.7
Ankle Abduction/Adduction	12.0	20.8	38.7	55.3
Moments [N*m]				
Hip Flexion/Extension	21.0	20.2	10.5	11.5
Hip Abduction/Adduction	18.1	16.9	13.5	13.2
Hip Internal/External	4.2	2.5	17.3	23.7
Knee Flexion/Extension	15.0	15.0	13.2	18.2
Knee Abduction/Adduction	10.9	12.8	16.2	19.2
Knee Internal/External	4.1	2.8	22.6	23.8
Ankle Dorsi/Plantarflexion	15.9	16.4	10.1	10.7
Ankle Eversion/Inversion	11.2	13.3	28.5	26.0
Ankle Abduction/Adduction	13.2	12.7	27.6	29.2

Table 2: Inter-protocol variability across each joint rotation and moment obtained by merging in a single virtual curve the four trials of subject AF. The maximum minus minimum value at each sample averaged over all samples (MAV) and the same normalized by the range of excursion of the relevant mean curve (MRV%) are reported for each variable.

When analysing the kinematic results of the patient in which abduction/adduction at the right knee was restrained by the joint prosthesis (SZM, Figure 5) the results from the PiG protocol were the most critical, with a range of about 35°. T3Dg, SAFLo, CAST and LAMB contained mean error within 2.5° (Table 3).

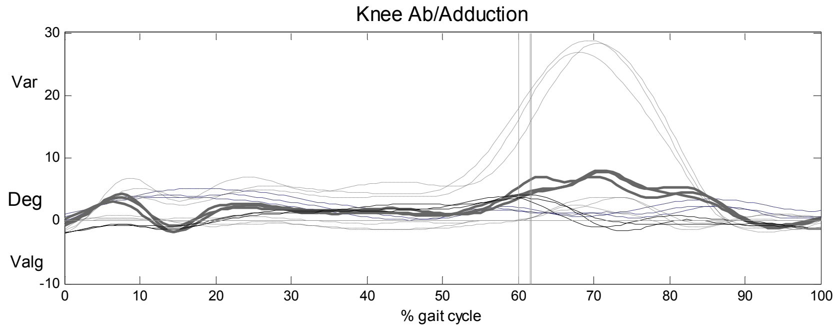

Fig 5: Abduction/adduction at the right knee of subject SZM, as calculated by the 5 protocols over the three trial repetitions (line styles as in Figure 2). In this joint, this rotation is fully restrained, therefore the gold standard for this variable is zero.

	T3Dg	PiG	SAFLo	CAST	LAMB
Mean	2.2	8.1	0.7	1.3	2.5
Standard deviation	1.2	8.2	1.0	1.5	2.2

Table 3: Mean and standard deviations of knee abduction/adduction along the three trials for subject SZM.

Not a single couple of protocols emerged to be the most correlated (Table 4 for subject AF) in no one of the two subjects. Negative values, particularly in rotations out-of-the-sagittal planes, reveal opposite trends. Good correlations between protocols were found for the kinetics variables, the largest being ankle dorsi/plantarflexion ($r>0.988$, $p<0.001$). As for the kinematics variables, correlations were found smaller for rotations out-of-sagittal planes than for flexion/extensions. The correlation coefficient r for these latter was never smaller than 0.993 ($p<0.001$) for the hip, 0.992 ($p<0.001$) for the knee and 0.957 ($p<0.001$) for the ankle joints

Table 4: Correlation coefficients obtained by comparing each couple of protocols and averaged over the four trials. These are reported for the right and left legs separately and for each joint rotation and moment variable. *** $p<0.001$; ** $p<0.01$; * $p<0.05$

Protocols	T3Dg vs PiG	T3Dg vs SAFLo	T3Dg vs CAST	T3Dg vs LAMB	PiG vs SAFLo	PiG vs CAST	PiG vs LAMB	SAFLo vs CAST	SAFLo vs LAMB	CAST vs LAMB
Rotations [deg]	**RIGHT side**									
Pelvic Tilt	0.984^{***}	0.838^{***}	0.986^{***}	0.977^{***}	0.825^{***}	0.989^{***}	0.970^{***}	0.835^{***}	0.841^{***}	0.988^{***}
Pelvic Obliquity	0.998^{***}	0.732^{***}	0.991^{***}	0.998^{***}	0.727^{***}	0.991^{***}	0.994^{***}	0.802^{***}	0.739^{***}	0.991^{***}
Pelvic Rotation	0.996^{***}	0.980^{***}	0.989^{***}	0.998^{***}	0.978^{***}	0.990^{***}	0.990^{***}	0.991^{***}	0.980^{***}	0.987^{***}
Hip Fl/Ext	0.997^{***}	0.998^{***}	0.999^{***}	0.999^{***}	0.994^{***}	0.995^{***}	0.998^{***}	0.997^{***}	0.997^{***}	0.998^{***}
Hip Ab/Add	0.998^{***}	0.945^{***}	0.994^{***}	0.988^{***}	0.946^{***}	0.994^{***}	0.986^{***}	0.963^{***}	0.981^{***}	0.994^{***}
Hip Int/Ext	0.241	-0.055	-0.184	0.686^{***}	-0.207	-0.182	0.646^{***}	0.847^{***}	0.111	0.137
Knee Fl/Ext	0.995^{***}	0.994^{***}	0.999^{***}	0.998^{***}	0.994^{***}	0.996^{***}	0.997^{***}	0.995^{***}	0.995^{***}	0.999^{***}
Knee Ab/Add	0.869^{***}	-0.108	-0.258	0.905^{***}	-0.367	-0.567^{***}	0.792^{***}	0.741^{***}	0.076	-0.046^{***}
Knee Int/Ext	-0.164	0.847^{***}	0.768^{***}	0.878^{***}	-0.176	-0.089	-0.168	0.700^{***}	0.798^{***}	0.855^{***}
Ankle Dor/Plan	0.984^{***}	0.988^{***}	0.988^{***}	0.987^{***}	0.987^{***}	0.980^{***}	0.992^{***}	0.977^{***}	0.984^{***}	0.978^{***}
Ankle Ev/Inv		-0.032	0.971^{***}	0.770^{***}				0.090	0.338^{**}	0.741^{***}
Ankle Ab/Add		0.817^{***}	0.926^{***}	0.679^{***}				0.797^{***}	0.736^{***}	0.717^{***}
Moments N*m										
Hip Fl/Ext	0.967^{***}	0.866^{***}	1.000^{***}	0.870^{***}	0.921^{***}	0.969^{***}	0.897^{***}	0.868^{***}	0.960^{***}	0.873^{***}
Hip Ab/Add	0.968^{***}	0.978^{***}	1.000^{***}	0.946^{***}	0.955^{***}	0.967^{***}	0.941^{***}	0.976^{***}	0.975^{***}	0.942^{***}
Hip Int/Ext	0.975^{***}		0.977^{***}	0.979^{***}		0.944^{***}	0.978^{***}			0.951^{***}
Knee Fl/Ext	0.970^{***}	0.930^{***}	0.991^{***}	0.932^{***}	0.952^{***}	0.979^{***}	0.904^{***}	0.968^{***}	0.952^{***}	0.950^{***}
Knee Ab/Add	0.968^{***}	0.974^{***}	0.932^{***}	0.929^{***}	0.932^{***}	0.842^{***}	0.860^{***}	0.922^{***}	0.952^{***}	0.950^{***}
Knee Int/Ext	0.969^{***}		0.966^{***}	0.978^{***}		0.958^{***}	0.955^{***}			0.977^{***}
Ankle Dor/Plan	0.994^{***}	0.998^{***}	1.000^{***}	0.995^{***}	0.996^{***}	0.992^{***}	0.988^{***}	0.998^{***}	0.993^{***}	0.996^{***}
Ankle Ev/Inv		0.712^{***}	0.992^{***}	0.977^{***}				0.753^{***}	0.729^{***}	0.987^{***}
Ankle Ab/Add			0.942^{***}	0.985^{***}						0.958^{***}
	LEFT side									
Hip Fl/Ext	0.998^{***}	0.997^{***}	0.999^{***}	0.999^{***}	0.999^{***}	0.995^{***}	0.996^{***}	0.993^{***}	0.994^{***}	0.999^{***}
Hip Ab/Add	0.999^{***}	0.924^{***}	0.996^{***}	0.989^{***}	0.929^{***}	0.997^{***}	0.985^{***}	0.950^{***}	0.866^{***}	0.976^{***}
Hip Int/Ext	0.467^{***}	0.102	0.246	0.796^{***}	0.472^{**}	0.007	0.151	0.720^{***}	0.321	0.641^{***}
Knee Fl/Ext	0.998^{***}	0.993^{***}	0.999^{***}	1.000^{***}	0.994^{***}	0.997^{***}	0.999^{***}	0.992^{***}	0.993^{***}	0.999^{***}
Knee Ab/Add	0.952^{***}	0.027	-0.029	0.887^{***}	-0.159^{*}	-0.303^{**}	0.740^{***}	0.553^{***}	0.147	0.317^{**}
Knee Int/Ext	-0.020	0.811^{***}	0.855^{***}	0.870^{***}	0.137	0.337^{*}	0.357^{*}	0.843^{***}	0.803^{***}	0.887^{***}
Ankle Dor/Plan	0.975^{***}	0.961^{***}	0.996^{***}	0.984^{***}	0.981^{***}	0.970^{***}	0.980^{***}	0.961^{***}	0.957^{***}	0.980^{***}
Ankle Ev/Inv		-0.051	0.979^{***}	0.850^{***}				-0.066	0.339^{*}	0.856^{***}
Ankle Ab/Add		0.422^{***}	0.702^{***}	0.665^{***}				0.880^{***}	0.878^{***}	0.909^{***}
Moments N*m										
Hip Fl/Ext	0.939^{***}	0.750^{***}	1.000^{***}	0.765^{***}	0.868^{***}	0.935^{***}	0.833^{***}	0.747^{***}	0.702^{***}	0.763^{***}
Hip Ab/Add	0.979^{***}	0.971^{***}	1.000^{***}	0.926^{***}	0.982^{***}	0.979^{***}	0.938^{***}	0.968^{***}	0.983^{***}	0.923^{***}
Hip Int/Ext	0.927^{***}		0.879^{***}	0.976^{***}		0.825^{***}	0.931^{***}			0.834^{***}
Knee Fl/Ext	0.976^{***}	0.798^{***}	0.969^{***}	0.850^{***}	0.864^{***}	0.940^{***}	0.882^{***}	0.789^{***}	0.968^{***}	0.826^{***}
Knee Ab/Add	0.945^{***}	0.968^{***}	0.983^{***}	0.933^{***}	0.968^{***}	0.972^{***}	0.919^{***}	0.980^{***}	0.986^{***}	0.939^{***}
Knee Int/Ext	0.961^{***}		0.963^{***}	0.987^{***}		0.916^{***}	0.968^{***}			0.939^{***}
Ankle Dor/Plan	0.997^{***}	0.995^{***}	1.000^{***}	0.998^{***}	0.997^{***}	0.995^{***}	0.993^{***}	0.995^{***}	0.996^{***}	0.998^{***}
Ankle Ev/Inv		0.738^{***}	0.996^{***}	0.985^{***}				0.740^{***}	0.678^{***}	0.990^{***}
Ankle Ab/Add			0.860^{***}	0.994^{***}						0.841^{***}

4. Discussion

Frequently, gait analysis results are interpreted and compared with limited consciousness of the conceptual and practical choices implied in the relevant protocol. In the present study, single gait cycles were analysed simultaneously by using five different protocols, which represent the large majority of those commonly used in gait analysis. Conformity with the original protocol design, i.e. biomechanical interpretation and marker-set, was ensured by direct participation of relevant experts, involved both in data collection and reduction.

The overall procedures were repeated in only three volunteers. However, the analyses of the right and left legs imply distinguished experiments, involving independent landmark identification, marker attachment, anthropometric measurement, and data processing. In addition, subject SZM had a special knee prosthesis in only one leg. Finally, it turned out that subject AF had congenital leg length discrepancy (about 4 cm), which resulted in considerably different patterns between legs. Therefore, the present study should be regarded as composed by independent analyses of three trunks and pelves and six legs.

Intra-protocol variability was small for all five protocols. This implies that intra-subject repeatability over the trials, however small in the three subjects analysed, was reported consistently over the protocols. In addition, the comparison of values in Tables 1 and 2 shows that inter-protocol variability is clearly larger than intra-protocol variability, except for pelvis rotation.

Overall the gait variables are comparable among protocols (Figure 3), despite the large differences between models and marker-sets. Joint kinematics showed larger inter-protocol differences than joint kinetics. Flexion/extension had good waveform correlations with small bias differences in all joints except the ankle. On the contrary, out-of-sagittal plane rotations, especially at the knee and ankle joints, revealed poor waveform correlations and even considerable bias differences. The largest variability was observed at knee abduction/adduction where even opposite trends were observed. The extent to which this is due to the different models, marker-set or to relevant skin artefact is not known. Because similar patterns were observed over the six knees, it is hypothesized that a bias associated to the axis of rotation and related cross talk is more plausible than an erroneous positioning of the markers. The larger consistency at joint moments is noteworthy because not expected when considering the relevant substantial methodological differences. LAMB, SAFLo and PiG use standard inverse dynamics, whereas T3Dg and CAST use only the external ground reaction force. Estimation of the joint centres is also very critical, and each protocol uses different techniques. This acceptable coherence on the results may further support the role of the external force, which must be predominant in gait at natural speed.

The PiG, based on the original Newington model, and SAFLo are among the pioneering protocols for gait analysis. When these were devised, basic instrumentation and limited knowledge of the skin artefacts were available. Therefore, it is remarkable that these protocols have obtained adequate correlation with the more recent ones for most of the gait variables. Bias and correlation differences of SAFLo are straightforwardly accounted for by the specific anatomical references particularly for the pelvis and the ankle. T3Dg is a recent development of the general CAST approach. The very similar relevant results support further the fact that a small deterioration of the results is expected when the location of markers in the central area of the segments and calibration of landmarks via an instrumented pointer are substituted with direct skin marker placement. T3Dg and LAMB protocols share most model definitions except the equations for hip joint centre estimation (according to [35] and [8] respectively). Slightly different choices are adopted also for the marker-set, but all this did not result in considerable final differences for the gait variables. Overall, the high correlation obtained for the variables calculated by CAST, LAMB and T3Dg (Table 4) suggests that a large uniformity of the results is associated more to the consistency of the biomechanical conventions than to the design of the relevant marker-sets.

The abduction/adduction of the right knee of subject SZM (Figure 5 and Table 3), i.e. the gold standard, revealed a considerably different performance of PiG with respect to the other protocols, though limited to the first half of the swing phase. This might have been due to an incorrect marker location resulting in incorrect alignment of the axis of rotation and therefore in cross-talk from flexion/extension, relatively large in that phase, to abduction/adduction. However, most of these markers are shared by the other protocols. In addition, a predisposition to larger abductions at the knee for this protocol was reported for all six knees. A larger variability for the joint rotations that require careful alignment of the wands was reported for this protocol also elsewhere [5,30]. The best performance in assessing this gold standard was obtained by SAFLo. This protocol identifies the flexion axis of the knee with a functional approach [36], which is expected to reduce this cross-talk.

The above remarks are only preliminary accounts of the observed differences. A thorough and rational comparison of the five techniques is possible by looking at every single gait variable and by inferring relevant justifications for these. The task is however not easy because the time-history of each variable results from an intrigued interplay of reference definitions, kinematics conventions, and artefactual motion.

In conclusion, the comparison of the results from the five protocols on the same gait cycles revealed first of all good intra-protocol repeatability. Despite the known large differences among the techniques, good correlations were observed for most of the gait variables. As for the exact variable patterns, good consistency was found for all joint flexion/extensions and pelvic rotations. Acceptable consistency was found for hip out-of-sagittal plane rotations and nearly all joint moments, whereas it was poor in knee and ankle out-of-sagittal plane rotations. For the latter therefore, it is recommended that comparison of the results among protocols be very careful. The variability associated to the protocol used seems much larger than that associated to inter-observer and even inter-laboratory comparisons [5,17,29,30] for most of the gait variables. It might be also pointed out that, in general, model conventions and definitions seem more crucial than the design of the relevant marker-sets, and that therefore sharing the former can be sufficient for worldwide clinical gait analysis data comparison.

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Chapter 3

'OUTWALK': A PROTOCOL FOR CLINICAL GAIT ANALYSIS BASED ON INERTIAL & MAGNETIC SENSORS

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Abstract

A protocol named Outwalk was developed to easily measure on children with cerebral palsy and amputees the thorax-pelvis and lower-limb 3D kinematics during gait in free-living conditions, by means of an Inertial and Magnetic Measurement System (IMMS). Outwalk defines the anatomical/functional coordinate systems for each body segment through three steps: 1) positioning the Sensing Units (SUs) of the IMMS on the subjects' thorax, pelvis, thighs, shanks and feet, following simple rules; 2) computing the orientation of the mean flexion-extension axis of the knees; 3) measuring the SUs' orientation while the subject's body is oriented in a predefined posture, either upright or supine. If the supine posture is chosen, e.g. when spasticity does not allow to maintain the upright posture, hips and knees static flexion angles must be measured through a standard goniometer and input into the equations that define Outwalk anatomical coordinate systems. To test for the inter-rater measurement reliability of these angles, a study was carried out involving 9 healthy children (7.9±2 year-old) and 2 physical therapists as raters. Results showed a RMS error of 1.4° and 1.8° and a negligible worst-case standard error of measurement of 2.0° and 2.5° for hip and knee angles, respectively. Results were thus smaller than those reported for the same measures when performed through an optoelectronic system with the CAST protocol, and support the beginning of clinical trials of Outwalk with children with cerebral palsy.

Keywords

Gait analysis; Kinematics; Protocol; Ambulatory; Inertial Sensors; Magnetic Sensors; Cerebral Palsy; Amputee.

Glossary

CP: cerebral palsy

CS: coordinate system

DR: right drop-rise

IMMS: inertial and magnetic measurement system

h: hip static flexion angle during Outwalk calibration in supine posture

k : knee static flexion angle during Outwalk calibration in supine posture

PAT: posterior-anterior tilting

RMS: root mean square

SEM_{se}: standard error of measurement considering systematic errors

SEM_{nse}: standard error of measurement not considering systematic errors

SU: sensing unit of an IMMS

TP: joint representing the movements of the Pelvis relative to the Thorax

T1, T2: physical therapists involved in the reliability study of *h* and *k*

1. Introduction

Instrumental gait analysis has become a valuable tool in clinical practice [1] establishing its usefulness particularly for children with Cerebral Palsy (CP) [7], but also for amputees [15, 24]. Nevertheless, its use is still limited to very few medical centres, and its ability to monitor a patient's spontaneous and typical walking capacity, opposed to best performance, has still to be fully explored. In our opinion, the reasons for the present situation can be predominantly traced back to limitations in the measurement systems. In particular, optoelectronic systems are costly, hardly portable, and have a restricted field of view [3]. These features limit their use to dedicated laboratories and restrict the acquisition of a subject's gait to few strides per trial, in conditions which can be far from steady state. In addition, the acquisition of gait in an unfamiliar and artificial environment, such as that of a laboratory, can psychologically condition the subject, who will over-perform with respect to his/her every-day-life ability [13].

The recent availability of Inertial & Magnetic Measurement Systems (IMMSs) might open new perspectives for the measurement of the gait kinematics. IMMSs are commercially available, cost effective, and portable motion analysis systems. Thanks to these features, IMMSs might allow the user to execute and acquire the movement in laboratory-free settings, in a continuous modality, for long periods; therefore they might allow the user to collect a great number of consecutive gait cycles during spontaneous walking in daily life environments [16].

An IMMS consists of Sensing Units (SUs), which are lightweight boxes. Each SU integrates one 3D accelerometer, gyroscope, and magnetometer. The data supplied by these sensors are combined [21, 22] in order to measure the 3D orientation (but not the position) of the SU's Coordinate System (CS) with respect to a global, earth-based CS. Given this 3D orientation, an IMMS has the potential to estimate joint kinematics when: 1) a SU is attached to each body-segment of interest; 2) at least one anatomical CS is defined for each body-segment; and 3) the orientation of the anatomical CS is expressed in the CS of the SU. Joints kinematics can then be obtained from the relative orientation of contiguous anatomical CSs. The critical part of this process is the definition of the anatomical CSs. In fact, the lack of information regarding the position of the sensors implies that the anatomical CSs cannot be defined through the calibration of single anatomical landmarks (as recommended by the ISB [32]). Therefore different techniques must be conceived.

Only a few studies investigated the use of IMMSs for gait kinematics measurement [18, 19]. O'Donovan and co-workers [18] defined a protocol for 3D inter-segment joint-angle measurement. However they specified their techniques just with respect to the ankle joint. In addition, the calibration steps require a rotation about the longitudinal axis of the whole body and a knee extension with minimal movement of the ankle, all tasks that may not be easily performed by certain populations of subjects, e.g. children with CP or amputees.

Picerno and co-workers [19] defined a protocol to estimate lower-limb joint kinematics. The definition of the anatomical CSs was partially based on the external anatomical landmarks described in [6]. However, this protocol requires for each body segment to establish the orientation of a minimum of two non-parallel lines using multiple calibration tasks, involving multiple specialized devices at the expense of simplicity and experiment duration.

In the effort of overcoming current limitations, the aim of this work was twofold.

First, it was intended to develop a new protocol, named 'Outwalk', satisfying the following constraints: 1) suitable for IMMSs; 2) able to measure the kinematics of the TP (pelvis relative to the thorax), hip, knee and ankle joints; oriented to children with CP and to lower-limb amputees, and therefore based on 3) fast sensors mounting; 4) fast and comfortable calibration procedures; 5) not requiring any additional specialized device than the IMMS itself.

Second, it was intended to test an essential requirement for Outwalk validity, i.e. to assess the inter-rater reliability of the goniometric measure of hip and knee static flexions in children laying supine on a mat. High reliability is searched for, as these measures are required as *input* to Outwalk when applied on subjects with irreducible knee flexion (e.g. in some forms of CP), laxity or deformities. Our hypothesis was that static hip and knee flexions can be measured with a precision not lower than that reported in [11] for hip and knee flexions measured with an optoelectronic system through the CAST protocol, assumed as clinical reference. Confirmation of this hypothesis would support the commencement of the clinical trial of Outwalk in CP children.

2. Methods

2.1 Development of 'Outwalk'

In developing Outwalk, the approach described in [8] for the upper-limb was used as reference.

2.1.1 TARGET POPULATION

Outwalk was designed to be suitable for above and below knee amputees and for children with CP. In particular, CP children can be both hemiplegic belonging to forms I- III of Winters et al. [30] and diplegic belonging to forms II- IV of Ferrari et al. [14].

2.1.2 REQUIREMENTS FOR THE MEASUREMENT SYSTEM

Outwalk was conceived for a motion tracking system: 1) capable to measure in time the orientation of the local CSs of its SUs with respect to a global CS; 2) featuring a visible reference between the orientation of the local CS and the physical appearance of its SU (e.g. the box containing the electronics of the SU), with the smallest possible misalignment.

The Xsens system (Xsens Technologies, NL), is an IMMS which satisfies these requirements (Fig. 1). As this was used in [12] for the validation of Outwalk, herein we will only explicitly refer to this IMMS. The Xsens consists of up to 10 SUs (called MTx) connected by-wire to a data-logger (Xbus Master), usually worn on the belt. The data-logger is connected via Bluetooth to a laptop which processes and stores the data collected. Each SU is hosted in a small box, weights 38g, and is 39x54x28mm. The local CS of the SU is aligned with the boundaries of the box with an error < 3° (Xsens Technical Manual). The orientation of each SU's CS with respect to an earth-based global CS is provided as an output.

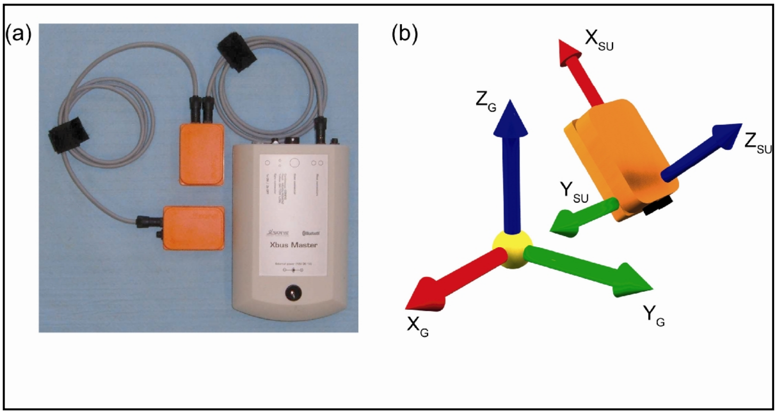

Fig 1: Xsens system. (a) Data-logger (Xbus Master) with two SUs connected; (b) an SU with its local CS, in the global (earth-based) CS.

2.1.3 DEFINITION OF THE REFERENCE KINEMATIC MODEL

The definition of the kinematic model of Outwalk was achieved by following the indications provided in [17].

Thorax, pelvis, thigh, shank and foot were assumed as the rigid segments forming the TP, hip, knee and ankle joints.

TP, hip and ankle joints were assumed as ball & sockets. The knee was assumed as a ‘loose’ double hinge-joint, with one rotation (flexion–extension) occurring about a mediolateral axis fixed in the distal femur and the other rotation (internal-external) occurring about a longitudinal axis fixed in the tibia [23]. The double-hinge is defined “loose” (using a term common for elbow endoprostheses), since it actually allows some ab-adduction. However, when the flexion-extension and internal-external rotations axes are correctly located, movement of the knee joint within a range of 5–90° of flexion can be almost entirely accounted for by simultaneous rotations about these two axes [23].

Following the standard Denavit-Hartenberg convention used in robotics [26], for each segment we defined as many CSs as the number of joints the segment forms, that is: one for the thorax and foot, and two for pelvis, thigh and shank. In the authors’ opinion, this approach mitigates a limitation of the current ISB standard, in which a single set of orthogonal axes is defined for a segment, and used to describe rotations of different joints. This is for example the case of the thigh anatomical CS, in which the Y axis is considered as the *hip* internal-external rotation axis, and Z the *knee* flexion-extension axis. Unfortunately, the orientation of Z is not directly controlled, as it derives from Y and X; as a consequence, it can be generally different from the (mean) axis of rotation of the knee, which should be preferably used instead [25].

As a general rule for naming, for each segment the CS describing the proximal joint is defined as the “proximal CS”, whereas the CS describing the distal joint is defined as the “distal CS”. Moreover, considering the right side of the body, in the segments’ CSs the Y axis points cranially, Z laterally and X anteriorly [32]. For the left side CSs Y points caudally, Z medially and X posteriorly. By so doing, a clinical flexion, abduction or internal rotation performed with the left side of the body assumes the same positive or negative sign assumed when performed with the right side. In other words, the kinematic patterns of the left side can be directly plotted over those of the right side.

The rotations describing the degrees of freedom of the joints were named: posterior-anterior tilting (PAT), right drop-rise (DR), right internal-external rotation (IE) for the TP joint; flexion-extension (FE), adduction-abduction (AA) and internal-external rotation (IE) for the hip; FE, varus-valgus (VV) and IE for the knee; dorsi-plantar flexion (DP), inversion-eversion (IV) and IE for the ankle. In each of these couples, the first rotation is expected to have a positive sign [32].

2.1.4 PROCEDURE TO MEASURE THE TP AND LOWER-LIMB KINEMATICS

The procedure to measure the TP, hip, knee and ankle kinematics of a subject consists of the following 4 steps: 1) positioning the SUs on the subject’ thorax, pelvis, thighs, shanks and feet; 2) computing the orientation of the mean FE axis of the knees in the thighs embedded CSs of the SUs; 3) defining anatomical/functional CSs for thorax, proximal pelvis, distal pelvis, proximal thighs, distal thighs, proximal shanks, distal shanks and feet, and expressing their orientation in the SU CS of the corresponding segment; 4) computing the joint-angles. These steps are described for the right leg only.

2.1.4.1 Positioning the SUs

One SU is positioned on each body-segment with double-sided tape, either over the skin or over elastic cuffs wrapped around the segments (Fig. 2). For the thorax, the SU is positioned over the flat portion of the sternum, with the Z axis of the SU pointing away from the body and X cranially. For the pelvis, the midline of the SU is aligned with the spine, and its X axis is oriented along the line linking the posterior superior iliac spines (PSIS), pointing toward the right PSIS. For the thigh, the SU is positioned laterally, within its median third. For the shank, the SU is positioned within the distal third, close to the lateral malleolus, with the X axis aligned with the long axis of the fibula. The Z axis of the SU points laterally in the body's frontal plane. For the foot, the base of the SU is positioned and oriented over the shoe in order to maximize its stability. In particular, it is recommended to place it over the midfoot, and ascertain that the orientation of the sensor is not affected by forefoot-midfoot relative motion during the third rocker.

Fig 2: Xsens SUs positioned over the body of a subject

2.1.4.2 Functional movements to compute the knee mean flexion-extension axis

To define the anatomical CS for the distal thigh and to express its orientation in the SU CS of the segment, the direction of knee FE axis must be estimated first. The orientation of the SUs over thigh and shank is measured during a pure knee FE task. If the patient can perform the task autonomously, he is instructed to stand in the upright posture and, helped by an examiner in keeping the posture, to flex-extend the knee five times up to 70°. If the patient cannot stand in upright posture or autonomously execute the task, the task can be performed passively, with the subject laying in supine position, while a therapist executes the knee FE movement 5 times up to 70° of flexion. The direction of the knee FE axis is estimated using the functional method described in [31] and it is expressed in the CS of the SU of the thigh (V_{FLEX}).

2.1.4.3 Static acquisition to complete the definition of the anatomical CSs

The anatomical CS of the proximal pelvis is assumed to be coincident with the SU CS. To define the anatomical CSs for thorax, distal pelvis, proximal and distal thigh, proximal and distal shank, and foot and to express the orientation of these anatomical CSs in the SU CS of the corresponding segment, the orientation of the SUs' CSs is measured during a 5 seconds static trial. During this static trial the subject is asked to stand still in one of the following two postures:

upright with the back straight, looking forward, knee centre aligned to the ASIS, and the line from the 2nd metatarsal head to the calcaneus of the right foot parallel to the same line of the left foot (Fig. 3);

in supine position on a mat, with the hip flexed *h* degrees and the knee flexed *k* degrees, knee centre aligned with the ASIS, feet in neutral position and parallel to each other as in posture 1 (Fig. 4).

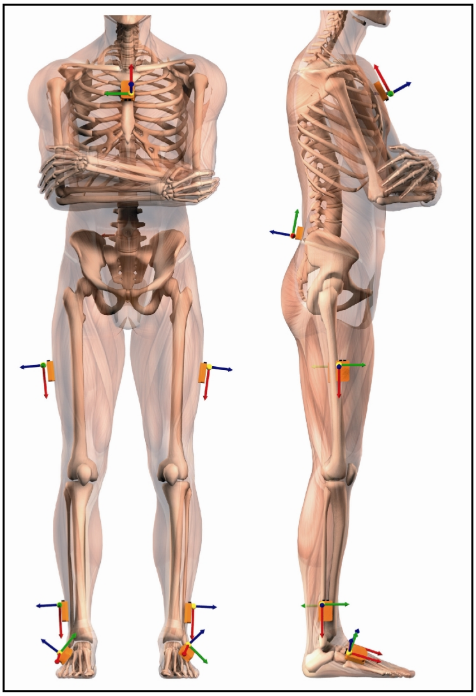

Fig 3: Upright calibration posture. Red, green and blue arrows indicate the X, Y and Z axes of the Xsens local CS.

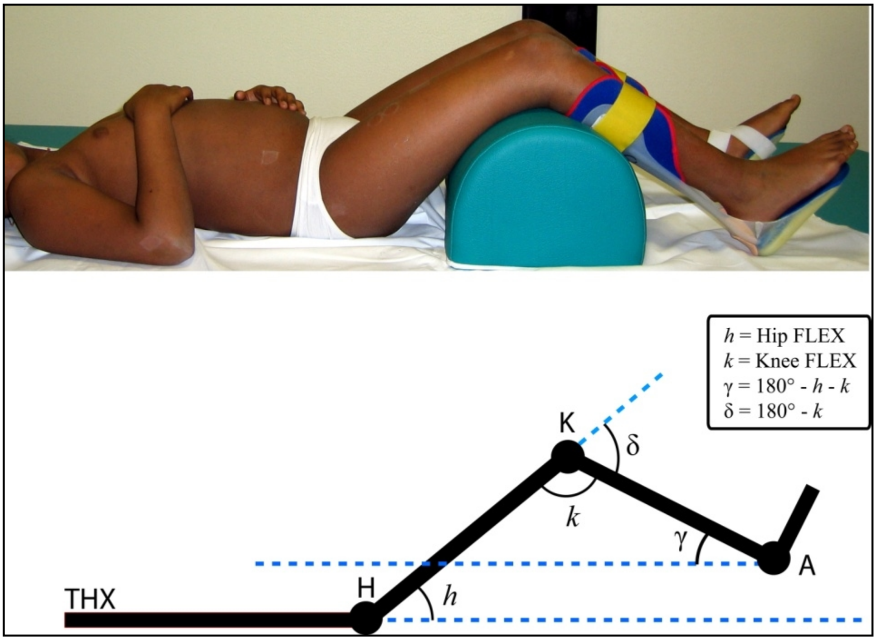

Fig 4: Supine calibration posture. Hips and knees can be flexed h° and k° degrees, respectively, in case of irreducible flexions of the subject. In this case, h and k must be measured through a static goniometer, and used to compute γ and δ; h, γ and δ are then input in the definition of the anatomical CSs (Table 2). If the subject wears AFOs, the zero-condition for the ankle joint-angles is the one assumed by the feet inside the AFO. THX: thorax; H: hip; K: knee; A: ankle.

Posture 2 should be used with CP children and subjects with irreducible knee flexion, laxity or deformities (genu varum, valgum, recurvatum and flexum). Angles *h* and *k* will depend on the specific patient, and they will be 0° if the leg can be fully extended. To sustain the subject's legs, a typical therapeutic foam cylinder (or wedge) is recommended (Fig. 4). A second foam cylinder or wedge can be used to maintain the expected foot calibration posture. If the subject uses an ankle-foot orthosis (AFO), the foot calibration posture is that imposed by the AFO. In posture 2, if the SU on the pelvis touches the mat, than two separate mats should be used and kept as close as possible, but allowing a gap below the SU.

The definitions of the anatomical CSs reported in Table 1 and Table 2 are then applied for the upright and supine posture, respectively. CSs were developed following the example of [8]; they have a constant orientation with respect to the SU's CS of the corresponding segment.

Definitions in Table 2 are based on those of Table 1, but take into account that:

1) hip and knee can be flexed h° and k°, and therefore the cranio-caudal axes of thigh and shank cannot be assumed to lie in the frontal plane. Their rotations

out of the frontal plane must be compensated to properly define the CSs of proximal and distal thigh, and proximal shank. To apply the definitions in Table 2, therefore, the examiner will need to measure h and k through a static goniometer;

2) when the calibration is executed in supine position, the Z axis of the SU on the thorax becomes almost parallel to the gravity line, and therefore the computation of a thorax medio-lateral direction from Z and gravity can be badly conditioned.

TABLE 1

Segment	Axes Definition	Anat. direction.	
Thorax (TH)	$Y_{TH} = {}^{SU\text{-}TH}Z_G / \|\cdot\|$	cranial	
	$Z_{TH} = [0\ 0\ 1] \wedge Y_{TH} / \|\cdot\|$	lateral	
	$X_{TH} = Y_{TH} \wedge Z_{TH} / \|\cdot\|$	anterior	
Pelvis – Proximal (pPL)	$X_{pPL} = -[0\ 0\ 1]$	anterior	
	$Y_{pPL} = [0\ 1\ 0]$	cranial	
	$Z_{pPL} = [1\ 0\ 0]$	lateral	
Pelvis - Distal (dPL)	${}^{SU\text{-}PL}R_{dPL} = {}^{SU\text{-}PL}R_{TH}$		
Thigh - Proximal (pTG)	${}^{SU\text{-}TG}R_{pTG} = {}^{SU\text{-}PL}R_{dPL}$		
Thigh - Distal (dTG)	$Y = Y_{pSK}$;		
	$Z_{dTG} = V_{FLEX} / \|\cdot\|$	lateral	
	$X_{dTG} = Y \wedge Z_{dTG} / \|\cdot\|$	anterior	
	$Y_{dTG} = Z_{dTG} \wedge X_{dTG} / \|\cdot\|$	cranial	
Shank - Proximal (pSK)	$Y = Y_{TH}$;		
	$Z_{pSK} = [0\ 0\ 1]$	lateral	
	$X_{pSK} = Y \wedge Z_{pSK} / \|\cdot\|$	anterior	
	$Y_{pSK} = Z_{pSK} \wedge X_{pSK} / \|\cdot\|$	cranial	
Shank - Distal (dSK)	${}^{SU\text{-}SK}R_{dSK} = {}^{SU\text{-}SK}R_{pSK}$		
Foot (FT)	${}^{SU\text{-}FT}R_{FT} = {}^{SU\text{-}SK}R_{dSK}$		

Table 1: Definition of the anatomical/functional CSs (thorax, pelvis, and right leg), to be used when the subject stands in the upright posture during the static calibration. CSs which share the same gray code in the right column have the same orientation during the calibration posture. For each segment, all vectors are expressed in the CS of the SU positioned on the segment.

Abbreviations. $\wedge$: cross product; R: 3x3 rotation matrix; ${}^{A}R_{B}$ indicates the relative orientation of the B CS with respect to the A CS; $\|\cdot\|$: indicates that the vector must be normalized; Z_G: Z axis of the global CS, assumed opposed to gravity; V_{FLEX}: direction of the flexion-extension axis of the knee; SU-TH: SU on thorax; SU-PL: SU on pelvis; SU-TG: SU on thigh; SU-SK: SU on shank; SU-FT: SU on foot.

TABLE 2

Segment	Axes Definition	Anat. direction.	
Thorax (TH)	$X_{TH} = {}^{SU\text{-}TH}Z_G$ / $\|\cdot\|$	anterior	
	$Z_{TH} = X_{TH} \wedge [1\ 0\ 0]$ / / $\|\cdot\|$	lateral	
	$Y_{TH} = Z_{TH} \wedge X_{TH}$ / / $\|\cdot\|$	cranial	
Pelvis – Proximal (pPL)	$X_{pPL} = -[0\ 0\ 1]$	anterior	
	$Y_{pPL} = [0\ 1\ 0]$	cranial	
	$Z_{pPL} = [1\ 0\ 0]$	lateral	
Pelvis - Distal (dPL)	${}^{SU\text{-}PL}R_{dPL} = {}^{SU\text{-}PL}R_{TH}$		
Thigh - Proximal (pTG)	${}^{SU\text{-}TG}R_{pTG} = {}^{SU\text{-}TG}R_{TH}\cdot R_Z(+h°)$		
Thigh - Distal (dTG)	$Y = 2^{nd}$ column of ${}^{SU\text{-}SK}R_{pSK}\cdot R_Z(+\delta°)$;		
	$Z_{dTG} = V_{FLEX}$ / $\|\cdot\|$	lateral	
	$X_{dTG} = Y \wedge Z_{dTG}$ / $\|\cdot\|$	anterior	
	$Y_{dTG} = Z_{dTG} \wedge X_{dTG}$ / $\|\cdot\|$	cranial	
Shank - Proximal (pSK)	$Y = 2^{nd}$ column of ${}^{SU\text{-}SK}R_{TH}\cdot R_Z(-\gamma°)$;		
	$Z_{pSK} = [0\ 0\ 1]$	lateral	
	$X_{pSK} = Y \wedge Z_{pSK}$ / $\|\cdot\|$	anterior	
	$Y_{pSK} = Z_{pSK} \wedge X_{pSK}$ / $\|\cdot\|$	cranial	
Shank - Distal (dSK)	${}^{SU\text{-}SK}R_{dSK} = {}^{SU\text{-}SK}R_{pSK}$		
Foot (FT)	${}^{SU\text{-}FT}R_{FT} = {}^{SU\text{-}SK}R_{dSK}$		

Table 2: Definition of the anatomical/functional CSs (thorax, pelvis, and right leg), to be used when the subject lies horizontally in supine position during the static calibration. CSs which share the same gray code in the right column have the same orientation during the calibration posture. For each segment, all vectors are expressed in the CS of the SU positioned on the segment. Angles h, k are the rotations in the sagittal plane of the hip and knee in the static posture, and have to be measured through static goniometry; δ = 180-k and γ = 180-h-k (see Fig. 4). Abbreviations. $\wedge$: cross product; R: 3x3 rotation matrix; ARB indicates the relative orientation of the B CS with respect to the A CS; RZ(+h°), RZ(+δ°), RZ(-γ°): indicate a constant rotation matrix around a Z axis of +h°, +δ° and –γ°; ||.||: indicates that the vector must be normalized; ZG: Z axis of the global CS, assumed opposed to gravity; VFLEX: direction of the flexion-extension axis of the knee; SU-TH: SU on thorax; SU-PL: SU on pelvis; SU-TG: SU on thigh; SU-SK: SU on shank; SU-FT: SU on foot.

It is worth noticing that the distal shank CS is assumed coincident with that of the proximal shank, since functional methods cannot still be reliably used for the estimation of the ankle axes of rotation [4].

2.1.4.4 Computation and interpretation of the joint-angles

During data acquisition for a walking task, the orientation of the anatomical CSs is updated sample-by-sample based on the orientation of the SUs' CS. The TP, hip, knee, and ankle joint-angles are then obtained, sample-by-sample, by decomposing the relative orientation of the anatomical CSs forming the joint with the Euler sequence ZX'Y'' [32]. Finally, the sign of the Z' rotation for the knee is reversed in order to have a positive flexion, as declared in section 2.1.3 and as expected in clinics [2].

It is worth noticing that, based on the definition for the distal thigh and proximal shank, the knee flexion in the static posture is 0° (since Z_{dTG} lies in the plane normal to X_{dTG} such as Y_{dTG}, Y_{pSK}), as it is also the case for all hip and ankle angles.

It has been widely demonstrated that the knee rotations other than the FE are strongly affected by the soft-tissue artefact problem when measured through skin-mounted markers, and are therefore unreliable [20, 25, 27]. For this reason, in our future clinical applications these angles will not be generally analysed.

2.2. Inter-rater reliability of the goniometric measure of hip and knee static flexion

High reliability in measuring *h* and *k* through a goniometer is required for the applicability of Outwalk when the supine calibration posture is used. Failure in this requirement would cast doubts about the offset measured for hip and knee flexion-extension patterns during gait (see Table 2), which would substantially depend by the rater leading the measurements.

Since the static posture will be typically used with CP children, a pre-clinical-trial inter-rater reliability study was carried out by involving 9 healthy children and 2 raters.

2.2.1 SUBJECTS AND RATERS

Nine healthy children (7.9±2 year-old, 27.5±7 Kg, 129±12 cm tall; 6 males, 3 females) were enrolled in the study after obtaining the informed consent from the parents. The study also involved two physical therapists (T1 and T2) as raters, with experience in the treatment of CP children. Before beginning the study, T1 and T2 practiced together in the measurement of *h* and *k* on two additional children who were not included in the study.

2.2.2 EXPERIMENTAL SET-UP

For the measurement of *h* and *k*, a standard plastic goniometer with two movable bars each of 20cm in length and 8cm in height was used.

Given a child, this was asked to lie supine on a mat with a foam cylinder under the knees (as in Fig. 4). Then T1 and T2 independently measured *h* and *k* of one of the legs. Between the two measurements, the child was asked not to move. The child was then free to move for a few minutes and then T1 and T2 independently measured *h* and *k* on the remaining side, as in the first measurement. The first side to be assessed was randomly selected, as well as the order of assessment by T1 and T2.

To measure *h*, one bar of the goniometer was lain on the mat and the other oriented to be on the line between the greater trochanter and the lateral epicondyle of the femur.

To measure *k*, one bar of the goniometer was oriented to be on the line between the greater trochanter and the lateral epicondyle of the femur, and the other to be on the line between the head of the fibula and the lateral malleolus.

2.2.3 HYPOTHESIS AND DATA ANALYSIS

To conclude that *h* and *k* have an inter-rater reliability adequate to begin the clinical trial of Outwalk, we tested the following hypothesis:

- H1: h and k reliability must be not lower than that reported in [11] for h and k measured with an optoelectronic system through the CAST protocol.

To test this hypothesis, we considered the *h* and *k* angles measured for each leg as a set of independent observations, and we computed the following root mean squared errors (RMS), consistently with [11]:

$$h_{RMS} = \sqrt{\frac{\sum_{i=1}^{18}\sum_{j=1}^{2}(h_{ij} - \overline{h}_i)^2}{18*2}}, \quad k_{RMS} = \sqrt{\frac{\sum_{i=1}^{18}\sum_{j=1}^{2}(k_{ij} - \overline{k}_i)^2}{18*2}}$$

where:

i=1…18: number of legs examined;

j=1…2: number of raters involved;

$\overline{h}_i = \dfrac{h_{i1} + h_{i2}}{2}$, mean hip flexion angle among T1 and T2 for leg *i;*

$\overline{k}_i = \dfrac{k_{i1} + k_{i2}}{2}$, mean knee flexion angle among T1 and T2 for leg *i.*

Based on the results reported in [11], H1 is true if:

$$h_{RMS} \leq 5° ; \qquad k_{RMS} \leq 3.7°$$

Following current recommendations about statistical parameters describing reliability [10], we also computed for *h* and *k* the Standard Error of Measurement (or 'typical error'), considering (SEM_{se}) and not considering (SEM_{nse}) the systematic error introduced by T1 and T2. Following [29], SEM_{se} and SEM_{nse} were obtained through a single-factor (i.e. raters) repeated measures ANOVA in the 1-way and 2-way model, respectively.

3. Results

The original data measured by T1 and T2 on the 18 legs are reported in Table 3. h_{RMS} and k_{RMS} were found to be 1.4° and 1.8°, i.e. less than those reported in [11]. It was concluded that H1 was fully satisfied. For *h*, both SEM_{se} and SEM_{nse} were 2.0°, while for *k* they were 2.4° and 2.5°, respectively.

TABLE 3

LEG	*h*°		*k*°	
	T1	T2	T1	T2
1	142	138	120	124
2	138	142	120	118
3	140	144	120	115
4	142	142	120	115
5	152	148	120	114
6	150	148	120	114
7	145	141	110	111
8	142	140	110	108
9	145	145	110	108
10	146	143	110	110
11	142	139	114	119
12	140	142	120	114
13	144	144	110	110
14	144	142	110	106
15	134	134	108	108
16	126	129	110	112
17	140	137	116	115
18	140	136	116	116

Table 3: Values measured for angle h (hip static flexion) and k (knee static flexion) by rater T1 and T2, on the 18 legs examined (9 children).

4. Discussion

Outwalk was developed to measure thorax-pelvis and lower-limb kinematics with IMMS, in clinical settings, and specifically in below/above knee amputees and CP children. In particular, the CP population described in section 2.1.1 was selected by considering the main goal of their rehabilitation treatments, that is the acquisition and preservation of gait, even for long distances.

Since IMMS cannot measure the position of their SUs, Outwalk was not based on the calibration of single anatomical landmarks for the construction of the anatomical CSs. The protocol takes about 10min to complete from subject arrival, and it does not require any specialized device other than the SUs, in contrast to [19]. Moreover, the two calibration postures (upright or supine) were selected to be comfortable for our population of interest. In general, we expect to use the upright posture for amputees, while the supine posture for CP children. Amputees can in fact easily maintain the predefined upright posture, while this cannot be assumed for children with CP, who may present a flexed knee and [28] hip-knee-ankle flexion (scissor pattern [5]). Similar considerations apply for the functional estimation of the knee mean FE axis of rotation. In general, on CP children the movement will be passively executed by the therapist, while amputees will actively perform the movement, or maintain the upright posture while a rater passively flexes and extends the prosthetic knee (if any).

Outwalk anatomical CSs were developed to best match the kinematic assumptions for the lower-limb joints. In particular, the definition of the distal knee CS presents an advantage with respect to the CS recommended by the ISB [32]. The advantage is that in Outwalk, the medio-lateral axis (Z) of the CS is defined along the mean FE axis of rotation of the knee, while in the ISB the femur Z axis is obtained as the last axis after the longitudinal and posterior axes are computed. This means that the medio-lateral axis of rotation of the knee in the ISB anatomical CS is not directly controlled, and its direction can be different from the inter-epicondilar axis [25]. Since a target population for Outwalk are the transfemoral amputees, the application of the ISB approach for the prosthetic knee would have been in explicit contradiction to the a-priori knowledge that the knee is a perfect hinge, with the axis of rotation oriented in a single direction. Outwalk, instead, respects this knowledge and takes it into account in the definition of the CS.

As a counter-balance of Outwalk ease of use, the operation of re-positioning a subject’s body in the calibration posture between acquisitions, can be a potential source of intra- and inter-examiner inaccuracy. A very similar problem, however, exists also for the protocols based on the identification of anatomical landmarks [6, 9, 19], and was named “anatomical landmarks mislocation”. The anatomical landmarks mislocation mostly affects the offset of segment axial rotations [11], and even though final conclusions require ad-hoc tests (which are underway), this might also be true for Outwalk.

As element supporting Outwalk validity, the inter-rater reliability for h and k was found to be very high, with values for h_{RMS} and k_{RMS} smaller than those reported in [11] for the same measurements obtained through an optoelectronic systems and the CAST protocols. Hypothesis H1 was thus confirmed. Results for SEM_{se} and SEM_{nse} also indicate that the ‘typical error’ in the offset of hip and knee flexion angles during gait is almost negligible, and thus it is not expected to substantially depend on the rater leading the measurements. This conclusion is further supported by the close values of SEM_{se} and SEM_{nse} (no difference for h, 0.1° for k), which show that the systematic error introduced by T1 and T2 is very limited. The measurement set-up, i.e. static measures with subjects lying on a mat, with the legs sustained by a foam cylinder, with hips and knees flexed, appears to have positively influenced the reliability of h and k. In this posture the anatomical landmarks can also be easily palpated and the mat can be used as a base for the goniometer in measuring *h*, which in fact resulted as the most reliable angle.

In conclusion, the results obtained support the commencement of a clinical trial of Outwalk with children with CP.

This further step will also take advantage of the possibility to apply Outwalk with any optoelectronic system as measurement device, and not only with IMMS. It should be noticed in fact that all available optoelectronic systems satisfy the hardware requirements described in section 2.1.2, if we 1) consider the SU as a cluster of at least three not aligned markers, and 2) we define a local CS for the cluster with a visible reference to its markers' position. The synchronous application of Outwalk and a reference clinical protocol (e.g. CAST [2]) with the optoelectronic system as only measurement device will allow, for instance, to compare the effect on joint kinematics of the different definitions of the anatomical/functional CSs among the two protocols. Based on the results on clinical populations, it could be even decided to use Outwalk as first screening gait protocol in combination with optoelectronic systems, due to its ease of use.

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Chapter 4

FIRST IN-VIVO ASSESSMENT OF ‘OUTWALK’ – A NOVEL PROTOCOL FOR CLINICAL GAIT ANALYSIS BASED ON INERTIAL & MAGNETIC SENSORS

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Abstract

A protocol named 'Outwalk' was recently proposed to measure the thorax-pelvis and lower-limb kinematics during gait in free-living conditions, by means of an Inertial and Magnetic Measurement System (IMMS). The aim of this work was to validate Outwalk on 4 healthy subjects when it is used in combination with a specific IMMS (Xsens Technologies, NL), against a reference protocol (CAST) and measurement system (optoelectronic system; Vicon, Oxford Metrics Group, UK).

For this purpose we developed an original approach based on 3 tests, which allowed to separately investigate: 1) the consequences on joint kinematics of the differences between protocols (Outwalk vs CAST), 2) the accuracy of the hardware (Xsens vs Vicon), and 3) the summation of protocols' differences and hardware accuracy (Outwalk+Xsens vs CAST+Vicon). To assess joint-angles similarity, the Coefficient of Multiple Correlation (CMC) was used. For test 3, the CMC showed that Outwalk+Xsens and CAST+Vicon kinematics can be interchanged, offset included, for hip, knee and ankle flexion-extension and hip ab-adduction (CMC>0.88). The other joint-angles can be interchanged offset excluded (CMC>0.85). Test 1 and 2 also showed that differences in offset between joint-angles were predominantly induced by differences in the protocols; differences in correlation by both hardware and protocols; differences in range of motion by the Xsens accuracy. Results thus support the commencement of a clinical trial of Outwalk on transtibial amputees.

Keywords

Gait analysis; Kinematics; Protocol; Ambulatory; Inertial Sensors; Magnetic Sensors; Cerebral Palsy; Amputee.

1. Introduction

Inertial and Magnetic Measurement Systems (IMMSs) might open new perspective in clinical gait analysis. They are commercially available, cost effective, portable motion analysis systems, and consist of lightweight boxes, called Sensing Units (SUs) which typically comprise a 3D accelerometer, gyroscope and magnetometer. Through sensor-fusion algorithms, the 3D real-time orientation of each SU is known relative to a global Coordinate System (CS), based on the magnetic north and the gravity. In other words, the output of a SU is equivalent to the orientation of a cluster of (at least) 3 markers relative to the laboratory frame of an optoelectronic system, but with the basic difference that gravity and the magnetic north are ubiquitous and therefore the reference frame of an IMMS system also exists outside the laboratory. This means that every time the magnetic field is not distorted [6], a SU can measure the orientation of the body to which it is attached whenever and wherever it is required, without the need of any camera or specially equipped laboratory. Thanks to these features, IMMSs might allow to execute and acquire the movement in laboratory-free settings, in a continuous modality, for long periods; therefore they might allow to collect a great number of consecutive gait cycles during spontaneous walking in daily life environments [12].

In [4] a protocol, named ‘Outwalk’, was proposed to measure the kinematics of the pelvis relative to the thorax (TP joint), and of the lower-limbs with an IMMS. Outwalk was designed to be suitable for children with Cerebral Palsy (CP; hemiplegic belonging to the I-III forms of the Winters et al. classification [22] and diplegic belonging to the II-IV of the Ferrari et al. classification [7]) and amputees.

Since IMMSs do not provide any information about the position of the SUs, Outwalk does not define the anatomical/functional CSs based on the identification of single anatomical landmarks, as done in most of the protocols for clinical gait analysis [8, 23]. On the contrary, Outwalk defines the anatomical CSs for each segment based on three steps (calibration procedure): 1) positioning the SUs on the subjects’ thorax, pelvis, thighs, shanks and feet following simple rules; 2) computing the orientation of the mean flexion-extension (FE) axis of the knees in the local CS of the SU on the thighs; 3) measuring the SUs orientation while the subject’s body is oriented (actively or passively) in a predefined posture (either upright or supine). These steps make the protocol extremely simple and comfortable for the subject, which are pre-requirements for Outwalk application in the clinical routine.

The aim of this work was to preliminary validate Outwalk on able-bodied subjects, using the calibration in upright posture. Positive results would support the commencement of a clinical trial of Outwalk with subjects able to keep this posture, e.g. transtibial amputees.

2. Methods

2.1 Outline of the validation procedure

For the validation of Outwalk we defined an original stepwise approach.

Since a non-invasive gold-standard for the lower-limb kinematics is missing [20], we compared the *new* protocol (Outwalk) based on the *new* system (IMMS) with respect to *a reference protocol* (CAST - [1, 2]) and *system* (optoelectronic). CAST is a clinical gait analysis protocol featured by anatomical CSs consistent with the ISB recommendations; differently from Outwalk, anatomical CSs are defined based on the identification of anatomical landmarks; the position of the anatomical landmarks is identified through a calibration stick, relative to clusters of (typically) 4 markers positioned over the body segments. This procedure optimizes the identification of the landmarks, the visibility of markers and contributes to reduce the soft-tissue artefact.

In particular, to isolate the differences generated *by the protocols* from those *by the systems,* we separately evaluated (Fig. 1):

- Test 1) the effect on joint kinematics of the different anatomical/functional CSs defined in Outwalk and CAST; this was done by processing the *two protocols* starting from the same raw data collected by *just one* system (the optoelectronic);
- Test 2) the accuracy of the IMMS, by comparing its measurements of joint kinematics with those of the optoelectronic system, when both sources of data are processed using the *same protocol* (CAST);
- Test 3) the differences between the kinematics of Outwalk and CAST, when the first is applied to the IMMS data, and the second to the optoelectronic system data; this represents the overall assessment and comprises the effect of Test 1 and Test 2.

Regarding Test 1 and 3,we both verified:

1a, 3a) to which extent Outwalk and CAST kinematics can be interchanged;

1b, 3b) if Outwalk and CAST kinematics are as similar as the kinematics measured by CAST and other four popular protocols for clinical gait analysis, namely Total3DGait (Total3Dg) [13], Plug-in Gait (PiG) [5], SAFLo [9] and LAMB [18], using [8] as reference.

The advantage of this approach is that results from Test 1 and 2 are independent. This means that a change in Outwalk, will not affect the accuracy of the hardware which will not need to be investigated again. Similarly, evolutions in the IMMS technology will not affect the similarity of Outwalk and CAST, which will keep its validity. Moreover, the separate evaluations of Tests 1 and 2 allow to identify the causes of the differences shown in Test 3 (overall assessment), i.e. to draw back differences to either the definition of the CSs or to the accuracy of the IMMS, thus guiding future improvements.

All the data required for Tests 1, 2 and 3 were acquired at the same time, on the same subjects.

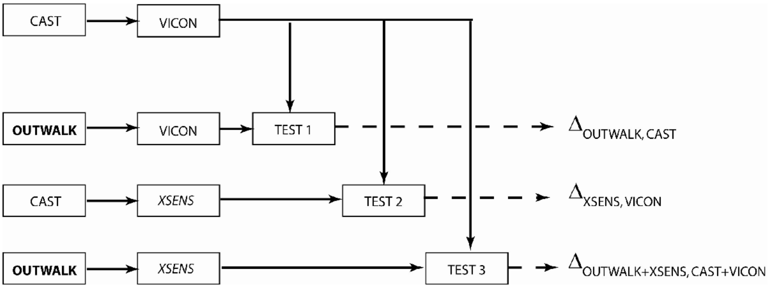

Fig 1: Schematic representation of the three-steps approach used for Outwalk validation in-vivo. Test 1 assesses the similarity between Outwalk and CAST, when both are applied with the Vicon (optoelectronic system). Test 2 assesses the accuracy of the Xsens system (IMMS) compared to Vicon, through the application of the same protocol (CAST) with both systems. Test 3 assesses the similarity between Outwalk and CAST when the former is applied with the Xsens and the latter with the Vicon system.

2.2 Subjects description

Four asymptomatic subjects (AF: 26 years, Body Mass Index (BMI) 21; PG 28 years, BMI 26; MR 29 years, BMI 21; AC 31 years, BMI 23) participated in the experiment after giving their informed consent. For subjects AF, PG, AC we acquired both legs. For MR we acquired the right leg only. On the whole, therefore, the kinematics of 4 TPs, and 7 limbs (i.e. 7 hips, 7 knees and 7 ankles) was acquired and processed.

2.3 IMMS and optoelectronic systems set-up

The Xsens system (Xsens Technologies, NL) was used as IMMS. It consists of up to 10 SUs (called MTx) connected by-wire to a data-logger, usually worn on the belt. The local CS of the SU is aligned with the boundaries of the SU's box with an error < 3° (Xsens Technical Manual). A Vicon MX 1.3 (Oxford Metrics Group, UK) was used as reference optoelectronic system.

As required by CAST, markers were arranged in clusters of four. The base for each cluster was a lightweight double-layer cardboard (11g), 12x12 cm. A SU was attached underneath each cluster. Through an hand-eye calibration [3, 15], the local CS of each cluster was defined in such a way that its axes were overlapped with those of the CS of the SU in static conditions. The clusters thus became "virtual SUs" measured by the optoelectronic system.

For all Tests, Xsens and Vicon were run simultaneously. Their sampling frequency was set to 100Hz. To allow the synchronous acquisition of data by the systems, the Xsens internal clock was output from the system (see Xsens Manual) and connected to the Vicon A/D converter, and sampled at 5000Hz. The rising edges of the Xsens clock (which is a square signal) were thus known in the Vicon time-line and were used to frame the Vicon data accordingly.

Before proceeding with the in-vivo tests, we checked the stability of the electromagnetic field of the laboratory [6]. The local magnetic field was found to be homogeneous.

2.4 Protocols application and trials performed

For each subject, the Xsens SUs with on top the clusters of 4 markers were positioned as described in [4], over thorax, pelvis, thighs, shanks and feet (Fig. 2).

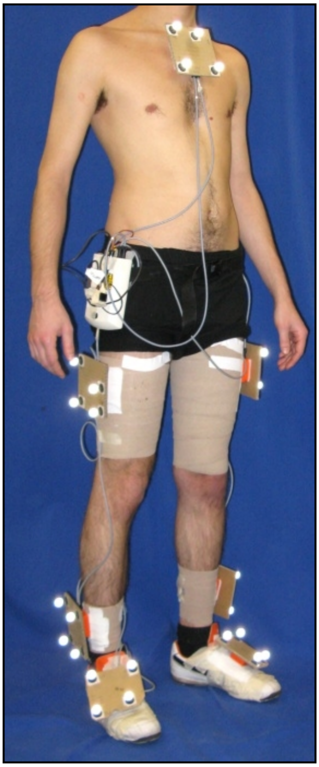

Fig 2: Eight Xsens SUs and clusters positioned over the body of a subject. The white box is the Xsens data-logger (called Xbus Master).

For CAST, the anatomical landmarks of thorax, pelvis, thigh, shank and foot described in [2], were calibrated relative to the clusters of the different segments using a calibration stick [2], while the subject stood in the upright posture; the orientation of the CAST anatomical CSs was then related to the clusters' CSs. In addition, for each segment the orientation of the CAST anatomical CS was also related to the SU' CS, as in static conditions the relative orientation between clusters' and SUs' CSs is null (see Sect. 2.3 about the hand-eye calibration). The orientation of the CAST anatomical CSs was thus available both in the Vicon and in the Xsens system.

For Outwalk, the calibration procedure described in [4] was followed. In particular, during the estimation of the knee FE axis, subjects actively flexed and extended the knee; during the static acquisitions subjects stood still in the upright posture. The orientations of Outwalk anatomical/functional frames were computed relative to both the CSs of the Xsens SUs, and to the CSs of the Vicon clusters. It is worth remembering, in fact, that thanks to the hand-eye calibration the clusters' local CSs were defined to overlap those of the SUs, and therefore the clusters could be treated as "virtual SUs" measurable by the Vicon system. Outwalk anatomical/functional CSs could therefore be computed relative to the clusters' orientation staring from the markers' trajectories. As for CAST anatomical CSs, the orientation of Outwalk functional/anatomical CSs were thus available both in the Vicon and in the Xsens system.

Once completed the calibration phases, subjects were asked to walk along a 10m walkway at a self-selected comfortable walking speed. For each subject 14 gait cycles for each limb were acquired. For the TP joint, the 14 *right limb* gait cycles were considered for subsequent analyses. After each acquisition, the gait events were manually identified in the Vicon data [1], and then used to define the corresponding gait cycles in the Xsens data.

2.5 Data processing for Test 1 – Outwalk+VICON vs CAST+VICON

The aim of Test 1 was to verify the effect on joint kinematics of the different anatomical/functional CSs defined in Outwalk and CAST, excluding the differences due to the measurement accuracy of Xsens with respect to Vicon.

For this purpose, in Test 1 we only considered the orientation during gait of the anatomical/functional CSs obtained applying Outwalk and CAST with the Vicon system *only*, with both protocols sharing the same marker-set.

From the anatomical/functional CSs of Outwalk and CAST measured in Vicon, the kinematics of the TP, hip, knee and ankle joints could therefore be independently computed for each protocol. In particular, the following joint-angles were computed: posterior-anterior tilting (PAT), right drop-rise (DR), right internal-external rotation (IE) for the TP joint; flexion-extension (FE), adduction-abduction (AA) and internal-external rotation (IE) for the hip; FE for the knee; dorsi-plantar flexion (DP), inversion-eversion (IV) and IE for the ankle. It has been widely demonstrated that the knee rotations other than the FE are strongly affected by the soft-tissue artefact problem when measured through skin-mounted markers, and are therefore unreliable [19-21]. For this reason, these angles were not analysed.

Since the protocols synchronously measured the same gait cycles, shared the same hardware, and suffered from the same soft-tissue artefact (as they shared the same marker-set), the differences in the kinematics could be related to differences in the definition of the CSs only.

2.6 Data processing for Test 2 – Xsens accuracy

The aim of Test 2 was to assess the accuracy of Xsens by comparing its measurements of joint kinematics with those of Vicon, when both sources of data are processed using the same protocol. For this purpose, in Test 2 we only considered the orientation during gait of the CAST anatomical CSs, independently measured by Vicon and Xsens as described in section 2.4. The same joint-angles described in Sect. 2.5 were then computed from each system.

Since Vicon and Xsens synchronously measured the same gait cycles, shared the same anatomical CSs definitions, and suffered from the same soft-tissue artefact, differences in the kinematics could be related to differences in the accuracy of the measurement systems only.

2.7 Data processing for Test 3 – Outwalk+Xsens vs CAST+VICON

The aim of Test 3 was to assess the differences between Outwalk and CAST joint kinematics, when the former is applied to the Xsens data, and the latter to the Vicon data.

For this purpose, from the relative orientation of Outwalk anatomical/functional CSs measured in Xsens (Outwalk+Xsens), and the relative orientation of CAST anatomical CSs measured in Vicon (CAST+Vicon), we computed the same joint-angles described in 2.5.

Differences between Outwalk+Xsens and CAST+Vicon kinematics were therefore the sum of the difference between protocols (Test 1), hardware (Test 2), and application of the protocols on the hardware.

2.8 Data analysis for Test 1

To verify the similarity of Outwalk and CAST joint-angle waveforms and to which extent they can be interchanged, we computed the 5 parameters, and tested the condition, described in section 2.8.1.

To verify if Outwalk kinematics was as similar to CAST kinematics as this latter to the kinematics of Total3Dg, PiG, SAFLo and LAMB we computed for subject AF the parameters described in section 2.8.2, and we compared these results with those reported in [8]. In [8], in fact, the same parameters were computed for AF between CAST, Total3Dg, PiG, Saflo and LAMB.

In what follows, O(t) and C(t) indicate waveforms measured (synchronously) for the same joint-angle, during the same gait cycle, by Outwalk and CAST, respectively. It is worth recalling that 14 couples (O(t), C(t)) were acquired for each joint-angle, as 14 is the number of gait trials measured for each TP and limb. O(t) and C(t) will be also referred to as “corresponding waveforms”.

2.8.1 OUTWALK – CAST SIMILARITY ASSESSMENT

Computations were performed firstly within each joint-angle of each TP and limb (2.8.1.1), then at sample level, i.e. between the 4 TPs and 7 limbs measured over the four subjects (2.8.1.2). The condition to conclude the similarity of Outwalk and CAST kinematics for a joint-angle is then reported in Section 2.8.1.3.

2.8.1.1 Computations within each TP and limb joint-angle

To assess the similarity between O(t) and C(t) in terms of offset, correlation and gain, we computed 3 parameters: the offset between O(t) and C(t) (off), their Pearson's correlation coefficient (*r*), and difference between their Range of Motion (ΔROM). In particular, off and ΔROM were defined as:

- *off* = mean(O(t)) - mean(C(t));
- ΔROM = ROM(O(t)) - ROM(C(t)).

In addition, to assess the overall effect of *off*, *r*, and ΔROM on the similarity of Outwalk and CAST waveforms, for each joint-angle we computed the adjusted coefficient of multiple correlation (CMC) between its 14 O(t) and its 14 C(t). To take into account that each O(t) must be compared only with its synchronous C(t), we developed a new formula for the CMC, which is a variation of the Kadaba within-day CMC [11], and removes all other sources of gait-cycle-to-gait-cycle variability. Details are provided in Appendix 1.

Finally, to measure the effect of the offset on the overall similarity, we recomputed the CMC after zeroing *off* for each couple O(t), C(t), following [11].

The CMCs before and after offset removal were named CMC_1 and CMC_2 respectively.

2.8.1.2 Computations between homonymic joint-angles of the TPs and limbs

For each joint-angle, the values of *off*, *r*, ΔROM, CMC_1 and CMC_2 over the 4 TPs and 7 limbs were reported with box-and-whisker plots and in terms of median and whiskers range. Median and whiskers were used since the 5 parameters did not generally present normal distributions for all joint-angles (normality was tested both with the Lilliefors test and normality plots). Based on previous publications [10, 11, 24], the values of CMC and *r*, were interpreted as follows:

- 0.65 - 0.75: moderate
- 0.75 - 0.85: good
- 0.85 - 0.95: very good
- 0.95 - 1 excellent

2.8.1.3 Condition T1.1

To conclude that the two kinematics measured by Outwalk and CAST for a joint-angle are so similar to be interchangeable, the following condition for CMC_1 distribution has to be met (Cond. T1.1):

- for TP DR and lower-limb sagittal plane angles: median $\in$ excellent; whiskers $\in$ excellent;
- for TP PAT and lower-limb frontal & transverse plane angles: median $\in$ very-good; whiskers $\in$ from very-good to excellent,

where the symbol '$\in$' means "to be part of the interval". When the condition is not satisfied by CMC_1 but by CMC_2, the similarity is verified only if the offset is not a concern. Cond. T1.1 imposes a global similarity between Outwalk and CAST kinematics, considering all the content information of the waveforms, as in current trends [10, 14]. The ranges for the CMCs values were assumed reasonable when dealing with the functional assessment of amputees people and CP children, and were defined starting from the authors' clinical experience and based on other protocol assessments [10, 11, 14, 24]. To ensure the robustness of the conclusions we imposed the respect of the conditions by the CMC values within the whiskers, that is by the greatest majority of CMC values (on at least the 95.4% of values, by analogy with normal distributions) [16].

2.8.2 OUTWALK-CAST vs CAST-Total3Dg-PiG-SAFLo-LAMB SIMILARITY ASSESSMENT

2.8.2.1 MAV and r for subject AF

In [8] the lower-limbs kinematics of subject AF was measured at the same time with 5 protocols, i.e. CAST, Total3Dg, PiG, SAFLo, and LAMB.

For each joint-angle, the similarity between the kinematics of the 5 protocols was measured through the *MAV* (mean absolute variability), i.e.:

$$\begin{cases} M(t) = \max\left(y(t)_{CAST}, y(t)_{PiG}, y(t)_{Total3Dg}, y(t)_{LAMB}\right) \\ m(t) = \min\left(y(t)_{CAST}, y(t)_{PiG}, y(t)_{Total3Dg}, y(t)_{LAMB}\right) \\ MAV = \dfrac{\sum_{t=0}^{T} |M(t) - m(t)|}{T} \end{cases}$$

where:

- $y(t)_P$ is a waveform obtained by appending one after the other the waveforms of all the trials performed by AF (4 in [8]), obtained applying the protocol P (with P=CAST, Total3Dg, PiG, SAFLo, LAMB) for the specific joint-angle;
- M(t), m(t) indicate the maximum and minimum values of $y(t)_P$ among the 5 protocols, at time frame t;
- T = total number of frames considering all the trials of subject AF.

As in [8], *MAV* was then computed here for each joint-angle of each side of AF considering the protocols Outwalk and CAST, and the *14 trials* performed.

In addition, in [8] *r* was also computed between the joint-angle waveforms of CAST and Total3Dg, PiG, Saflo, and LAMB for AF, providing an estimate of the correlation between pairs of protocols. *r* (Sect. 2.8.1.1) was also computed here for each joint-angle of each side of AF.

2.8.2.2 Conditions T1.2 and T1.3

Based on *MAV* and *r*, to conclude that Outwalk could be potentially used in clinics as it is the case for CAST, Total3Dg, PiG, Saflo, and LAMB, the following 2 conditions have to be met for each joint-angle:

Cond. T1.2) the MAV for Outwalk - CAST must be lower than the values reported in [8] for CAST - Total3Dg – PiG – Saflo - LAMB;

Cond. T1.3) the value of *r* for Outwalk - CAST must be higher than the lowest *r* reported in [8] for the pairwise comparisons CAST vs Total3Dg, PiG, Saflo, and LAMB.

It is important to notice that the satisfaction of Conds T1.2 and T1.3 is required to support Outwalk potentials in clinics, but not sufficient: conclusions will need to be further confirmed on clinical populations.

2.9 Data analysis for Test 2

In what follows, X(t) and V(t), indicate waveforms measured synchronously for the same joint-angle, during the same gait cycle, by Xsens and Vicon, respectively. As for (O(t), C(t)), 14 couples (X(t), V(t)) were acquired for each joint-angle. X(t) and V(t) will be referred to as "corresponding waveforms".

To measure the accuracy of Xsens in measuring the TP and lower-limb kinematics, we used the same parameters computed for Test 1. Specifically, the similarity of X(t) and V(t) was assessed through the 5 parameters *off*, *r*, ΔROM, CMC_1 and CMC_2, firstly within each joint-angle and then over the 4 TPs and 7 limbs acquired.

To conclude that for a given joint-angle, the dynamic accuracy of Xsens is suitable for clinical applications, the same condition for CMC_1 and CMC_2 described in Sect. 2.8.1.3 has to be met. When referred to Test 2, the condition will be named Condition T2.1 (Cond. T2.1).

2.10 Data analysis for Test 3

Similarly to Test 1 and 2, in what follows OX(t) and CV(t) indicate waveforms measured synchronously for the same joint-angle, during the same gait cycle, by Outwalk+Xsens and by CAST+Vicon, respectively. Fourteen couples (OX(t), CV(t)) were acquired for each joint-angle of each TP and limb. OX(t) and CV(t) will be also referred to as "corresponding waveforms".

2.10.1 PARAMETERS AND CONDITION FOR "OUTWALK+XSENS" AND "CAST+VICON" SIMILARITY ASSESMENT

As for Tests 1 and 2, the similarity of OX(t) and CV(t) was assessed through the 5 parameters *off*, *r*, ΔROM, CMC_1 and CMC_2, firstly within each joint-angle of each limb and then over the 4 TPs and 7 limbs acquired. To conclude that the two kinematics measured by Outwalk+Xsens and CAST+Vicon for a joint-angle are so similar to be interchangeable, the same condition for CMC_1 and CMC_2 described in Sect. 2.8.1.3 has to be met. When referred to Outwalk+Xsens and CAST+Vicon, the condition will be named Condition T3.1 (Cond. T3.1).

2.10.2 OUTWALK-CAST vs CAST-Total3Dg-PiG-SAFLo-LAMB SIMILARITY ASSESSMENT

To verify if Outwalk+Xsens kinematics was as similar to CAST+Vicon kinematics as this latter to the kinematics of Total3Dg, PiG, SAFLo and LAMB (through Vicon) we proceeded as for Test 1 [8]. Specifically, we computed, for subject AF, *MAV* and *r* between Outwalk and CAST joint-angles waveforms, and we compared the results with those reported in [8]. Based on *MAV* and *r*, to conclude that Outwalk can be potentially used in the clinical practice as CAST, Total3Dg, PiG, Saflo, and LAMB, the same conditions described in Sect. 2.8.2.2 for Test 1 has to be met. When referred to Test 3, the conditions will be named Condition T3.2 and T3.3.

3. Results

3.1 Test 1

Figure 3, reports the Outwalk and CAST kinematics for one subject (AF), over the 14 gait cycles. Similar results were obtained for the other subjects.

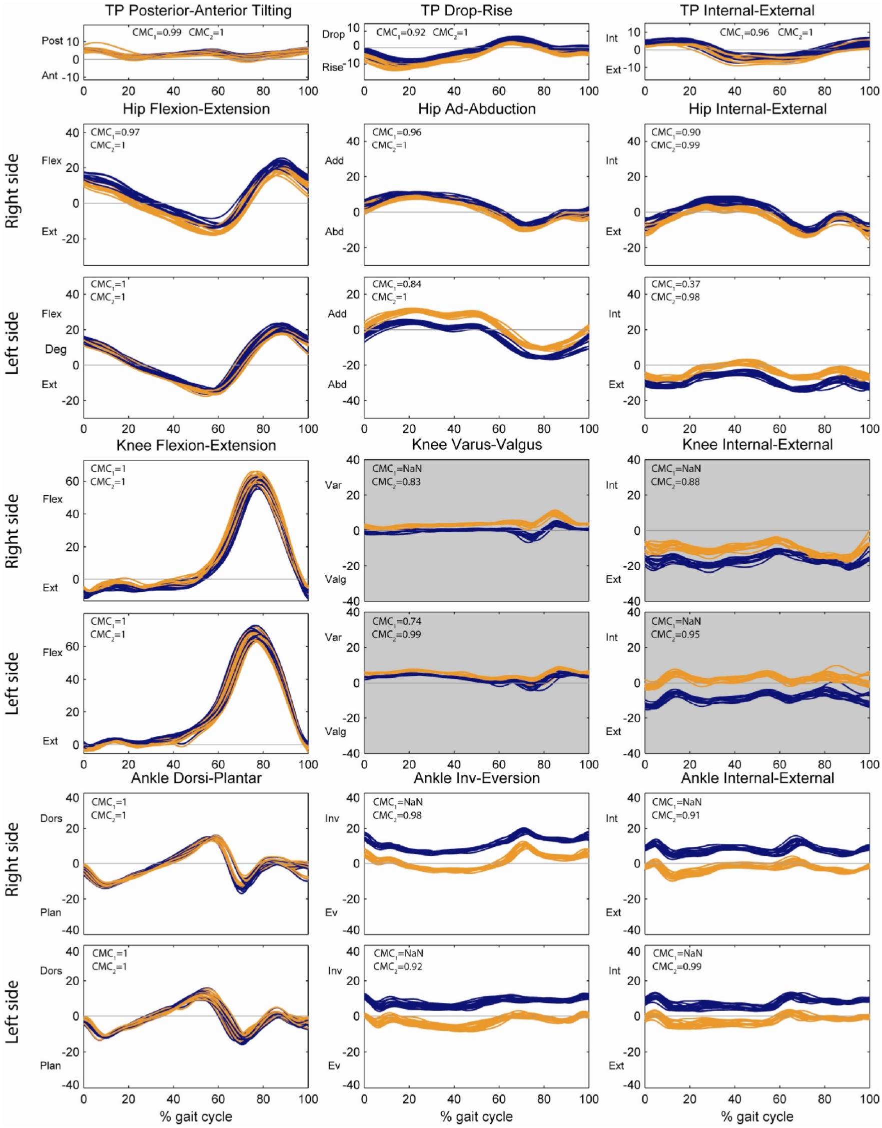

Fig 3: 14 gait cycles for subject AF, as measured by Outwalk (bright plots) and CAST (dark plots). For each joint-angle, the CMC_1 and CMC_2 are provided. Since the knee varus-valgus and internal-external rotation will not be considered in the clinical routine due to their low accuracy [19], they are reported over a gray background

3.1.1 OUTWALK – CAST COMPARABILITY ASSESSMENT

Results for *off*, *r* and ΔROM are reported in Appendix 2, while results for CMC_1 and CMC_2 follow. This was done in the interest of brevity, and since CMC_1 and CMC_2 are expressions of the conjoint effect of *off*, *r* and ΔROM on joint kinematics.

Figure 4 reports the CMC_1 and CMC_2 values for each joint-angle. Each box-plot contains 1 CMC value for each TP and limb examined, i.e. 4 for the TP and 7 for the hip, knee and ankle joints. To provide a visual analogy for the CMC values, Figure 3 also reports the values of CMC_1 and CMC_2 for the waveforms of subject AF.

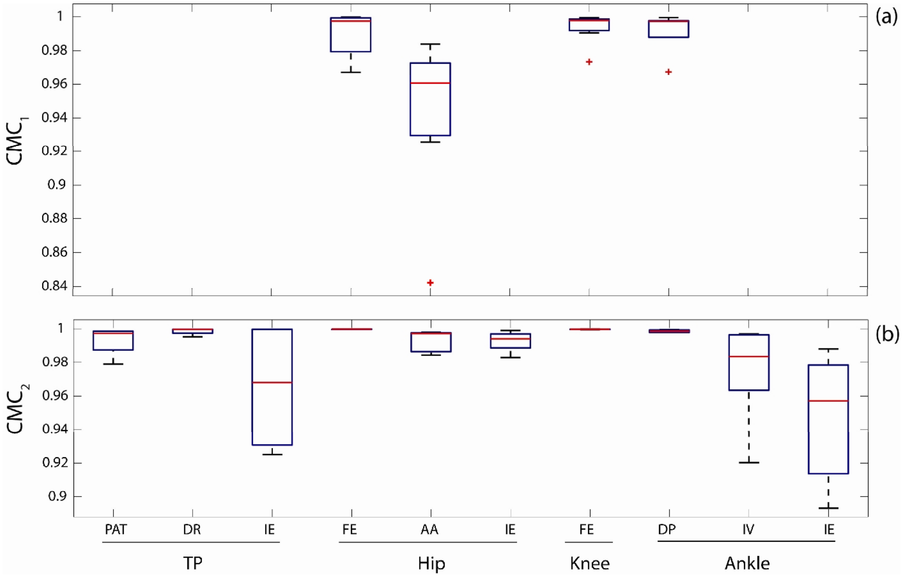

Fig 4a,b: TEST 1: Box-and-whiskers plots for CMC1 (a) and CMC2 (b). CMC1 and CMC2 measure the within-joint-angle similarity between CAST and Outwalk waveforms. Distributions are here reported over 4 TPs and 7 hips, knees and ankles. Box-plots are reported only for those joint-angles in which all values were real numbers.

In Figure 4a, CMC_1 box-plots are reported only for those joint-angles in which all values were real numbers. Since the CMC_1 takes into account the overall effect of offset, correlation and gain between waveforms, if the offset is comparable with the ROM, the numerator of CMC can be greater than the denominator, thus leading CMC_1 to complex values. Real CMC_1 values were obtained for the sagittal plane kinematics and the hip AA, with at least very-good similarity. In particular, all values within whiskers for hip FE, knee FE and ankle DP were always higher than 0.97, with median equal to 1, i.e. with an excellent similarity. For the hip AA, values within whiskers were greater than 0.93 (very good similarity), with a median equal to 0.96 (excellent similarity).

Once removed the offset between corresponding waveforms of Outwalk and CAST, CMC values greatly improved (Fig. 4b). CMC_2 values were greater than 0.9 for all joint-angles, that is representative of a very-good to excellent similarity. In particular, sagittal plane joint-angles presented an excellent similarity with values always greater than 0.98, and equal to 1 for hip FE, knee FE and ankle DP. For frontal plane joint-angles, the similarity ranged between very-good to excellent for all values, with medians in the "excellent" range. If the analysis is limited to the TP DR and hip AA, all values were within the "excellent" range, similarly to sagittal plane angles. The transverse plane angles presented result slightly worse that the other planes, but still with all values within the very-good to excellent range and median values within the excellent range.

Based on CMC_1 results, Cond. T1.1 was satisfied only by hip FE, AA, knee FE and ankle DP. Based on CMC_2, instead, the condition was satisfied by all joint-angles.

3.1.2 OUTWALK-CAST vs CAST-Total3Dg-PiG-SAFLo-LAMB SIMILARITY ASSESSMENT

Table 1 reports the *MAV* values between Outwalk and CAST. The corresponding values for *MAV* between CAST-Total3Dg-PiG-SAFLo-LAMB are also reported as in [8]. All *MAV* values reported for Outwalk-CAST were smaller than those reported for CAST-Total3Dg-PiG-SAFLo-LAMB. Cond. T1.2 was thus completely satisfied.

TABLE 1

	***MAV* [deg]**					
	RIGHT SIDE			**LEFT SIDE**		
	TEST 1	***TEST 3***	***Reference values***	***TEST 1***	***TEST 3***	***Reference values***
Hip FE	***4.2***	***5.2***	20.4	***1.1***	***2.3***	18.2
Hip AA	***2.3***	***2.8***	6.1	***6.0***	***6.7***	8.2
Hip IE	***3.4***	***2.4***	17.0	***5.5***	***7.0***	21.0
Knee FE	***2.1***	***3.6***	5.8	***1.7***	***1.5***	7.7
Ankle DP	***0.6***	***1.4***	25.5	***0.6***	***1.1***	26.8
Ankle IV	***9.9***	***10.0***	18.5	***10.6***	***10.5***	18.2
Ankle IE	***10.5***	***11.8***	12.0	***9.5***	***7.8***	20.8

Table 1: MAV values for the right and left side joint-angles of subject AF. For each side, the left column reports the results for Test 1 (Outwalk+Vicon vs CAST+Vicon), the central column for Test 3 (Outwalk+Xsens vs CAST+Vicon), while the right column the reference values for CAST - Total3Dg – PiG – SAFLo - LAMB, used in combination with a Vicon system, reproduced from [8]. Italic bold fonts indicate those joint-angles for which Outwalk-CAST has smaller values than the reference. Results for the TP joint are not reported since it was not considered in [8].

Table 2 finally reports the *r* values between Outwalk and CAST. It also reports the reference values as presented in [8], for the pairwise comparisons CAST vs Total3Dg-PiG-SAFLo-LAMB. The correlation between Outwalk and CAST was always the best, or the second best. This means that Cond. T1.3 was also largely satisfied.

TABLE 2

	Right side							**Left side**						
	Hip			Knee	Ankle			Hip			Knee	Ankle		
	FE	AA	IE	FE	DP	IV	IE	FE	AA	IE	FE	DP	IV	IE
Test 1	*1.000*	*0.997*	*0.993*	*1.000*	*0.997*	0.958	0.840	*1.000*	*0.997*	*0.966*	*1.000*	*0.997*	0.867	*0.979*
Test 3	*0.999*	*0.994*	*0.973*	*0.999*	*0.988*	0.939	0.750	0.997	*0.998*	*0.948*	*0.999*	0.990	0.850	*0.912*
T3Dg	0.999	0.994	-0.184	0.999	0.988	0.971	0.926	0.999	0.996	0.246	0.999	0.996	*0.979*	0.702
PiG	0.995	0.994	-0.182	0.996	0.980			0.995	*0.997*	0.007	0.997	0.970		
SAFLo	0.997	0.963	0.847	0.995	0.977	0.090	0.797	0.993	0.950	0.720	0.992	0.961	-0.066	0.880
LAMB	0.998	0.994	0.137	0.999	0.978	0.741	0.717	0.999	0.976	0.641	0.999	0.980	0.856	0.909

Table 2: r values for the right and left side joint-angles of subject AF. Row 1 reports the results for the correlation between Outwalk and CAST applied with the Vicon only (TEST 1); row 2 the results for the correlation between Outwalk+Xsens and CAST+Vicon (TEST 3); rows 3-6 the results for the correlation between Total3Dg, PiG, SAFLo, LAMB and CAST, as in [8]. In row 1, ***italic bold*** and **bold** indicate those joint-angles for which the correlation reported in the row is the highest and the second highest relative to the correlations reported in rows 3-6. Similarly in row 2, ***italic bold,*** **bold**, and underlined fonts indicate those joint-angles for which the correlation in the row is the highest, the second, and the third highest with respect to the correlations reported in rows 3-6. Results for the TP joint are not reported since it was not considered in [8]. Gray cells were used for PiG on ankle IV and IE, since PiG does not compute these two joint-angles.

3.2 Test 2

Figure 5, reports the Xsens and Vicon kinematics over the 14 gait cycles of subject AF, the same subject whose results are reported in Fig. 3 of Test 1. Similar results were obtained for the other subjects.

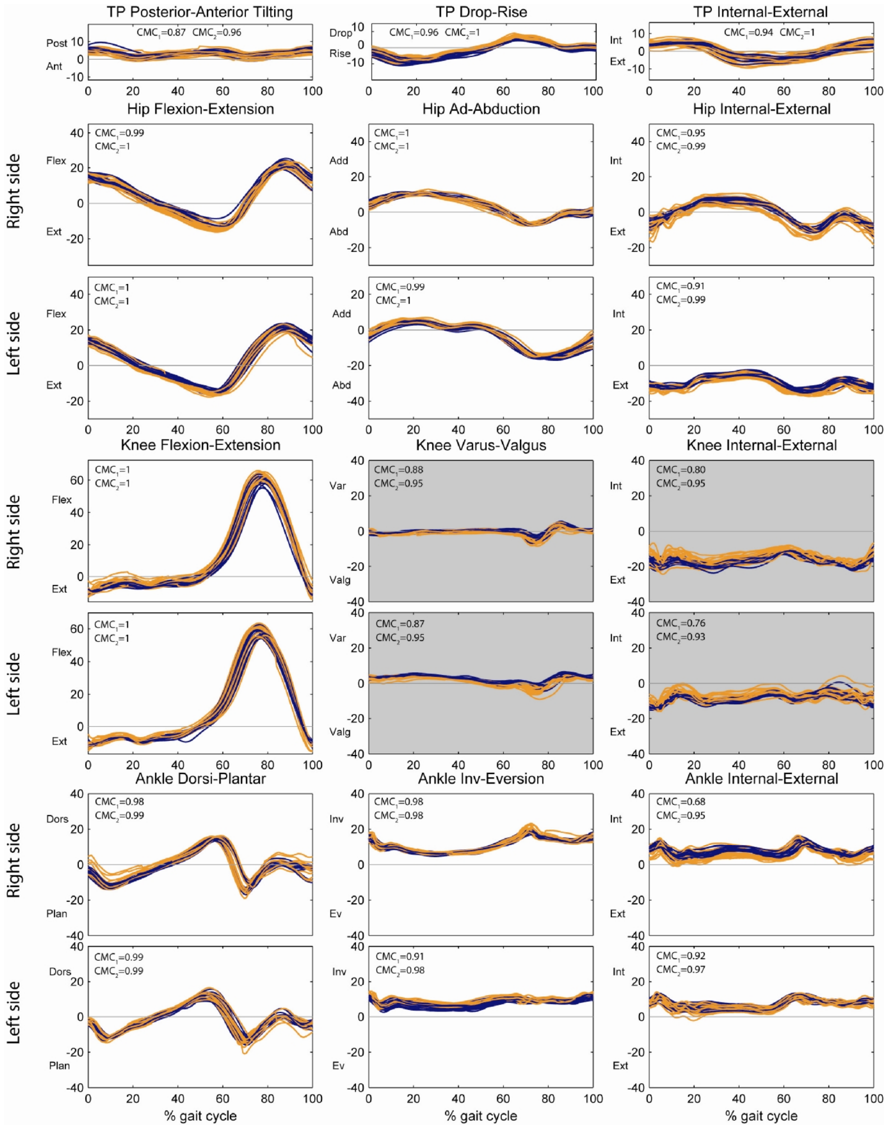

Fig 5: TEST 2: 14 gait cycles for subject AF, as measured by Xsens (bright plots) and Vicon (dark plots). For each joint-angle, the CMC1 and CMC2 is provided. Since the knee varus-valgus and internal-external rotation will not be considered in the clinical routine due to their low accuracy [19], they are reported over a gray background.

It can be noticed a very good agreement, especially for the joint-angles with greater ROM. Occasionally, sudden orientation adjustments were observed in the Xsens signals, especially at the ankle. These were generally associated to those parts of the gait cycle where a sudden change from high to low acceleration takes place, and were related to the Kalman filter (XKF-3 0.8.3) used in these experiments. This issue was reported to Xsens, which claims to have fixed it in later versions (as of firmware version 2.3.5). In a clinical perspective, however, these abnormal patterns are immediately visible and can even be automatically discarded by looking at the first derivative of the signal which will present a theoretically infinite value. These abnormal patterns resulted in 51 of 1050 waveforms and were not removed from the analysis.

As for Test 1, results for *off*, *r* and ΔROM are reported in Appendix 2, while results for CMC_1 and CMC_2 follow. Figure 6 reports the CMC_1 and CMC_2 values for each joint-angle, as in Figure 4 of Test 1.

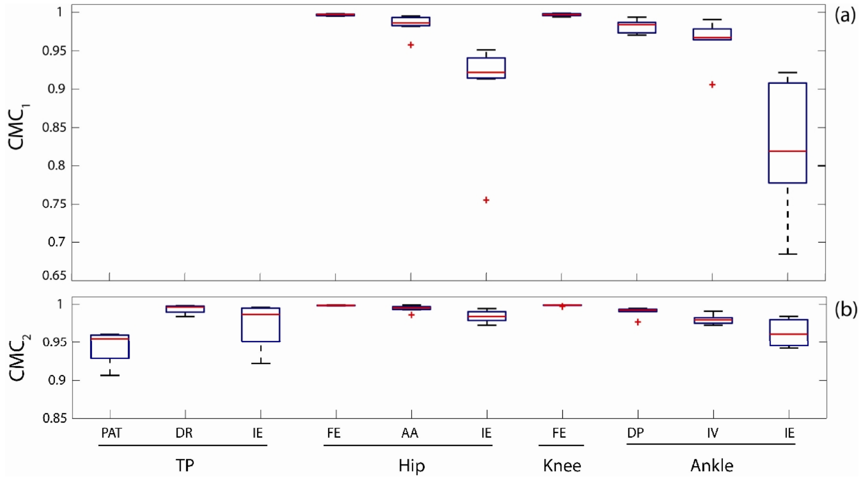

Fig 6a,b: TEST 2: Box-and-whiskers plots for CMC1 (a) and CMC2 (b). CMC1 and CMC2 measure the within- joint-angle similarity between Xsens and Vicon waveforms, when the CAST is used as protocol. Distributions are here reported over 4 TPs and 7 hips, knees and ankles. Box-plots are reported only for those joint-angles in which all values were real numbers.

In Figure 6a, CMC_1 box-plots are reported for all joint-angles excepted the TP' ones, i.e. only for those joint-angles in which all values were real numbers. With the exception of the hip and ankle IE, all values within whiskers were above 0.95, i.e. showed excellent similarity between Xsens and Vicon joint-angles. Values for the hip IE were within 0.92 and 0.95, while lower values were found for the ankle IE (0.68 to 0.92, median 0.82).

Once removed the offset between corresponding waveforms of Xsens and Vicon, CMC values improved (Fig. 6b). CMC_2 medians were greater than 0.95 for all joint-angles, and values were always greater than 0.91, i.e. representative of a very-good to excellent similarity.

Based on CMC_1 results, Cond. T2.1 was thus satisfied by hip FE, AA, knee FE and ankle DP and IV. Based on CMC_2, instead, the condition was satisfied by all joint-angles.

3.3 Test 3

Figure 7, reports for Outwalk+Xsens and CAST+Vicon the kinematics of the same 14 gait-cycles reported in Fig. 3 of Test 1 and in Fig. 5 of Test 2 (subject AF).

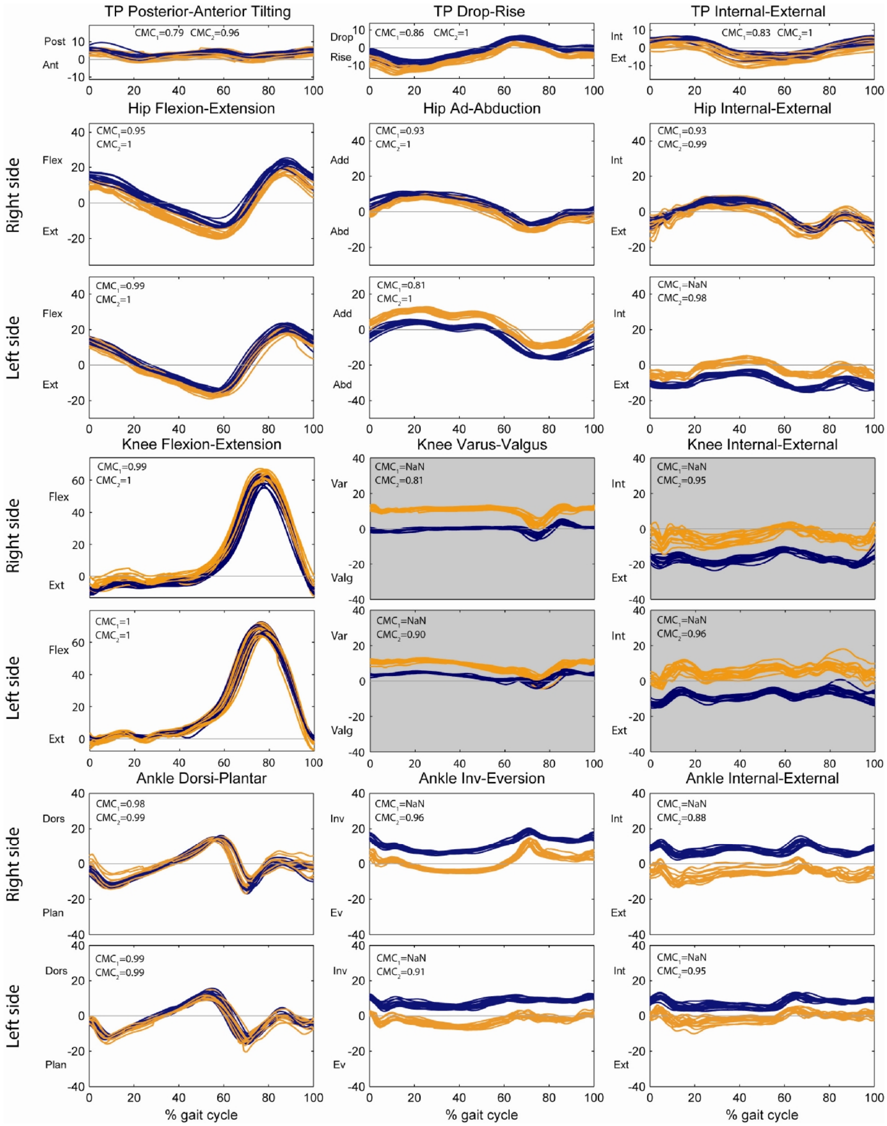

Fig 7: TEST 3: 14 gait cycles for subject AF, as measured by Outwalk+Xsens (bright plots) and CAST+Vicon (dark plots). For each joint-angle, the CMC_1 and CMC_2 is provided. Since the knee Varus-Valgus and Internal-External will not be generally considered in the clinical routine due to their low accuracy [19], they are reported over a gray background.

3.3.1 OUTWALK+XSENS – CAST+VICON COMPARABILITY ASSESSMENT

As for Test 1 and 2, results for *off*, *r* and ΔROM are reported in Appendix 2, while results for CMC_1 and CMC_2 follow.

Figure 8 reports the CMC_1 and CMC_2 values for each joint-angle, consistently with Figs. 4 and 6.

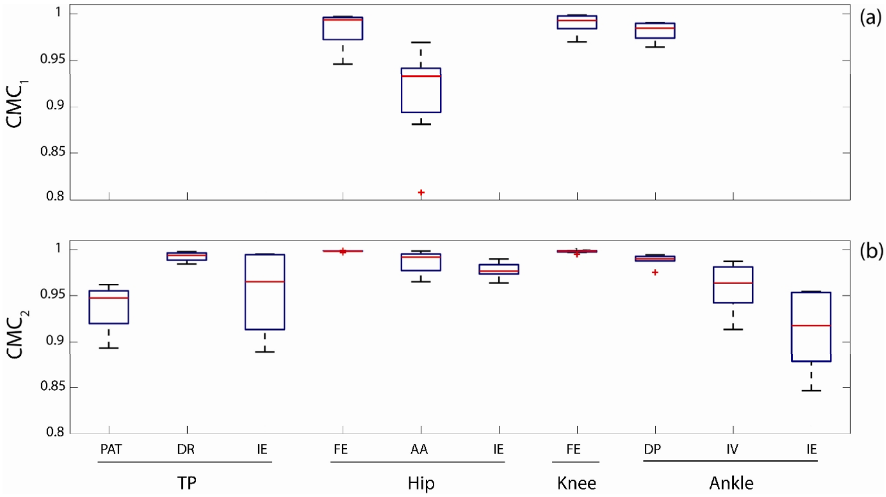

Fig 8a,b TEST 3: Box-and-whiskers plots for CMC_1 (a) and CMC_2 (b). CMC_1 and CMC_2 measure the within- joint angle similarity between Outwalk+Xsens and CAST+Vicon waveforms. Distributions are here reported over 4 TPs and 7 hips, knees and ankles. Box-plots are reported only for those joint-angles in which all values were real numbers.

Figure 8a reports the CMC_1 distributions for the hip FE, AA, knee FE and ankle DP, which were the only angles with all real numbers values. For hip and knee FE, and ankle DP, whiskers were greater than 0.95, i.e. an excellent similarity between Outwalk+Xsens and CAST+Vicon. For the hip AA the median (0.93) is close to the excellent range and whiskers are within the very good range.

As for Test 1 and 2, once removed the offset between corresponding waveforms, CMC values greatly improved (Fig. 8b). CMC_2 values were greater than 0.85 for all joint-angles, i.e. representative of a very-good to excellent similarity. In particular, sagittal plane joint-angles and the TP DR presented an excellent similarity with values always greater than 0.98. For frontal plane joint-angles and the TP PAT, the similarity ranged between very-good to excellent for all values, with medians in the "excellent" range". For the transverse plane angles, the hip IE presented values always higher than 0.95, i.e. in the excellent range. Slightly poorer results were found for the TP and the ankle (in particular the ankle IE), but still with all values within the very-good to excellent range.

Based on CMC_1 results, Cond. T3.1 was thus satisfied by hip FE, AA, knee FE and ankle DP. Based on CMC_2, instead, the condition was satisfied by all joint-angles.

3.3.2 OUTWALK-CAST vs CAST-Total3Dg-PiG-SAFLo-LAMB SIMILARITY ASSESSMENT

Table 1 reports the *MAV* values between Outwalk+Xsens and CAST+Vicon for each limb of subject AF, for all joint-angles except TP (since it was not considered in [8]), consistently with Table 1 of Test 1. All *MAV* values reported for Outwalk-CAST were smaller than those reported for CAST-Total3Dg-PiG-SAFLo-LAMB, even though for the right ankle IE the *MAV* was very close to the limit. Cond. T3.2 was thus satisfied for all joint-angles, consistently with Test 1.

Table 2 finally reports the *r* values between Outwalk+Xsens and CAST+Vicon for each limb of subject AF, for all joint-angle except TP. The correlation between Outwalk and CAST was the best for 9 out of 14 angles, the second best for 3, and third best for the others. This means that Cond. T3.3 was also satisfied, consistently with Test 1.

4. Discussion

The aim of this work was to initiate the validation of Outwalk in-vivo, by involving healthy subjects, and considering the upright as calibration posture with active FEs of the knee, consistently with the indication provided in [4]. This was done since below-knee amputees will be the first population on which Outwalk will be applied. These subjects will be preferably calibrated in the upright posture, and are able to actively flex and extend both knees. The supine calibration has been performed for all the 4 subjects of this study, and future work will report about the difference in terms of joint kinematics between the two postures.

As described in Sect. 2.1 the assessment of a new protocol (Outwalk) applied on a novel hardware (IMMS) relative to a reference protocol (CAST) and hardware (optoelectronic system), was faced through an innovative stepwise approach, which requires the execution of 3 tests. As also discussed in Sect. 2.1, results from Test 1 represent the lower-bound errors, and thus form the basis for comparison. Test 1, in fact, evaluated Outwalk when used in combination with a reference hardware (the optoelectronic system), which is equivalent to thinking Outwalk tested in combination with the "perfect" IMMS (i.e. equivalent to the reference hardware). Results from Test 1 will *not* need to be updated based on evolutions in the IMMS technology or on Kalman filters advancements, while Test 2 and 3 will need to. Similarly, results from Test 2 will *not* need to be updated if new functional calibration algorithms will be used. Moreover, thanks to the separate analysis of the main factors affecting the similarity of Outwalk+Xsens and CAST+Vicon, it is possible to more clearly identify future direction of improvement. All these advantages, in our opinion, strongly support the need to always split the assessment of new protocols based on new hardware, in the three tests reported here.

As introduced in Sect. 2.1, among the clinical protocols, CAST was used as a reference for 4 main reasons:

1. its anatomical CSs are consistent with ISB recommendations;

2. its performances are widely tested and documented [1, 2, 8];
3. it was the reference protocol used in [17];
4. it requires the use of clusters of markers, which can be thought as SU, and the definition of technical frames, which are analog to the local CS of a SU.

These features ease the simultaneous application of CAST and Outwalk. Moreover, the two protocols could share the same marker-set, and thus were affected by the same soft-tissue artifact, which was thus filtered in the comparison.

Results for *off*, ΔROM and *r* (Appendix 2) demonstrate a general close relationship between Outwalk+Xsens and CAST+Vicon kinematics (Test 3). Based on the results for Tests 1 and 2, *off* is predominantly induced by differences in the protocols; differences in *r* by both hardware and protocols; differences in ROM by the accuracy of the Xsens system. These last two aspects are therefore expected to improve with IMMS advancements. In terms of *off*, the most critical remain the ankle IV and the transverse plane angles. In terms of *r*, the most critical are the angles with small ROM (less or equal to 10°), e.g. the TP PAT and the ankle IE; this is consistent with previous finding for the upper-limb [3]. For ΔROM, values are in the limited range of about ±5°.

Since Picerno et al [17] measured the hip, knee and ankle kinematics through a protocol in combination with an Xsens system, and reported the results for *r* and ΔROM, a comparison with Outwalk+Xsens is possible. Despite the fact that Picerno et al. measured just one subject on just one gait-cycle, the values reported here for *r* were very close (0.94 to 1). We found lower correlations only for ankle IV and IE, even though these correlations still range between good to excellent, and are thus acceptable. Picerno reported lower ΔROM (from 0.5° to 2°) but the range reported here (on a wider population) appears still largely acceptable in clinical practice (median within -0.3 and 1.7°, and all values ±5°). It could be concluded, therefore, that the simplification of the construction of the anatomical/functional CS from [17] to Outwalk did not substantially affect the similarity of results with CAST.

In more details, regarding Test 1 the CMC_1 values of hip FE, AA, knee FE and ankle DP satisfied Cond. T1.1. Therefore, we can conclude that for these angles the kinematics of Outwalk and CAST can be wholly interchanged, offset included. Moreover, when CMC_2 results are tested, Cond. T1.1 is satisfied by all joint-angles. It follows that for all joint-angles CAST and Outwalk kinematics can be interchanged when the offset is not of primary concerns. CMC_1 and CMC_2 results thus support the similarity between the two protocols.

The test of Cond. T1.2 on *MAV*, confirmed that Outwalk kinematic is closer to that of CAST, than those of CAST - Total3Dg – PiG – Saflo - LAMB among each other. The same conclusion can be drawn from the results for *r* between Outwalk and CAST, and CAST versus the other 4 protocols; for all joint-angles *r* satisfied cond. T1.3. From the results for Conds. T1.1, T1.2 and T1.3 it can be concluded that the anatomical CS defined in Outwalk make it potentially suitable for clinical measurement as it is the case for CAST, Total3Dg, PiG, Saflo, and LAMB. Based on these results, we can even speculate that Outwalk applied with an optoelectronic system may also become a first gait analysis screening protocol, due to its ease of applicability. Further assessment on clinical populations are however required before this can happen.

Regarding Test 2 (Xsens accuracy), CMC_1 values for all angles except the ankle IE and the TP joints, satisfied Cond. T2.1. We can conclude therefore that for these angles the Xsens is highly accurate, offset included. When CMC_2 results are considered instead, Cond. T2.1 was satisfied by all joint-angles. We can conclude therefore that even for those angles with more limited ROM (e.g. the TP joints), the Xsens has high dynamic accuracy, but the absolute estimation of orientation should be used with care.

Regarding Test 3, CMC_1 and CMC_2 confirmed that the kinematics measured by Outwalk+Xsens and CAST+Vicon for hip, knee and ankle sagittal plane and hip AA can be interchanged, also in terms of offset. If the offset is not of primary concern, all joint-angles can be interchanged. In particular, the TP DR, all hip angles, the knee FE and the ankle DP are the angles with the highest level of trust; then follow the TP PAT, IE, and the ankle IV; and finally the ankle IE, which has the lowest values at the lowest acceptability threshold, and thus its interchange is discouraged.

Results from Cond. T3.2 and T3.3 confirmed the results from Test 1. In particular, results from Cond. T3.2 about *MAV* for subject AF, confirmed that the Outwalk+Xsens kinematics is closer to that of CAST+Vicon's than those of CAST - Total3Dg – PiG – Saflo - LAMB among each other. The only angle which is close to the non acceptability level is the right ankle IE, consistently with findings for CMC_1 and CMC_2. Similar conclusion can be drawn from the results for the correlation between Outwalk+Xsens and CAST+Vicon, and CAST versus the other 4 protocols; for all joint-angles r values satisfied Cond. T3.3.

On the whole, therefore, conditions T3.1, T3.2 and T3.3 support the conclusion that Outwalk+Xsens can be potentially used in the clinical practice as it is the case for CAST, Total3Dg, PiG, Saflo, and LAMB. In particular, the results support the commencement of clinical trials of Outwalk on our first target population, i.e. transtibial amputees.

5. References

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APPENDIX 1 - INTER-PROTOCOL CMC

To quantify the similarity of joint-angle waveforms, Kadaba et al. [2] proposed the adjusted Coefficient of Multiple Correlation (CMC). The CMC allows to establish the overall similarity of waveforms taking into account the concurrent effects of differences in offset, correlation, and gain among them. The CMC was originally proposed in two formulations, originally named *within-day* and *between-day* CMC [2], and these are now widely used in gait analysis [1, 3].

In particular, the within-day CMC is computed as follows, e.g. when for a subject and a joint-angle, W waveforms are acquired in each of S different sessions, and for each waveform F frames are available:

$$\mathrm{CMC}=\sqrt{1-\frac{\sum_{s=1}^{\mathrm{S}}\sum_{w=1}^{\mathrm{W}}\sum_{f=1}^{\mathrm{F}}(Y_{swf}-\overline{Y}_{sf})^2/\mathrm{SF(W}-1)}{\sum_{s=1}^{\mathrm{S}}\sum_{w=1}^{\mathrm{W}}\sum_{f=1}^{\mathrm{F}}(Y_{swf}-\overline{Y}_{s})^2/\mathrm{S(WF}-1)}} \qquad \text{(Eq.1)}$$

where,

- $\overline{Y}_{sf}$: ordinate at frame *f,* of the average waveform among the W waveforms of session *s*;
- $\overline{Y}_{s}$: grand mean of the $\overline{Y}_{sf}$ of session *s*.

The effect of this formula is to provide an index of the overall similarity between waveforms, *filtered from the inter-session variability* (e.g. caused by the reapplication of markers or calibration of anatomical landmarks).

When the *inter-protocol similarity* is of interest, e.g. the kinematics measured for a subject by two protocols as in this paper, Eq. 1 must be reinterpreted in order to filter the "gait-cycle -to- gait-cycle": 1) biological variability of the subject's lower-limb kinematics, 2) variability in the propagation of the soft-tissue artifact on lower-limb kinematics, and 3) variability in the measurement system performance.

Let us assume that for a subject and a joint-angle the kinematics is measured synchronously through P protocols, on G gait-cycles: P waveforms are therefore available for each *g*-th gait-cycle, one per protocol, each of F_g frames.

To assess the *inter-protocol similarity*, Eq. 1 can be re-formalized as:

$$CMC = \sqrt{1 - \frac{\sum_{g=1}^{G} \left[\sum_{p=1}^{P} \sum_{f=1}^{F} (Y_{gpf} - \overline{Y}_{gf})^2 / GF_g (P-1) \right]}{\sum_{g=1}^{G} \left[\sum_{p=1}^{P} \sum_{f=1}^{F} (Y_{gpf} - \overline{Y}_{g})^2 / G(PF_g - 1) \right]}} \quad \text{(Eq.2)}$$

where:

- $\overline{Y}_{gf}$: ordinate at frame *f,* of the average waveform among the P waveforms of gait-cycle *g*;
- $\overline{Y}_{g}$: grand mean for the gait-cycle *g* among its P waveforms;

When, within each gait-cycle, the variability of the P waveforms around their mean waveform is smaller than the variance about their grand mean, CMC approaches 1. Otherwise the CMC will tend towards zero or even become a complex number. This is for example the case when the range of motion (ROM) of the P waveforms is comparable with the offset among them.

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APPENDIX 2 - Results for *off*, *r* and ∆ROM

Test 1 - Outwalk+VICON vs CAST+VICON

Figure 1 reports *off*, *r* and ∆ROM distributions for each joint-angle of interest, over the articulations measured (4 TPs and 7 hips, knees and ankles) considering all the gait cycles acquired. The TP joint-angles box-plots contain 4 * 14 = 56 values (14 being the right side gait cycles); the hip, knee, and ankle joint-angles box-plots contain instead 7 *14 = 98 values.

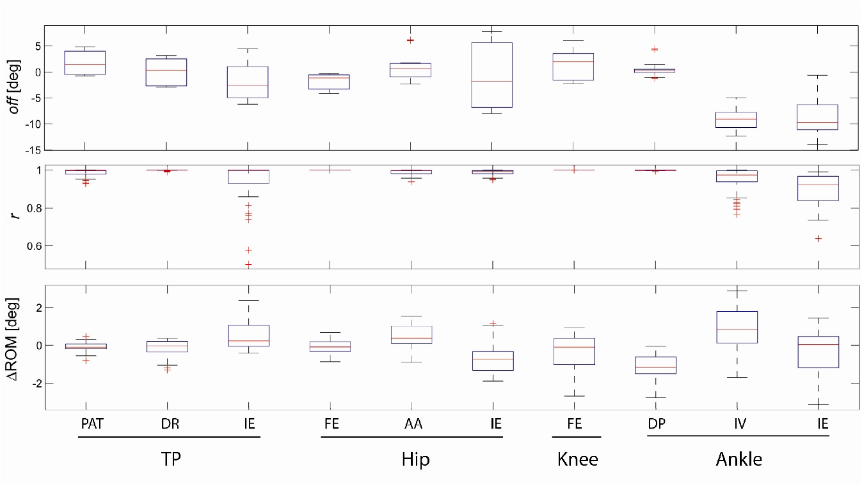

Figure 1 Box-and-whiskers plots for off, r and ∆ROM regarding the comparison Outwalk+Vicon vs CAST+Vicon. Off, r and ∆ROM were firstly computed within each articulation measured. Distributions were then reported here over 4 TPs and 7 hips, knees and ankles.

With the exception of ankle IV and IE, and hip IE, *off* values always ranged between a limited interval of ±5°, with medians within ±2°. This indicates that the average difference in alignment between CAST and Outwalk CS is limited. For ankle IV and IE, the median of *off* is a negative value which is consistent with expectations: due to the relative location of shank and foot anatomical landmarks, CAST generally measures an inversion and intra-rotation of the ankle during the gait-cycle [1]; on the contrary, Outwalk measures rotations around 0°, since 0° is the value imposed to the ankle IV and IE in the calibration posture; these intrinsic characteristics in Outwalk and CAST cause therefore the negative values of *off*. For the hip IE, the median is about 2°, and values cover the range ±8°. These results should be considered as positive, since the intra-examiner hip IE measured by CAST alone has a RMS error of 6° [2], i.e. about ±12° if a 95% probability interval is considered. In addition, CAST inter-subjects confidence bands for hip IE, for healthy subjects, has a range of ±12° (1 standard deviation) [1].

For all joint-angles, *r* values within whiskers (that is at least the 95% of values) were always higher than 0.75, that is Outwalk and CAST waveforms demonstrated at least a good correlation. With the exception of the ankle IE, the correlation was always higher than very-good, and it was excellent for all sagittal angles, hip AA and IE, and TP DR.

Finally, ΔROM was very limited for all joint-angles, i.e. within the range of ±3°, with median values always within ±1°.

Test 2 - Xsens accuracy

Figure 2 reports *off*, *r* and ΔROM distributions for each joint-angle of interest, over the articulations measured (4 TPs and 7 hips, knees and ankles) considering all gait cycles acquired. The TP joint-angles box-plot thus contain 4 * 14 = 56 values (14 being the right side gait cycles). The hip, knee, and ankle joint-angles instead, contain 7 *14 = 98 values.

O*ff* values always ranged between a limited interval, with medians within ±2° and whiskers within -5° to 4°. For *r*, medians were always higher than 0.95, i.e. within the excellent range; values within whiskers were always higher than 0.9 with the only exception of the TP PAT (greater that 0.72). On the whole, the correlation between Xsens and Vicon was therefore at least good and most commonly from very-good to excellent.

Finally, ΔROM for all joint-angles was very limited, with median values always within +0.6° to +1.5° and whiskers always within -2° to 5°.

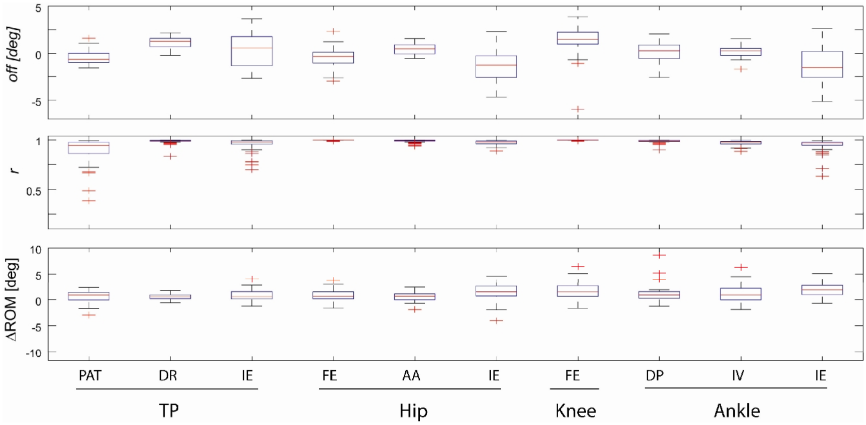

Figure 2 Box-and-whiskers plots for off, r and ΔROM, regarding the Xsens accuracy. Off, r and ΔROM were firstly computed within each articulation measured. Distributions were then reported here over 4 TPs and 7 hips, knees and ankles.

Considering the results for Test 1, the differences between the Xsens and Vicon waveforms were smaller than the differences between protocols Outwalk and CAST for *off,* comparable for *r,* and from 1° to 2° larger for ΔROM.

Test 3 - Outwalk+Xsens vs CAST+VICON

Figure 3 reports the results for *off*, *r* and ΔROM, similarly to Figure 1 and 2.

For *off*, results were close to those reported for Test 1. Medians did not change significantly, now spanning the range from -3° to 2° (from the original ±2°) for all joint angles excepted the ankle IV and IE, whose medians remained unchanged at about -10° due to Outwalk/CAST protocol differences. Transverse plane angles confirmed to be the angles most affected by offset. The hip IE and the ankle IE increased the whiskers range, summing the effect of the different protocols and hardware.

Also the results for *r* were very close to those reported for Test 1, with lower values only for the TP PAT (lower whiskers = 0.72), due to the Xsens accuracy. For all joint angles, medians ranged between very-good to excellent correlation, and values within whiskers were generally within the good to excellent range. Only 3 out of 56 trials for the TP PAT and 6 out of 98 for the ankle IE showed a moderate to good correlation.

Finally, ΔROM median values ranged between -0.3° and 1.7°, confirming the results from Test 1 (medians ranged within ±1°). Whiskers were generally within a limited range of ±5°, but wider than in Test 1 (±3°); the increase can thus be drawn back to the Xsens accuracy.

Based on the results for Tests 1 and 2, offsets are predominantly induced by differences in the protocols; sudden orientation adjustments and differences in ROM due to hardware differences; differences in correlation by both hardware and protocols.

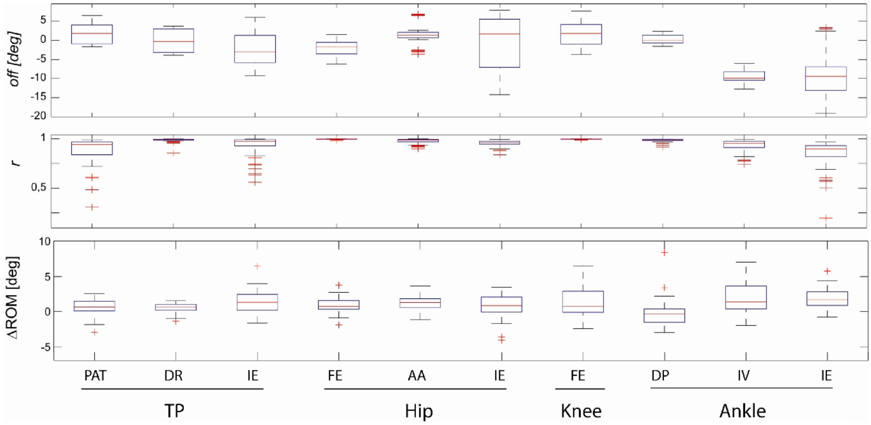

Figure 3 Box-and-whiskers plots for off, r and ΔROM, regarding the comparison Outwalk+Xsens vs CAST+Vicon. Off, r and ΔROM were firstly computed within each articulation measured. Distributions were then reported here over 4 TPs and 7 hips, knees and ankles.

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Chapter 5

TEST OF 'OUTWALK' ON CHILDREN WITH CP

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Manuscript in preparation:

FERRARI A, Van den NOORT J, CUTTI A, HARLAAR J, BECHER J (in preparation)
Validation and test of the protocol "Outwalk" on a population of children with cerebral palsy.

Long abstract

1. Introduction and rationale

Cerebral Palsy (CP) is the problem of greatest interest among all child motor disabilities due to its frequency and severity (1). The core aim of the rehabilitation treatments for most of children with CP is the acquisition and maintenance of the walk (2). The evaluation of walking performances therefore is necessary for clinical decision-making and treatment planning.

Instrumental GA provides an evaluation of walking, by quantifying the biomechanical aspects of the gait such as joint kinematic, functional alterations and compensatory schemes. This technique is considered as the most refined tool available for the documentation and the functional assessment of the locomotion (3,4). Literature increasingly provides evidences of the larger efficacy of the instrumental GA compared to the routine observational GA i) in the clinical assessment of patients (5), ii) in diagnosis (6), and especially in classification processes (7), and iii) in the judgment of the rehabilitation treatments adopted (8,9).

GA is generally achieved by means of stereophotogrammetric systems, mainly based on optoelectronic technology. These systems consist of cameras able to track in time the position of skin-mounted markers. They have been very well characterized and customized for human movement analysis applications (10-12). However, the installation of these systems requires ad hoc environments, moreover they are expensive, hardly portable, and have a restricted field of view (13). These features limit their use to specifically dedicated laboratories and restrict the acquisition of a subject's walk to few strides per trial, under conditions which can be far from a steady state. In addition, the acquisition of gait in an unfamiliar environment, such as that of a laboratory, can psychologically condition the child, who will generally over-perform with respect to his/her everyday life ability. All these drawbacks weaken the stereophotogrammetric as a technology able to effectively acquire the most representative gait pattern of a child with CP (14).

A possible solution to these problems is represented by the recent availability of 3D motion tracking systems based on a new generation technology that is miniature MEMS (Microelectromechanical systems) inertial sensor. These are the Inertial & Magnetic Measurement Systems (IMMSs), and they may open a new perspective for measuring human movement kinematic (15-18). IMMSs, in fact, can provide information about the joint angular displacements with high dynamic accuracy (root mean square error inferior to 4°, (19)), and they are widely commercially available, cost effective, portable, and fully wearable (InterSense, USA; Microstrain, USA; Xsens Technologies, NL). These features give to IMMSs the potential to achieve GA in laboratory-free settings, in conditions that can properly be linked to an *holter* modality. In fact, avoiding the use of cameras, they are suitable to be used in daily life environments in a continuous modality, thus to collect great numbers of consecutive gait cycles during spontaneous walking, hence simplifying the recognition of the most representative gait pattern (15,20).

A standard IMMS consists of multiple Sensing Units (SUs) integrated in lightweight boxes. Each SU integrates an inertial measurement system, comprised of one 3D accelerometer and one 3D gyroscope, with a 3D magnetometer. The data supplied by the accelerometer, gyroscope, and magnetometer are combined through sensor-fusion algorithms (27-29) in order to measure the 3D orientation of the SU's Coordinate System (CS) - defined based on the sensing axes of the inertial and magnetic sensors - with respect to a global, earth-based CS. Given this 3D orientation, an IMMS has the potential to estimate joints kinematics when: 1) a SU is attached to each body-segment of interest; 2) at least one anatomical CS is defined for each body-segment; and 3) the orientation of the anatomical CS is expressed in the CS of the SU. Joint kinematics are then obtained from the relative orientation of anatomical CSs relative to adjacent segments. The critical part of this process is the definition of the anatomical CSs. The lack of information regarding the position of the sensors implies that anatomical CSs cannot be defined through the calibration of position of single anatomical landmarks (as recommended by the International Society of Biomechanics, (30)). Different techniques must therefore be conceived in order to obtain joint kinematic from raw SUs information (22), and these may be based mainly on functional movements and static acquisitions (24,31).

Hence, before application of IMMSs in routine clinical settings, ad hoc kinematic protocols must be conceived and developed for children with CP. The design of the protocols should rigorously take into account the postural and motor disabilities exhibited by children with CP, thus to allow: i) fast sensors mounting, ii) fast and comfortable calibration procedures, and iii) not require any additional specialized device than the IMMS itself.

Only few protocols have been developed so far for gait kinematics measurement (17,18), and just the one proposed by Cutti and coworkers (17) was specifically designed for children with CP. This protocol, named Outwalk, was developed by means of the Xsens IMMS (Xsens Technologies, NL) in order to result extremely simple to be performed and comfortable for the CP population. Outwalk flexibility is obtained by not requiring any specialized device other than the SUs and for the possibility to execute the calibrations passively and in a supine position (see section 1.1). Moreover, in order to make Outwalk really effective in the clinical practice, a dedicated easy-to-use clinical software was made available. The software, named 'Outwalk Manager' software permits a comfortable, extremely fast and semi-automatic implementation of the GA exam (24). The execution of the protocol in combination with Outwalk Manager, takes advantage from the potentiality provided by Xsens, and it allows a visualization of the joint kinematics in real-time and the achievement of classical gait analysis reports (15) as soon as the trial acquisition is stopped, through an automatic procedure that do not require any additional effort to elaborate the data collected.

1.1 Brief description of the protocol "Outwalk" for gait analysis with inertial & magnetic sensors

A protocol, named Outwalk, has been recently proposed (24) to measure the kinematics of the pelvis relative to the trunk, and of the lower-limbs with an IMMS. Outwalk is designed to achieve GA both for hemiplegic children belonging to the I, II or III forms Winters et al. (33), and for diplegic children belonging to the II, III, IV or V of the Ferrari et al. classification (34).

This protocol defines the anatomical/functional CSs for each segment body by means of the following three steps:

1. positioning the SUs on the subjects' thorax, pelvis, thighs, shanks and feet, following simple geometric rules;
2. computing the orientation of the mean FE axis of the knees during knee FE tasks. Considering the motor impairments showed by the children, these tasks can be carried out:
   - actively, with the subject laying down in supine position, computing the axis on a pure knee FE movement,
   - passively, with the subject laying down in supine position, computing the axis while a therapist executes the knee FE movement in a range of flexion comfortable for the patient;
3. measuring the SUs orientation while the subject's body is oriented in a static predefined posture. Considering the motor skills presented by the different patients, this static posture can be carried out with the subject standing:
   - upright, with the back straight, looking forward, knee centre medial to the ASIS, and the virtual line from the 2nd metatarsal head to the calcaneus of the right foot parallel to the same line of the left foot;
   - supine on a mat, knee extended, knee centre medial to the ASIS, feet in neutral plantar-dorsiflexion, inversion-eversion and parallel to each other as previously described. This static posture can be achieved also passively, with the assistance of a therapist assuring the maintenance of the correct joint alignment.
   - supine on a mat, with the hip flexed α° and the knee flexed β° degrees (see the Figure 1), knee centre medial to the ASIS, feet in neutral plantar-dorsiflexion, inversion-eversion and parallel to each other as in option 3.1.

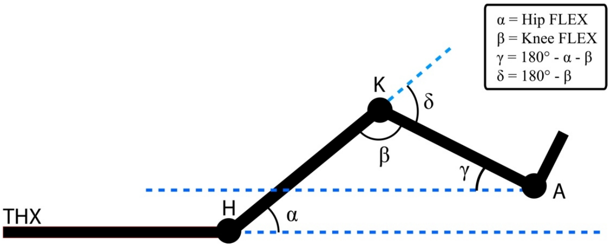

Fig 1: This posture appears suitable to be used for children with irreducible knee flexion, laxity or deformities. The angles α° and β° will be 0° if the leg can be fully extended.

The calibration procedures above briefly presented seem adequate for the majority of children with CP. In general, the upright posture combined with an active estimation of the knee FE axis may be used for those children, such as the hemiplegic forms, with good posture abilities. On the contrary, the supine posture combined with the passive estimation of the knee FE axis may be adopted for more severe forms, such as the diplegic forms with crouched knees and/or hip-knee-ankle flexion gait pattern (scissor pattern). The possibility to obtain the FE axis passively, with the assistance of just one operator, makes Outwalk potentially suitable for routinely clinical applications.

A preliminary validation of Outwalk combined with the Xbus kit (see Xsens Manual) of an Xsens system on a population of four healthy subjects has been recently accomplished (15). Very good results were obtained in terms of validity, accuracy and precision. However, the feasibility of the different modalities of calibration and protocol set up proposed, must be fully explored on the pathologic population of interest. Furthermore, the validity of Outwalk in showing the features of the pathological gait patterns, hence its validity in GA on CP children has still to be tested and demonstrated.

The aim of the present study was to test and validate Outwalk on diplegic and hemiplegic CP children in order to promote the use of the protocol in the clinical practice. As in (15), a reference clinical protocol and a reference optoelectronic system were used to validate and assess the accuracy of Outwalk in combination with the Xsens system.

2. Materials and methods

2.1 Study population

Four children with purely spastic forms of CP (3 female, age range 7–12 years) participated in the study. Eligibility criteria included: a documented CT or MRI diagnosis of CP, ability to stand and walk independently without walking aids, no major sensory or cognitive deficits, absence of visual field deficits, belonging to the I, II, or III GMFCS classification (27).

An informed consent was obtained before participation. The study was conducted according to the principles of the Declaration of Helsinki (version 2004) and in accordance with the Medical Research Involving Human Subjects Act (WMO, version March 2006) and approved by the ethical committee

2.1 Study design

As performed in (15),the evaluation of the accuracy of the new system (Xsens) based on Outwalk was performed by comparing it with respect to a reference protocol and system. The reference system was the optoelectronic camera system Optotrak (Optotrak Northern Digital Inc, Ontario, Canada) while the reference clinical protocol was the CAST (28).

As provided by Optotrak, active markers in clusters of four were used. Each of the 8 SUs used, was hosted in a customized elasticized strap provided by Xsens (see Xsens Manual). Above each strap in correspondence of the SU, the Optotrak clusters were attached with double side tape. For the trials acquired inside the laboratory, Xsens and Optotrak were run simultaneously. Their sampling frequency was set to 100 Hz. In order to allow the synchronous acquisition of data by the systems, the Optotrak internal clock was output from the system and sampled by the SU positioned on the left foot (see Xsens Manual).

Before proceeding with the in vivo tests, we checked the stability of the electromagnetic field of the laboratory (29). The local magnetic field was found to be homogeneous.

For each subject, the Xsens SUs with on top the clusters of markers were positioned as described in (17), over thorax, pelvis, thighs, shanks, and feet. For CAST, the anatomical landmarks of thorax, pelvis, thigh, shank, and foot described in (28) were calibrated relative to the clusters of the different segments using a calibration stick while the subject was standing in upright posture; the orientation of the CAST anatomical CSs was then related to the clusters' CSs.

2.3 Trials performed

The calibration procedures necessary to implement the two protocols, CAST and Outwalk, were accomplished in the laboratory. Once completed the calibration phases, the subjects were asked to walk along a 10m walkway at a self-selected comfortable walking speed. After each trial, the gait events were identified through (30), and then used to define the corresponding gait cycles in the Optotrak data. The Optotrak data were processed through the open source software program BodyMech (www.bodymech.nl, (31)). For each subject, at least 5 gait cycles for each limb were acquired. The joint kinematic of the trunk, pelvis and lower limbs was measured.

The differences between Outwalk and CAST joint kinematics, when the former is applied to the Xsens data, and the latter to the Optotrak data, were then assessed. For this purpose, from the relative orientation of Outwalk anatomical/functional CSs measured in Xsens (Outwalk + Xsens), and the relative orientation of CAST anatomical CSs measured in Optotrak (CAST + Optotrak), the kinematics of the thorax and the pelvis-thorax, hip, knee, and ankle joints could therefore be independently computed. In particular, the following joint-angles were computed: posterior–anterior tilting (PAT), right drop–rise (DR), and right internal–external rotation (IE) for the TP joint; flexion–extension (FE), adduction–abduction (AA), and internal–external rotation (IE) for the hip; FE for the knee; dorsi–plantar flexion (DP), inversion–eversion (IV), and IE for the ankle. It has been widely demonstrated that the knee rotations other than the FE are strongly affected by the soft-tissue artifact problem when measured through skin-mounted markers, and are therefore unreliable (32). For this reason, these angles were not analyzed.

In what follows, CO(t) and OX(t) indicate corresponding waveforms measured (synchronously) for the same joint angle, during the same gait cycle, by CAST+Optotrak and Outwalk+Xsens, and Outwalk+Xsens, respectively. Beside, $\overline{CO(t)}$ and $\overline{OX(t)}$ indicate the two mean waveforms obtained considering all the CO(t) and all the OX(t) respectively. For each subject, to assess the similarity between the series of CO(t) and OX(t) in terms of offset, correlation and gain, we computed 4 parameters: the Root Mean Square difference (RMSd) between $\overline{CO(t)}$ and $\overline{OX(t)}$, their Pearson's correlation coefficient (r), and the difference between their Range of Motion (ΔROM) and their offset (Δoffset). In particular, Δoffset and ΔROM were defined as (15):

- off = mean($\overline{CO(t)}$) - mean($\overline{OX(t)}$);
- ΔROM = ROM($\overline{CO(t)}$) - ROM($\overline{OX(t)}$).

In addition, to assess the overall effect of Δoffset, r, and ΔROM, for each joint-angle of each subject, between CO(t) and OX(t) series we computed the *within-day* Coefficient of Multiple Correlation (CMC, hereinafter CMC_1) as defined by Kadaba et al. (33); and the *inter-protocol* CMC (hereinafter CMC_2) as defined by Ferrari et al. (15).

3. Results

Figure 2 reports the joint kinematics as expressed by CO(t) and OX(t) for the first subject acquired. Similar results were obtained for the other subjects.

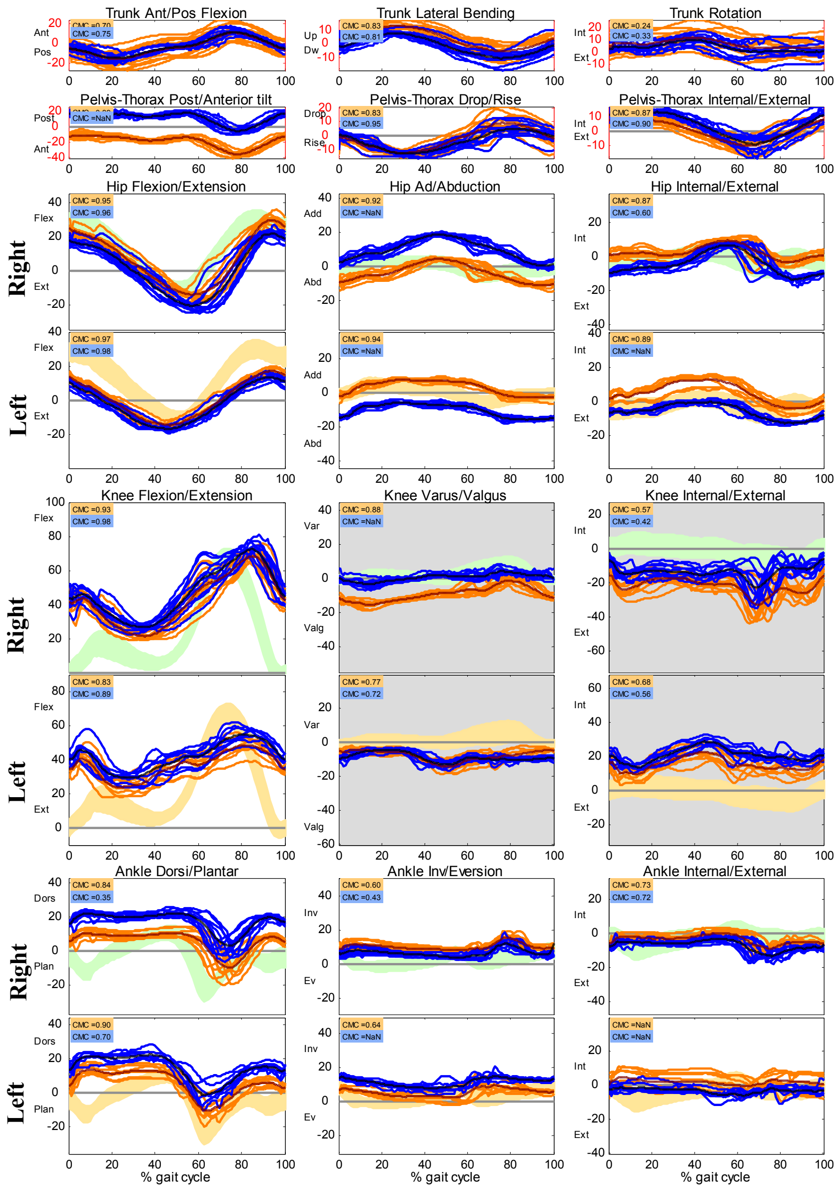

Fig. 2: 10 right gait cycles and 8 left gait cycles for the first subject, as measured by Xsens+Outwalk (bright plots) and Optotrak+CAST (dark plots). For each joint-angle, the CMC_1 (bright boxes) and CMC_2 (dark boxes) are also provided. Since the knee varus–valgus and internal–external rotation will not be considered in the clinical routine due to their low accuracy (32), they are reported over a gray background

Table 1 report the means over the four subjects for the parameters RMSd, ΔROM, ΔOffset CMC_1 and CMC_2. In particular, the mean value for *r*, CMC_1 and CMC_2 were calculated after a 'z-distribution' transformation (34).

Table 1: mean values of RMSd, ΔROM, ΔOffset CMC_1 and CMC_2 over the four subjects

Joint angle	RMSd	r	CMC_1	CMC_2	ΔROM		ΔOffset	
					mean	std	mean	std
Right Knee FE	5.9	0.979	0.887	0.918	2.0	1.0	-0.8	6.9
Right Hip FE	8.2	0.975	0.912	0.806	1.2	2.6	-4.3	8.9
Right Hip AA	9.2	0.934	0.842	0.264	-1.2	2.0	2.8	11.6
Right Hip IE	20.5	0.880	0.716	0.170	-2.0	4.3	-15.6	20.0
Right Ankle DP	4.7	0.977	0.804	0.837	0.0	2.0	-4.0	6.7
Right Ankle IE	3.5	0.521	0.549	0.289	0.1	1.2	-2.6	1.0
Right Ankle IE	16.0	0.874	0.582	0.224	-0.1	1.0	-13.7	16.7
Left Knee FE	6.7	0.994	0.946	0.951	-1.2	1.2	-0.8	7.9
Left Hip FE	7.8	0.997	0.978	0.929	0.2	6.0	-6.1	7.9
Left Hip AA	8.1	0.981	0.953	0.530	-1.6	1.7	-5.7	8.1
Left Hip IE	15.1	0.919	0.835	0	1.5	2.2	9.7	14.0
Left Ankle DP	6.0	0.975	0.817	0.742	-0.5	1.7	-3.9	6.2
Left Ankle IE	5.3	0.820	0.675	0.139	3.6	3.7	3.0	5.0
Left Ankle IE	5.7	0.888	0.459	0	1.1	0.6	-0.3	7.5
Pelvis-Thorax PAT	15.7	0.920			-1.3	2.6	-15.5	12.2
Pelvis-Thorax DR	7.1	0.943			2.5	1.3	-3.4	10.2
Pelvis-Thorax IE	4.9	0.985			-0.5	3.4	-1.0	5.1
Thorax Ant/Pos Flexion	6.5	0.983			-0.2	0.8	6.1	6.5
Thorax Lateral Bending	4.9	0.989			0.8	1.1	2.1	6.1
Thorax Rotation	12.2	0.991			0.4	2.3	1.7	15.7

Overall good results were obtained for the ΔROM with a mean value never bigger than 3.6°.

In the sagittal plane, good results were also obtained for the ΔOffset with mean values always lower than 4.5°. In the sagittal plane, CMC_1 and CMC_2 were also good, with values never lower than 0.7. Out of sagittal plane the results obtained were not as good as in the sagittal plane. Good results were obtained for *r*. However, CMC_1, CMC_2 and ΔOffset were consistent with those obtained in (15).

4. Discussion

As concluded in (15), Outwalk+Xsens can be potentially used in the clinical practice just once its validation on a CP target population is accomplished. IMMSs by not requiring a fully equipped movement analysis laboratory, will then have the potential to be used in everyday life situations and, therefore, to increase the use of GA and in the end the quality of the treatments provided to children with CP.

As expected, the results reported in this experiment relative to four CP children are affected by a relevant standard deviation and they are not generally coherent with those reported in (15). This just means that additional subjects have to be enrolled in order to allow more reliable considerations.

Nevertheless, the results obtained show that the most important difference between CO(t) and OX(t) series are due to offset. Indeed, while r was overall above 0.8 (except for just the right ankle IV) and no significant differences were present in terms of ΔROM; the ΔOffset showed relevant offset distances among the waveforms. Coherently, every time ΔOffset was low and the ROM of the joint angle considered was relevant, the values for CMC_2 were larger than those of CMC_1.

In clinical settings, IMMSs already demonstrated their extremely usefulness as reliable tool aimed at evaluating spasticity in terms of measuring the angle of catch with an augmented precision (35). In the next future it is easy to imagine that IMMSs will substitute the use of the goniometer in the majority of the assessments usually performed during clinical evaluation of CP children. Indeed, a sensors set up as the one proposed with Outwalk is suitable to perform several clinical assessments in succession without any additional effort by the operators. Once the sensors are applied on the subject's body, they do not only have the potential to acquire gait analysis, but also to execute, on a bed or a mat, several clinical measurements such as:

- the degree of spasticity, for example with the protocol already provide by Van den Noort et al. (35), or
- the joint range of motion starting from different segments poses, and
- specific tests or manipulations, such as the ones described in (36-38).

The use of an IMMS with dedicated graphical user interfaces, as already provided for Outwalk (24), will guide the operator through the execution of the tests both avoiding the use of papers and goniometer, obtaining greater precision and accuracy, and storing each test result in simple and well-organized digital databases. Furthermore, the results could then be loaded in digital medical records giving the possibility to the health care personnel to have updated information anywhere and anytime, and to GA technique to be vital part of the digital revolution that is underway in medicine (39).

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Chapter 6

A NEW FORMULATION OF THE COEFFICIENT OF MULTIPLE CORRELATION TO ASSESS THE SIMILARITY OF WAVEFORMS MEASURED SYNCHRONOUSLY BY DIFFERENT MOTION ANALYSIS PROTOCOLS

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Abstract

Different 3D motion analysis protocols are currently available, but little is known regarding the level of similarity of their outcomes, e.g. whether a joint-angle waveform from one protocol can be interchanged with that measured by another protocol. Similarity assessments are therefore urgent to ease the comparison of results. In this context, a major issue is how to quantify the similarity between waveforms measured synchronously through different protocols, within each of many movement-cycles (e.g. gait-cycle), when the effect of protocols on waveforms similarity is the only of interest. For this purpose we developed a new formulation of the statistical index called Coefficient of Multiple Correlation (CMC). The CMC measures the overall similarity of waveforms taking into account the concurrent effects of differences in offset, correlation, and gain. The within-day CMC originally proposed by Kadaba et al. (J Orthop Res 1989; 7(6): 849-860), was firstly reinterpreted in terms of "excluded factors". Then, the new formulation was set to assess the inter-protocol similarity, removing the between-gait-cycle variability. An example showing the effectiveness of the new formulation is presented regarding the pelvis-trunk and ankle kinematics.

KEYWORDS

Motion analysis; kinematics; measurement protocols; biomechanical signals; waveform similarity.

1. INTRODUCTION

At present, different protocols are available to measure the lower and upper-limb kinematics/kinetics [1,2]. Since very little is known regarding the level of similarity of their outcomes [1,3,4], i.e. to which extent outcomes can be interchanged, the integration of results from studies using different protocols is complicated. The need to increase this knowledge is therefore urgent [1,5,6].

To compare the outcomes of protocols, two major issues have to be faced: 1) the definition of an ad-hoc experimental design, and 2) how to measure the similarity of the kinematics/kinetics waveforms generated by the protocols, e.g. the different joint-angles expressed as a function of time during a gait-cycle.

Regarding the first issue, since protocols' kinematics/kinetics is the object of study, the between-subject variability and the between-gait-cycle variability are the two main confounding factors to be "excluded". The study should then see the protocols applied synchronously on each subject, and differences between protocols should be analysed within each gait-cycle [1].

Regarding the second issue, Kadaba and co-workers [7], stressed that in describing the similarity of waveforms, simple statistics does not yield satisfactory results. Hence, they proposed the 'Coefficient of Multiple Correlation' (CMC), which measures the overall similarity of waveforms taking into account the concurrent effects of differences in offset, correlation, and gain. Since Kadaba's original proposal, there have been many advances in pattern recognition of complex datasets mainly based on frequency or wavelet domain [8], but still the CMC is the most used parameter. The CMC was originally proposed in two formulations, named *within-day* and *between-day* [7], and these are now widely used [4, 9]. However, none of the two formulations is applicable to the experimental design described above.

The aim of this work was therefore to propose a new CMC formulation to assess the similarity of waveforms (e.g. joint-angles, joint-moments) acquired synchronously through different media (e.g. different protocols, different measurement systems), within each of many movement-cycles (e.g. gait-cycle, shoulder flexion-extension), when the effect of the media on waveforms similarity is the only of interest. For this purpose, the within-day CMC will be firstly reinterpreted in terms of "excluded factors". Then, the new formulation will be proposed and an example showing its effectiveness will be presented.

In the interest of clarity, the new formulation is here described referring to the comparison of kinematic waveforms acquired synchronously by different protocols during gait.

2. METHODS

2.1 Reinterpretation of the Within-Day CMC

Referring to a single subject, the within-day CMC provided in [7] can be used to measure the overall similarity among S sets of W waveforms of a joint-angle, measured during W gait-cycles, in S testing sessions pertaining to S different experimental days. Assuming F frames to be available for *each* waveform, the *within-day* CMC formulation is:

$$CMC = \sqrt{1 - \frac{\sum_{s=1}^{S}\sum_{w=1}^{W}\sum_{f=1}^{F}(Y_{swf} - \overline{Y}_{sf})^2 / \mathrm{SF(W-1)}}{\sum_{s=1}^{S}\sum_{w=1}^{W}\sum_{f=1}^{F}(Y_{swf} - \overline{Y}_{s})^2 / \mathrm{S(WF-1)}}} \quad \text{(Eq.1)}$$

where:

- Y_{swf} : ordinate at frame *f* of the waveform *w* of session *s*;
- $\overline{Y}_{sf}$: ordinate at frame *f,* of the average waveform among the W waveforms of session *s*;
- $\overline{Y}_{s}$: grand mean of the Y_{swf} of session *s.*

The within-day CMC is thus computed through a 4-step process:

A) calculation of the variability of the waveforms of each session with respect to the within-session mean waveform, and sum of this variability over sessions;
B) calculation of the variability of the waveforms of each session with respect to the within-session grand mean, and sum of this variability over sessions;
C) normalization of A and B by their number of terms, i.e. SF(W-1) and S(WF-1);
D) square root of "1 minus the ratio of A-normalized over B-normalized".

Reinterpreting Eq.1, the effect of this 4-step process is to provide an index of the overall similarity among waveforms *cleared from the inter-session variability*, as the W waveforms of each session are compared to their average waveform and to their within-session grand-mean.

For protocols comparison, Eq.1 has to be modified to:

1) identify the new factor to be excluded, i.e. the equivalent of "sessions" in Eq.1;
2) rearrange the normalization by the degrees-of-freedom (step C): since the protocols are applied synchronously, there is no need to resample all gait-cycles to the same number of frames F.

2.2 FORMALISATION OF THE NEW CMC

Let us assume that for a subject and a joint-angle, the kinematics is measured synchronously through P protocols, on G gait-cycles, and that Fg is the number of frames measured for the *g*-th gait-cycle. P waveforms are therefore available for each gait-cycle, one per protocol.

The aim is to measure the similarity among the P waveforms acquired by the P protocols within each gait-cycle, that is *cleared from* the "gait-cycle-to-gait-cycle": 1) biological variability of the subject's lower-limb kinematics (e.g. in speed), 2) variability in the propagation of the soft-tissue artifact, 3) variability in the measurement system performance (only when all protocols are applied with a single system). Altogether these three types of variability will be called herein "between-gait-cycle variability". The confounding factor that has to be excluded is therefore the gait-cycle.

Regarding step C, since F changes from one gait-cycle to the next, the normalization by the degrees of freedom will need to be done within the summation over the gait-cycles.

As both indexes P and W indicate the waveforms acquired, the new CMC equation becomes:

$$CMC = \sqrt{1 - \frac{\sum_{g=1}^{G}\left[\sum_{p=1}^{P}\sum_{f=1}^{F}(Y_{gpf}-\overline{Y}_{gf})^2 / \mathrm{GF}_g(\mathrm{P}-1)\right]}{\sum_{g=1}^{G}\left[\sum_{p=1}^{P}\sum_{f=1}^{F}(Y_{gpf}-\overline{Y}_{g})^2 / \mathrm{G}(\mathrm{PF}_g-1)\right]}} \quad \text{(Eq.2)}$$

where:

- Y_{gpf} : ordinate at frame *f* of the waveform provided by protocol *p* at gait-cycle *g*;
- $\overline{Y}_{gf}$: ordinate at frame *f* of the average waveform among the P waveforms for the gait-cycle *g*:
- $$\overline{Y}_{gf} = \frac{1}{\mathrm{P}}\sum_{p=1}^{\mathrm{P}} Y_{gpf}$$
- $\overline{Y}_{g}$: grand mean for the gait-cycle *g* among its P waveforms:
- $$\overline{Y}_{g} = \frac{1}{\mathrm{PF}}\sum_{p=1}^{\mathrm{P}}\sum_{f=1}^{\mathrm{F}} Y_{gpf}$$

When, within each gait-cycle, the variability of the P waveforms around their mean waveform is considerably smaller than the variance about their grand mean, CMC approaches 1. Otherwise the CMC will tend towards zero or *even become a complex* *number.* This is for example the case when the peak-to-peak amplitude of the P waveforms (giving the context, referred to hereinafter as the waveforms Range of Motion - ROM) is comparable with respect to the offset among them. Contrary to what stated in [7] therefore, CMC^2 is not inferiorly limited to 0, both considering Eq.2 and Eq.1 (see also Sect. 3).

2.3 In-vivo application

To show that Eq. 2 provides an accurate estimation of the protocol similarity, excluding the "between-gait-cycle variability", the pelvis-to-trunk anterior-posterior tilting and the ankle planta-dorsi flexion and inversion-eversion of a subject were measured synchronously by two protocols (CAST [10], and Outwalk [11]), on 6 gait-cycles, through an optoelectronic system (Vicon MX, Oxford Metrics, UK). We then compared: 1) the similarity between the waveforms of the two protocols within each gait-cycle following Eq. 2 (inter-protocol CMC, CMC_{IP}), and 2) the between-gait-cycle variability, by applying the within-protocol CMC from Eq. 1 (CMC_{WP}) and assuming, in this case, "the protocols" as "the sessions" and re-sampling the waveforms over the same amount of frames.

3. RESULTS

Figure 1a reports the waveforms for the pelvis-to-trunk anterior-posterior tilting. The CMC_{WP} value is a complex number, due to the consistent offset among the waveforms of different gait-cycles and the limited ROM. On the contrary, CMC_{IP} equals 1, as the waveforms acquired by the two protocols for each gait-cycle (i.e. corresponding waveforms) are almost overlapped.

Figure 1b reports the waveforms for the ankle planta-dorsiflexion. Due to the increased ROM and decreased offset, CMC_{WP} = 0.85, i.e. a better but non-perfect similarity. On the contrary, corresponding waveforms are very close to each other, and this is confirmed by CMC_{IP} = 0.99.

Figure 1c reports the waveforms for the ankle inversion-eversion. Considerations similar to the previous case apply here to CMC_{WP}, which equals 0.72. However, the difference between protocols is now significant, resulting in a complex number for CMC_{IP}.

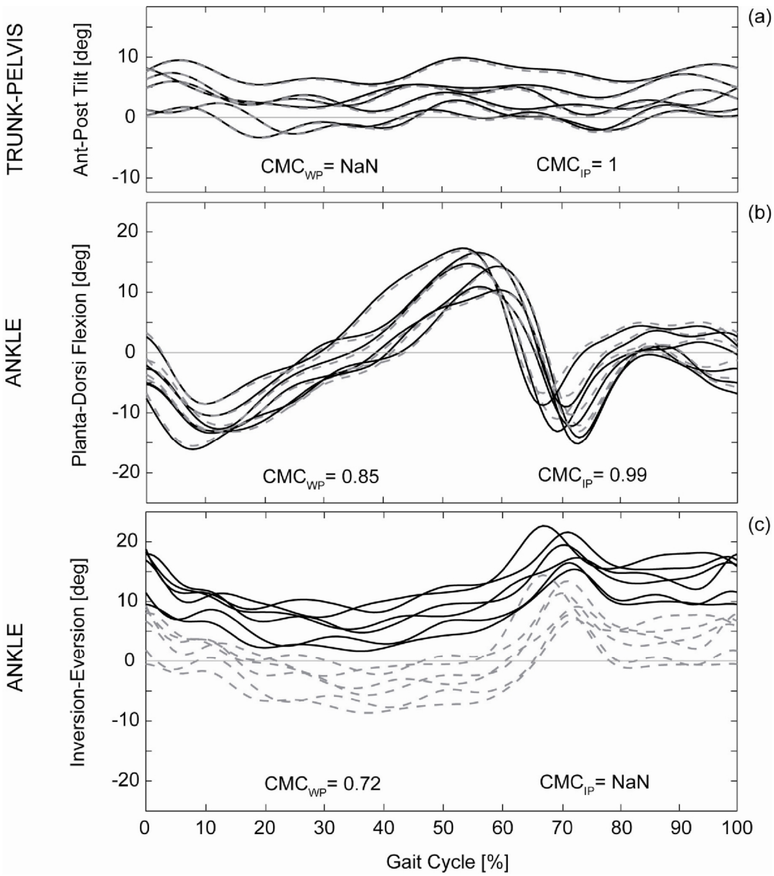

Fig 1 The solid black lines (CAST) and the dashed gray lines (Outwalk) indicate the kinematics measured by the two protocols whose similarity is of interest: (a) pelvis-to-trunk anterior-posterior tilting, (b) ankle planta-dorsiflexion, and (c) ankle inversion-eversion. CMC_{WP}: within-protocol CMC; CMC_{IP}: inter-protocol CMC (Eq.2). NaN: indicates that the CMC is a complex number.

4. Discussion and conclusions

The CMC reported in Eq.2 measures the similarity of joint-angle waveforms acquired synchronously through different protocols when the effect of protocols is the only of interest. The results reported confirmed that the new CMC values are consistent with expectation. In particular, the comparison of the results revealed the ability of Eq.1 to assess the between-gait-cycle similarity cleared from the inter-protocol variability and the ability of Eq.2 to assess the inter-protocol similarity cleared from the between-gait-cycle variability.

The complex values obtained are not infrequent when computing the CMC over joint-angles with limited ROM and great dispersion. They also demonstrate that the statement formulated in [7] about the CMC^2 within-day being inferiorly limited to 0 is erroneous. From an clinical perspective, the authors think that null or complex CMC values (either from Eq. 1 and 2) should be interpreted in the same way, that is a complete dissimilarity of the waveforms. However, from a mathematical standpoint, null and complex values cannot be assimilated and the users of the equations must be aware of the possibility to obtain both.

In a more general perspective, it is important to notice that the application of Eq.2 is not limited to inter-protocol comparisons, but can be used to compare kinematics waveforms obtained through different synchronized media (e.g. optoelectronic and inertial measurement systems) during whatsoever movement-cycle through a single motion analysis protocol.

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PART IV

“OMAC”: proposal of a new orthosis to treat the valgus-pronated foot on children with Cerebral Palsy

“OMAC”: proposal of a new orthosis to treat the valgus-pronated foot on children with Cerebral Palsy

Abstract

Children with Cerebral Palsy (CP) are functionally limited to varying degrees because of their decreased central control and motor deficits (1). The effect of growth predispose children to secondary problems such as muscle contractures, bony deformities, and unusual gait abnormalities (2).

Motor deficits and spasticity frequently provoke a walking pattern characterized by the presence of a foot in equinus position, by an exaggerated knee flexion (crouch), and an hip adducted and internal rotated (3). The crouch pose is often unsolvable for the whole gait cycle in correspondence of a foot affected by a planovalgus deformity (Fig. 1, (4)).

Fig. 1: CP child affected by a flat and valgus-pronated foot, an extra-torted tibia, a flexed-valgus knee, an abducted and intra-torted thigh, and an antiverted pelvis

The flat and valgus-pronated foot deformity reduces the stability of gait because of the ground reaction force shifts posteriorly and laterally, increasing the flexion, valgus, and external rotation moments at the knee (5).

Health care programs are aimed at preventing deformities and encouraging the development of functional and independent skills and abilities. Commonly prescribed

treatments in addressing gait abnormalities in CP children include physical therapy, surgery (orthopedic and rhizotomy), and *orthoses*. The orthotic approach is conservative, being reversible, and common in many therapeutic regimes. Orthoses are used to improve the gait of children with CP, by preventing deformities, controlling joint position, offering an effective lever arm, and thus raising the stability and decreasing muscular fatigue. Optimal clinical decision-making for improving gait through orthotic management requires an understanding of the biomechanics of the foot and ankle during normal gait, the pathophysiology and pathomechanics of gait disruption and the biomechanical characteristics of the various orthoses.

The ankle-foot orthosis (AFO), with a rigid ankle, is primarily designed to prevent or eliminate a foot equinus position. While AFO has a direct effect only on foot and ankle joint alignment, a positive effect on more proximal joints is achieved by simplifying to the central nervous system the control of walking. For example, by restraining anterior tibia1 translation on the tibiotarsal joint, the AFO may reduce excessive midstance knee flexion or crouch. However, AFOs prevent the natural excursion of the tibio-tarsic joint during the second rocker, hence hampering the natural leaning progression of the whole body under the effect of inertia (6).

The clinician must seek to integrate his/her own goals with those of the child and family. Design, indications, and cost should therefore be considered when choosing an orthosis. In this context, AFO is an evident and unaesthetic brace that underline the motor defect, thus it causes relevant discomforts in the context of social life.

Aim of the present chapter is to counter the drawbacks of the AFOs prescribed in presence of a flat and valgus-pronated foot, an extra-torted tibia, a flexed-valgus knee, an abducted and intra-torted thigh (fig. 1) through the proposal of a new modular (submalleolar) astragalus-calcanear orthosis, named OMAC. In particular the chapter will demonstrate how the mechanic and aesthetic limitations imposed by the use of a classical AFO have been overcome with OMAC.

In the first part of the chapter the integral document of the deposited Italian patent of OMAC, is provided. In the second part a study of OMAC efficacy in the context of children with diplegic CP is reported.

Chapter 7

Herein is reported the text relative to the description of the orthosis OMAC as deposited in the Italian patent and trademark office

Original title:

"ORTESI MODULARE ASTRAGALO CALCANEARE E RELATIVA CALZATURA ORTOPEDICA"

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Date of Deposit: 20 March 2009
Number of the registered demand: **MC2009A0000057**

Ing. Claudio Baldi s.r.l.
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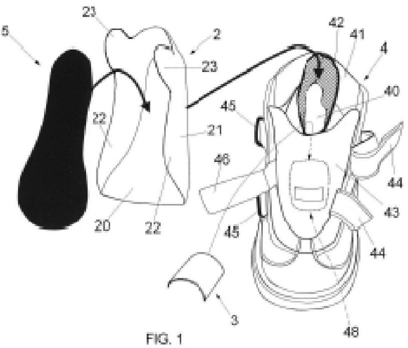

FIG. 1

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DESCRIPTION

The following patent application for industrial invention concerns a modular astragalus-calcanear orthosis and an orthopedic shoe equipped with this orthosis.

The prescription of orthopedic orthoses for the ankle (ankle-foot and foot orthoses) is standard for those subjects presenting a flat and valgus-pronated foot, an extra-torted tibia, a flexed-valgus knee, an abducted and intra-torted thigh, and an antiverted pelvis. These impairments are commonly provoked by the main orthopedic and neurological pathologies, such as Cerebral Palsy, Spina Bifida and neuro-muscular diseases.

The foot of the subjects affected by these segments misalignments is unable to provide an effective lever arm during walking. Thus, in order to promote the deambulation and functional autonomy of the children affected by the above mentioned pathologies, ankle foot orthoses and foot orthoses were conceived. The orthoses achieve the following functions:

- sustain of the plantar vault (flat foot deformity),
- prevent the astragalus turn in toward the medial side of the foot and the calcaneus misalignment in valgus deformity
- correct the position of the forefoot with respect the midfoot and the rearfoot in the frontal and transversal plane
- contrast the shut of the sinus of the tarsus (eversion deformity of the fore-foot)
- solve the torsional conflict at the knee (intra-rotated femur vs extra-torted tibia)
- guide to the ankle kinematic during walking through:
    - correcting the position and orientation of the foot with respect to shank in order to provide an effective lever arm,
    - preventing the excessive span of the angle between foot and shank on the transversal plane (extratorted shank and flat-valgus-pronation foot deformity),
    - restraining the recruitment of the “equinus pattern”, that is the inverse of physiological kinematic interaction between foot and ground (talus to tip), and
    - restraining the pathological scheme in adduction-intrarotation of the thigh.

In this context is standard the prescription of ankle-foot orthoses and submalleolar plantar orthosis (to be inserted inside orthopedic shoes) and the shank-ankle-foot orthoses, also known as AFOs. The AFOs act peripherally toward the sustain of the activity of the muscular groups more fatigable and toward the stabilization of the tibio-tarsic joint not effectively controllable due to the presence of hyposthenic muscles.

The different models of AFOs can be clustered as follow:

- supramalleolar AFOs, obtained form a conventional model of a shank, with a plantar region internal to the footwear and an external one that cover posteriorly the shank, tied underneath the tibial tuberosity with a Velcro strap; and

- custom made supramalleolar AFOs, obtained starting from positive models of shank and foot segments of the patient, made according to profile and cut lines able to guarantee sustains differentiated with respect the medial and lateral and the proximal and distal areas; acting both in compression (anti-talus) and in traction (anti-equinus).

The submalleolar orthosis are subjected to fast plastic deformation and they lose quickly their efficacy. The supramalleolar AFOs with a standard design provide a plantar sustain often not sufficient, limit the range of motion of the tibio-tarsic joint, prevent the rotation of the shank on the foot in the stance phase with respect to the “second rocker” (rotation around the mechanical axis coincident approximately with the inter-malleolar axis) and are aesthetically scarcely tolerated by the young patients. The custom made AFOs are mechanically much more effective, but remarkable difficulties affect their realization and the costs of production are relevant with respect the other models. Furthermore, they are as well aesthetically not pleasant.

A typical AFO is shown in figure 15. The AFO takes place in the plantar area of the midfoot (A), along the posterior side of the shank (B), up to the head of the fibula (C). A strap (D) (fasten in correspondence of the anterior side of the shank, over the tibial-tuberosity) tights the AFO to the shank of the patient and provides a mechanical sustain that support the muscular inefficiency of the gastrocnemious. The AFO is made with rigid plastic materials not deformable during walking that stiff the tibio-tarsic joint.

Many works indicate how the use AFOs during walking allows to stabilize and easy the gait phases of load acceptance, however it inhibits the onset and the conclusion of the swing phase. Indeed, the geometric shape of the AFOs prevent the natural excursion of the tibio-tarsic joint during the second rocker, hence hampering the natural leaning progression of the whole body under the effect of the inertia.

The mechanical constraint that limit the plantar-dorsiflexion excursion, both do not allow to minimize the energetic consumption during walking and increase the muscular fatigue. In addition, the AFO do not provide a consistent support able to restrain the deformation in valgus-pronation of the fore-foot.

Moreover, the supramalleolar portion of the AFO is clearly visible, resulting unaesthetic and underlining the motor defect, thus provoking relevant discomforts in the context of the social life.

Aim of the present invention is to counter the drawbacks of the above cited standard technique, that is to design a modular (submalleolar) astragalus-calcanear orthosis housed inside an orthopedic shoe, able to accomplish all the therapeutic functions it is prescribed for, and to avoid quick plastic deformation.

Additional aim of the present invention is to provide a standardized product, cost effective, safe and efficient. The device should be intended as pre-set up for an in situ custom manufacturing with respect to the patient dimensions.

This aims are accomplished according with the invention by the modular astragalus-calcanear orthosis whose features are listed in the attached *independent claims*.

Useful realization of the invention appears from the independent claims.

According to the invention, the modular astragalus-calcanear orthosis enclose:

- a first component made with a plastic rigid material, suitable to be placed inside a shoe, and
- a second component made with a plastic rigid material, suitable to be placed inside the tongue of the above cited shoe.

The first component incorporate a plantar portion, which cover the rear- and the mid-foot areas, and a peripheral portion, joined and erected orthogonally with respect the plantar portion, over the mid-foot, with an outline similar to a “U”. The peripheral portion incorporate two anterior parts that tight each other forming an open ring.

The second component has a curved plate shape aimed at overlap the anterior parts of the peripheral portion of the first component, over the mid-foot, in order to close the ring and to impose a rigid circular conformation to the orthosis when the shoe is laced up.

The outline of the orthosis is designed not only to result complementary to the internal volume of the shoe, but also to be integrated with and to rigidly support the structure of the shoe.

The orthopedic shoe together with the orthosis according to the invention overcome the intrinsic drawbacks of the AFOs and improve the walking performances through:

- preventing the medial translation/dislocation of the astragalus, thus also precluding the valgus deformity of the calcaneus;
- preventing the pronation deformity of the fore-foot and the shut of the sinus of the tarsus (eversion deformity of the fore-foot), hence the lost of an effective lever arm at the foot;
- promoting the natural progression of the body over the foot through the effect of the forces of inertia, during the second rocker (rotation around the ankle joint) and third rocker (rotation around the metatarsus-phalanges joint);
- restraining the flat foot deformity;
- increasing the joints stability;
- increasing the speed and the safety of the march taking advantage from the physiological excursion of the ankle (second rocker) during the progression of the body in the stance phase;
- reducing the muscles fatigability;
- rising the compliance of the child provide by the exterior aspect of the medical device fully comparable with the one of a sportive walking boot (low aesthetic impact)

In other words with the orthopaedic shoe and the orthosis according to the invention, it is obtained an improvement of the kinematic of the walk. The improvement has to be ascribed to the preservation of the angular excursions over the ankle joint and over the metatarsus-phalanges joint during the gait phases crucial- and final-stance.

Further characteristic of the orthosis are going to appear more clear in the following detailed description of a model realized as a template, thus purely illustrative and not restraining any other possible realization according to the invention, showed in the drawings attached, where:

- Figure 1 is a perspective view from the top showing with a scheme and an exploded diagram, according to the invention, the assembling of the orthosis inside an orthopaedic shoe;
- Figure 2 is a medial view, showing, according to the invention, the orthosis applied to the foot omitting the shoe;
- Figure 3 is a frontal view of the first component of the orthosis according to the invention;
- Figure 4 is a perspective view of the first component of the orthosis according to the invention;
- Figure 5 is a plantar view from the top of the first component of the orthosis according to the invention;
- Figure 6 is a frontal view of the first and the second component of the orthosis according to the invention;
- Figure 7 is a perspective view of the two components of the orthosis of Figure 6;
- Figure 8 is a lateral view of the two components of the orthosis of Figure 6;
- Figure 9 is a medial view of the two components of the orthosis of Figure 6;
- Figure 10 is a frontal view of an orthopaedic shoe according to the invention, in an open configuration;
- Figure 11 is a view as Figure 10, but showing the orthopaedic shoe laced up;
- Figure 12 is a lateral view of the shoe of Figure 11
- Figure 13 is a medial view of the shoe of Figure 11
- Figure 14 is a sectional view along the vertical sectional plane XIV-XIV of Figure 11; and
- Figure 15 is a perspective view of an AFO according to the standard technique

With respect to Figure 1 and 2, is shown an orthosis realized according to the invention; from now on it will be indicated with the reference number (1).

The orthosis (1) is realized with two different components (2, 3) made with a plastic rigid material.

The first component (2) incorporate a plantar portion (20) which cover the mid- and rear-foot areas. The plantar portion (20) is joined to a peripheral portion (21) that present an outline similar to an “U”, erected orthogonally to the plantar portion (20). The peripheral portion (21) has two anterior parts (22) over the mid-foot which are tight each other without touching, shaping as an open ring. In addition the peripheral portion (21) may present two posterior tabs (23) which rise over to the ankle joint, in diametrically opposite positions.

As shown in the Figures 3, 4, 5, the first component of the orthosis is equipped with a particular inclination of the plantar vault (25); with a niche (26) to house the malleolus and with an anterior cut line (27) designed in order to allow free rotation of the metatarsal-phalangeal joint.

The second component (3) has got the shape of a rectangular convex plate, with a radius of curvature designed in order to be overlapped to the anterior parts (22) of the peripheral portion of the first component (20) in the area of the midfoot, closing the ring and realizing a rigid circular conformation every time the shoe is laced up. Preferably the second component (3) is shaped with a butterfly outline in order to result compliant with the neck of the foot. In the Figures 6-9 is shown the entire orthosis (1) provided of the first (2) and of the second component (3).

In the figures 1 and 10-14 is showed an orthopedic shoe (4) able to house the orthosis (1). The shoe (4) comprise a base (40) joined with an upper (41) equipped with an internal lining that can be tipped-up (42) to house the first component (2) of the orthosis. The sole with benefit is provided with a nonslip material.

The extremity of the lining (42) can be can be equipped with a Velcro closure system.

To the upper (41) is connected a tongue (43) designed to cover the neck of the foot. The tongue (43) present a compartment or pocket (48) turned toward the inside of the shoe, outlined to house the second component (3) of the orthosis. The pocket of the tongue (48) can be equipped with a Velcro closure system.

Two fastener straps (44), of Velcro, are sewed in the medial side of the upper (41) to be bund into correspondent buckles (45) placed on the opposite side of the upper (laterally). A third fasten strap, of Velcro, sewed on the lateral side of the upper in the middle of the previous two buckles (46) to be bound into a buckle placed in the medial side of the upper (see Figure 10).

The shoe (4) enclose also a removable insole (5) separated from the base (40) of the shoe.

The lining (42) of the upper is lifted up and the first component (2) of the orthosis is inserted in the shoe (4), allowing the plantar portion (20) to be set into the bottom (40) of the shoe.

Consequently the insole (5) is placed over the plantar portion (20) of the first component of the orthosis. The lining (42) of the upper is then tip over the peripheral portion (21) of the first component of the shoe.

The second component of the orthosis (3) is introduced in the pocket of the tongue (50) of the shoe.

The upper (41) thus assumes its own final features of rigidity and toughness just when it is combined with the orthosis (1).

The closure of the shoe (4) is obtained through the Velcro straps (44, 46) sewed on the upper, and it determines the assumption and the maintenance by the two component of the orthosis (2, 3) of a circular profile as a close ring, with a partial overlap of the second (3) over the first component (2).

The close ring profile allow to maximize the yield point of the orthosis (delivering stress and loads over the whole surface of the orthosis) and then to optimize the value of the mechanical resistance to the static and cyclic stress.

The lining (42) of the upper is not sewed on the base of the shoe (40), thus the first component (2) of the orthosis is available to be covered with it, hence guarantying an excellent comfort during walking and the best fitting of the shoes.

The modular astragalus-calcanear orthosis (1) provide an improvement of the kinematic of the walking without preventing the progression of the body but allowing the free rotation of the tibio-tarsic joint (second rocker) and of the metatarsus-phalanges joint (third rocker), increasing the stability, the safety, and the speed of the walking; increasing the resistance and reducing the muscular fatigue; and hiding the motor impairment of the patient by hiding the orthopaedic device into the shoe.

The modular astragalus-calcanear orthosis (1) is made with standard components pre-set up on a model of a spastic foot; it can be fully integrated in the shoe because it allows a complete compatibility of the volumes, of the loading and of the flexion lines between the orthosis and the shoe. The orthosis is customable on the specific foot of the patient with simple modifications to be carried out by a specialized orthopedic technician; it is enough resistant to not require frequent reparations.

The orthopedic shoe was studied to interact with the orthosis and it is an integral and not alienable part of the orthosis. Indeed, the shoe and the orthosis cannot be used independently. Feature the shoe the internal lining (42) of the upper partially removable, the triple fasten with Velcro straps (44,46), and the tongue (43) equipped with a pocket (48) able to house the second component of the orthosis (3). The shoes are available in pre-set up series starting from shoe trees designed with volumes able to house the foot and the orthosis. Together with the orthoses, the shoes have to be customized on the patient dimensions by a specialized orthopedic technician.

While the foregoing written description of the invention enables one of ordinary skill to make and use what is considered presently to be the best mode thereof, those of ordinary skill will understand and appreciate the existence of variations, combinations, and equivalents of the specific embodiment, method, and examples herein. The invention should therefore not be limited by the above described embodiment, method, and examples, but by all embodiments and methods within the scope and spirit of the invention. The broad embodiment as previously conceived can be subjected to modification and changes within the inventive concept. Furthermore, all the details can be replaced with others technically equivalent. Practically, all the materials employed, as the shapes, as the dimensions, could be varied according to specific requirements without, for this reason, exit from the protection field of the following claims.

CLAIMS

1. Orthosis (1) modular astragalus-calcanear, incorporating:
   - a first component (2) in a plastic rigid material, suitable to be inserted inside a shoe (4). This first component (2) including a plantar portion (20), aimed at cover the rear- and the mid-foot areas, is joined to a peripheral portion (21) with an outline similar to an “U”, orthogonally erected over the plantar portion (20) in the mid-foot area. The peripheral portion (21) comprise two anterior portions (22) that are tighten each other forming an open ring in the mid-foot area; and
   - a second component (3) in a plastic rigid material, suitable to be inserted in the tongue (43) of the shoe. This second component (3) has got the shape of a curved plate aimed at overlap the anterior portions (22) of the peripheral part of the first component (20), in the rear-foot area, with the aim of close the ring in a rigid circular conformation.
2. Orthosis (1) according to the claim 1, wherein the first component (2) is characterized by the presence of two posterior tabs (23) which rise over to the ankle joint, in diametrically opposite positions.
3. Orthosis (1) according to the claim 1 or 2, wherein the first component (2) is characterized by the presence of an inclination in the plantar vault (25).
4. Orthosis (1) according to any of the previous claims, wherein the first component (2) is characterized by the presence of a niche (26) to house the malleolus.
5. Orthosis (1) according to any of the previous claims, wherein the first component (2) is characterized by the presence of an anterior cut line (27) design in order to allow free rotation of the metatarsal phalangeal joint.
6. Orthosis (1) according to any of the previous claims, wherein the second component (3) is shaped with a butterfly outline in order to result compliant with the neck of the foot
7. Orthopedic shoe (4) to support an orthosis (1) according to any of the previous claims, incorporating:
   - a base (40) connected to an upper (41),
   - a tongue (43) connected to the above mentioned upper (41), and
   - a plurality of closing straps (44, 46) sewed on the above mentioned upper (41) in order to assume a transversal layout over the above mentioned tongue (46),

   characterized by:
   - the presence of a lining (41) partially removable (42) able to cover the above mentioned peripheral portion (21) of the first component (2) of the orthosis, and
   - the presence of a tongue with a pocket (48) able to house the second component (3) of the orthosis.

8. Orthopedic shoe (4) according to the claim 7, characterized by the presence of an insole (5) suitable to be placed over the plantar portion (20) of the above mentioned first component (2) of the orthosis.
9. Orthopedic shoe (4) according to any of the claims 7 or 8, wherein the above mentioned partially removable lining (42) of the upper enclose a Velcro fixing system to close within the upper the above mentioned peripheral portion (21) of the orthosis.
10. Orthopedic shoe (4) according to any of the claims 7 - 9, wherein the above mentioned pocket (48) of the tongue (43) of the orthopedic shoe comprise a Velcro closing system to close within the pocket (48) the above mentioned second component of the orthosis (3).
11. Orthopedic shoe (4) characterized by the fact to enclose an orthosis (1) according to any of the claims 1 - 7.

SUMMARY

It has been described a modular astragalus-calcanear orthosis (1) comprising a first component (2) suitable to be inserted inside a shoe (4), and a second component (3) suitable to be placed inside the tongue (43) of the same shoe. The first component (2) incorporate a plantar portion (20), which cover the rear- and the mid-foot areas, and a peripheral portion (21), joined and erected orthogonally with respect the plantar portion (20), over the mid-foot, with an outline similar to a "U". The peripheral portion (21) incorporate two anterior parts (22) that tight each other forming an open ring in the mid-foot area. The second component (3) has a curved plate shape aimed at overlap the anterior parts (22) of the peripheral portion of the first component (20), over the mid-foot, in order to close the ring imposing a rigid circular conformation to the orthosis.

Chapter 8

ORTESI MODULARE ASTRAGALO CALCANEARE (OMAC): STUDY OF ITS EFFICACY IN THE CORRECTION OF THE VALGUS-PRONATUS FOOT IN CHILDREN WITH CEREBRAL PALSY

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Ortesi Modulare Astragalo Calcaneare (OMAC): study of its efficacy in the correction of the valgus-pronatus foot in children with cerebral palsy

LONG ABSTRACT

1. Introduction:

Ankle Foot Orthoses (AFOs) are frequently prescribed for ambulatory children with Cerebral Palsy (CP) to improve their walking pattern. In particular, AFOs are currently indicated to reduce and correct the valgus-pronation deformity of the foot. However, several studies indicated that AFOs impair the second rocker (7). As a consequence the push-off decreases when compared to barefoot or shoe walking condition (8).
A new model of orthosis, named "Ortesi Modulare Astragalo Calcaneare" (OMAC, fig. 1), has recently been proposed and patented (see chapter 7). OMAC was designed to overcome AFOs limitations, by reducing the valgus-pronation deformity of the foot without hampering second rocker.

A prospective study was designed to evaluate the effect of the two types of orthoses an AFO classical and OMAC, with the same goal settings, on gait, in a homogeneous group of CP children with diplegia. Both the orthoses are aimed at correcting the flat valgus-pronation foot deformity and at preventing ankle plantar flexion during swing, but opposite to AFO, OMAC is expected to allow the ankle dorsiflexion during the second rocker and to increase the push off during third rocker.

The compliance of children with CP using OMAC with respect to AFO was also tested using: i) the semi-quantitive test QUEST (Quebec User Evaluation of Satisfaction with assisive Technology, (10)) and ii) a daily diary reporting the motor activity performed during a the days of the study.

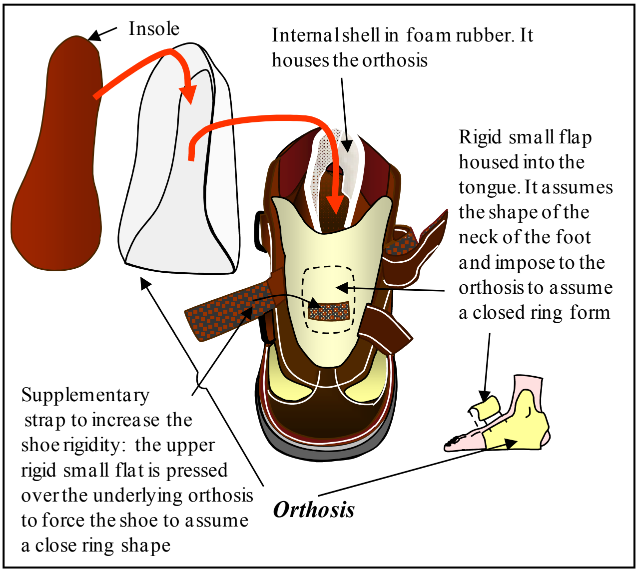

Fig. 1: Ortesi Modulare Astragalo Calcaneare (OMAC)

2. Materials and Methods

2.1 Subjects

Three children with purely spastic forms of diplegic CP (mean age 7.7 ± 3 years old) already familiar with the use of AFO in both the right and left legs participated in the study. Eligibility criteria included: a documented CT or MRI diagnosis of CP, acquired walking with or without walking aids, no major sensory or cognitive deficits, absence of visual field deficits and no functional surgery or botulinum toxin injection during the previous year. The children presented a foot (flat) valgus-pronated which along the years caused the insurance of the following segments misalignments:

- shank extra-rotated,
- knee flexed-valgus,
- thigh intra-rotated,
- anterior pelvic tilt,

The patients wore AFOs since, at least, one month before the enrollment.

2.2 Design of the experiment:

The design of the experiment is summarized in Fig. 2.

At T0 the effect of AFOs on gait was assessed by means of: 1) a quantification of the energy expenditure during walking with a Cosmed K4b^2 (Cosmed, IT) and 2) a gait analysis exam.

Similarly to Piccinini et al. (9), the protocol followed to assess the energy expenditure was: 1) 10min of resting phase (supine position) in order to compute the baseline energy expenditure; 2) walking at a self-selected pace in a 30m wide corridor and 3) walking at enhanced speed till reaching of a steady state of oxygen uptake. The same parameters adopted by Piccinini et al. (9) were then computed.

For the subsequent four weeks children were provided the OMACs and temporarily deprived of the AFOs. At the end of this period (T1) the efficacy of the OMAC was assessed repeating the measures performed in T0. In T0 and T1 parents filled in a modified version of QUEST (10), a simple questionnaire aimed at evaluate which was the preferred orthosis between the two under test. For the subsequent four weeks (the end of which is T2) children were asked to wear the orthosis they were preferring. Patients and their parents were also requested to fulfill a daily diary since T0 until T2, where they had to note down the type of motor activity sustained during the day and the amount of time spent wearing the orthoses.

The kinematic, kinetic and EMG data were collected with an 8 camera Vicon MX+ (Oxford Metrics Group, UK), 2 AMTI force plates (AMTI, USA) and a Zerowire EMG system (Aurion, IT). The protocol used to achieve gait analysis was the Total3Dgait (11,12). Retroreflective passive markers with a diameter of 1.4cm were used. However, to strictly compare the effect of OMAC with respect to AFO on the ankle joint, special calibrations procedures based on CAST technique (13) were adopted (see section 2.2.1). A minimum of 3 representative gait cycles for each side of each subject were collected.

Fig. 2: Design of the experiment

2.2.1 Technical procedures adopted in order to increase the accuracy in the measure of the ankle joint kinematic

Being the ankle kinematic the main goal of the orthosis treatment, a particular methodological attention was dedicated to the measure of this joint. In the attempt to describe the ankle joint kinematic in the condition with the subjects wearing the shoes and the orthoses as close as possible to the one barefoot, that is a relative rotation of the foot with respect to the shank, special calibration procedure were designed. Indeed, by reporting the joint angles relative to the same segments (in this case shank and foot) in the two condition wearing AFO and wearing OMAC is possible to effectively compare the influence and the effect of the orthoses on walking filtering the misleading effect due to the use of different pair of shoes in the two conditions.

The procedures carried out to obtain the anatomical Coordinate Systems (CSs) of the shank and of the foot in the condition with the subjects wearing the shoes were the following.

<u>*Time T0:*</u>

STATIC 1: up right acquisition with the subject wearing just the AFO (not the shoes, fig. 3):

- ${}^{t\_AFO}\overline{R}_{a\_foot} = ({}^{G}\overline{R}_{t\_AFO})' * {}^{G}\overline{R}_{a\_foot}$
- ${}^{t\_shank}\overline{R}_{a\_shank} = ({}^{G}\overline{R}_{t\_shank})' * {}^{G}\overline{R}_{a\_shank}$

where:

G: CS of the laboratory;

t_AFO: technical CS realized with 4 markers applied with double side tape on the AFO,

t_shank: technical CS realized with 4 markers applied with double side tape on the frontal aspect of the shank,

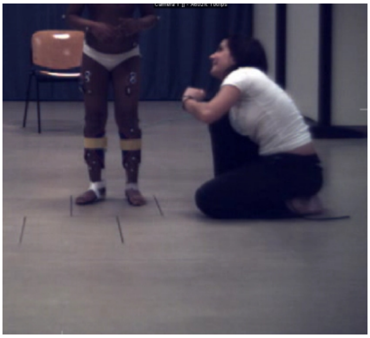

Fig. 3: AFO static 1

a_foot: foot anatomical CS formed by the landmarks I, II, V metatarsal heads and calcaneus calibrated with an instrumented pointer (13),

a_shank: shank anatomical CS formed by the landmarks head of the fibula and tibial tuberosity reconstructed with a direct application of two passive markers, and lateral and medial malleoli calibrated with an instrumented pointer (13);

R: 3 x 3 rotation matrix,

${}^{A}\overline{R}_{B}$: relative orientation of the *B* CS with respect to the *A* CS.

STATIC 2: up right acquisition with the subject wearing the AFO *and* the shoes (fig. 4):

- ${}^{t\_shoe}\overline{\overline{R}}_{a\_foot} = ({}^{G}\overline{\overline{R}}_{t\_AFO})' * {}^{G}\overline{\overline{R}}_{t\_shoe})' * {}^{t\_AFO}\overline{R}_{a\_foot}$

where:

t_shoe: technical CS realized with 4 markers applied with double side tape on the shoe.

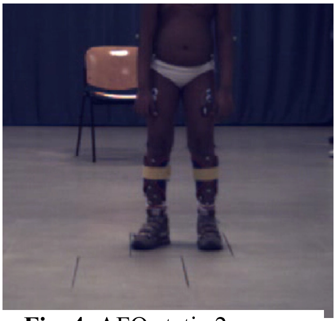

Fig. 4: AFO static 2

WALKING: ankle kinematic

- ${}^{a\_shank}R_{a\_foot} = ({}^{G}R_{t\_shank} * {}^{t\_shank}\overline{R}_{a\_shank})' * ({}^{G}R_{t\_shoe} * {}^{t\_shoe}\overline{\overline{R}}_{a\_foot})$

Under the two hypotheses:

1. ${}^{a\_shank}\overline{R}_{a\_foot} = {}^{a\_shank}\overline{\overline{R}}_{a\_foot}$
2. ${}^{t\_shoe}\overline{\overline{R}}_{a\_foot}$ = *constant during walking*

the ankle kinematic is described by the relative orientation of two anatomical CSs.

In order to use the same technical CS associated with the AFO also in T1, the following procedure was implemented:

Time T1:

$\overleftrightarrow{\textbf{STATIC 1}}$: wearing the AFO inside the OMAC shoes (figure 5):

- ${}^{t\_shoeOMAC}\overleftrightarrow{R}_{a\_foot} = (({}^{G}\overleftrightarrow{R}_{t\_AFO})' * {}^{G}\overleftrightarrow{R}_{t\_shoeOMAC})' * {}^{t\_AFO}\overline{R}_{a\_foot}$
- ${}^{t\_shank}\overleftrightarrow{R}_{a\_shank} = ({}^{G}\overleftrightarrow{R}_{t\_shank})' * {}^{G}\overleftrightarrow{R}_{a\_shank}$

where t_AFO CS is the same used in static 1 (the markers position on the AFO assumed in T0 were signed with an indelible pen)

WALKING: ankle kinematic

- ${}^{a\_shank}R_{a\_foot} = (({}^{G}R_{t\_shank} * {}^{t\_shank}\overleftrightarrow{R}_{a\_shank})' * ({}^{G}R_{t\_shoeOMAC} * {}^{t\_shoeOMAC}\overleftrightarrow{R}_{a\_foot})$

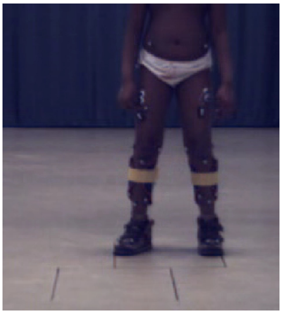

Fig. 5: OMAC static 1

Under the hypothesis:

1. ${}^{t\_AFO}\overline{R}_{a\_foot}$: is equal to the pose assumed in static 1;

the ankle kinematic is described by the relative orientation of the two anatomical CSs as well as in T0.

The procedure designed is original and never presented in the literature before. It tries to overcome the limit imposed by comparing two orthoses with two different shoes when the influence of one (as in this case) or both shoes is not of interest.

3. Results

The QUEST showed increased compliance in favor of OMAC versus AFO: +0.56, +0.66 and +0.89 for the three patients. Coherently, the daily diary showed an overall increase in the autonomy of the patients in the management of the orthosis and as well an increased daily time spent wearing OMAC with respect to the AFO.

The comparison of OMAC vs AFO during gait revealed: i) for the kinematics, a increased mean ROM at the ankle dorsi-plantarflexion of +10°, +24°, +15°, for the three patients respectively (left and right side were consistent, fig 6 and 7); ii) for the kinetic, an increased ankle power generation during push off, but just for one subject significantly (+20W; fig 8), iii) for the energy cost, any significant difference. EMG data demonstrated that OMAC allows to recover a physiological activity of the calf muscles (fig 9).

Right kinematic OMAC vs AFO

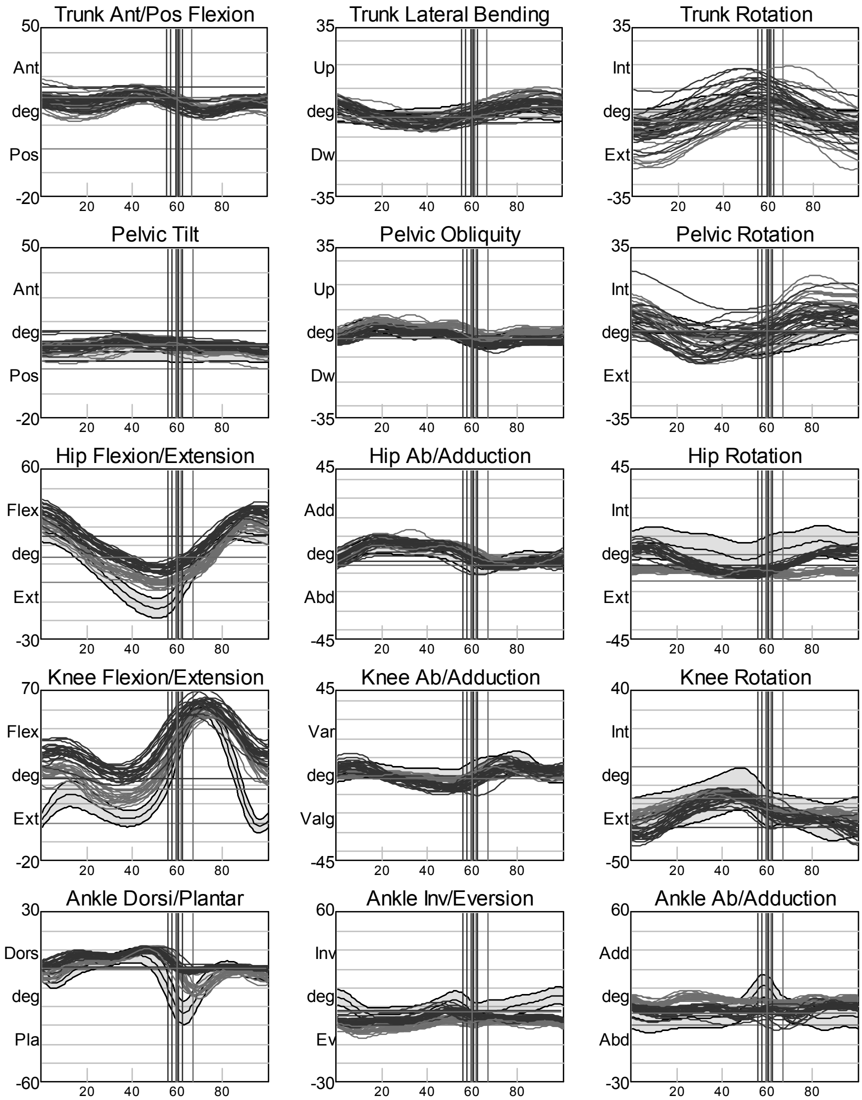

Fig 6: 14 gait cycles for the right side of subject KS, as measured in the condition wearing OMAC (bright plots) and AFO (dark plots).

Left kinematic OMAC vs AFO

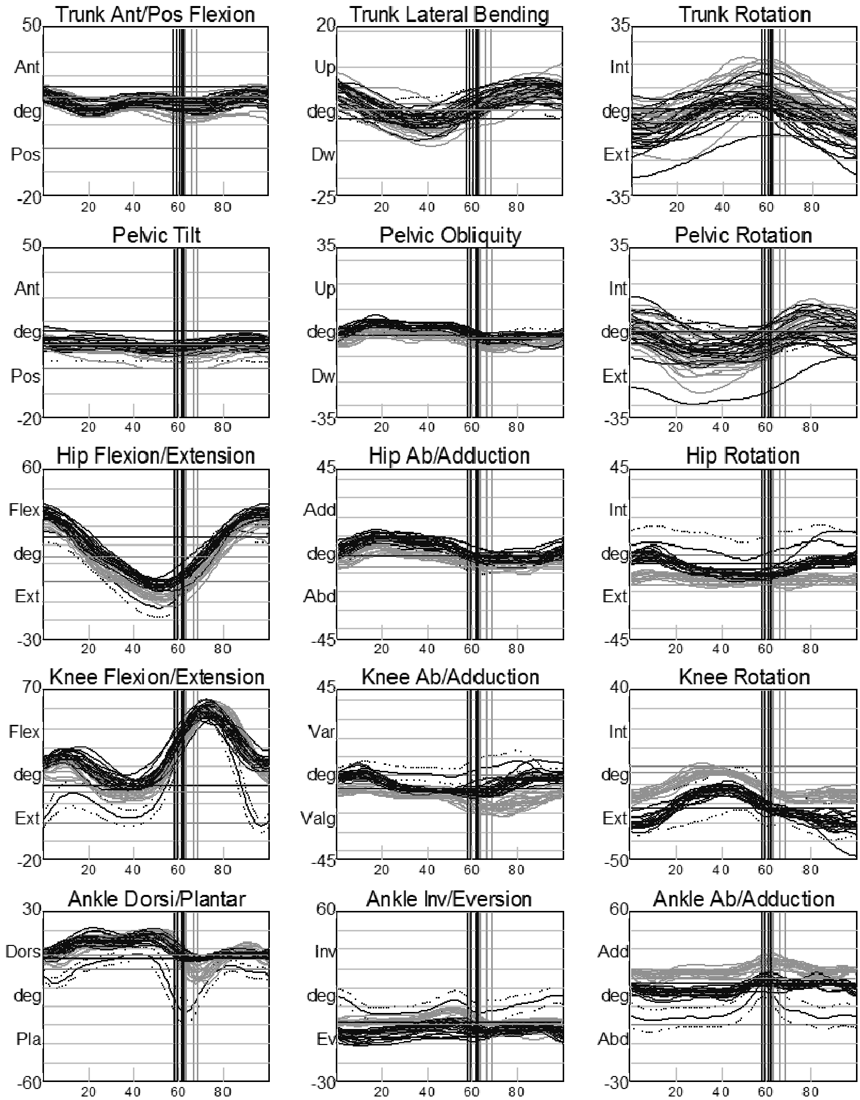

Fig 7: 14 gait cycles for the left side of subject KS, as measured in the condition wearing OMAC (bright plots) and AFO (dark plots).

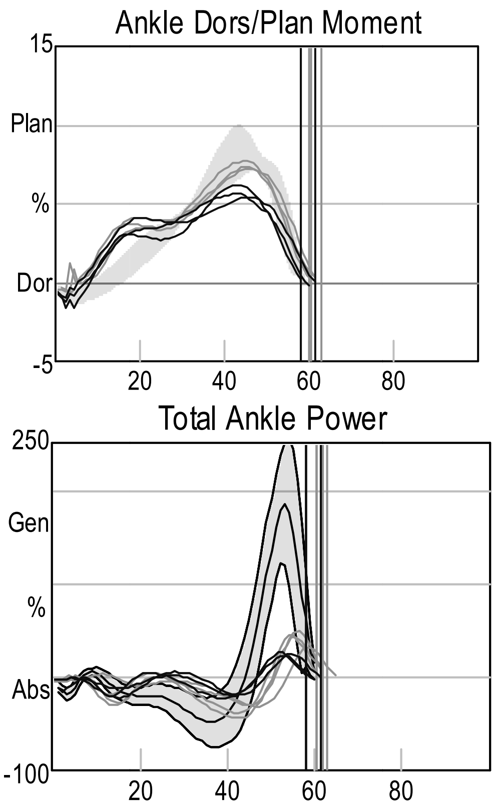

Fig 8: ankle kinetic (left side) of subject KS, as measured in the condition wearing OMAC (bright plots) and AFO (dark plots).

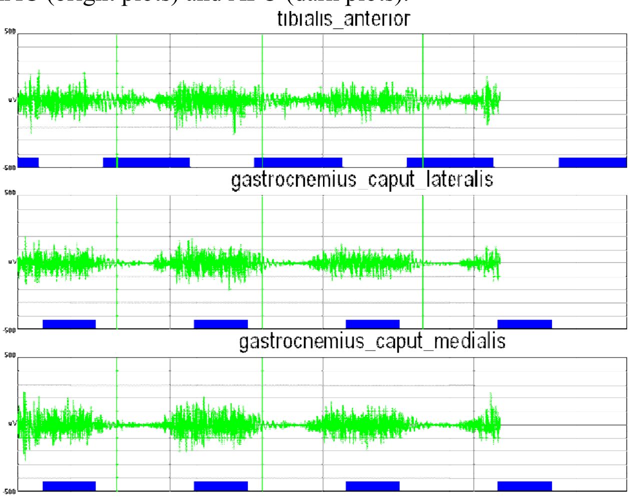

Fig 9: ankle EMG left side of subject KS, as measured in the condition wearing OMAC (bright plots). The dark rectangles indicates the physiological muscle activation along a gait cycle.

4. Discussion

OMAC is intended to be prescribed for those children, mainly diplegic with CP, presenting a flat-valgus-pronated foot. OMAC opposite to AFO hides the orthosis inside the shoe, thus it hides the motor deficit and it promotes participation in activities of the social life.

At time T2 OMAC resulted the preferred orthosis for all the children included in the study.

The comparison of OMAC versus AFO during walking revealed an improvement at the ankle dorsi-plantarflexion kinematic towards the recovery of the second rocker with a moderate increase at ankle power generation during push off. EMG data demonstrated that OMAC allows to recover a physiological activity of the calf muscles (fig 9). However the results relative to energy cost did not show significant differences among the two conditions Partially this incoherent result is to ascribe to the cover used to acquire the patients, since it did not perfectly fit all the children included in the experiment.

The preliminarily results are therefore promising but further tests are still necessary in order to fully establish the mechanical efficacy of OMAC with respect to AFO.

In conclusion, the results of this experiment demonstrate that OMAC can improve, or at least preserve, the gait performances reachable with AFO, preventing the valgus-pronation deformity of the foot but opposite to AFO, encouraging motor and social activity of CP children.

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PART V

Perceptive impairment in the diplegic children with CP

Perceptive impairment in the diplegic children with CP

Abstract

1. Definition of Perception

The motor action is designed to serve a specific purpose, according to the characteristics of the task to be carried out and the result to be achieved, but also according to sensitive and sensorial information that needs to be collected (a finger exploring temperature is not the same as that appreciates texture, or that touches an edge, or that presses a computer button, etc). The ability to make a correct movement depends on the integrity of the sensations that are needed to guide the execution of the action. Lack of attention and negligence testify to the inability to use a limb, which would potentially be able to move, due to a poor perceptive support. There could be a difficulty in peripheral collection and transfer to the information center (sensations), or there could be a problem related to their recognition and comparison (perceptions), or their subsequent processing (representations) (1).

Considering perception as a sensory interpretation, the perceptive process is useful to automatically guide the selection of movement patterns for specific activities, and plays a fundamental role in the programming of developmental patterns for specific and personalized goals.

Action Organizes Perception

Let's make an example. Consider you are looking for a particular key in your pocket, just using your finger. If you are able to distinguish a key from a coin and to further distinguish if it is a house key or a car key, it means you can produce, through a certain use of your hand, those "specialized" movements that are needed for perceptive recognition (tactile, pressure, thermal, etc) of the features of the object you are exploring (dimension, surface, profile, consistency, etc). We could state that the hand movements guide the sensory systems and that only by making adequately "selected" movements will you be able to collect, differentiate, and process that meaningful and discriminating sensitive information necessary to recognize the object. Due to the incapacity to produce the necessary specialized movements, therefore, we can easily understand why a CP child can have a sensory functions disorder, which does not necessarily directly derive from the presence of specific CNS lesions but which results from the difficulty in collecting information needed for motor control.

Perception Leads Action

Let's now make another example. Imagine you have to grab an object, after being informed that it could burn, dirty, or sting from your hand. The way you grasp it will be influenced by the nature and the degree of the sensory information you will collect as soon as you touch it, and provided that you have previously chosen the most suitable way to execute this task. We could state that your movement is guided by sensory information.

Sensations and perceptions are "active" processes whose results are widely anticipated in the organism, consciously or unconsciously. In the active perception of intelligent organisms, the distinction between sensory and motor variables tends to disappear: perceptive and motor processes are considered as mechanisms for the development of multimodal sensory patterns that are parallel, arranged, and adaptive.

Perception and movement are therefore the two sides of the same coin, which are combined by the motor control concept (2,3). However, perception cannot only be interpreted as information selection, recognition and processing, that is as perceptive attention, but also in the opposite way, as perceptive tolerance. For each type of perception it is possible in fact to identify a measure, which is specific for each individual, over which the collected information can become unbearable.

A subgroup of children with diplegia present some relevant perceptive disorders, intolerances, that are by far more important than the motor ones.

Without considering the relevance of the dysperceptive impairment, it will not be possible to explain the real difficulties of the dysperceptive children and, thus, the long-term prognosis will result misdirected and overly optimistic.

Aim of the present chapter is to explain what is considered dysperception in CP and to present the results of a functional reaching experiment aimed at disclosing the presence of the dysperceptive impairment in the diplegic children.

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Chapter 9

DYSPERCEPTIVE FORMS

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1. Introduction

In over thirty years of clinical observation of cerebral palsied (CP) children, especially among premature babies with bilateral motor damage, we have repeatedly found a group of patients with a unique combination of clinical characteristics which, we believe, could represent a specific group within the CP categorization. For convenience, we have termed them "dysperceptive" and we have been studying their behavior in a fairly large group of patients in order to see if some phenomena, unmistakably observed in single cases, were recognizable, also in different degrees, in larger groups. We have maintained the term "perceptual disturbance or dysperception" for the first and most interesting hypothesis that the errors performed by these children could happen during the collection, interpretation, and re-elaboration of information, especially of "the sense of movement", even if other fascinating theories can be found especially in the field of psychology. These complex behaviors, for example fear, can be observed during clinical examination or physiotherapeutic treatments. In addition, parents and older children often describe some specific situations, which are recurrent and typical, that take place in everyday life in different settings (at school, on holiday, with friends, etc.), often underlining the limitations produced by these phenomena regarding motor independence and quality of life. These signs can be observed in CP children with diverse motor damage (diplegia, tetraplegia, but not hemiplegia) and at different development levels. In order to explore consistency and recurrence of the more important or frequent dysperceptive signs, describe them in detail and collect evidence by suitable instruments, we have been and are still employing video recording sessions (natural history of these signs).

In chapter 5 we analyzed the three levels of sensation, perception, and representation and formulated some different hypotheses concerning the origin of dysperception that could explain some of these phenomena. Obviously we are just at the beginning of the long process necessary to test and accept or refuse a new scientific hypothesis, but we are convinced of the absolute importance of these aspects for CP interpretation and treatment and would like to draw the greater attention of the scientific community to them.

From the motor point of view, dysperceptive children belong to the category of bilateral CP and should be classified as either diplegic or tetraplegic (we have never observed these signs in true hemiplegic forms). In diplegic forms the perceptual components are milder and with a generally more favorable evolution than the analogous situation occurring in tetraplegic ones, where the expression of these components are more severe and often insurmountable. Taking into account only motor aspects, we do not consider that, in addition to the disturbance of posture and movement, some patients also have other significant disturbances which can interfere with motor performance. While classic diplegias and tetraplegias usually present with prevalent motor aspects in every stage of their evolution, in the corresponding CP dysperceptive forms the perceptive disorders are by far more important than the motor ones. Consequently, if we base our diagnostic framework only on the analysis of motor problems (classifying the child on his posture/movement patterns as tetraplegic

- mainly with vertical trunk antigravity - or diplegic), we will not be able to explain the real difficulties of the child and, thus, our long-term prognosis will be misdirected and overly optimistic. For this reason we have decided to describe these forms of cerebral palsy in a separate chapter, rather than in those devoted to tetraparesis or diplegias, because we think the key to their interpretation lies fundamentally in perception and not in movement.

Clinical features of perceptual disturbances in diplegias (semiotics)

The hypothesis of the existence of two groups of diplegic children, one with prevalent motor problems and the other with prevalent dysperceptive ones, is becoming more and more convincing. The diagnosis of diplegic forms with dominant perceptual disturbances, analogously to what happens in the corresponding forms with prevalent motor problems, is performed through the observations of some specific key clinical signs in the perceptual domain during the standard clinical examination or, in our case, more precisely, through a specific assessment protocol created in order to detect the key perceptual disturbance features. The systematic use of this assessment tool on many children with diplegia has allowed us to distinguish when and how children with "dysperceptive" forms are different from those with "motor" ones. In these two groups the studied sign was considered statistically significant if present in over 70% of the individuals. Beside direct observation of the signs, we also collect indirect descriptions through a semi-structured questionnaire administered to parents. This has further confirmed the important differences between the two groups in "spontaneous" behavior in various life settings (home, school, holidays, etc.).

Our study is mainly a qualitative type of research given that it uses assessment tools that emphasize verbal descriptions. In the future, in order to satisfy also quantitative aspects, we will need to enhance our research project by increasing the number of enrolled and instrumentally tested diplegic subjects. The final aim remains, obviously, to improve the comprehension of the problems of CP children and, separately, to test the results of therapeutic treatments for the two categories of motor disorders, with and without associated perceptual disturbances, using evidence based medicine practices.

It is well known that clinical research into developmental age is very complex and presents many limits in the application of the scientific method. This is due to both the variability among subjects with the same clinical phenotype and the spontaneous changes that occur in the same individual during the period of observation (natural development). Through the use of video recording, following standard shared protocols, it is possible to greatly reduce inter-observer variability, compare subjects, and document significant changes over time. The systematic video recording of many CP children has allowed us to create a database transforming initial descriptions of meaningful signs observed in single cases into systematically designed operative definitions, that is, a neutral, pragmatic, atheoretic description with the aim of obtaining a common language among professional workers.

According to the type of selected patients attending our leading national centers, research has been performed on diplegic children between the ages of 4 and 17. All the enrolled subjects had a well established rehabilitation history and a long term relationship with the center. All the children had already acquired the upright position and were able to walk with or without devices, and did not present any severe visual or hearing impairment or important cognitive, behavioral or attention disturbances. Furthermore they had not undergone any functional surgery or botulinum toxin injection during the previous year.

A selected group of examiners performed the assessment over a period of at least one year. In general terms, we can note that the most typical behaviors were related to different stimuli, particularly the surrounding space and type of posture and gesture being performed.

A short list of operative descriptions of the main clinical signs is as follows:

- startle reaction
- upper limbs in startle position
- averted eye gaze
- frequent eye blinking and closing
- facial grimaces
- freezing of posture
- verbal expressions

The Startle Reaction

To startle means to undergo a sudden involuntary movement of the body, caused by surprise, alarm, or acute pain (Simpson, 1989).

According to Meinck (2006), we can define startle as a "stereotypical response to a sudden and unexpected stimulus (acoustic, visual, tactile, vestibular); similar in all mammals. The response is composed of motor, autonomic, and emotional components. The motor component is an involuntary, brief and jerky movement that cannot be suppressed by will" (Koch, 1998).

A lot of information can be found in the international scientific literature on the startlereaction and this phenomenon has been specifically studied in CP subjects. Studies on the physiologic startle reaction suggested that the bulbo-pontine reticular formation could be the probable matrix of the human startle generator; this area is subjected to a sophisticated and complex modulation by upper centers (other nuclei of the brainstem, limbic system, cortical areas, etc.) (Mirte J et al. 2006).

The motor startle pattern has been quantified with surface EMG and described by video recording. The main experimental setting to study the startle reaction (SR) is the auditory startle reaction (ASR). In this setting, the SR is analyzed through the activation pattern detected by a surface EMG after a sudden auditory stimulus (orbicularis oculi muscle, sternocleidomastoid, spinal extensors, finger extensors) matched with a video recording analysis. It is necessary to carefully control the stimulus parameters (intensity, presence of a pre-stimulus, repetition rate, location) and the posture (presence of voluntary contraction), because it has been demonstrated that both the physiologic and pathologic SR are influenced by many different factors, such as attention, posture and movement.

The heterogeneity of SR causes and the complexity of its modulation suggest that a variety of mechanisms contribute to amplify the SR. This exaggerated SR can be distinguished from the physiologic one since it can be evoked by ordinary, weak, and expected (not sudden) stimuli (ineffective under normal condition) because it presents a lower threshold, greater extension pattern, resistance to habituation after repeated stimulation and reduction after pre-stimulus (Brown P, 1991, 2002; Nieuwenhujizen PH, 2000).

We can observe this exaggerated SR (according to response intensity and frequency) in many neurological pathologies: hyperekplexia literarily means to startle excessively (hyperstartling) and this term has been introduced to define a specific hereditary disorder.

The primary acquired exaggerated SR (symptomatic hyperekplexia) is a clinical sign of cerebral or brainstem disorder without specificity for etiology or lesion site. The pathological SR observable in CP can be allocated in this category. Pyramidal lesions can explain the phenomenon from a neuroanatomical point of view. In fact in CP corticospinal motor pathways can exert inhibitory effects on the ASR (Mirte J et al. 2006).

An interesting review on startle syndromes has been made recently by Mirte, who states that the SR is a bilaterally synchronous shock-like set of movements. The most prominent features are forceful closure of the eyes, raising bent arms over the head, and flexion of the neck, trunk, elbows, hips and knees (Mirte J et al. 2006).

We have compared this literature data with our own video recordings in order to achieve an operative definition of the SR sign.

Startle Reaction: Operative Definition

What can we observe?

Startle reaction is a sudden and involuntary movement, executed almost immediately (milliseconds) after an efficacious stimulus, with an "opening" motor pattern which can be seen in the upper limbs (in their maximum range of motion flexed at the shoulder, usually with the elbow flexed at 90°, a flexed wrist and abducted-extended fingers); sometimes in association with head extension, anguised facial expression (grimace), wide-open or shut eyes, open mouth, and forced inspiration position of the chest. SR is an involuntary behavior that strongly limits the acquisition of motor abilities since it produces important perturbations of posture and gesture which can not always be modulated or blocked by the child.

The SR sign can be observed in different contexts and postures and following different kinds of stimuli. It is not truly a reflex but a reaction, that is, a complex behavior modifiable by the child. In some occasions, for example, SR can be inhibited by hand grasping. This aspect can be interpreted as a strategy used by the child to overcome the imbalance produced by the SR itself. Is grasping therefore a coping behavior? When this strategy is inadequate to inhibit SR, it is impossible for the child to use grasping to support himself with devices or to drive a powered wheelchair. In this sense, grasping can be considered a coping solution.

In the sitting position, lower limb movements, given their response variability, are less significant in recognizing the SR pattern than upper ones. In the most evident expression, lower limbs are semiabducted, with extended knees and equinus-varus-supination of the feet. If the child is seated and tightly holding onto the armrests with a forward leaning trunk, there is often a triple flexion (ankle, knee, foot) response of the lower limbs with increased flexor pattern and loss of foot ground contact.

In older children, SR can still be partially expressed: we can recognize the residual SR pattern at hand level. It consists of sudden movements of fingers that abduct and extend rapidly, with a subsequent hand opening, occurring immediately after the stimulus. Normally it is a bilateral and symmetric sign, but if the child is grasping something with only one hand, we can see the SR pattern on the opposite upper side. The SR can threaten balance and compromise postural control (both sitting and standing) and gesture (walking, manipulating, etc.).

When?

Many different stimuli can produce the SR; here is a short simple list:

- auditory stimuli (normal intensity – low threshold - familiar or unknown)
- vestibular stimuli (sudden shift of the center of gravity, postural perturbations produced by the subject himself or by others)
- visual stimuli (object or person moving quickly forward or away from the child)
- tactile stimuli (loss of physical contact with objects and persons)

Among the different sounds, dysperceptive children can show SR with very common noises such as the telephone, door bell, vacuum cleaner, or pets, especially barking. The essential condition in order to produce SR is the fact that the stimulus must be sudden and unexpected rather than loud.

Not only child-independent stimuli can produce SR, but also stimuli directly produced by the child himself and theoretically foreseen (i.e., the child lets an object fall voluntary, but the noise or the sight of falling provokes SR) or linked with a wrong anticipation of the consequences of an event (i.e., the child touches an object and believes it is going to fall, so he will have a SR even if the object actually does not fall).

Sometimes we observe SR even in a child simply lying supine on a mat. In this situation the child’s behavior is surprising, because it is impossible to fall and consequently feel unsafe or threatened, given the great postural stability.

The SR and the upper limbs in SR position during walking can be observed almost in every diplegic child with perceptual disturbances; analyzing a group of 41 diplegic subjects walking with hands free from any kind of grasping (without devices or adult hand) these two signs distinguished the two groups of diplegic children with and without perceptual disturbances.

Our studies confirm the variability of this sign in clinical observations, but we have been able to find SR even when its characteristics are less evident. In order to recognize this sign we must pay particular attention to time. In fact it occurs an instant after the efficacious provocative stimuli. Finally, the SR description is a gestalt pattern and not a kinesthetic one; the single element can be involved in the SR in slightly different ways and with variable characteristics (i.e., the wrist is usually flexed but can be seen also in neutral or extended position).

Upper Limbs in Startle Reaction Position: Operative Definition

What can we observe?

This sign consists of a typical static position (posture) of the upper limbs in which it is possible to easily recognize the influence of the dynamic SR pattern (gesture).

In sitting position, the child maintains his upper limbs in slight abduction, with flexed and abducted shoulders, opened hands, and flexed or aligned wrists. The upper limbs are usually kept in this "opened" position also during activities like manipulation, in which greater adduction towards the trunk is normally required. The difficulty in keeping the upper limbs lowered and alongside the trunk, together with flexion or hyperflexion of the wrists with generally abducted and extended fingers, is the main distinguishing element of the presence of SR. In addition, sometimes we can observe also a slight arm adduction, with abducted and pronated forearms and partially extended elbows. In this case, arm adduction improves manipulation ability. Upper limbs in SR position can be observed also during walking, especially in the initial learning phases, and during postural changes, mainly moving towards the standing position. In the latter, the sign is observable in particular when the awareness of exposure to the surrounding space is greater. In some cases it is even possible to detect the sign in this supine position.

Averted Eye Gaze: Operative Definition

What can we observe?

Gaze is intentionally oriented away from the target of the ongoing function (the object of grasping, the direction of walk, etc.) towards other unrelated or insignificant targets.

When?

This sign can be seen during both the manipulation-praxis function and walking. This could underline a common standard strategy utilized for different situations and functions.

For example, the diplegic child can use this strategy during upper limb reaching movement toward a target: the child looks at the object to localize it before starting the gesture, then, during the reaching phase, looks elsewhere, thus eliminating visual control of the current action. Another typical situation in which we can observe the use of this strategy is climbing down stairs. At each step, the eyes are deliberately turned laterally or towards a target which has nothing to do with the current movement, the general action, or control of the surrounding environment.

Frequent Eye Blinking and Closing

What can we observe?

Eye blinking observable in diplegic children with perceptual disturbances differs from that of healthy subjects, being characterized by a prolonged and intense eye closure or by an increased blinking frequency.

When?

This sign can be observed in relation to many of the stimuli that can produce the startle reaction; however it is a separate sign because it can be seen also without the SR motor pattern. The eye blinking can occur after sudden stimuli, as in healthy subjects, but in CP children the phenomenon can take place also after well known, self produced, foreseen, or weak stimuli. Furthermore, we can sometime observe this sign without any visual or acoustic stimulus, as a consequence of an expectation of what is about to happen. For example if a child is playing with a toy that has a cause-effect system, he could start blinking repeatedly before activating the device, i.e., pushing the start button.

Facial Grimaces: Operative Definition

What can we observe?

Facial grimaces of a child usually express anguish or fear. It is a reaction that involves mimic muscles, eyes (wide open or tightly closed), and mouth.

When?

Similar to what happens in the startle reaction, facial grimaces can be produced by loud or unexpected sounds or by visual stimuli of fast traveling objects moving towards or away from the child. Facial grimaces can be caused if the distance of the child from the ground increases (i.e., sitting on a high stool rather than a chair), or during motion generated either by the child or by others, or if the surrounding space becomes increasingly emptier. Facial grimaces in CP are a pathological expression of severe anguish relative to harmless stimuli.

Freezing: Operative Definition

What can we observe?

The child freezes one or more body joints to avoid or reduce movement. This produces an interruption of ongoing motor activity and anxious glances at everything that is happening in the surrounding space. In this situation, the child frequently verbally expresses uneasiness and implores the caregiver to come nearer. The child shows great difficulty or refusal to incline the trunk in sitting position (shifting the center of gravity) and lifting the upper limb such as for the task of leaning over and reaching a distant object). During tests, this behavior becomes very evident during reaching activities executed in a sitting position or during a task of visually following a ball thrown quickly toward the child, in both the sitting or standing position. The trunk and the head are petrified or blocked in rigid and fixed positions that inhibit the child from using his motor repertoire at all. In extreme cases, we can interpret the choice of immobility as an extreme need for steadiness.

When?

We observe this sign when the enclosure of surrounding space disappears. This is due to loss of contact or to the presence or closeness of reference objects and people. During activities that require leaning, freezing is usually directly proportional to depth perception of the surrounding space and/or height of the support base which the child is sitting on.

Verbal Expressions: Operative Definition

What can we observe?

Use of language to express uneasiness in particular situations or tenacious refusal to perform required tasks by the CP child. The most common verbal expressions are: I am falling, help me, hold me, catch me, I can't do it, etc.

When?

These expressions are typical in older children. The conditions and stimuli in which the phenomenon can be observed are more or less the same as those that determine the previous signs.

HOW TO DETECT CLINICAL SIGNS OF PERCEPTUAL DISORDERS

The clinicians that work with diplegic children must carefully investigate signs (startle reaction …) and symptoms (fear, anxiety ...) due to dysperception. Observation (without prejudice) should be sufficient in order to detect their presence/absence. The following assessment tries to attribute a meaning to these signs, determining if they are defects or compensation strategies.

In cerebral palsy, none of these signs, per se, is pathognomonic for perceptual disturbances, and some of them might even be recognized in normal subjects, but with significantly qualitative differences. In fact it is unusual to observe a startle reaction in healthy subjects, perhaps occasionally after a very intense and sudden noise (i.e., when two trains on parallel tracks pass each other). But we all agree that the same reaction for a recognizable ordinary noise (i.e., a pencil that falls on the floor) is not so physiologically acceptable. So it is necessary to establish standardized and reproducible conditions for clinical observation (setting, stimuli, posture, functional activity) in order to explore and analyze the main dysperceptive signs. Since this evaluation deals with child fear, it must be carried out in a game-like fashion and should be stress free. In addition, the stimuli and the setting must reproduce ordinary daily life conditions as much as possible. In this way we are obviously very far from the scientific approach of neurophysiologic studies of startle reaction. Artificial settings can in fact unacceptably alter child behavior (collaboration, interest, prejudice).

We have developed a series of clinical tests suitable in observing dysperceptual signs.

These clinical tests have some limits but also great advantages: they are easy to reproduce in any physiotherapeutic settings (secondary health centers) and do not require complex instruments. They are very simple to perform, easy to reproduce, and not at all stressful for the child and the family. The objectivity of the observation is guaranteed by videotaping performances of examined children. The overall duration of the tests is about one hour. The reliability and validation procedures of the protocols are currently under development. In addition to direct assessment of signs through clinical tests, it is important also to investigate the presence of perceptive disorders of spontaneous behavior in different daily life settings (school, home, on holiday, with friends ...). An interview with 37 multiple choice questions, subdivided into 11 paragraphs, was created in order to help simplify the work of the investigators. This interview explores child behavior in different conditions and periods (diaper changes, sleeping habits, child initiatives, etc.) regarding external stimuli, moving around, walking, going up and down stairs, interaction with adults, and tolerance to being alone. Particular attention is directed to behavior in water, fear of falling, and psychological elaboration of real falls.

The results of the interview indicate that diplegic children with perceptive disorders do not tolerate sudden noises like doorbells, telephones, fireworks, loud motorcycles, trains, and barking dogs. Often these children experience so much anxiety that their condition borders on a real noise phobia. In some cases advanced warning of the potentially disturbing event can reduce the intolerance and help the child prepare for the incoming stimulus.

It is useless to say that child and parent behavior is extremely correlated, so that the living environment and experiences of these children can usually be swept free of disturbing stimuli.

Fear of falling and experiences of real falling events are not related. In reality these children do not fall more often than other diplegic ones, but they can become very upset at only the thought of falling, especially backwards. Also instability of support surfaces are poorly tolerable. When the chair on which the child is sitting is struck by someone or moved by himself, the subject manifests one or more signs of perceptual disorders. At this point we can obviously understand the consequences of ground unevenness during outside walking, or the refusal to ride a seesaw. We can easily document this intolerance by inducing small lateral or anterior-posterior movements on the wheelchair: the child with perceptive disorders usually responds to the kinesthetic stimulus with a startle reaction and other typical signs. Supine position might be particularly annoying, especially on a raised surface like an examination table. In this case the child needs to hold on to the edges with both hands and, if this is not sufficient, in order to control discomfort, parents have to embrace and assure him that it is impossible to fall. The prone position may be very disturbing, too. Some patients find it intolerable, even as adults. In order to sleep, children with very grave perceptive disorders need contact with adults or have a very large bed placed against a wall. In the first case, one of the parents, generally the father, eventually has to leave the matrimonial bed when the child becomes bigger. Instead, it is incredible to witness the great motor initiative and the reduction of discomfort when the same child is placed in water.

When we observe these signs or behaviors in a diplegic child, or when they emerge from interviews with parents, we have to suspect the presence of perceptive disorders.

We want to point out that some walking characteristics are typical of children with perceptive disorders and are part of the characteristic semiotics. Here are some examples: trunk antepulsion is a postural strategy to avoid any possible backward fall, both in free standing (far from any wall) or in walking; speed and freezing are contrasting coping solutions in order to face the conflict between movement and empty space during locomotion.

The above mentioned signs we have described, taken individually, are a necessary but not sufficient condition for the diagnosis of perceptive disorders. We should reach a diagnostic system, like DSM IV, through the presence of a main guiding sign (i.e., startle reaction) and one or more minor signs (blinking, freezing, etc.) A single SR can not justify the diagnosis of perceptive disorder, but if it is observed several times in different situations, such as supine position, walking, sitting, etc., and other signs or characteristic behaviors (from interview) are also present, we can identify this particular group of diplegic children with greater probability.

The recognition of perceptive disorders is a fundamental element in order to make a correct prognosis and the right rehabilitative choices. It has been seen that perceptive disorders have a negative influence on functional autonomy. Comparing our two groups of diplegic children one with and the other without perceptive disorders, there are no significant differences regarding the time of the acquisition of assisted walk. Subjects without perceptive disorders however are able to quickly acquire autonomous walking (with or without devices) whereas children with perceptive disorders remain dependent on caregiver assistance for much longer periods (physical contact, verbal reassurance etc.) (Ferrari A et al. 2008a). The application of GMFCS clearly bears out this difference also in regard to gross motor abilities, that is, perceptive disorders negatively influence functional motor autonomy (Palisano et al. 1997).

SOME HYPOTHESES ON THE NATURE OF PERCEPTUAL DISORDERS

Up to now a direct connection between structure and function has not been established and CNS MRI has never revealed any significant difference in lesions, especially PVL, in diplegic children with or without perceptual disorders.

The clinical characteristics of cerebral palsy are continuously changing. This is probably due to the higher rate of cerebral injuries deriving from a greater prematurity rate and a progressive lowering of pregnancy length.

An evident progressive reduction of support reaction efficacy in diplegic and tetraplegic children is a very important and frequent clinical behavior. This problem is often associated with perceptual disorders. A possible hypothesis suggests that these children, due to their notable postural instability, have a consequently greater fear of falling.

According to Alain Berthoz (1997), we consider the “sense of movement”, i.e., the perception of body position and motion, a determinant factor in motor control. An alteration of this sense might clarify some particular behaviors observable in dysperceptive CP children.

It is possible that errors in multiple sensory integration can be present among CP disorders. Sensations, originally segregated on the basis of their physical properties, could lead to ambiguous interpretations of reality. In the effort to achieve more coherence, the subject may learn how to suppress incoherent information. An example of this can be averted eye gaze” while walking down a set of stairs as a compensatory strategy of a probable visuokinesthetic conflict (Berthoz et al. 1999).

The existence of visuo-perceptive disorders in diplegic children is well documented, but neuropsychological tests do not allow us to study the more complicated integration problems regarding movement (visuo-kinesthetic collimation).

Concerning the difficulty in multisensory integration, we can identify other perceptive processes that, when affected, seem to worsen the functional ability of these children: for example, the ability to use more appropriate frame references for a specifically requested action, or the possibility to access opportune representations of motor action organization, especially in terms of postural anticipatory adjustments.

For perception, the brain uses several reference systems relative to the task at hand and to the sensory indexes available at the moment and most suitable for the sought out result. Body scheme represents the sum of these reference systems (Berthoz, 1997).

Actions are coded in relation to different reference systems that correspond to different spaces concerning body or environment (ego-allo-geo-centric). The choice of the reference system depends on the type of action, and during the same action there may be a shift from one reference frame to another. Clinical observations of CP dysperceptive subjects suggest a possible difficulty in this process. This hypothesis could explain the difficulty these children have in starting to walk, letting go of stable supports, and the relative facilitation allowed by the close physical presence of a caregiver (behind, next to, in front of the child), or by visual references such as a wall corner or a piece of furniture on which to fix gaze. The caregiver, parent, or therapist seems to function like an external reference that the child relies on for simple tasks like standing in the middle of the room.

The activation of the subjective vertical also seems to be affected in different situations, in particular when the subject is exposed to empty space. This aspect could be interpreted as an error of multisensory integration. In fact subjective vertical is the final synthesis of different types of vertical coming from the various sensorial systems (visual, vestibular, proprioceptive, tactile, etc.). If a caregiver walks slowly away from a standing diplegic child with perceptive disorders, that child will usually start to gradually slant in the same direction.

A recent research area concerning perceptive impairment explores anticipatory postural adjustment (APA) in diplegic children in the sitting position during a reaching task. In an experimental set-up, some parameters of the stimulus are modified (stool height, object reaching distance, reaching direction). The behavior of the child is evaluated through the observation of videotapes (qualitative analysis) and by the displacement of the center of pressure (COP) as detected by a force plate placed under the stool (quantitative analysis). Preliminary results seem to confirm the clinical observation of the freezing strategy of posture and give us interesting information about APAs. These are practically absent in the majority of subjects with perceptual disorders, whereas they are constantly present in the control group of diplegic children without dysperceptive disorders.

APAs are based on preventive representations of actions we are about to do. When APAs are lacking, postural control is carried out only through feedback mechanisms during movement. We can image the subject with perceptual problems as being surprised by the loss of balance as a consequence of his own movements (Adkin et al. 2002; Ferrari et al. 2008b).

In chapter 5, the functioning of the process of perceptual transcription of motor programs was analyzed. According to that theory, we may also justify many other phenomena observable in dysperceptive children. If there is an error in perceptual transcription (corollary discharge), simple actions, feasible from a motor point of view, may be mentally inhibited because they are considered potentially dangerous: the CNS in this case rejects the consensus to act. The lack of action consensus may even be linked to an anticipatory simulation of a threatening perception that could appear during the action. Examples of this phenomena are frequent eye blinking and startle reactions before the occurrence of the triggering factor, therefore anticipating the justified reaction to the relatively disturbing stimulus. With regard to this aspect, neurophysiological research has recently demonstrated the existence of bimodal neurons with a tactile and three-dimensional visual perceptive field, whose depth corresponds approximately to the arm length (peripersonal space). This space codification is needed in order to execute actions in the peripersonal area. According to this hypothesis, if we think that in normal subjects there is a codification of space in motor terms (Fogassi, 2005), it is probable that subjects with central motor disturbances can have difficulties in analyzing and coding their own movements, the space surrounding them, and the reciprocal relations between movement and space.

Memory of previous movement perceptions (located in hippocampus, prefrontal and parietal cortex) is an essential guide for future actions (Berthoz, 1997).

Why does action inhibition continue in children with perceptive disorders even after they have directly experienced the same situation or activity many times, verifying that it is not effectively dangerous? Can these phenomena be interpreted as a result of a cognitive disorder characterized by difficulties in experience elaboration and learning process?

Fear and negative experiences in these children concerning movement, open space, and depth and height from the ground might be interpreted also psychiatrically, and we could place these phenomena among the various manifestations of anxiety. A harmful event produces anxiety and may generate a lifetime negative experience, so it is difficult to understand if anxiety and panic are the "primum movens" or the consequences created by a series of negative incidents.

This interpretation does not conflict with other hypotheses, because experiencing intolerant sensations leads to a continuous negative reinforcement regarding action and movement.

General psychopathology recognizes some perceptual disorders and could explain some types of illusion and hallucination that some children seem to experience. Also for this reason, it is easy to foresee that much work has yet to be done in order to better understand the nature of perceptual disorders in CP children.

CLINICAL ASPECTS OF PERCEPTUAL DISORDERS

Many years ago two characteristic CP dysperceptive forms were identified: the falling child and the stand-up child (Ferrari, 2000). In the following pages, we will review this original subdivision, which can still be considered helpful in clinical evaluation in severe cases of CP.

1. The Falling Child

The falling child cannot perceptually tolerate the depth of the surrounding space and does not react properly to the force of gravity. The child frequently experiences the feeling of losing posture control, being dragged down by his own body weight; he feels and believes to be endlessly falling, even if he is aware of lying flat on the floor. As if in a nightmare, he lives the sensation of his body breaking up and spreading out. The child seems to believe the whole world is slipping though his fingers; as a consequence, the child tries desperately to grab onto any real or imaginable object.

The falling sensation, felt also in supine position, is not the result of previous catastrophic experiences, but a distorted perception, between illusion and hallucination, associated with an understandable state of anxiety.

The falling child cannot tolerate externally induced postural changes and often even self-induced ones; he manifests distress and fear through repeated startle reactions and quite often expresses this sensation with the words "I'm falling! I'm falling!". Movement is better tolerated in confined spaces (i.e., in a wrap-around stroller or in an electronic wheelchair with belts) or in tight physical contact with the caregiver's body (holding).

This conflict with space usually disappears in water, where the child can better express his motorpotential, maybe because water acts as an enclosed, defensive, protective, and supportive element (water is an old acquaintance, since it greatly reduces the sensation of emptiness and heaviness). The falling child has trouble in defining the borders of his own body, in keeping the intrapersonal (autonomic) world separate from the extrapersonal (contextual) one, in distinguishing the space which can be perceived from that in which motor activities can be performed. The perceivable space, in fact, is wider than the performing one. The surrounding space is experienced and internalized (memorized) in a distorted way, as if the individual were not able to keep his body well contained inside his skin. The skin of the falling child is an insufficient container and he looks for substitutes, inside and outside himself, such as muscle tone, the caregiver's body, or a "pleasant ecological nest", appropriately built in the surrounding environment:

- Internally (inside) → spasticity ("muscle" skin, defensive shield): it allows better posture and emotional stability, but it turns out to be so rapidly exhaustive that the child quickly tires. This spasticity is similar to the features of hypertonia that derives from the pathological support reaction, but it over-reacts to antispastic drugs and is difficult to "calibrate" with functional orthopedic surgery. It can be diminished by application of orthosis, usually AFO and KAFO, or supporting devices such as wrap-around padded seats and thoraco-lumbo-sacral corsets.
- In body contact → clothes: these children never like to be completely undressed. In fact their naked body induces a feeling of anguish and despair. Simple motor performances, such as turning over, possible if the child is covered with only a thin sheet, become impossible if the child feels too exposed to the surrounding space and vulnerable to the perception of emptiness.
- Externally (outside) → an adult body, particularly that of the mother, becomes an instrument for physical and psychological holding (containment) for the falling child.

"The tactile, visual, acoustic sensations etc., evoked by environmental inputs, must be transformed and "mentalized", so that they can be "contained", "tolerated" and not become devastating. In the endouterine life, the environment itself functions as a "container", while in extrauterine one there are no "physical" enclosures and the child has to face environmental inputs no longer mediated by the uterus. The activity of the mind must be that of containing inputs and subsequently to "mentalize" them. This is possible in children without severe neurological deficiencies only if this containment is guided by the maternal "rèverie" (Bion, 1962) which acts as a "filter", as a mediator, between environmental inputs (therefore also physical sensations) and the mind of the child" (Ferrari Ar, 1992).

Commonly, these children have sufficient cognitive abilities but, as they grow older, they face great difficulties in being separated from the mother. With the adult, especially the mother, they have a binding relationship of fusion/confusion, in a situation that can be defined as more parasitic than symbiotic. In the arms of the caregiver, the falling child becomes more courageous and interested in acting and interacting with the surrounding environment. This situation very often ends up making the patient poorer, because it eventually forces the child to live through the body and the mind of the caregiver in an illusion of ability that prevents the individual from objectively becoming aware of his own limits. However, we must ask ourselves which psychomotor progress this child could autonomously achieve, if movement generates feelings of uneasiness, vertigo, fear of falling: if it allows him to overcome the boundary separating excitement from anguish, or if it leads to depression and ultimately to giving up.

The need for holding is often psychologically expressed:

- as uneasiness when the child goes to sleep (falling asleep is perceived as a change of state: from a controlled to an uncontrolled one)
- as difficulty to be separated from the mother's body (perceived as change in place)
- as uneasiness and unwillingness to remain alone, even for a short time
- as difficulty to be outside the hearing or visual range of caregivers.

Marzani (2005) calls this separation anxiety and assumes that the missing function may be phantasmal, because this disorder decreases with the simple physical presence of a family member or their voice which is used as a support to movement.

The falling child would like to be a mind without a body, able to direct a body without a mind of a consenting adult (usually the mother).

Drug treatment for the disperceptive disorders of the falling child includes antidepressants (tradozone) and anxiolytics (benzodiazepine, such as nitrazepam and clonazepam) that are anyway not always effective.

The falling child usually has a fairly good intellectual capacity and employs an adult language, sometimes overly elaborated, that is used to verbally express even experiences that the child has never been able to perform, preferring to imagine rather than to experiment, but showing knowledge of the mechanisms and processes underlying the actions. Usually, such children do not present with severe visual or oculomotor problems and can adequately coordinate eye and head movements. However, the child prolongs the optic defense (blinking reflex) for a longer period and employs gaze to map out his position within the surrounding space, aiming at nearby "targets", constantly substituting them each time he moves. Sometimes the child can face problems in orientating walking trajectory, that is to correctly direct the walking frame or the powered wheelchair, especially when helpful visual references are lacking. The child usually fails to achieve advanced manipulation skills but can be quite self-reliant for table sitting activities, such as using cutlery or computer keyboards. Under resting conditions, the upper limbs are usually kept adducted to the trunk with flexed elbows and wrists, semi-flexed metacarpus phalanx, and semi-extended interphalanx (hands in "drooping" position).

The generalized stiffness (muscle-like skin) exhibited in difficult situations or in conditions of uneasiness is usually proportional to the severity of the dysperceptive disorder still present.

Defensive spasticity in the falling child must be differentiated from the antigravity spasticity related to the organization of the support reaction. Tone changes generated in relation to an insufficient sensorial calibration (perception) are reduced whenever the patient learns to suppress them and is more organized from an emotional viewpoint, irrespective of the course of the antigravity behavior. Conversely, a pharmacological or surgical reduction of spasticity imposed on the child before solving the perception problem would only make the difficulties worse and force the child to give up or even refuse standing position and locomotion instead of improving them.

The motion prognosis of the falling child is not always the same. In many patients, the disperceptive disorder slowly fades away, allowing for the separation from adults during the second or third phase of childhood, so that the child can be left alone even to sleep before the beginning of adolescence. In this case, motor disorders progressively improve and patients can eventually move around with a walking frame or, in some rare cases, with four point canes. For other patients, independently of the therapeutic choices they have followed, there are no improvements in perceptive disorders, while better control of the state of anguish and development of the separation-individuation process can be achieved. The only attainable form of motion independence for such patients is obtained by the use of powered wheelchairs, which should also be applied early.

Functional orthopedic surgery should be proposed as late as possible due both to the risk of severe psychological regressions (return of fear of being undressed, touched, moved or left alone, etc.) and the possible occurrence of a secondary muscle failure and a definitive abatement of the support reaction in standing position (reappearance of astasia and abasia). Orthopedic surgery in fact upsets the whole control strategy previously developed through an enormous effort by the patient (i.e., the use of spasticity as perceptive defence).

2. The Stand-Up Child

The mechanism this child applies in order to limit the negative consequences of perceptive disorders is the suppression of sensations related to kinesthesis, bathyesthesis, and baresthesis (sense of movement, sense of position and sense of pressure), that is, all the information that initially is poorly tolerated by the child. It is as if the child continuously repeats to himself: "You' re not falling and nothing' s happening to you", etc. By doing so, the child neglects to carry out the required posture corrections in order to orient, align and balance himself and in the end inevitably loses control of his position.

Some authors consider this phenomenon as a sign of "hypotonia" or "hypoposture" (Bobath and Bobath, 1975; Giannoni and Zerbino, 2000), misinterpreting the inability to perform posture corrections (motor aspects) as the inability to autonomously realize the need to urgently perform them (perception aspects). Marzani (2005) attributes this to a dysfunction of the body schema or sometimes to a problem of internal stability of the "physical self". Instead, for other children it could represent a primitive attention disorder which may explain why they are able to perform "voluntarily" (however usually "upon request") those posture corrections that otherwise they are not able to perform "spontaneously" or "automatically".

Perception elimination is a complex mental process which requires a certain degree of mental "maturity" by the individual. It usually emerges during the second part of childhood. Before then, the stand-up child presents many similarities with the perceptive and motor behavior of the falling child, even though, at the beginning, the clinical conditions overall appear less severe.

From the motion point of view, the stand-up child can produce an effective anti-gravity reaction, but is unable to do so automatically and stably because he suppresses the analysis of information required for this purpose. From the posture point of view, the child seems as if he is falling asleep in a chair, lowering his head while closing his eyes, then suddenly bolting up, as if "awakened" by the perception of the performed movement.

By not paying attention to self-perception, the stand-up child constantly needs additional external signals or advice and verbal support to control posture. The child realizes what is happening only when informed by other organs, mostly by sight, or more often by the caregiver who repeats sentences like "Stand-up, sit straight, don't slouch!".

Due to the inability to simultaneously perform different mental activities, the difficulty of posture control is increased if the child's attention is shifted to another task, for example, speaking, reading, or other cognitive activities.

Speech ability in this group of CP children is not particularly impaired, but it tends to become less understandable when the patient, due to the reduction of the support reaction, lowers the head and leans the trunk forward.

From the "motor" point of view, the stand-up child can appear diplegic, or in some rare cases even tetraplegic (with vertical trunk antigravity), able to reach and hold a standing position only with support and move around exclusively with a walker, tiring very quickly. When asked to stop, the child needs a considerably long time, taking additional steps in order to adjust the position upon hearing this request.

In the support reaction, the child tends to over-react at the beginning of the activity only to underperform after just a few minutes. The emotional state or motivation may prolong or strengthen the standing and walking ability, but it is difficult to quantify a real psychological determination for these activities.

On the ground, these babies can move by creeping like a seal (upper limbs pulling the trunk and lower limbs forward, the latter are held in flexion-adduction-intrarotation).

The risk of hip deformity is high due to flexion-adduction contractures, which sometimes are severe and accentuated by very intense emotional reactions.

Usually antispastic drugs generate over-reactions. Functional orthopedic surgery, even if well performed, often leads to an over-release of operated muscles. The application of AFO orthosis is justified even in sitting position, because it contributes to improve posture control. Posture systems instead have demonstrated not to be very successful because the trunk tends to lean forward and for this reason the belt system is often over-loaded and therefore uncomfortable.

The presence of perceptual disorders can be detected very early. In the first months of life there is already a reduced capacity by the infant to deal with and process perceptual information (indicated by startle reactions, frequent blinking and postural freezing). These are a consequence of emotional stress, have a low-threshold and maintain a constant response to sudden acoustic, tactile or proprioceptive stimulations. Afterwards, dysperceptive infants show a strong and persistent dependence on perceptual indexes for posture control (e.g., a constant need for visual cues, close support and external reference, a persistent lack of automated control, etc.). Preliminary results of a prospective study, indicate that sense of motion disorders can be clinically detected in a follow-up study. The videotapes taken at 2 and 12 months of age in a group of 29 children, who went on to develop spastic tetraplegia or diplegia, as well a corresponding set of tapes of pre-term infants with normal outcome were scored for perceptual disorders by observers blind to the final outcome. The presence and severity of perceptual disorders were highlighted by a reduced capacity of the infant to deal with and process perceptual information. As reported in Table 14.1, children who already presented severe perceptual disorders between 2 and 6 months post-term, maintained a similar degree of severity afterwards. Postural and motor milestones such as sitting position, walking with support devices, and independent walking, were achieved much later when compared to controls, or even never. These were the same dysperceptive children who developed more severe motor disorders at subsequent stages of development, as indicated by the GMFCS score (Palisano et al. 1997). Such perceptual disorders were never observed in controls.

Table 14.1: Correlations between early signs of "sense of motion" disorders (at 2-12 months) and the severity of motor impairment, measured at greater than 4 years by GMFCS, Gross Motor Function Classification System (Palisano et al. 1997); TP, tetraplegia; DP, diplegia, (defined according to Hagberg et al. 1975) (modified from Paolicelli and Bianchini, 2002).

Case n.	CP type	Perceptual disorders	GMFCS	Sitting position (months)	Walking with support devices (months)	Autonomous walking (months)
1	DP	-	1	16	30	36
2	DP	-	1	8	12	28
3	DP	-	1	8	12	18
4	DP	-	1	16	20	30
5	DP	-	1	9	20	30
6	DP	-	1	11	15	19
7	DP	+	1	9	21	22
8	DP	+	1	9	20	25
9	DP	+	1	10	15	18
10	DP	+	1	18	22	32
11	TP	++	5	/	/	/
12	TP	++	5	/	/	/
13	TP	++	3	36	54	/
14	DP	++	2	18	42	66
15	DP	++	3	13	84	/
16	DP	++	3	16	84	156
17	DP	++	2	/	48	96
18	TP	++	3	21	80	/
19	TP	++	5	/	/	/
20	DP	+++	2	18	30	72
21	TP	+++	5	/	/	/
22	TP	+++	5	/	/	/
23	DP	+++	3	19	/	/
24	TP	+++	4	84	/	/
25	TP	+++	5	/	/	/
26	TP	+++	4	72	/	/
27	TP	+++	4	/	/	/
28	TP	+++	4	48	/	/
29	TP	+++	3	48	108	/

These results seem to indicate that these types perceptual disorders can be detected early and are predictive of a later motor outcome.

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Chapter 10

FUNCTIONAL REACHING DISCLOSES PERCEPTIVE IMPAIRMENT IN DIPLEGIC CHILDREN WITH CEREBRAL PALSY

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Acronyms

Angle Error	AE
Anticipatory Postural Adjustment	APA
APA Magnitude	M
Diplegic CP children affected by PI	*dysp*
Diplegic CP children unaffected by PI	non*dysp*
Maximum Distance	MD
Percentage of APA onset	%APA
Percentage of touched target	%Touched
Perceptive Impairment	PI
Reaching Direction	RD
Reaching Time	RT
Typically Developing	TD

Abstract

The currently accepted definition classifies Cerebral Palsy (CP) as a mere posture and movement disorder. Conversely, some authors have recently associated the presence of several motor dysfunctions exhibited by diplegic children with CP, to an impairment in the perceptive system. The aim of the present study was to investigate the influence of the Perceptive Impairment (PI) on motor control and to assess if the PI can be detected by a reaching task.

A functional reach and touch experiment was accomplished from a sitting position considering different directions and distances. Typically developing and diplegic children with CP were enrolled and, the latter, a priori divided in two subgroups considering a positive or negative diagnosis of PI. The reaching trials were quantified by means of centre of pressure analysis in terms of the overall quality of the task, and accuracy and effectiveness of postural adjustments and Anticipatory Postural Adjustments (APAs).

The three groups showed statistically significant differences in terms of percentage of touched target, and of time spent and maximum distance covered to reach the target. In particular, PI caused a major difficulty in accomplishing the reaching tasks, thus a lower autonomy level for the action. Overall, the PI strongly affected the anticipatory control system. Children with PI, rarely recruited APAs, each of which was characterized by small amplitude and inaccuracy in direction. The lack of effective APAs indicated how PI strongly influenced the motor control strategy.

The present study demonstrates that PI is a primary syndrome responsible for long-term prognosis as well as motor and postural disorders in CP.

1. Introduction

The currently accepted definition classifies Cerebral Palsy (CP) as a mere posture and movement disorder [9], disregarding the influence of perceptive as well as cognitive, communicative and emotional problems [10],[11]. Conversely, some authors have stressed the role played by the perception disorders while assessing the quality (nature) and the quantity (measure) of the functional impairment exhibited by CP children [10],[11]. As asserted by some authors [10],[12-15], Perceptive Impairment (PI) in CP is the failure of a complex neurological process that enables the individual to take in, integrate, interpret and use the spatial-temporal aspects of sensory information from one's body and the environment, in order to plan, control, guide and produce organized motor behavior. In other words, PI is a cognitive-perceptual-motor dysfunction that entails with the inability to adapt and to integrate environmental experiences [15]. Some studies highlighted the presence of perceptive dysfunctions in children with CP [15],[16], however in the literature the following issues remain unclear: i) which disabilities arise from disorders in the locomotor apparatus, and which ones from disorders in the perceptive system, ii) if PI affects uniformly the hemiplegic, diplegic and tetraplegic cluster or whether ailment differences are present among and within each cluster, and iii) which is the mainly responsible deficit for the long term prognosis between the motor impairment and the PI. Only very recently some authors have begun to face these issues. Ferrari et al. [10] assessed that the PI is very frequent in tetraplegia, present in some forms of diplegia [17], and almost absent in hemiplegia. In particular, these authors proposed a categorization of the different forms of diplegia based on kinematic criteria [17], in which children were classified as "*dysperceptive*" and "*nondysperceptive*" based on a positive or negative diagnosis of PI [10]. The PI diagnosis is carried out through the detection of seven clinical signs each assessed on the basis of an operative definition [10] in the course of specific environmental stimuli. The signs are: i) exaggerated and low threshold startle reaction, ii) upper limb in startle position, iii) averted eye gaze, iv) frequent eye blinking and closing, v) facial grimaces, vi) freezing of posture, and vii) verbal expressions.

There is a strong evidence from the literature that movement and perception are tightly linked as the two side of the same coin [13]. The theory of sensory integration [14] states that perception is not merely the acquisition of sensory information, but an active process aimed at guiding the execution of a correct movement, i.e. coherent with the motor programme planned before the action. This process is carried out through the integration of sensory information properly representing the state of one's body and of the environment. Visual, somatosensory and vestibular systems are the primary redundant sources of sensory information, whose integration within the Central Nervous System (CNS) must result effective and consistent in order to obtain correct execution of movements. In case of disagreement among the perceptive inputs, the CNS may lead to execute incorrect movements with abrupt adaptations [12] thus also preventing to provide sound information for the construction of *perceptive representations* of the actions [13]. Hence, a "secondary" incapacity to effectively guide the subsequent movement on the basis of accurate perceptive representations. At a prognostic level, therefore, an impairment in the perceptive system may significantly affect the patient's development of independent life skills [18],[12]. At a kinematic level, in addition, the PI may cause an overall fear of moving, provoking years of delay in achieving independent walking, and the onset of strongly unnatural walking schemes, as described by Ferrari et al. [17] with the upper limbs raised in a lateral position, up to the shoulder, swinging in the frontal plane.

Besides walking, the reaching task is one of the most studied tests to assess the motor and perceptive disorders in CP children [19-21]. In particular, reaching from a sitting posture, is used to investigate the postural control ability and it strongly deals with the development of independent life skills [22]. Postural control during reaching has been often assessed by looking at both i) overall movements by means of the analysis of the Centre Of Pressure (COP), as measured with a force platform [23],[16], and ii) specialized control strategy by means of electromyography (EMG) [24],[16].

Motor control during voluntary movements, such as reaching, is carried out through the performance of Postural Adjustments (PAs). Complex PAs are exhibited by Typically Developing (TD) children since the age of 4 months [19]. For TD, experience and learning from selves' activities play a key role in fine-tuning modulation of muscle contraction during postural adjustments [19] resulting in a variable recruitment of the direction-specific muscles [21]. Conversely to TD, diplegic CP children i) use proximal to distal muscle recruitment strategy [21],[25],[26], ii) show a reduced capacity in fine-tuning their PAs to task specific conditions [27],[28], iii) usually perform jerky movements [29], and iv) present stereotyped and direction-inappropriate muscular activities [30],[27] more pronounced in diplegic rather than hemiplegic children [22].

The trajectory of the end-effector during reaching exhibited by TD children is straight and characterized by smooth, bell-shaped velocity profiles [31], suggesting that reaching is mostly feedforward controlled [32]. Anticipatory PA (APA), that is the feedforward parallel command aimed at minimizing the equilibrium disturbance occurring in correspondence of a voluntary movement, is one of the main clues of the adoption of this feedforward control strategy [33]. It appears as an opposite movement with respect to the target direction, and it is mainly tuned by the perceptive representations of the PA that is about to come [12],[13]. Riach and Hayes [34] and Johnston et al. [35] detected APAs in TD children during arm movement in standing. Conversely, other authors found that the development of APAs during a natural reaching task is absent throughout pre-adolescent age (2-11 years) [36]. Overall, the postural control of CP children seems less guided by feedforward processes based on prior experience and more by feedback mechanisms [21].

To the authors' knowledge, no study approached the topic of motor control in CP children during reaching *a priori* considering the presence of perceptive as well as postural-movement disorders, thus trying to interpret the performances considering independently these two complementary sources of disability. Furthermore, no relation between the presence/absence of APAs in CP children and the diagnosis of a PI has been investigated so far.

Two groups of diplegic children, one with and one without a diagnosis of PI as assessed through the criteria provided by Ferrari et al. [10], and a control group of TD children were enrolled for a functional reaching task experiment from sitting position. The aim of the study was to assess if the *dysperceptive* children present poorer perceptive organization abilities and lower autonomy in actions than aged-matched TD and *nondysperceptive* children. In particular, by means of COP analysis we addressed if the PI causes differences in the motor control strategies and in the quality of the motor performance. The reaching trials were quantified in terms of the overall quality of the task and accuracy and effectiveness of PAs and APAs.

2. MATERIALS AND METHODS

2.1 Participants

Twenty-four diplegic children with purely spastic forms of CP and nine asymptomatic typically developing (TD) children (4 male, age range 7–10 years) participated in the study. Eligibility criteria included: a documented CT or MRI diagnosis of CP, ability to sit independently on a stool, acquired walking with or without walking aids, no major sensory or cognitive deficits, absence of visual field deficits, ability to sustain visual fixation for at least 3s and no functional surgery or botulinum toxin injection during the previous year.

During routine clinical evaluation sessions, the diagnosis of PI was assessed by the same operator according to the standardized criteria described in [10]. Hence, out of the 24 diplegic CP children, 12 were positive to PI (*dysperceptive* group - *dysp*; 7 male, age range 6–14 years), and 12 were negative (*nondysperceptive* group - non*dysp*; 10 male, age range 5-11 years). All the *dysp* children exhibited the seven clinical signs associated to the diagnosis of the PI (see section 1). TD, non*dysp* and *dysp* groups resulted both age matched, as tested by one-way ANOVA ($p>0.05$), and anthropometrically matched, as tested by one-way ANOVA ($p>0.05$) on the dominant arm length (distances from the acromion up to the tip of the middle finger).

None of the participants had prior knowledge of the purpose of the study. An informed consent was obtained before participation.

2.2 Experimental protocol

The experimental setting (Figure 1) consisted of a functional reach and touch task from a sitting position. The participants were seated on a height adjustable stool without any back, foot, and arms support, while a force platform (Bertec 4060A, sampling rate 100Hz), placed under the stool, registered the COP trajectories during the trials. The reaching target was an appealing small ball containing an accelerometer synchronized with the force platform. The ball was dangling from an adjustable arm

(Figure 1), the fulcrum of which was positioned above the greater trochanter of the dominant side of the subject (spatial correspondence set with a laser-pointer). A climbing-rope was tight to a non-hampering body-harness to protect the subjects from falling.

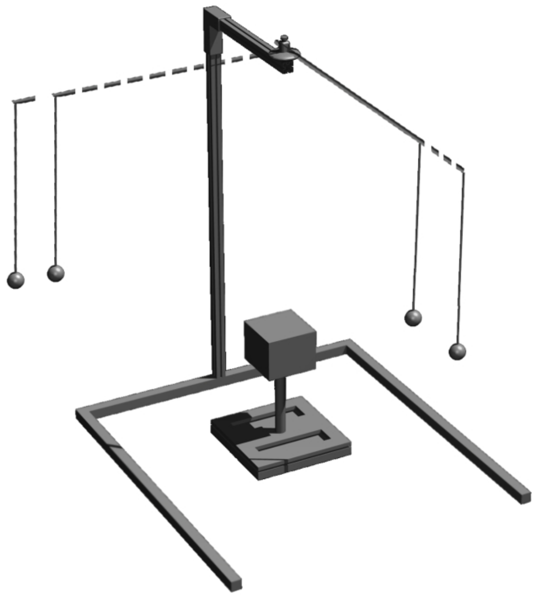

Fig 1: Set-up of the functional reaching experiment. The reaching target (ball) and the arm adjustable in direction and length are shown in the four configurations resulting from the combination of dir and dist.

The subjects were asked to sit still, gazing at a fixed spot at their eyes height, 4m apart in front of the stool, and to restore the same initial position of head, trunk and hands among the trials. A whistle, ringing 3s after the beginning of the recording, triggered the subject to reach and touch the ball with the dominant hand at a natural self-paced speed. The acquisition ended when the subject reached the object (detected with the accelerometer) or when he/she performed the maximum affordable displacement. Six repetitions were accomplished for each of the trials resulting from the combination of 2 directions (*dir*) and 2 distances (*dist*). In particular, *dir* was set to *frontal* (movement occurring in the sagittal plane) or *lateral* (movement occurring in the frontal plane) with respect to the dominant hand, being the latter more difficult because of the reduced base of support. The target *dist* was set to 120% and 140% of the arm length. The shorter distance was chosen as an easy reaching, the farther to evaluate the perceived functional limit of stability. The stool height *h* was set to 100cm for each child.

2.3 Data reduction

The raw COP trajectory was low-pass filtered at 25Hz with a zero-phase, 2nd-order Butterworth digital filter. Each trial, and its relevant COP trajectory, was divided (offline) in three different intervals: i) the *waiting interval* during the first 3s of quiet sitting (W_{int}), ii) the *APA interval* (APA_{int}) if present, and iii) the *reaching interval* (R_{int}), from the end of the APA to the end of the task in case of APA detection, or from the whistle to the end of the task in case of no APA detection. The COP trajectory was then re-centred to its midpoint during W_{int}, while its direction of maximum variance during R_{int} was interpreted as the Reaching Direction (RD) performed by the subject.

The reaching performances were quantified by means of six different parameters. The overall functional abilities were assessed through 1) the percentage of touched target (%Touched), 2) the Reaching Time (RT), 3) the Maximum Displacement (MD) of the COP during R_{int} (computed only for the trials with *dist*=140% being the trials with *dist*=120% not representative of the functional limits of stability), and 4) the percentage of APA onsets (%APA). This latter was automatically identified as the shifting of the COP opposite to the RD during the initial phase of the gesture (2 standard deviations higher than the baseline value during W_{int}). In case APAs were detected, the following parameters were computed to quantitatively describe their features: 5) the Angle Error (AE), being the angle between the RD and the APA direction (computed as the maximum variance direction during APA_{int}), and 6) the APA Magnitude (M), being the maximum COP displacement reached during APA_{int} from the midpoint (see Figure 2).

2.4 Statistical analyses

In order to filter the effects of lacks of attention, habituation and fatigue, only the most representative trial among the six repetitions was considered for the statistical analysis. This was detected in a space of four dimensions created from the parameters RT, MD, M and AE each normalized with respect its own standard deviation (computed considering the whole amount of trials performed by the subjects). In this space, the closest point to the midpoint of the six repetitions was considered as the most representative trial. In case RT, M and AE were not a number due to the failure of the task and to the absence of APA, the trial corresponding to the median value of MD among the six was considered as the most representative.

A logarithmic transformation of RT, MD, M and AE was performed in order to normally distribute these parameters. The normality was then ascertained with a Kolmogorov–Smirnov test. The effects of direction, distance and diagnosis were tested with 3-way ANOVAs on the logarithmically transformed parameters. The post-hoc Bonferroni correction was then used for multiple comparison. Non-parametric Kruskal-Wallis tests were carried out to detect differences among the TD, *dysp* and non*dysp* groups of the non-normally-distributed parameters (%Touched, %APA). All statistical analyses were performed with NCSS (NCSS, Kaysville USA).

3. Results

Figure 2a reports a typical pattern of the COP trajectory in the platform reference frame. Figure 2b, 2c and 2d reports three typical COP trajectories along the RD relative to the performances with frontal *dir*, *dist*=140% as collected from a TD, a non*dysp* and a *dysp* child, respectively.

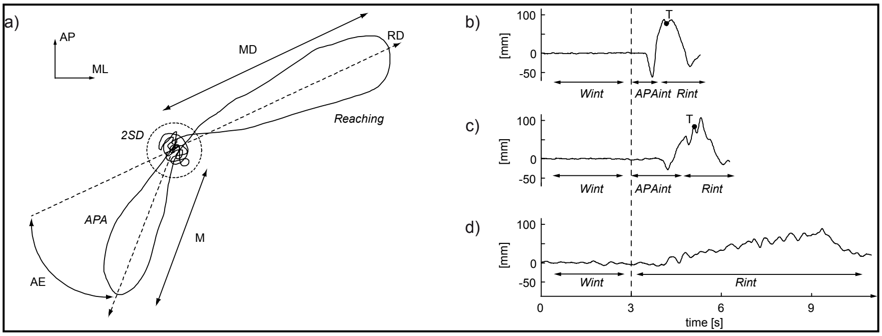

Fig 2: (**a**) A typical pattern of the COP trajectory in the force platform reference frame. Three typical COP trajectories after a projection along the RD relative to the performances with dir=90, dist=140%, as collected from a TD (**b**), a nondysp (**c**) and a dysp (**d**) child respectively, are also reported. The trials are divided in W_{int}, APA_{int} when present, and R_{int}. 'T' indicates the instant of the target touch.

Figure 3 reports the %Touched resulted among the three groups considering all the trials performed. *Dysp* children resulted functionally more compromised: the Kruskal-Wallis test highlighted that %Touched was lower in all the trials with respect to both non*dysp* and TD. Moreover, the trial factors (*dir, dist*) influenced %Touched: if no statistically significant difference among the groups was found in the easiest trial (*dist*=120%, frontal *dir*), difference became significant increasing the difficulty of the task. In the worst case (*dist*=140%, lateral *dir*) the %Touched revealed significant differences between non*dysp* and TD and between *dysp* and TD. Moreover, when *dysp* reached the target, they were slower than the other groups: no differences were revealed for RT for the cases with *dist*=120% (mean RT=2.39s), while significant differences were obtained with *dist*=140% ($p<0.01$, mean RT equal to 2.53s, 3.02s, 4,68s for TD, non*dysp*, *dysp*, respectively).

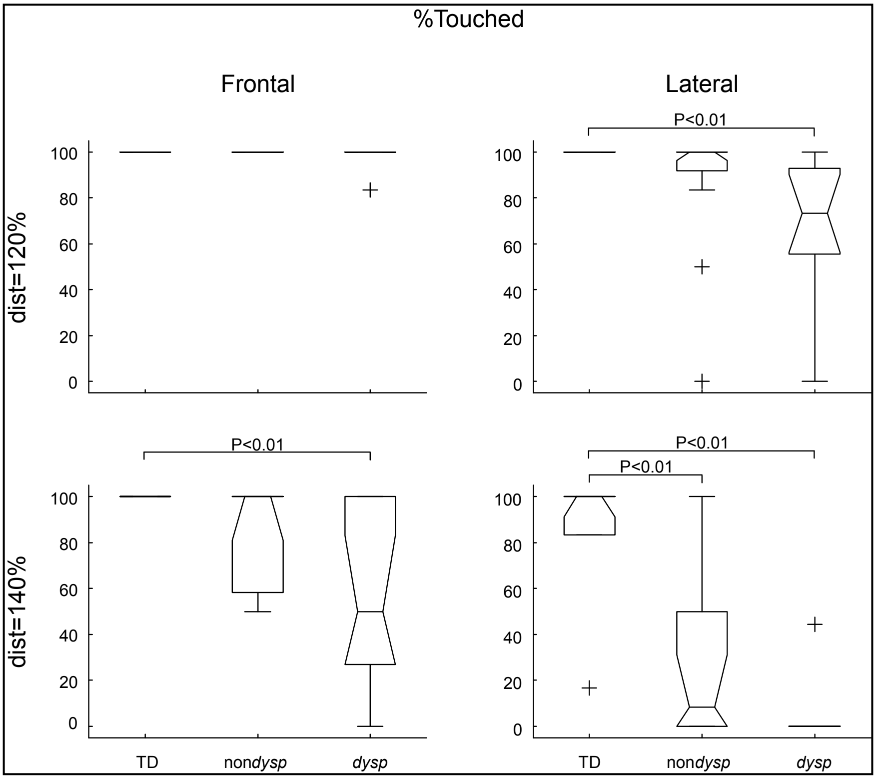

Fig 3: Distributions of the %Touched of the most representative trials for each of the TD, nondysp and dysp groups. All the combination of dir and dist are shown.

Functional limits of stability quantified by MD during the tasks at *dist*=140% showed an increasing discrepancy between the groups stepping from the frontal to the lateral direction (see Figure 4). In this last case, significant differences were obtained between *dysp* and TD and also between non*dysp* and *dysp*.

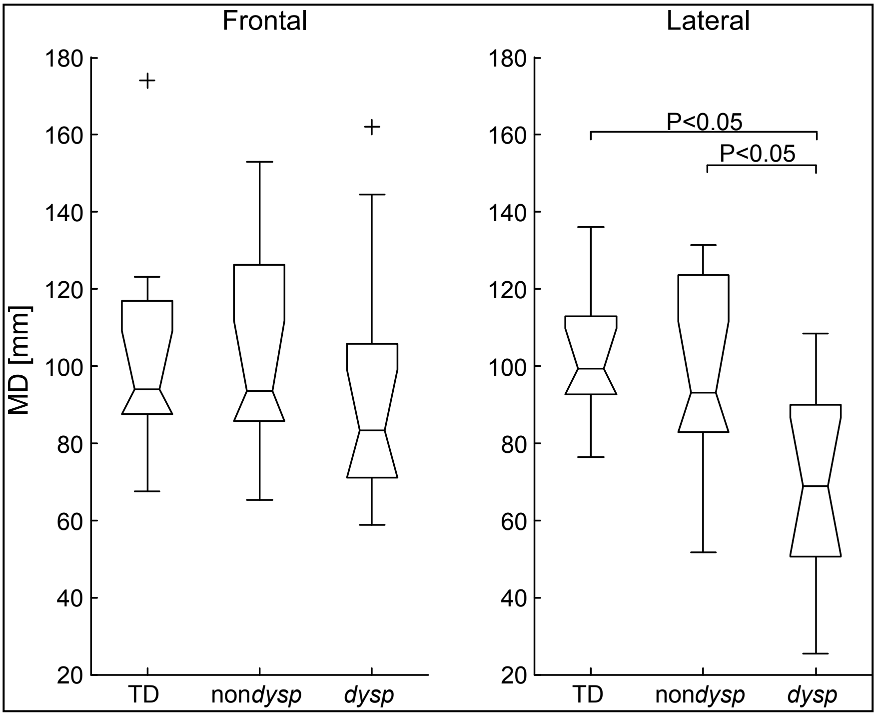

Fig 4: Distributions of the MD of the most representative trials for each of the TD, nondysp and dysp groups when dist=140% and divided with respect to dir.

Figure 5 reports %APA, AE and M distributions. Considering both lateral and frontal *dir*, for *dysp* the APA was detected in fewer cases (41%) as compared to non*dysp* (81%) and TD (87%). These differences were statistically significant as assessed through the Kruskal-Wallis test (Figure 5a). Statistically significant differences were observed for the parameters quantified on the detected APA. Figure 5b and 5c report the results for AE and M with *dist*=120%, since *dist* had no significant effect. With respect AE and M, the diagnosis had an effect statistically significant ($p<0.05$ and $p<0.01$ respectively). With respect AE, a statistically significant effect of *dir* was found just for *dysp* ($p<0.01$, Figure 5b).

Considering both *dir*, a statistically significant difference was obtained between TD and *dysp* on AE ($p<0.01$), and between *dysp* and non*dysp* on M ($p<0.01$). Considering lateral *dir*, a statistically significant difference between *dysp* and TD was observed on AE (Figure 5b). Finally, with frontal *dir*, a statistically significant difference was obtained between *dysp* and non*dysp* on M (Figure 5c).

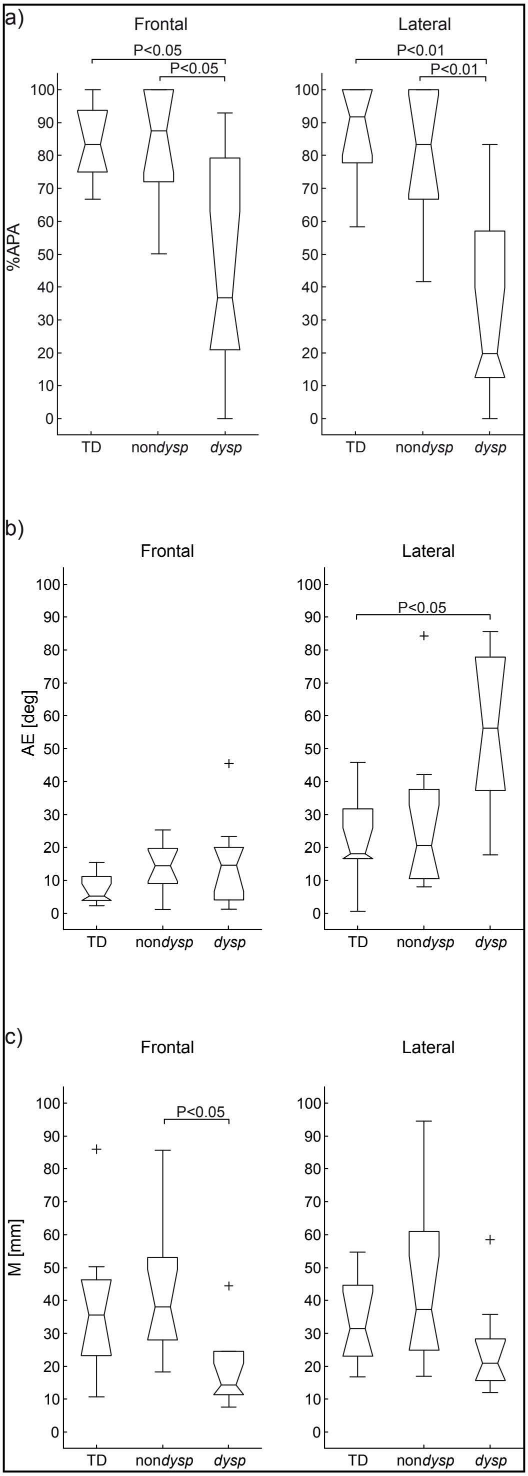

Figure 5: Distributions of the %APA divided with respect to dir of the most representative trials for each of the TD, nondysp and dysp groups (**a**). On the detected APA, the distributions of the AE (**b**) and M (**c**) with dist=120% are also reported.

4. Discussion

Functional disabilities in daily living activities exhibited by some forms of CP children cannot be thoroughly explained on the basis of a pure motor dysfunction but should also be ascribed to an impaired perceptive system [15],[21],[20]. The PI is considered as a syndrome that entails the failure of a complex multisensory process involving the integration and use of the spatial-temporal aspects of the sensory information to plan and guide organized motor behavior. PI was previously detected in CP children, especially in the diplegia cluster [15].

A functional reaching experiment aimed at appraising the influence of PI on motor control was accomplished. TD and diplegic CP children were enrolled and, the latter, a priori divided into the subgroups *dysperceptive* and *nondysperceptive* on the basis of the presence of the PI as clinically diagnosable through the operative definition provided by Ferrari et al. [10]. To investigate performances especially focusing on global postural control strategy, COP parameters were preferred to EMG, allowing better test–retest reliability [23].

By looking at the functional abilities, the three groups showed significant differences in terms of %Touch, RT and MD, with a trend that increased with task difficulty. In particular, during the increase of the difficulty, the *dysp* revealed a significantly slower and less effective reaching performance also with respect to the non*dysp* group, demonstrating a poorer functional autonomy. With lateral *dir*, they also showed a significant drop of MD. This result is coherent with the observations carried out by Ferrari et al. [10], that showed how the *dysp* cluster presents freezing posture with reduced stability limits in correspondence of a perception of depth.

The TD children showed APAs basically in every trial (Figure 5). These results sustain the findings of [34],[35] but are in contrast with [35]. The PI negatively influenced the anticipatory control system: the anticipatory strategies of the *dysp* resulted frequently ineffective. As compared to non*dysp* and TD, they rarely recruited APAs, each of which was characterized by low magnitude and inaccuracy in direction. The lack of effective APAs testify that *dysp* less often rely on feedforward programming of reaching than non*dysp* and TD, thus indicating how PI strongly influenced the motor control strategy. Hence, PI caused a major difficulty in accomplishing reaching tasks, that is related to a lower autonomy level in action.

To the authors' opinion these findings sustain the hypothesis that PI might have played a "confounding effect" role in all the previous researches that explored the reaching performances in diplegic children without assuming possible perceptive skill differences within the cluster.

In conclusion, the results of the present study demonstrate that the PI might be considered as a primary syndrome responsible for the long-term prognosis and that its diagnosis is relevant both in clinic and in research.

PI in diplegic CP children seems related to a lack of 'perceptual approval' to motion directly related to a major difficulty in solving the sensory-motor integration problem. Further research aimed at quantitatively characterizing the influence of the PI on the daily life functions should be addressed. In particular, the role of canes and/or orthoses for the *dysp* group might be further studied in order to appraise if these aids, besides a motor support, sustain a ‘perceptive facilitation’ that ease the sensory-motor integration problem increasing the reliability of some sensory inputs [10].

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CONCLUSIONS

The aim of this thesis was to translate technical innovations into the diagnosis and the rehabilitation of motor and perceptive impairments in children with Cerebral Palsy (CP). In order to achieve this target, new instruments, protocols, devices and tests were proposed and set up to be specifically applied to CP children. Among the numerous methodological and technical issues faced and solved, the most important being:

1. assessment of the state of the art about the inter-protocol variability in gait analysis,
2. design of a new protocol, named Outwalk, able to perform gait analysis by means of an inertial and magnetic measurement system,
3. validation of Outwalk with respect to the state of the art on a population of healthy subjects and study of its accuracy on a population of CP children,
4. proposal of a new equation able to effectively measure the similarity of joint angle waveforms acquired synchronously through different protocols when the effect of the protocol is the only relevant aspect,
5. proposal of a new model of orthosis, named OMAC, aimed at replacing the use of AFO in those children affected by the presence of a flat-valgus-pronated foot,
6. study of the efficacy of OMAC in a population of diplegic CP children,
7. definition of the *Perceptive Impairment* on diplegic CP children and proposal of a reaching task as disclosure test.

CP is a complex disorder that can be faced and solved neither through an unique standpoint, nor through considering just the motor impairment. Conversely, CP should be considered as the result of the interaction between the different residual motor, sensorial, perceptive, or cognitive abilities and their adaptive transformation based on evolution, that is to say a “continuously evolving disability of an individual who is continuously evolving”.

The lack of a single treatment able to solve all the deficits affecting CP children, constrain the operators to use multiple methods and techniques in order to effectively assess and detect the different disorders caused by the palsy. Only by adopting approaches aimed at separately considering the motor and perceptive impairments, is it possible to provide an accurate prognosis. In particular, the role of the perceptive impairment is as relevant as the motor one, therefore a proper rehabilitation program could not do without disclosing its presence through appropriate evaluation tests.

All children with CP deserve careful monitoring for motor as well as perceptive, intentional and cognitive problems. Dissemination knowledge and promoting discussion about classification and definition of the CP disorders, can enhance the treatment level provided by the rehabilitation services. With the aim of guiding and supporting this process, the tools and instruments designed to help in the diagnosis and disclosure of defects and deficits must be non-invasive, cost effective, portable, and not requiring a specifically dedicated environment. For this reason, in this thesis the prevalence was assigned to the design of a gait analysis protocol which is simple to apply to children, based on wearable and wireless technology, not requiring specialized personnel or specifically dedicated environment. In particular, the proposed protocol, named Outwalk, is based on the Xsens system, a cost effective inertial and magnetic sensor system. This system allows for the execution of gait analysis in laboratory-free settings, the collection of great numbers of consecutive gait cycles during spontaneous walking, and the automatic and the real time creation of clinical reports without requiring any further elaboration time. Therefore promoting:

1. a diffusion of the objective assessment of the motor impairments in CP,
2. the possibility to use gait analysis as a didactic tool in order to teach and discuss how to recognize pathological patterns,
3. the involvement of families and children in monitoring the physical condition (family centered therapy).

In the near future, it is easy to imagine that systems such as Xsens will substitute the use of the goniometer in the majority of the assessments usually performed during a clinical evaluation of a CP child. Indeed, a sensors set up as the one proposed with Outwalk is suitable to perform several clinical assessments in succession without any additional effort by the operators. Once the sensors are applied on the subject's body, they do not only have the potential to acquire gait analysis, but also to execute, on a bed or a mat, several clinical measurements such as the degree of spasticity or joint range of motion. The use of an Xsens system with dedicated graphical user interfaces, as already provided for Outwalk, will guide the operator through the execution of the tests avoiding the use of the goniometer, obtaining greater precision and accuracy, and recording each test result in simple and well-organized digital databases. In addition, the ability to execute gait analysis with fast and automatic procedures allows for the possibility to perform multiple analysis under different conditions, such as different models of orthoses or shoes, and to monitor at regular intervals the state of treatments, such as surgery or drugs. The comparison of multiple reports, or the direct creation of specific reports showing overlapped joint angle waveforms acquired at different times, will provide, with extreme efficacy, an evaluation of a treatment outcome such as surgery, thus demonstrating its value and the duration of its effect. Furthermore, each result could then be loaded into digital medical records, thus giving to health care personnel the possibility of having updated information anywhere and anytime.

Every progress in the CP treatment should be based on the contemporary involvement of operators coming from different fields, such as physiatrists, bioengineers, orthopedic technicians, physical therapists, movement scientists, etc. This means that, from the start, educational levels, languages, know-how and definitions must be common and universal. In this way, a tool such as Outwalk applied to the Xsens system could become a platform on which it is possible to learn how to detect signs and abilities, defects and compensations, basing these assessments on objective and reliable data obtained through reports able to show and explore gait analysis and motor patterns in an effective, easy-to-read and complete manner.

Much is still left to do though, from the point of view of the application and validation of the protocols and development with new and cost effective instrumentation. In the author's opinion, successful applications of motion analysis are those in which the quantitative measure helps clinicians better understand a pathology or assist them when forming an opinion on the therapeutic treatment to provide to a patient. This latter appears, all in all, the definitive goal, because it means the measurements it provides are reliable, validated and, therefore, widely accepted. This thesis is therefore just a small step toward the application of systems based on new generation technology in gait analysis for children with CP. However the steps accomplished so far, more than justify a further effort in attempting to promote a greater widespread use of inertial sensor technology in clinics.

It is well accepted that treatment programs for children with CP, should not only involve the rehabilitative services but should also include the families. For this reason it is important to look for cost effective, esthetically tolerable and overall comfortable therapeutic solutions for CP children. In the challenge of meeting these requirements, the orthosis proposed here in order to solve one of the most frequent pathologic pattern that originates from the presence of a flat-valgus-pronated foot, was designed with the aim to be handled directly by the child and to be esthetically tolerable. The result is an orthosis, named OMAC, that has demonstrated the ability to increase patient autonomy level and, contextually, the motivation in performing motor activity, thus promoting social integration.