Evaluation of Gyroscope as a Sensor in Functional Electrical Stimulation for Children with Cerebral Palsy

by

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Abstract

Cerebral Palsy (CP) refers to a motor disorder, which affects 2 to 4 per 1000 live births. A common outcome is an imbalance in the muscles that control the ankle resulting in increased effort for walking, risks of falls and possibilities for permanent contractures and deformations.

Electrical stimulation has been proposed as a method by which a more normal walking pattern may be achieved. One of the limitations of this approach is the sensor commonly used to start and stop stimulation. Several sensors have been proposed as alternatives, but these have mainly been tested in adults.

The key objective of the present work was to evaluate the performance of the gyroscope as a sensor to detect gait events in unimpaired children and those with CP, with particular application during stair and ramp walking.

To enable the evaluation to take place, two reference systems were first developed with adults based on kinematic and in-shoe pressure sensing data. Both of these showed accuracy within the predefined values when compared with the force plate. In addition a new algorithm for gait event detection using the gyroscope was also developed.

The gyroscope sensor was subsequently evaluated in six unimpaired and two CP children while walking on level ground, and on seven unimpaired children while walking on a path that included level ground walking, ramps and stairs. In both cases, its performance was compared with the reference systems and, where possible, with a conventional foot switch.

Overall, the results showed a tendency for the gyroscope to be more accurate for initial contact detection and less accurate for foot off detection than foot switches. The gyroscope was slightly more reliable in ramps and stairs than the footswitch.

Additional testing on a larger patient population should be performed before the sensor is used in the clinical environment. If the results of such evaluations support the findings of this study, further work should be directed towards the development of a self-contained unit that includes the stimulator and sensor.
Nomenclature

CA: contact area detection method
CP: cerebral palsy
EMG: electromyography
ENG: electroneurography
FES: functional electrical stimulation
FO: foot off
FS: foot switch
FSR: force sensitive resistor
GD: gyroscope detection method
HC: heel contact
HO: heel off
IC: initial contact
KD: kinematic detection method of events
KN: kinetic detection method of events
TA: tibialis anterior muscle
TC: toe contact
TO: toe off
VFS: virtual foot switch
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1. Introduction

Chapter 1
Introduction

1.1 Background

Cerebral Palsy (CP) refers to a disorder of motor function resulting from non-progressive damage occurring before the brain is fully mature and affects 2 to 4 per 1000 of live births, which would account for approximately 1400 to 3000 new cases every year in the UK.

Although the damage to the brain is non-progressive, the manifestations do change and evolve. Treatment applied during the first stages of life, while the child is still growing is crucial not only to maximise functionality and, ultimately, improve quality of life, but also to avoid permanent deformations that may occur as a result of muscle imbalance during growth.

One of the outcomes of cerebral palsy is an imbalance in the muscles that govern the ankle movement. This affects walking pattern, increasing the energy and effort needed to walk and the risks of falls.

Functional Electrical Stimulation (FES) has been proposed as a treatment option to alleviate this problem. FES is the application of electrical pulses to neural pathways or muscles in order to achieve an effective muscle contraction with the aim of restoring a lost or impaired function. It has been shown that FES applied to the muscles that govern the ankle improves the walking pattern of some patients with CP.

Users of FES systems, clinicians and researchers have reported areas of improvement that could broaden the acceptability of the stimulation techniques. One of those areas is the sensor used to start and stop stimulation. Most of the commercially available stimulators for gait assist use a sensor placed inside the shoe (foot switch) to control the timing of stimulation. Although widely used, some limitations have been indicated for foot switches such as failures, cosmetically undesirable, unreliable with some gait patterns, unreliable behaviour due to age and use and limited potential for further improvement (in terms of size and implantability).
The literature review shows that there are several different sensors under investigation for use in FES systems. Most of these have been evaluated in adults walking on level ground and further work is needed to evaluate their applicability in different situations (terrains and speeds) and in a wider patient population, which would include children.

It has also been noted in the literature that children walk with a greater variety of speeds and patterns than adults and that it is likely that the number of children who could benefit from FES would be greater if the stimulator and its components were designed specifically for this population.

1.2 Previous Work at the University of Surrey

Previous research at the Centre for Biomedical Engineering has used gyroscopes as sensors for gait event detection.

Henty [2003] evaluated a gyroscope placed on the foot above the metatarsals in unimpaired subjects and in subjects with foot drop, and compared the detection of events with foot switches and kinematic data. The results showed that four events were successfully determined with the gyroscope; the absolute mean difference between the gyroscope and foot switches for all events was less than 115 ms for unimpaired and pathological gait.

Ghoussayni [2004] evaluated a gyroscope placed on the shank of unimpaired subjects and patients with foot drop, and also compared the detection of events with foot switches and kinematic data. These results showed that the gyroscope allowed for successful detection of heel contact and heel rise, and that the gyroscope provided with similar, but slightly better overall accuracy than the foot switch.

It was decided then to start the evaluation with the gyroscope taking advantage of the in-house experience with the sensor and extending the research so that if the results of this study showed that it is a good alternative for children then a gyroscope-based stimulator system could be available for both adults and paediatric populations.
1.3 Aim of this Work

This project is part of an overall project at the University of Surrey, towards the design and development of a stimulator that would be more appropriate for routine use in children with cerebral palsy.

Part of that project is to select a sensor that could be used as part of the stimulator. In that respect, the hypothesis is that “a gyroscope can be used effectively as part of a functional electrical stimulator dedicated for gait assist in children with CP”.

Clearly the term effective must be defined. For this project the definition was largely restricted to investigations of accuracy and reliability, although issues of weight and size were also reviewed.

As very crude guidelines, it would be expected for the differences between the gyroscope and foot switch to be smaller than (absolute mean difference ± one standard deviation) 400 ms ± 200 ms for foot off and 100 ± 200 ms for initial contact. As will be explained in section 3.6.3.1, these can only be considered to be very crude guidelines. Future work should establish the real effect of the differences in stimulation timing for patients with CP, and these values are used here only on the basis of the lack of more appropriate guidelines. Also, the reliability (in terms of the number of correctly detected events) of the new sensor should be at least as good as (or better) than the FSR.

The overarching objective of this PhD project was to provide data that could be used for a preliminary review of the above hypothesis.

The particular objectives were:

1) To undertake a literature review to underpin further technical development.

2) To develop and evaluate reference detection systems that could provide accurate timing of events for comparison with the gyroscope. It was considered that reference systems would provide extra information that would allow for a more complete analysis of the behaviour of the sensors.

3) To develop hardware and software that would allow synchronized gyroscope and foot switch data collection and analysis.

4) To evaluate the detection from the gyroscope by
Chapter 1. Introduction

4.1) quantifying the time difference between a reference system and the gyroscope;
4.2) quantifying the time difference between foot switches (either real or virtual force sensing resistors) and the gyroscope;
4.3) comparing the differences between gyroscope and foot switches detection when referred to the reference system;
4.4) comparing the reliability of gyroscope and foot switch detection;

in unimpaired and cerebral palsied children on level ground and then extend the evaluation to different terrains, particularly ramps and stairs and discuss the results.

5) To comment on the feasibility of the gyroscope as a sensor for use in FES gait assist systems with children with CP.

1.4 Layout of the Thesis

Initially, cerebral palsy, its effects in gait and the treatments commonly used in its management were reviewed. These are presented in Chapter 2 with the objective of setting the context regarding the patient population involved in this project and the role of functional electrical stimulation as a treatment option.

Chapter 3 provides a description of functional electrical stimulation, its use in children with CP and the limitations of the technique as reported by users, clinicians and researchers. From the suggested areas of improvement, this project focused on the sensor to control stimulation. A review of sensors proposed for detection of gait events is then presented.

Chapter 4 describes the hardware and software developed for the gyroscope and foot switch data collection and analysis, with a description of the methods used for detection.

Chapter 5 presents the assessment of two proposed reference methods for detection of events. Data from a motion analysis system and a pressure measurement system were
compared with kinetic data. The methods used in each case for detection are described together with the results obtained from the evaluation.

Chapter 6 reports on the evaluation of gyroscope in unimpaired and cerebral palsyed children, when walking inside a gait laboratory on a level path. The methods used for the evaluation, the results, and a discussion of those results are presented.

Chapter 7 reports on the evaluation of the gyroscope in unimpaired children, when walking on an outside path, which included level ground walking, a ramp and stairs. Again in this case, the methods used for evaluation, the results and a discussion of the results is presented.

Chapter 8 presents the conclusion of the project as a whole, including the limitations of the present work and further work that should be undertaken if the gyroscope would be considered to be part of a clinical electrical stimulator used in children with cerebral palsy.
Chapter 2
Cerebral Palsy

2.1 Introduction

As explained before, this project involves the evaluation of a new sensor as a way to improve technology for the delivery of treatment of the gait of cerebral palsy children.

The purpose of this chapter is, then, to set the context that surrounds this work regarding the motor disorder towards which the research is focused.

A definition of cerebral palsy is presented and its effects on the gait of children affected are described. However, in order to understand the pathological gait it is necessary to understand the unimpaired gait and a brief description of this is also provided.

The treatments involved in the management of CP children are presented (Functional Electrical Stimulation is only mentioned in this chapter, but described in detail in Chapter 3) and a brief discussion regarding the evidence to support the treatments included. The objective of this review was to establish the different treatment options available for CP and their supporting evidence, which would allow setting the clinical and research evidence of FES in the context of the concerns and limitations of the other treatment options.

2.2 Cerebral Palsy Condition

Cerebral Palsy (CP) refers to a disorder of motor function resulting from non-progressive damage occurring before the brain is fully mature [Gage 1991; Gelber and Jeffery 2002]. Although the term refers only to the motor dysfunction, patients may present other symptoms such as impairment in their hearing or visual abilities.

The etiologies of cerebral palsy are varied and can occur either prenatally or postnatally [Gage 1991]. They include cerebral maldevelopment, cerebral hemorrhages, hypoxic events, postnatal trauma, infections and toxicities [Shevell et
al. 2003; Meberg and Broch 2004; Miller 2004]. It has been suggested that multiple causes may interact to produce cerebral damage [Lawson and Badawi 2003].

Cerebral Palsy can be classified according to the type of the motor dysfunction, the part of the body involved and the degree of severity presented. The classification described by [Gage 1991], is as follows.

According to the type of motor dysfunction:

- **Spastic**: refers to the presence of an increased stretch reflex when passively flexing and extending muscle groups.

- **Dyskinetic**: refers to abnormal motor movements, involuntary and unpredictable, more noticeable during movement but present even at rest. Three movement patterns can be used to classify dyskinesias: dystonia, athetosis and chorea or ballismus [Miller 2004]. Children in the dystonic group have abnormal shifts of general muscle tone and assume and retain abnormal and distorted posture in the same stereotyped patterns. Athetosis is a movement disorder presenting as large movements of proximal joints, induced by voluntary effort (although sometimes this effort is as remote as trying to speak). Chorea is a movement disorder defined by jerky, rhythmic, small-range movement whereas ballismus is defined by large, unpredictable and jerky movements based at the proximal joints.

- **Ataxic**: refers to a disturbance in the coordination of voluntary movements, with presence of unsteady shaky movements or tremor.

- **Mixed**: combination of spasticity and dystonia is the commonest; also, some degree of ataxia could be present.

Topographic classification:

- **Hemiplegia**: the leg and arm of one side of the body are affected.

- **Diplegia**: both legs are affected significantly more than the arms.

- **Quadriplegia**: both arms and legs are affected.

Classification according to the degree of severity:

- **Mild**: independent walker, unlimited fine motor function.

- **Moderate**: supported walk, limited fine motor function.
Severe: no locomotion and absence of fine motor function.

The reported incidence of Cerebral Palsy varies depending on the study. A rate of 2 to 4 cases per 1000 live births has been reported [Lau and Lao 1999]. The same authors reported that population studies in the United Kingdom, Australia, Ireland and Sweden have revealed little change in the overall incidence and little difference between populations. Of those, 75% present spasticity [Griffiths and Clegg 1988].

2.3 Normal and CP Gait

2.3.1 Definition of Gait

Walking is a complex process that involves the use of the brain, spinal cord, peripheral nerves, muscles, bones and joints. It has been defined [Whittle 1991] as “a method of locomotion involving the use of two legs, alternately, to provide both support and propulsion, at least one foot being in contact with the ground at all times”. However, as the author himself pointed out, this definition does not include some forms of pathological walking. Due to the intrinsic complexity of the process and the wide variety of different patterns, it is difficult to find a definition that covers all the possibilities.

2.3.2 Gait Cycle

The gait cycle is defined as the time interval between two successive occurrences of one of the repetitive events of walking [Whittle 1991]. For example, if the event chosen is the right heel contact, then a gait cycle is the time between two successive right heel contacts. Normally, the gait cycle is divided into two major phases, which are stance (when the foot is in contact with the floor) and swing phase (when the foot is not in contact with the floor), and particular events are used to subdivide them. The major events that occur during each cycle and the phases between events, taken from [Whittle 1991] are shown in figure 2.1; the gait events are shown with the typical position of the legs in circles and between one and the other circle, the name of the phases.
2.3.3 Development of Gait

The control of movement in healthy children is developed gradually as the brain matures [Griffiths and Clegg 1988]. As a consequence, the number and complexity of movements that a child makes increases also gradually from birth. Gait, in particular, starts at around one year of age [Griffiths and Clegg 1988; Gage 1991], but it does not develop an adult, heel-toe gait until three and a half years [Gage 1991].

As this project involved children older than six years old, the reference to normal gait pattern is represented by the adult gait.

2.3.4 Normal Gait

As stated before gait is a complex process. Below is a simple description of the chain of events initiated by the first step that constitute gait, focused on the sagittal plane and based on the descriptions by Perry [1992] and Whittle [1991].
2.3.4.1 First Step

Three actions occur, according to Perry, in order to initiate walking. First, a partial shift of the body weight towards the limb to be lifted. Second, a total shift of body weight towards the limb in stance (figure 2.2). Finally, either the soleus muscle reduces its holding force so that the tibia is allowed to move whereas the body is allowed to fall, both movements being made in the forward direction or the pretibial muscles contract to actively pull the tibia forward. The mechanism used depends on the standing position of the person. After the first step, a progression cycle starts.

Figure 2.2 Centre of pressure pattern for first step. First a partial shift from the centre (1) towards the limb to be lifted (2) and then a total shift towards the limb in stance (3) [Perry 1992].

2.3.4.2 Initial Contact and Loading Response (Heel Rocker)

The ankle is generally close to its neutral position in plantarflexion/dorsiflexion at the time of initial contact. As the body weight is dropped onto the stance limb, the heel is used as a fulcrum and the foot rolls into plantar flexion (heel rocker, figure 2.3). The tibialis anterior muscle, which had been active throughout swing to maintain dorsiflexion, control the deceleration of the foot and, at the same time, they move the tibia forward.

The quadriceps muscles restrain the flexion of the knee, and by doing so, they tie the femur to the tibia, making it move forward.

The hamstrings are active during the latter part of the swing phase (to prevent knee hyperextension) and gluteus maximus begins to contract around the time of initial contact. Together these muscles start the extension of the hip.
Chapter 2. Cerebral Palsy

Figure 2.3 Heel rocker: the heel being the fulcrum for the foot rolling into plantar flexion. Pretibial muscles decelerate the foot drop and draw the tibia forward, whereas the quadriceps restrain the flexion of the knee, and make the thigh move forward [Perry 1992].

2.3.4.3 Mid Stance and Ankle Rocker

Opposite toe off is the end of loading response and the beginning of mid-stance. Once the forefoot contacts the floor, which occurs around the time of opposite toe off, the ankle becomes the fulcrum and the tibia moves over the now stationary foot. The knee continues to flex, reaching the peak of stance phase flexion early in mid stance, after which it begins to extend again, through contraction of the quadriceps, while the soleus muscles are active in order to provide a stable base for knee extension (Figure 2.4).

The hip continues to extend by contraction of the gluteus maximus and hamstrings.

2.3.4.4 Terminal Stance and Forefoot Rocker

As the centre of pressure reaches the metatarsal heads, the heel rises, which marks the transition from mid stance to terminal stance. The metatarsals heads now serve as forefoot rocker.

The knee has an extension peak close to the time of heel rise. Around this time active ankle plantarflexion brings the ground reaction force forward, moving it into the forefoot and in front of the knee joint. This attempts to extend the knee, an effect known as the platarflexion/knee extension couple.
Contraction of the gastrocnemius augments the action of the soleus to decelerate the rate of tibial advancement (Figure 2.4), but it also acts as a flexor at the knee, preventing hyperextension and subsequently initiating knee flexion.

The hip continues to extend during this period.

![Figure 2.4 Ankle (left) and forefoot (right) rockers. During ankle rocker the tibia moves forward decelerated by the soleus muscle. Tibia progression is continued over the forefoot rocker, when both gastrocnemius and soleus act vigorously to decelerate the rate of tibial advancement [Perry 1992].](image)

2.3.4.5 Pre-swing

Opposite initial contact marks the end of terminal stance and the beginning of pre-swing.

The limb is rapidly unloaded, residual action of gastrocnemius and soleus muscles plantarflexes the foot, resulting in advancement of tibia and flexion of the knee (Figure 2.5).

At opposite initial contact, the hip reaches its most extended position and motion reverses in the direction of flexion. Adductor longus acts as the primary hip flexor, combined with effects of gravity.
2.3.4.6 Toe Off and Initial Swing

The ankle dorsiflexes due to the action of the tibialis anterior muscles, so that the foot is in the right position to allow for floor clearance during swing (figure 2.6). However, ankle dorsiflexion on its own is insufficient to provide clearance of the foot, which is the reason why the knee is actively further flexed. By the time of Toe Off, the knee has flexed to around half of the angle it will achieve at the peak of swing phase flexion. As the foot leaves the ground, the major part of knee flexion results from hip flexion: the leg acts as a jointed double pendulum, so that as the hip flexes the shank is “left behind” due to its inertia, resulting in flexion of the knee [Whittle 1991].

The hip continues to flex by gravity as well as by the contraction of the rectus femoris and adductor longus.

2.3.4.7 Mid Swing

Feet adjacent separates initial swing from mid swing (figure 2.6). It is the time when the swinging leg passes the stance phase leg, and the two feet are side by side.

The ankle is moving from a plantarflexed position around toe off towards a neutral or dorsiflexed position in terminal swing. Most of the shortening of the swing phase leg
required to achieve toe clearance comes from flexion of the knee, but the ankle also needs to correct the plantarflexion, which is achieved through contraction of the tibialis anterior.

The flexion of the knee during the whole swing phase results largely from the flexion of the hip. The peak swing phase knee flexion occurs before the feet are adjacent, by which time the knee has started to extend again.

The hip is flexed, achieved by a powerful contraction of the iliopsoas.

2.3.4.8 Terminal Swing

When the tibia of the swinging leg becomes vertical, mid swing finishes and terminal swing begins (figure 2.6).

Once the toe clearance has occurred, generally before the tibia becomes vertical, the ankle position becomes less important: it may be anywhere between a few degrees plantarflexed and a few degrees dorsiflexed. Tibialis anterior continues to contract to hold the ankle in position but its activity usually increases prior to initial contact in anticipation of the greater contraction forces that will be needed during the loading response.

Figure 2.6 Swing phase of gait. At initial swing, the hip and knee are flexed and the foot is dorsiflexed. During swing, this pattern gradually changes and at terminal swing, the knee is extended and the ankle is near neutral position [Perry 1992].
Also, once the toe clearance has occurred, the flexion of the knee is no longer needed, so passive extension first, and active extension later, completes the swing phase, preparing the knee.

Tibia vertical marks the time when the hip flexion ceases. The hamstrings contract increasingly strongly during terminal swing to limit the rate of knee extension, while maintaining the hip joint in this flexed position.

### 2.3.5 Cerebral Palsy Gait

Normal walking has five major attributes which are frequently lost in pathological gait: stability in stance, sufficient foot clearance during swing, appropriate swing phase prepositioning of the foot, adequate step length and energy conservation [Gage 1991].

The features that could appear, isolated or as a combination, in spasticCP children due to damage to the central control system are [Lin and Gage 1990; Gage 1991]:

- Loss of selective muscle control
- Dependence on primitive reflex patterns for ambulation
- Abnormal muscle tone
- Relative imbalance between muscle agonists and antagonists across joints.
- Deficient equilibrium reactions.

These are responsible for changes in the normal pattern of gait, described above. And since normal gait is the most efficient, any deviation from the normal results in excessive energy consumption [Gage 1991].

Researchers have described the common changes in gait for children with cerebral palsy in different ways. Perry and Gage [Perry 1975; Gage 1991; Perry 1993] described the common abnormalities that CP children present at the different phases of gait described above. Another approach, based on the fact that the majority of the patients who are able to walk have either spastic hemiplegia or spastic diplegia [Whittle 1991], is to describe the common patterns presented by spastic hemiplegic patients [Winters et al. 1987; Hullin et al. 1996] and by spastic diplegic patients [Miller 2004; Rodda et al. 2004]. This patterns are then used as a basis to which
appropriate intervention strategies are linked [Chambers 2001; Rodda and Graham 2001]. It was preferred for this chapter to describe the basic common abnormalities that CP children could present during different phases of the gait cycle, from which the actual pattern of involvement for each child would derive, following the description of Perry and Gage [Perry 1975; Gage 1991; Perry 1993].

2.3.5.1 Initial Contact and Loading Response (Heel Rocker)

During this phase, the most common deviations are excessive flexion at the knee and excessive plantarflexion of the foot. If only one abnormality occurs, the result is usually a foot flat gait (it could still be the heel that initiates floor contact but the foot is nearly parallel with the floor). If both occur, the patient will begin the gait cycle with toe contact (figure 2.7).

When foot flat occurs, the gait cycle starts with the second rocker. As a consequence, during loading response, the flexion of the knee and the plantarflexion of the foot are replaced with extension of the knee and dorsiflexion of the foot. This demands the lengthening of the gastrocnemius, which spans both joints. This may result in clonus (as the predictable response of a spastic muscle). The premature activity of triceps surae may also restrict second rocker.

![Initial contact gait deviations: low heel contact, with foot nearly parallel with the floor (left) and toe contact (right).](image)

When toe contact occurs the effect of weight-bearing is to produce a backwards movement of the tibia as body weight pushes the whole foot to the floor. This prevents the limb from advancing and halts the advancement of trunk for a moment. If
the foot is in such severe equinus that weight is borne only on toes, the foot serves as a small rocker and forward movement is uninterrupted (figure 2.8).

### 2.3.5.2 Mid Stance and Ankle Rocker

The principal gait deviations in this phase are underactivity and overactivity of the soleus muscle, the former being an iatrogenic problem caused by overweakening of the muscle in surgery. During the ankle rocker in normal gait, a key feature is the graded intensity of this muscle that provides a stable base for knee extension but still allows the tibia to move forward.

If there is overactivity the forward movement of the tibia is retarded unless there is premature heel rise, knee hyperextension or forward trunk lean (figure 2.9). As a result one or more of those adaptations are used: premature heel rise that now occurs during mid stance instead of terminal stance results in a shortened period of stance and a resultant short step on the opposite side; knee hyperextension, as the femur follows the body movement over a immobile tibia; forward lean of trunk with anterior tilt of the pelvis, to maintained balance over the flat foot.

![Figure 2.8 Common abnormalities during loading response after toe contact. Toe contact sustained and use of the foot as a rocker (left) and toe contact drop to foot flat with backwards movement of the tibia (right). [Perry 1992]](image)

If the overactivity is more pronounced, the individual would have to use a toe-toe gait through mid-stance. This creates instability in stance, concentrates pressure in an
extremely small area of the forefoot and requires intense activity of quadriceps and hip extensors to maintain balance.

If the soleus is weak, the lack of restraint to the tibia advancement allows the tibia to move forward faster than the hip and trunk and consequently, the knee and hip tend to flex. Extensive quadriceps and hip extensors activity would be required to maintain stability.

2.3.5.3 Terminal Stance and Pre-swing

In this phase, the most common abnormalities are inadequate plantarflexion strength and flexion contractures of hip or knee.

If plantarflexion is excessive, heel rise will occur prematurely and knee will hyperextend. Usually hamstring will become active to reduce knee hyperextension, but their action will oppose the action of hip flexor, which are normally active at this stage. As muscles are recruited to help with further hip flexion, they usually act as knee extensors as well. The result is inadequate knee flexion at toe off and co contraction of flexors and extensors at hip and knee.

Figure 2.9 Common abnormalities of mid stance due to overactivity of the soleus muscle: a) premature heel rise, b) hyperextension of the knee, c) forward trunk lean.[Perry 1992]
If there is insufficient plantarflexion, heel rise will not occur and knee extension will not be maintained (figure 2.10). And, as the forefoot rocker cannot occur, the individual is forced to enter pre-swing from the second rocker position. Momentum for swing and foot clearance must be obtained by the hip flexors.

During the pre-swing, the knee usually is in full extension, rather than flexion, due to full tension of the quadriceps.

2.3.5.4 Swing

During Initial Swing and Mid Swing phases, foot clearance is difficult to achieve due to insufficient hip or knee flexion. The muscle imbalance usually found in CP patients, frequently results in inadequate hip flexors and ankle dorsiflexors. Continuous action of the rectus femoris through mid-swing, which is almost universal in CP [Gage 1991], will also limit knee flexion. All of these factors result in foot clearance problems.

Figure 2.10 Gait abnormalities with insufficient plantarflexion: a) prolonged heel contact accompanying tibial displacement; b) additional tibial advancement with excessive knee flexion.

During Terminal Swing, a combination of factors leads to incomplete final position of knee and foot for initial contact. Hamstrings spasticity could reduce knee extension.
More over, dependence on patterned locomotor control permits flexion or extension but not a combination. Thus, while the hip is held in flexion, the knee automatically flexes an equal amount. The result is a vertical shank, with foot parallel to the floor and a short stride.

Foot posture is similarly influenced by patterned action. As the knee is extended to reach forward, the triceps surae are also activated, causing plantarflexion at the ankle. A combination of increasing ankle plantarflexion, a loss of hip flexion and incomplete knee extension, results in a "toe-down" foot position. The anterior tibialis commonly exhibits a response but is too weak to hold up the foot.

2.4 Treatments

Because of the complexity in treating a child with CP it has been suggested that treatment should be determined using a multidisciplinary team approach with clearly outlined goals [Craig 1999; Gormley 2001]. Most children can benefit from different treatments, so each child should be evaluated individually.

Bleck [1987] listed different treatments for children affected with spastic CP, some of them are briefly described below with the supporting evidence for their application in this group of patients.

The aim of the current review is to analyse the context on which Functional Electrical Stimulation appears as an option treatment.

2.4.1 Central Nervous System Surgery

Stereotactic surgery, used to destroy a region of the brain by electrical current or cryosurgery, has been one of the options. Bleck [1987] emphasized that due to the diffuse nature of brain damage and the complexity of the brain itself, it seems unlikely that destroying one or several spots in the brain will be successful in alleviating the motor disorder and it should remain in the experimental stage. More recently, studies have shown that it has a positive effect in reducing spasticity [Chang 1997] and dystonia [Imer et al. 2005]. However, researchers agree that due to the frequency of complications encountered in ablative surgical procedures ranging from 7% to 47%
and mortality rates in the range of 2 to 4.5%, the surgical procedure should be considered only when medical therapy remains ineffective [Imer et al. 2005].

Cerebellar Stimulation is the electrical stimulation of the cerebellum with the objective of diminishing general extensor hypertonia. Researchers disagree about the benefits of this method and it is no longer used [Gormley 2001; Miller 2004].

Selective Dorsal Rhizotomy is a procedure in which the dorsal nerve roots are partially transected with the objective of diminishing muscle tone by diminishing sensory afferent input to the spinal reflex arc [Green et al. 2002]. Although the efficacy of the procedure to decrease spasticity is well established, there is still controversy as to the long-term benefits and the functional improvements achieved [Gormley 2001; Petersen and Palmer 2001; Miller 2004].

From the literature review, it is possible to see that from those procedures still in use, clinicians consider their application only when less invasive forms of treatments are ineffective. Also, more studies regarding the long-term effect of the treatments are needed.

2.4.2 Physiotherapy

Different approaches have been proposed to improve motor performance in children with CP. It has been mentioned, however, that there is insufficient evidence to indicate which of the methods is the best to improve the basic motor function [Calderon Gonzalez and Calderon Sepulveda 2002].

Although it has been suggested that aggressive therapy (in the form of range of motion exercises, applied 20 hours per week, for a month, 4 to 5 hours per week for the next 5 months and 1 to 2 hours per week for the subsequent 6 months) can provide improvements in their gross motor skills [McLaughlin et al. 1996], there are still authors with controversial views about those outcomes [Hartley 2002].

There seems to be a general agreement in that although physical therapy may not significantly reduce spasticity, still remains an integral part in the management of children with CP [Gormley 2001; Calderon Gonzalez and Calderon Sepulveda 2002], being useful in some cases to offer parents and careers with practical strategies to
work with their children but overall, helping them in the management of the motor disorder to allow optimal function for daily living [Bleck 1987].

Scrutton [1984] mentions three different principles that could be used as criteria to classify those methods. It has been suggested that they should be applied in combination to treat all the aspects of deficiency in a CP child [Calderon Gonzalez and Calderon Sepulveda 2002]:

- Treatments led by the mechanical approach would have some influence on muscle power, joint range and postural stability.

- Treatments led by the neurological approach makes use of different aspects of neurology, for example by utilizing exteroception (making the child aware of handling objects and evaluating distances), proprioception (making them appreciate weight and shape) or a central approach (focussed on learning skills and voluntary changing the patterns of movement to make it more efficient) [Pierson 2002].

- Finally, the educational approach leads treatments where the intervention aims more to educate than to treat. With respect to this approach, Jahnsen et al [2003] published the results of a survey on adults with CP in Norway about their experiences with physiotherapy and physical activity. The results of 406 adults showed that most of them (92%) had received physiotherapy as children. However, less than half of the respondents (46%) reported having learnt something from physiotherapy that they still used as adults, namely, how to take personal responsibility for their personal health and they coincided with those who reported being physically active on their own as adults. The authors concluded that it is important that therapy programs have contents that create motivation and understanding of the importance of life long active and balanced use of the body.

From the literature review and from informal communications with physiotherapists, it is clear that this is a treatment that provides benefits to patients with CP. However, the evidence in the literature supporting the benefits is still limited, as is the best approach to apply the techniques to different patients.
2.4.3 Casting

Plaster casts (figure 2.11) may be applied to the lower extremity to prevent contractures as the application of a prolonged, mild tension results in elongation of tendon and muscle [Pierson 2002]. The joint is usually positioned 5 degrees less than maximal point of the range of the joint (if the stretch were maintained at the maximal passive range, patients would experience pain and discomfort resulting in further increase in tone). Casts are regularly changed every three to seven days, towards a progressive stretching and increased range of motion, during a period that may last three to six weeks [Rogers and Vanderbilt 1990]. Then the procedure may be repeated.

Cottalorda, Gautheron et al. [2000] evaluated the use of serial corrective casts in 20 children with CP (30 feet). Three successive casts were applied over a period of three weeks. After the removal of the cast, a below-knee night splint was used for a period of three months or more and physiotherapy was applied for “as long as possible”. The mean passive dorsiflexion with knee extended and flexed, before the treatment, were 3° and 12°, respectively. After removal of casts, the means were 20° and 28° respectively. At the latest follow up (mean three years and one month), the means were 9° and 18°, equinus deformity had recurred in 15 feet and in 22 feet the children had returned to toe-walking. This study supports the idea that serial casts have been shown to improve range of motion and gait but their beneficial effects lasted only about 18 month (others reported less than 12 weeks[Corry et al. 1998]).

Casting has been reported as a tedious and time-consuming method, which has the risks of skin pressure sores and blister and could induce atrophy by immobilization and stretching [Bleck 1987].

From the literature review, it is possible to see that casts can provide an improved range of motion in the short term. However, practical complications are associated with the treatment, which in some cases, e.g. muscle atrophy, can accumulate if repetitive applications are needed.
2.4.4 Orthoses

An orthoses has been defined by Kogler [2002] as an external force system applied to a segment of the body to control motion and correct or prevent deformities.

One of the most common orthoses used for CP children is the ankle foot orthoses (AFO, figure 2.12) [Bleck 1987]. During the stance phase of gait, the orthoses helps the extremity to support a portion of the body weight, allow forward progression and resist unstable forces due to uneven terrain, impaired balance, weakness or pathological motion [Lin and Gage 1990]. During swing phase, by keeping the ankle joint at 90°, clearance can be achieved.

Different AFO designs have been evaluated and compared [Hassani et al. 2004; Radtka et al. 2005]. The results of such evaluations show an improvement in the kinematic variables of gait while the orthoses are being used. Bleck [1987] reported that in her experience, even when the deformity may not be corrected by the use of orthoses, it may be held until a surgical correction is considered appropriate. Regarding the parents perception of the use of orthoses, different views have been reported. In a study by Naslund et al. [2003] it was reported that parents had positive views regarding the use of orthoses, as they provided postural control and balance that
helped the children to participate in social activities. On the other hand, Bleck reported that when parents were free to choose, they removed the braces after school so that the child “could play and run about”. Similar findings were reported with the children who participated in the study carried out by Stevens [2003], who preferred not using orthoses.

Figure 2.12 Two types of AFOs, on the left, the conventional plastic AFO and on right the Silicone Ankle Foot Orthoses (SAFO) [www.dorset-ortho.co.uk, accessed on September 2006]. The SAFO orthoses represents a comfortable and more cosmetic solution although as it is a non-rigid structure it is normally only appropriate for a ‘flaccid’ foot drop.

Autti-Ramo et al [2006] in an overview of review articles that evaluated the use of casting and orthoses in children with CP, found a total of 20 different studies that involved the use of lower limb orthoses. They mentioned that a major problem when summarizing the effect of orthoses in a review is the wide variety of available orthoses, that the possible negative effects of orthoses in restricting functionality (such as climbing stairs or running) should be evaluated and that the improvement in particular gait parameters (such as stride length or range of dorsiflexion) should be considered in the context of functional significance. They finally said that “the lack of long-term follow ups prevents any conclusions on the protective effect of any orthotic devices … on structure during growth in children with CP”.

From the literature review, it is possible to see that AFOs improve the kinematic variables (such as peak ankle dorsiflexion and plantarflexion), however the restriction of the treatment on activities other than walking (such as climbing stairs) and the long-term effect of the treatment, e.g. muscle weakness with continued used, still need to be investigated.
2.4.5 Orthopaedic Surgery

Some of the surgical procedures that may be considered as treatment for CP are tendon lengthening, tenotomies (division of a tendon), tendon transfer and muscle slide [Pollock 1961; Banks 1975].

Granata et al. [2000] measured several kinematic variables and time distance parameters (forward velocity, stride length, cadence, joint angles at hip, knee and ankle and joint angular velocities at the same joints) together with muscle activity, through electromyography in forty paediatric patients diagnosed with spastic cerebral palsy and seventy-three age-matched, unimpaired children. The patients had had different and several muscle-tendon lengthening so no conclusions about specific units lengthened can be derived. The patients were evaluated before the operation and nine months after treatment. The results showed that there were significant improvement in dorsiflexion of foot at heel strike and midstance, although no changes were noticeable at the hip and knee between preoperative and postoperative conditions. Postoperatively, the activity of gastrocnemius-soleus increased in mid stance and reduced during weight-acceptance when compared with preoperatively values. Although in all conditions, the values postoperatively were still significantly different from those corresponding to unimpaired children, the changes after the operation had tendency towards normal values.

More recently, Orendurff et al [2002] reported on nine children (eight of them had been diagnosed with CP) who presented an equinus deformity which persisted when the knee was flexed at 90 degrees. They all had tendo Achilles lengthening and were evaluated prior to and one year after the surgical procedure. The results showed an improvement in sagittal motion of the ankle (more similar to normal motion), the length of gastrocnemius and soleus increased significantly as well as the force output of the triceps surae during push-off. No recurrence occurred a year after the operation but the authors suggested that a longer follow up should be done in order to ensure that no recurrence occurs in the long-term.

Researches have emphasized some factors that would favourably affect the results of surgical procedures [Pollock 1961; Bleck 1987; Woo 2001]: careful preoperative analysis, correct selection of surgical procedure, proper surgical technique and follow-up care, clear definition of the aims of surgery, with those aims tailored to the patient.
In terms of the long-term benefits of surgery, in a study involving children with diplegic cerebral palsy, Gough [2004] remarks that “there is a considerable need for long-term outcome studies". The author also suggested that the concept of a single procedure (multilevel surgery) aimed at correcting all deformities and maintaining function until maturity may need to be changed to that of a procedure aimed at prolonging function and mobility but accepting a gradual recurrence of deformity and a decrease in mobility with growth in children with spastic diplegic cerebral palsy.

From the review, one can conclude that surgical procedure can provide benefits in terms of kinematic variables to children with CP. However, more work is needed to establish the selection criteria for the patients, the type of procedure performed in each case, the realistic goals that could be established, and the long-term effect of such interventions.

2.4.6 Medication

Medication can be used to reduced spasticity and associated movement [Green et al. 2002]. Some are effective at the level of the central nervous system and others at the muscle level.

Most of them, such as benzodiazepines and baclofen, have side effects that include sedation, daytime sleepiness and fatigue and others specific to each drug for example, increased secretions and change in bladder habits. Overall the medications reduce spasticity but, functionally the change often is only minimal and the benefit may not be substantial enough to warrant the side effects of increased weakness and sedation [Tilton 2003].

Botulinum toxin has gained popularity in the treatment of spasticity associated with CP [Graham et al. 2000]. It acts by interfering with presynaptic acetylcholine release at the nerve terminals [Koman et al. 1994]. The toxin is injected in the spastic muscle where it diffuses in the neuromuscular junction, is taken up by presynaptic nerve terminals and interrupts the release of acetylcholine. This is equivalent to a chemical denervation of the muscle that produces weakening and reduction of tone [Green et al. 2002]. The evidence suggests that it is effective in temporarily reducing spasticity and delaying the shortening of spastic muscles [Petersen and Palmer 2001].
Sutherland et al. [1996] investigated the effects of using Botulinum A toxin for treatment of patients with cerebral palsy. Twenty-six patients, equinus walkers, without fixed contracture of the triceps-surae muscle received a botulinum A toxin injection into the gastrocnemius muscle. Injections were repeated at 3 months intervals, if considered necessary by the pediatric orthopedist. Kinematic and electromyographical data was taken prior to and 30, 45 and 55 weeks after the first injection. The analysis of the results showed significant improvements in dynamic ankle dorsiflexion in both stance and swing phases and electromyography of the tibialis anterior. Although the results were positive, it has been established that the effect of a single dose develops within weeks and lasts 12 to 16 weeks [Graham et al. 2000]. Repeated injections have been shown to produced a trend towards further improvement in the long term [Molenaers et al. 2005].

Sutherland et al. [1996] indicated that botulinum A toxin will not replace other treatments and suggested that it should not be a stand alone treatment. However, the "window" offered may make it feasible to apply some other adjunctive treatment in order to maximize effectiveness [Graham et al. 2000; Green et al. 2002]. One of the possibilities is to combine it with Functional Electrical Stimulation (FES) [Detrembleur et al. 2002; Galen et al. 2002].

From the literature review, botulinum toxin A provides a window during which spasticity is reduced and provides an opportunity to use it in combination with other treatments to maximise the benefits of that reduction. However, the long term effects of repeated application have yet to be investigated, and for maximum benefit, effective use of the window does require a well co-ordinated programme of therapy/orthotics to be in place.

2.4.7 Functional Electrical Stimulation

Functional Electrical Stimulation (FES) is explained in detail in Chapter 3.

2.4.8 Choice of Treatment

From the literature review, it is clear that researchers and clinicians agree that children with CP receive benefits from each of the treatment options discussed and the benefit may be maximised if more than one treatment is applied. However, there is also
agreement on the need for further studies to establish the actual benefits that each
treatment represents for children with CP (both in the short term and also in the long
term), the significance of those benefits in the quality of life of the patients, the
selection criteria that would maximise the benefits, as well as realistic goals that could
be established for each of them.

Currently, the choice of which treatment to apply frequently depends on the
experience and preferences of the team involved in the decision [Rodda and Graham
2001].

Although much work has been done towards evaluating the outcome of treatments,
there are some reasons that may delay the appearance of further work. Firstly,
cerebral palsy is not a diagnosis but a clinical description of a neurological disorder,
often with an unknown etiology. Consequently the assessment of benefits is
complicated by difficulties in identifying closely matched controls [White et al. 1999]
or closely matched subjects within the treatment group [Morris et al. 2002].

Secondly, as mentioned before, 75% of the patients present spasticity and most of the
treatments have to, directly or indirectly, overcome it in order to improve function.
However, there is a lack of consensus as to the most clinically applicable definition of
spasticity, and as a consequence, there is a lack of standardization of techniques to
measure it [Johnson 2004; Wood et al. 2005]. This makes it difficult to compare
results from different studies.

Also, outcome measures themselves are an issue to take into account. Goldberg’s
[1991] answer for the question “how do we measure the success or failure of
treatment programs for children with cerebral palsy?”, emphasizes that medical
outcome studies should include the technical outcome, a functional health assessment
and the patient satisfaction. This is also the idea behind the measurement of health
related quality of life to evaluate the effects of different treatments for children with
cerebral palsy proposed by Bjornson and McLaughlin [2001]. Until all the variables
are considered, the conclusion would be that the treatments may make patients
different, but not always better.

Not only is the appropriate selection of outcome measurements being reviewed, but
also the method used for reporting. In this respect, Blair et al. [2001] suggested that as
well as reporting the absolute change in the outcome as a consequence of the
intervention, the proportional change (defined as the observed change in outcome divided by the maximum or targeted possible change in outcome for that individual) should be reported to account for the patient history in a manner that is both individualized and generalizable. For example, consider a patient who presents an angle of the ankle of –10 degrees (in plantarflexion) at the time of initial contact. Blair suggests that first, the clinician needs to establish a maximum or targeted angle of the ankle at IC (this value would be determined, for example, from the passive range of motion of the subject). Considering now that the clinician sets this value as 0 degrees and latter applies the treatment to the patient who reaches –5 degrees (still in plantarflexion), the approach by Blair would imply that two absolute values should be reported, the absolute change in the measurement performed (in this case, 5 degrees towards dorsiflexion) and also the proportional change (in this case 5/10 or 0.5). The proportional change would be 1 if the target value were reached.

2.5 Conclusion

Cerebral Palsy (CP) refers to a disorder of motor function resulting from non-progressive damage occurring before the brain is fully mature which affects 2 to 4 children per 1000 live births. An important percentage of children affected with CP presents with spasticity.

For those spastic children who are able to walk, the motor disorder will affect their gait and since normal gait is the most efficient, any deviation from the normal results in excessive energy consumption [Gage 1991; Perry et al. 2003].

Several treatments are available for management of spasticity in children with CP. The literature review has shown that researchers agree on the need for further work to clearly establish their short and long-term benefits in the motor skills of CP children and define appropriate selection criteria. The review however also showed that the treatments can be successful and they are still in used while research continues.
Chapter 3
Functional Electrical Stimulation

3.1 Introduction

Having presented the context regarding Cerebral Palsy (CP) in chapter 2, this chapter will focus on Functional Electrical Stimulation (FES) as one of the treatment options for improving the gait in children with CP.

FES is the application of electrical pulses to neural pathways or muscles in order to achieve an effective muscle contraction with the aim of restoring a lost or impaired function. Several parameters may be altered in order to achieve an optimal function and these are briefly described in the first place. Then, representative research on the effects of FES on the gait of children is presented and a description of the systems used to provide the stimulation follows. These systems have been mainly used in the correction of foot drop in the adult population and researchers that use the same systems for the paediatric population agree in that those should be adapted to augment children compliance and acceptability. Also the experience on using the systems on adults has highlighted areas for further improvement of the equipment, which could also be applied for children.

From the literature review, two main areas for improvement have been spotted. One is related to the positioning of surface electrodes and the sensation caused by surface stimulation. The other is the improvement of the sensor used to control the trigger and stop of stimulation. As one of the projects at the Centre for Biomedical Engineering at the University of Surrey is the design and development of an electrical stimulator for children, both of these areas are of interest, but this project has been focused on the latter area.

As a final part of this chapter, a review of some of the sensors proposed to improve the control of stimulation is.
3.2 Functional Electrical Stimulation

The principle behind FES is that the application of electrical pulses (near) to a motor neuron axon will produce (if the characteristics of the stimulus are adequate to depolarize the membrane to its threshold) an action potential, which in turn will result in muscle contraction.

In general, the system used for FES comprises a device that produces the electrical pulses (stimulator), electrodes that deliver the pulses and some devices (sensors) that will provide information to control, for example start and stop, stimulation.

Often, the stimulus would need to be adjusted for every patient and every muscle stimulated, so the stimulator provides means of adjusting it to achieve the desire contraction. The parameters that could be adjusted (further described in Appendix A) are:

- **Pulse Amplitude and Duration:** the amplitude, or intensity, of the current pulse and its duration must be adequate to meet or exceed the threshold of excitability of the stimulated tissue.

- **Frequency:** the frequency of the stimulation determines the rate at which nerves fire action potentials; when applying functional stimulation, a smooth tetanic contraction of the muscles is desirable.

- **Waveforms:** the electrical pulses delivered could be monophasic (current moving in one direction only – from the active to the indifferent electrode) or biphasic (in this case, during half of the cycle one electrode is the active and it becomes the indifferent during the other half. In general, biphasic waveforms diminish skin irritation. The biphasic waveforms could be balanced (if the charge moving in both directions is the same) and they could be symmetrical or asymmetrical.

- **Ramp times and extension.**

Rising ramps are used in order to increase the comfort of stimulation and avoid evoking a clonus contraction of an antagonist muscle by gradually recruiting the motor units (Figure 3.1). This is achieved either by gradually increasing the amplitude of the electrical pulses or the pulse duration. Both will cause a gradual excitation of increasing number of nerve fibres.
The rising ramp should be short enough as to allow the maximum current to be delivered during the time of stimulation [Taylor et al. 1998]. The ramp down is useful for diminishing the contraction slowly.

An extension time could be used if it is necessary to prolong the stimulation after sensing the (gait) event that would stop it.

![Diagram of ramp and extension during gait stimulation](image)

Figure 3.1 Use of ramp and extension during the swing phase of gait for stimulation of dorsiflexors of the foot. The “triggering” event in this case is the end of contact of the foot with the floor and the stopping event is the initial contact of the foot with the floor. Adapted from [Taylor et al. 1998].

In terms of frequency, in general a frequency that would allow for sustained contraction, but minimizes fatigue effects is desirable. In terms of FES applied to CP children, frequencies in the range of 30 to 50 Hz have been used [Carmick 1997; Comeaux et al. 1997; Durham et al. 2004; Postans and Granat 2005], with the most common ones in the range from 30 to 40 Hz.

There are different ways of applying the stimulation: transcutaneously (through surface electrodes), percutaneously or through implanted electrodes. Of these, however, commercial devices available are primarily single channel surface stimulators [Lyons et al. 2002] and transcutaneous stimulation systems make up the majority of published reports [Chae and Yu 2000].

In terms of surface stimulation, self-adhesive electrodes represent the easiest to apply [Nelson et al. 1980] and they are the commonly used in the clinical environment.

Regarding the size of the electrode, it should be taken into account that the smaller the electrode, the more specific is the stimulation. On the other hand, comfort studies
show that the bigger the electrode, the more comfortable the stimulation is reported [Alon et al. 1994]. Standard sizes electrodes of 25, 32, 38 and 50 mm diameter are available (Axelgaard Manufacturing Co. Ltd\(^1\), Nidd Valley Medical Ltd\(^2\)).

The surface electrodes can be positioned either over a peripheral nerve or over a muscle, normally near to the motor point. For example, to achieve dorsiflexion of the foot, the usual technique is to place the active electrode (cathode) over the common peroneal nerve just below the head of the fibula and the anode over the motor point of tibialis anterior as shown in figure 3.2 [Taylor et al. 1998].

![Diagram of electrode positioning](image)

Figure 3.2 Positioning of the electrodes: usually, the active electrode is placed over the common peroneal nerve and the anode over the motor point of tibialis [Taylor et al. 1998].

### 3.3 Use of FES as a Treatment for CP

Electrical stimulation as a treatment option for cerebral palsy has been applied in different ways. First, stimulation may be applied at a low intensity below contraction level for several hours during day or night under the hypothesis that it may promote muscle growth by increasing blood flow [Pape et al. 1993; Pape 1997; Sommerfelt et

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1 Axelgaard Manufacturing Co. Ltd, Fallbrook CA 92028, USA; [www.axelgaard.com](http://www.axelgaard.com)

2 Nidd Valley Medical Ltd, Knaresborough, North Yorkshire, England HG5 9AY; [www.niddvalley.co.uk](http://www.niddvalley.co.uk)
al. 2001; Dali et al. 2002]. Second, stimulation could be applied therapeutically for shorter durations and at an intensity sufficient to cause contraction [Hazlewood et al. 1994; Bertoti et al. 1997; van der Linden et al. 2003] with the aim of improving or avoiding deterioration of passive and active range of motion and strengthening the muscles. Finally, stimulation could be applied functionally, so that it is triggered to assist in a functional activity.

The idea of applying electrical stimulation for improving gait in CP children is based on the assumption that the activation of certain muscles during different phases of gait, would allow for some correction of the gait abnormalities described in Chapter 2.

Much of the work in this respect has concentrated on the correction of the position of the ankle joint during gait (position of the foot during swing, at initial contact and during stance). Two different approaches have been proposed in the literature for correction of ankle position using FES.

One of them is the stimulation of tibialis anterior muscles during the swing phase of gait. As explained before (in Section 2.3.5.1), during late swing, a combination of increasing ankle plantarflexion, a loss of hip flexion and excessive flexion at the knee, results in a “toe-down” foot position. And, although the anterior tibialis commonly exhibit a response, this is too weak to hold up the foot. By stimulating this muscle, a stronger response would be allowed and the foot could be better positioned for initial contact. Also, the stimulation of the muscles at the beginning of the swing phase could help with toe clearance during swing, which could minimize the risks of tripping and falling.

Another approach is the stimulation of the triceps surae during the stance phase of gait. This method is used to provide knee stability through graded advancement of the tibia during the stance (in order to obtain knee extension, the advancement of the tibia should be restrained by action of the calf muscles), to minimize the excessive dorsiflexion during stance that accompanies crouch gait and, as evaluated by some investigators, to improve the position of the foot at initial contact (towards heel contact). In this respect, Comeaux et al [1997] suggested four possible mechanisms through which this would happen:

- The constant state of activity in the spastic gastrocnemius may be interrupted by the on-off of the stimulation (and a possible explanation for this would be
that the Golgi tendon acts as a tension feedback system so that increasing muscle tension in a muscle which is already taut, would elicit inhibition rather than excitation).

- Stimulation of the gastrocnemius may produce reciprocal inhibition of the tibialis anterior and in this way interrupt the constant co-activation of the muscles during the gait cycle, having a similar result as the previous point.

- Increase of gastrocnemius activity may produce a stretch reflex to the tibialis anterior initiating contraction of that muscle.

- Stimulation may serve as a proprioceptive input, which as it is also repetitive could provide the opportunity of learning.

It is the opinion of the author of this project that these mechanisms are plausible, however, since the results of Comeaux [1997] could not be reproduced by Pierce et al [2002; 2004a] and there are no further publications that would support those findings, further work is needed in order to establish the real outcome of this approach.

It has also been reported that adding calf stimulation during preswing to spinal cord injury patients who already had stimulation of their knee extensors and peroneal nerve, resulted in noticeable improvement in the forward and upward propulsion of the limb during swing, providing increased ground clearance and shortened the swing time [Bajd et al. 1995; Bajd et al. 1997; Bajd et al. 1999]. These authors also observed that in incomplete spinal cord injured patients, stimulation with the electrodes positioned over the triceps surae, could provoke the flexion withdrawal response of the whole limb.

Research carried out on the effects of FES when used as an orthotic device in CP children, through any of the described approaches, suggests that FES could provide improvements in gait for this population. Early works [Gracanin et al. 1976; Riso and Makley 1981; Naumann et al. 1985; Carmick 1993b] have been described in the literature [Stevens 2003], here a brief description of later representative research from different groups studying the use of FES as an orthotic device follows.

Johnson et al [2002] reported on the clinical work carried out with children in the Salisbury FES Clinic, U.K. Of the 65 children treated in this clinic at the time of writing the report, 68.2 % had cerebral palsy. Twenty-nine children used a single channel dropped foot stimulator for FES during gait. In the majority of cases the
common peroneal nerve was stimulated and timed to the swing phase of walking. Ten children used a two channel stimulator; of these, 6 had their common peroneal nerve stimulated bilaterally, 3 the common peroneal nerve and tibial nerve, one the common peroneal nerve and femoral nerve (quadriceps femoral muscle), one the tibial nerve bilaterally. Analysis of walking speed was carried out in 6 patients and physiological cost index measured in 4 patients; there was an increase in walking speed and reduction in physiological cost index when stimulation was applied (there is no mention of normalization of data to account for growth of the children). The authors reported that qualitative improvements in walking pattern do not always correlate with increases in walking speed.

Betz and Mulcahey [2000], on the other hand, described the experience of using FES at the Shriners Hospital in Philadelphia, U.S.A. in the form of a general review including its use in upper and lower limbs, their opinion regarding the use of implanted systems in children, and also their future application of FES in combination with surgery in children with CP. When describing in particular their experience using FES as an option treatment for improving walking, the authors reported that preliminary results of FES suggested that step length could be increased, range of motion could be maintained or improved, and joint kinematics appear nearer normal values, when stimulation is applied. Unfortunately, as said before, they presented the information in a general review of the use of FES in the hospital and did not provide any details respect to the parameters used for stimulation. However, as it is one of the only two references describing the use of FES in clinical practice, the author of this project considered it appropriate to include this reference, in order to illustrate the clinical use of FES.

Later, this group has also investigated the benefits in moving from conventional surgery (as normally prescribed by the orthopaedic surgeon) to fewer (or non) surgical procedures augmented with functional electrical stimulation applied during walking [Johnston et al. 2004]. In this case they compared passive range of motion, gait spatiotemporal parameters, gross motor function (through the Gross Motor Function Measure) and energy cost of walking (through the volume of oxygen consumed) in seventeen children, 9 of which underwent traditional orthopaedic procedures and 8 underwent limited (or non) surgery plus training with FES. Five of the 8 children who
received FES underwent surgical procedure because of significant skeletal malalignment and/or limitations in passive ROM; however the FES group had 4.5 fewer surgical procedures per child than the surgical group. The measurements were done at baseline, 4 months after the operation and 12 months after the operation or start of the FES program, without FES. One year after intervention all children showed improvements in passive range of motion, spatiotemporal parameters and gross motor function. No differences were seen between groups before or after intervention. These results suggest that FES in combination with limited surgery may provide similar functional gains with fewer surgical procedures than traditional orthopaedic surgery.

In terms of correction of ankle dysfunction using FES, Carmick [1995] presented 3 different cases of study. The first case was a 34-month-old child diagnosed with spastic diplegic cerebral palsy. Initially, the treatment consisted of stimulation of the tibialis anterior muscles while the child was sitting, standing or walking, with stimulation being remotely triggered by the physiotherapist. The results were an apparent stronger plantar flexion. The treatment was then changed to stimulation of triceps surae during the stance phase of gait and the results of this approach were a plantigrade walking. This result was repeated in a second case with a 47-month-old child diagnosed with spastic diplegic cerebral palsy. In the third case with a 56-month-old child, diagnosed with spastic quadriplegic CP, the triceps surae were stimulated together with gluteus maximus and lateral hamstring. The results showed an increase in active and passive range of motion with no increase in spasticity. Unfortunately, the report lacks of objective measures that could indicate the significance of the improvements described.

Pierce et al. [2002; 2004a] further investigated the use of electrical stimulation on ankle kinematics, in this case, applied percutaneously. In the first study, four CP children (mean age 8.4 years) participated. The tibialis anterior and the gastrocnemius were stimulated during the swing phase and push off, respectively, through implanted electrodes. Kinematic data was obtained and the dorsiflexion angle at initial contact and peak angle of dorsiflexion in swing were measured for each condition. Significant
differences were found in both parameters when stimulation was applied only to the tibialis anterior compared with no stimulation applied. Also there was a significant difference between no stimulation and stimulation of both tibialis anterior and gastrocnemius. However, no significant differences in any of the parameters were found between the no stimulation condition and the stimulation of only gastrocnemius muscle. These results disagree with those presented in an earlier study by Comeaux et al. [1997], where significant differences were found in the mean ankle range of motion at initial contact, when stimulation was applied only to the gastrocnemius of 14 children with cerebral palsy compared to no stimulation condition. Also, significant differences were found when both, gastrocnemius and tibialis anterior muscles were stimulated. There were differences in the studies with respect to timing of stimulation of gastrocnemius: they were stimulated during push off in the study by Pierce but they were stimulated from just before initial contact until just after toe off in the study by Comeaux, which could have influenced the results. Another difference is that while in the study by Comeaux stimulation was triggered with a hand switch, in the study by Pierce, they used two or three foot switches per subject and the placement for those switches was determined by high areas of pressure previously analysed by a pressure measurement system. These studies were the only ones found (apart from the previous work by Carmick) where the stimulation was applied to the plantarflexors during stance with the aim of improving dorsiflexion angle during swing and at initial contact. Because the results do not coincide, further work would be needed to clarify if a different timing of stimulation (more similar to the one applied by Comeaux et al) would obtain results where dorsiflexion angles during swing and IC are improved.

Stevens et al. [2001; 2002; 2003] and Durham et al [2004] used an ABA approach (A: no intervention, B: intervention) to evaluate the orthotic and therapeutic effect of FES of the tibialis anterior muscles in children with cerebral palsy. The tibialis anterior of 10 children were stimulated and kinematic, kinetic, energy consumption and clinical measurements were made during each phase of the study. The results showed increased speed, increased heel-toe interval on the affected side, increased step and stride lengths, reduction on the contralateral side heel-toe interval and reduction in PCI when stimulation was applied. Some carry over effects were also
detected: significant increase in speed and stride length, comparing two consecutive sessions without stimulation. All the parameters were normalized to account for the effects of changes in height due to footwear and growth. Also, a questionnaire was distributed between parents and children. The answers cite improvements in type of initial contact (towards heel strike), standing with flat feet, toe clearance during swing and increased stability.

Instead of evaluating one particular approach in several children, Postans and Granat [2002; 2005] assessed the orthotic effect of FES on the gait of CP children by selecting different stimulation strategies according to the individual gait deviations. This approach would be more in accordance with the recommendations of evaluating each child individually and setting individual targets. In their study, eight children with a diagnosis of diplegic or hemiplegic spastic CP, aged between 8.11 and 17.6 years participated in the study. Each of the children underwent a baseline gait analysis to identify and quantify gait deviations. From this data, outcome measures and targets for improvement of these outcome measures were set for each of the children. Outcome measures defined included temporal-spatial variables, mode of initial contact and summary variables of the kinematic data (e.g. minimum dorsiflexion in swing phase). Different FES strategies were tested to determine the most effective intervention for each subject. The strategies used were bilateral ankle dorsiflexion in swing (four subjects), unilateral ankle dorsiflexion in swing (one subject), unilateral knee extension and ankle dorsiflexion in swing (two subjects) and unilateral knee extension and ankle plantar flexion in stance (one subject). Simulation was triggered by a foot switch. Kinematic and kinetic data was collected. The results showed consistent improvements for four children, mixed results for one child (who had assisted ankle dorsiflexion during swing) and little or no change in the remaining three children (two had unilateral knee extension and ankle dorsiflexion in swing and one had bilateral ankle dorsiflexion in swing).

As is the case with other treatments for CP, the evidence of the effects of FES on children is not conclusive. In most of the studies reported the number of children included is not sufficient to generalize the results and, even with reduced numbers, the
Chapter 3. Functional Electrical Stimulation

results are not homogeneous to all children. Some of the factors already discussed in Chapter 2, for example differences in severity of cerebral palsy, also apply to the evaluation of FES. Often, researchers mention that the treatment has clearer benefits in some children than in others, however the criteria to select those who could benefit still need to be developed. The research work done so far suggests that FES can provide benefit for children with CP but further work needs to be carried out into stimulation approaches and the definition of clearer patients selection criteria.

3.4 Equipment Used to Apply FES in CP Patients

Pioneering the use of functional electrical stimulation to restore gait, Liberson and colleagues [1961] proposed a system to compensate for foot drop in hemiplegic patients.

Foot drop is a condition in which the patient has difficulty dorsiflexing the foot during swing and is a common problem following stroke and multiple sclerosis. As a consequence, there is not sufficient clearance during walking, which can lead to stumbling and falling [Popovic et al. 2001]. The use of functional electrical stimulation to correct it requires stimulation to be applied during the swing phase of the affected leg so that the foot is dorsiflexed and prevention of an equinovarus position is achieved, which permits patients to walk faster and reduce the effort of walking [Rozman et al. 1997; Taylor et al. 1999a].

The system proposed by Liberson consisted of a single-channel stimulator unit, electrodes positioned for stimulation of the common peroneal nerve, a heel switch that triggered and stopped stimulation and wires connecting the stimulator (worn on a belt in the waist) with the sensor and electrodes (Figure 3.3). Stimulation was applied at heel off and terminated at heel strike. Since the work of Liberson, other stimulators have been developed for foot drop correction, evolving from single channel surface system, to multichannel surface system, to partially implanted systems and moving towards the totally implantable system (which would also incorporate an implantable sensor)[Lyons et al. 2002].

Multichannel stimulators have been used mainly in the research environment[Brandell 1982; Naumann et al. 1985; Michael and Ewins 1995; Bijak et al. 1997; Michael et al.
1997; Bijak et al. 1999; Ewins et al. 1999; Wright et al. 1999; O'Keeffe and Lyons 2002]. The main characteristic of these stimulators is their versatility in terms of stimulation channels, stimulation programs and/or sensor inputs. Their main objective is to investigate different patterns of stimulation or different triggering sequences. An additional versatility is achieved if an interface with a computer allows changing the parameters.

![Diagram](image)

Figure 3.3 The system proposed by Liberson et al. S: stimulator, R: shunt resistor, E1: active electrode, E2: inactive electrode, K: foot switch [Liberson et al. 1961].

In terms of drop foot correction, some of the commercially available stimulators with their characteristics are listed in Table 3.1 (information regarding the stimulators produced in Slovenia, Fepa 10 and Microfes, was obtained from the works by Acimovic [1987] and Vodovnik [1978], which were improved versions of the Functional Peroneal Splint [Vodovnik et al. 1965]). The devices described are single-channel surface stimulator, except for the Compex Motion which is a four channel surface stimulators, all recommended for correction of drop foot condition.

The stimulators used for foot drop correction in adults are also used for correction of toe walking in children with CP, in research and in clinical application. However,
none of these devices have been designed specially for children and most of the researchers involved in the paediatric application of FES agree that in terms of transcutaneous electrical stimulation, the convenience and cosmesis of the device should be improved to encourage use and increase acceptability from children and parents or careers [Wright 2001; Johnson et al. 2002; Stevens 2003; Durham et al. 2004].

3.5 Current Limitations of the Technique and the Focus of this Work

Researchers at Salisbury District Hospital evaluated the difficulties that adult users of the Odstock one channel surface stimulator experienced [Taylor et al. 1999b]. A questionnaire was sent to 168 current users and 123 past users of the stimulator, of which 107 (64%) current users and 53 (43%) past users replied.

The survey investigated, among other issues, the main reasons for continuing using the stimulator in the case of current users and the main reasons for discontinuing its use for past users.

The results showed that the main reasons for using the stimulator were reduced effort of walking (and that represented the main reason for 29% of the respondents), reduced risk of tripping (and this was the primary reason for 15%) and increased walking distance (for the 9.4% of the surveys). The main difficulties experienced by this group were positioning of electrodes (43.9%), unreliable equipment (39.3%) and skin allergies (22.4%).
Table 3.1 Commercially available functional electrical stimulators for foot drop correction with their general characteristics. F.S.: foot switch, FSR: Force Sensitive Resistor; G: gyroscope. Production: the approximate number of unites produced until 2002 according to Lyons [Lyons et al. 2002].

<table>
<thead>
<tr>
<th>Manufactured or Commercialised</th>
<th>Walking-Man II</th>
<th>Compex Motion</th>
<th>WalkAid</th>
<th>Footlifter KDC 2000A</th>
<th>Odstock (ODFS III)</th>
<th>FEPA –</th>
<th>Microfes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manuf. or Commercialised</td>
<td>CyberMedic Co LTD³</td>
<td>Compex S.A.⁴</td>
<td>Neuromotion, Inc.⁵</td>
<td>Elmetec⁷</td>
<td>Odstock Medical Limited⁸</td>
<td>Institute of Rehab. Rep of Slovenia and AMF⁹</td>
<td>Gorenje, Slovenia¹⁰</td>
</tr>
<tr>
<td>Size [mm]</td>
<td>115 x 80 x 18</td>
<td>148 x 80 x 20</td>
<td>--</td>
<td>50 x 62 x 20</td>
<td>95 x 60 x 25</td>
<td>112 x 73 x 38</td>
<td>65 x 45 x 18</td>
</tr>
<tr>
<td>Weight [g]</td>
<td>112</td>
<td>420</td>
<td>--</td>
<td>75</td>
<td>142.6</td>
<td>190</td>
<td>65</td>
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<tr>
<td>Production</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>6000</td>
<td>1500</td>
<td>5500</td>
<td>500</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Picture</th>
<th>Walking Man</th>
<th>Compex</th>
<th>WalkAid</th>
<th>Foot Lifter</th>
<th>Odstock</th>
</tr>
</thead>
</table>

³ CyberMedic Co, LTD, 191-17 Young-Deung Dong, Ik-San Si, Cheon-buk, Korea, [www.cybermedic.co.kr](http://www.cybermedic.co.kr)
⁵ Neuromotion, Inc., University of Alberta spin off company, Edmonton, Alberta, Canada
⁶ Hanger Orthopedic Group Inc, Two Bethesda Metro Center, Suite 1200, Bethesda, 20814 Maryland, USA, [http://www.hanger.com](http://www.hanger.com)
⁷ Elmetec S/A, Nordlandsvej 64-66, 8240 Risskov, Denmark, [www.elmetec.dk](http://www.elmetec.dk)
⁸ Odstock Medical Limited, The National Clinic FES Centre, Salisbury District Hospital, Salisbury, Wiltshire, SP2 8BJ, United Kingdom, [www.odstockmedical.com](http://www.odstockmedical.com)
⁹ [Acimovic, Gross et al, 1987]
¹⁰ [Acimovic, Gross et al, 1987]
Past users reported their main reason for discontinuing the use of the stimulator as:

- improvement in mobility (10 subjects, 18.8%),
- deterioration in condition (18.8%),
- problems with electrode positioning (6 subjects, 11.3%),
- no benefits in walking (5.7%),
- skin allergies (5.7%),
- equipment too difficult to use (3.8%),
- unreliable equipment (3.8%),
- equipment too much bother (1 subject, 1.9%)
- pain from stimulation (1 subject, 1.9%)

The results of this study and experience of other authors [Rushton 1997; Chae and Yu 2000; Burridge 2001] show that the main difficulties experienced by functional electrical stimulators users specifically related to the application of the technology are:

- difficulty placing the electrodes at the correct location on a daily basis,
- difficulty operating the equipment, including setting up the foot switch,
- unreliable equipment (in the opinion of the authors of the study, the majority of the problems were related to the foot switch),
- skin allergy problems,
- difficulty tolerating the sensation produced by stimulation.

Although the survey was of an adult population, it is considered that children and their careers, as users of the technology, would experience similar difficulties using it, on top of the already mentioned issues of cosmesis.

3.5.1 Problems Related to Electrodes and Sensation

In order to minimize the difficulty placing the electrodes, it has been recommended that patients and careers should receive a thorough training in the positioning of electrodes and skin care. Also initial marking of the most appropriate site for the electrodes could be of extra help [Karsznia et al. 1990].
Also to minimize this difficulty, research has focused on the development of surface electrodes arrays that could help detecting the most appropriate position for the electrodes [Hernandez Silveira and Ewins 2005] and on the possibility of using percutaneous or implanted electrodes, which has been evaluated in adults [Kenney et al. 2001] and children [Pierce et al. 2002; Pierce et al. 2004a; Pierce et al. 2004b].

The sensation associated with stimulation is more than an issue in the case of children. Postans and Granat [2005], for example, reported that of the 21 children that attended a trial session, six did not tolerate electrical stimulation. Durham et al. [2004] also mentioned this as a problem. Percutaneous and implanted electrodes could eliminate the skin irritation problems and the sensation produced by stimulation, however due to the fact that percutaneous electrodes could contribute to skin infection and many patients dislike having wires emerging from the skin of their legs [Rushton 1997], clinicians and researchers suggest that for those subjects expected to be long-term users of the stimulator, the possibility of a total implanted device should be considered [Lyons et al. 2002].

3.5.2 Problems Related with the Sensor

In order to trigger and stop stimulation for toe walking in CP children, researchers have reported the use of hand held switches activated by the therapist at the appropriate time [Carmick 1993b; Carmick 1995; Comeaux et al. 1997] and foot switches activated by the contact (or lack of contact) of the foot with the floor [Betz and Mulcahey 2000; Pierce et al. 2002; Johnston et al. 2004; Pierce et al. 2004a; Pierce et al. 2004b; Lauer et al. 2005a].

Of these, the foot switch is the most widely used. As seen from Table 3.1, six of the seven commercial stimulators mentioned use a foot switch.

Some of these foot switches consist of one force sensitive resistors (FSR), placed under the heel or toe of the patient and connected through wires to the stimulator. However, as mentioned before, the use of the foot switch contributes to the difficulties operating the system and to the unreliability of the device. Also researchers have indicated that:

➢ it is cosmetically undesirable and is exposed to adverse conditions, causing frequent failures [Kostov et al. 1999],

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variation in both gait style and footwear can lead to occasional failure of the sensor or different detection pattern [Wall and Crosbie 1996; Henty et al. 1999; Ott 1999],

- they are prone to solder joints breakage and resistance change with age and use [Munih and Ichie 2001]

- the reliability is diminished due to their tendency to detect heel contact during the swing phase of gait as small forces are exerted on the heel during swing [Mansfield and Lyons 2003]

- its potential for further improvement (size, implantability) is limited [Willemsen et al. 1990].

Another practical limitation is that the subject should be shod in order to use the device.

In terms of the use of sensors specifically in children, Wright [2001] has pointed out that children appear to walk with a much greater variability in gait than adults so if an orthotic stimulator for children is to be more generally effective, the sensor will need to recognize a wide variety of patterns and speeds and adjust its timing accordingly. In such cases, the consistency of an effective heel strike may vary, so the footswitch type trigger, which can be effective for foot drop correction in adults may not be the best trigger to use in CP children.

Researchers have evaluated sensors that could replace or augment the use of foot switches, although the main focus of those evaluations have been their use in adults with foot drop condition.

From the commercially available stimulators listed, the Compex Motion [Keller et al. 2002] has been used with a combination of gyroscope and force sensitive resistors (described in Section 3.6 of this chapter), which could provide additional reliability for the detection, compared with force sensitive resistor alone [Pappas et al. 2001].

The WalkAid stimulator [Wieler et al. 1996], on the other hand, uses a tilt sensor [Dai et al. 1996], described in Section 3.6, which is contained as part of the stimulator itself. At the moment of writing, and to the best of the author knowledge, no publication regarding the evaluation of the stimulator has been published.
Other sensors have been evaluated as either gait event detectors (used in gait analysis, but potentially applicable for FES systems) or for replacing or augmenting the use of foot switches as control sensors for functional electrical stimulators. Some of the possibilities are also described in Section 3.6.

3.5.3 Focus of this Work

As mentioned in Section 1.3, this work is directed towards solving some of the problems related to the sensor part of the stimulator, focusing particularly in its use for children with CP. The project would be part of an overall project at the University of Surrey, towards the design and development of a stimulator that would be more appropriate for routine use in children.

3.6 Sensors Proposed to Control FES Systems

Some of the sensors that have been proposed for detection of gait events, either suggested for gait analysis applications or for their use as part of electrical stimulation systems are:

- Electromyograms (EMG) [Mokrusch and Klimmek 1995; Coiro et al. 2001; Kamono et al. 2001]
- Electroneurogram (ENG) [Haugland and Sinkjaer 1995]
- Tilt sensors [Dai et al. 1996; Chen et al. 2004]
- Accelerometers [Willemsen et al. 1990; Williamson and Andrews 2000a; Mansfield and Lyons 2003; Jasiewicz et al. 2006]
- Goniometers

Those sensors which use signals produced by the body itself are usually called "natural sensors", whereas the others are called "artificial sensors". A brief description of some of the studies involving these sensors follows.
3.6.1 Natural Sensors

So called "natural" sensors, having the intrinsic property of using signals being produced in the body, could represent a forward step (in current technology terms) for a total implantable stimulator system.

Electromyograms, measured both with percutaneous intramuscular electrodes [Coiro et al. 2001] and surface electrodes [Kamono et al. 2001] have been proposed. In the study by Coiro et al., four phases of gait were detected (weight acceptance, mid-stance, terminal-stance and initial swing) using EMG data from quadriceps muscles of a CP child. The authors proposed this method as the basis of a future FES control system to assist gait. The detections were done using a fuzzy algorithm, which was trained with the first trial of a series of 5. The system was evaluated using the other 4 trials. The detection was compared with kinematic detection using a motion analysis system. For four of the five events detected the error between the kinematic detection and the EMG detection was, on average, 3% of the gait cycle or less. The difference for terminal stance was 8.5%. Later, the same fuzzy algorithm was further developed [Lauer et al. 2004; Lauer et al. 2005b] and evaluated on two CP children with percutaneous electrodes and six with surface electrodes. Results showed that the overall (all subjects) time difference between kinematic detection and EMG detection was within 30 ms and individual accuracy (for all events) ranged from 95.3% to 98.7%.

The study by Kamono et al. involved the development of a functional electrical assist device, which uses surface EMG for detection of activation of tibialis anterior. As soon as the activation is detected, the muscles are stimulated. The system was evaluated on two stroke patients who improved their gait when using this device respect to the no stimulation condition, as shown by video picture analysis.

Researchers at Aalborg University in Denmark have been investigating the possibility of using electroneurograms to control peroneal nerve stimulators. Upshaw et. al. [1995] reported on the results obtained from a nerve-cuff electrode implanted around the calcaneal nerve of a multiple sclerosis patient (figure 3.4). The calcaneal nerve, which innervates the heel area, is believed to transmit purely afferent signals. The
signal from the nerve was amplified and the energy content of the nerve signal in a preset frequency range (1.2 to 1.6 Hz) was calculated. A threshold was applied to this new signal in order to determine heel contact. The results showed that for 1100 steps analysed, 85% of the heel contacts were detected using this signal, with 8% of false detections, compared with 2% of false detections with a foot switch. For push off detection using the same signal, only 60% of the events were detected, which the authors considered an unacceptable low rate.

Figure 3.4 Position of the nerve cuff electrode proposed by Upshaw et al [1995] around the calcaneal nerve.

Haugland and Sinjkaer [1995] at the same University explored the possibility of recording the signal from the sural nerve, instead (figure 3.5). The sural nerve transmits purely afferent (sensory) information and its inputs are touch sensors on the lateral part of the foot (shaded area in figure 3.5). A cuff electrode was implanted on the sural nerve of a spastic hemiplegic subject with drop foot. Recordings were made while the subject walked on a flat floor with and without shoes and with and without electrical stimulation. The recordings of the signal showed that when the foot touched the ground, the nerve responded with a sharp peak of activity which was followed by a series of small bursts in the stance phase of the step (these were attributed by the authors to tremor of the muscles of the foot when the subject was bare footed and to the influence of the shoes and socks when shod). There was no clear feature indicating heel lift and the signal remained high until the foot was in the air. The authors found some false detections of heel contact, although the extent of this problem was not reported, and it was attributed to the high sensitivity of the nerve signal to small, fast inputs to the skin, for example if the foot slid lightly across the floor during swing. Further signal conditioning and processing followed [Kostov et al. 1999; Hansen et al.
and the researchers evaluated the performance of the system when the subject was performing different tasks (walking, walking with stops and walking on stairs).

The results showed that both heel contact and foot off could be detected for all tasks. Walking on level ground could be detected without errors while the other activities presented approximately 10% errors (combination of missing events and extra events) when compared with FSR switches. For walking on level ground on a given day, 95% of HC detection fell within a 60 ms window of the FSR detection, while 95% of the foot off detections fell within 130 ms of the FSR detection.

More recently, Hansen et al. from the same university have evaluated the possibility of using peroneal nerve activity, which seem to mainly contain information from cutaneous sensors to derive timing control for stimulation in foot drop correction [Hansen et al. 2003]. In this case, the accuracy of the detection is highly dependant on the signal to noise ratio of the recorded ENG and in one of the two subjects tested, the performance was considered to be too poor for reliably use.
3.6.2 Artificial Sensors

Artificial sensors have also been proposed either alone or in combination to control foot drop stimulators. Other sensors have also been proposed either for multichannel stimulation [Fisekovic and Popovic 2001] or gait retraining [Cikajlo and Bajd 2001] or to be used as a portable kinematic data acquisition system [Nene et al. 1999; Mayagoitia et al. 2002; Sabatini et al. 2005]. A combination of sensors are mainly suggested when the complexity of the task (walking, standing, retraining) requires more than one sensor.

Dai et al. [1996] studied the use of tilt sensors to provide information about the time to start and stop stimulation for foot drop correction. Tilt sensors measure the angle between the sensor axis and a reference vector such as gravity or the earths magnetic field. After selecting the most appropriate tilt sensor for the application, the sensor was attached to a Velcro tape on the shank and used to control a peroneal nerve stimulator. Stimulation was turned on when the tilt signal exceeded the “on” threshold which corresponds to a predefined forward leg position (approximately, heel off) and turned off either if the tilt falls below a second level or a preset maximum period of stimulation was exceeded (approximately at heel contact). The initial trials with the sensor controlling the stimulator showed that a subject who had suffered a stroke could walk as fast as with the AFO. The authors pointed out that the threshold might need to be adjusted for different speeds of walking and that erratic tilt outputs from the shank that produced errors in detecting step intention was observed in subjects who have limited movement of the leg during swing.

Willemsen et al. [1990] proposed the use of an arrangement of four commercial single-axis accelerometers placed on the shank as shown in figure 3.6. The researchers were able to distinguish between different phases of the gait cycle (push off, swing, foot down and stance) using the equivalent acceleration at the ankle joint as calculated from the four accelerometers.

The system was evaluated in four unimpaired and four hemiplegic subjects and the results showed that from the 152 total steps from the healthy group 5 steps produced errors in detection of one of the phases and from the 106 steps from three of the
hemiplegics, there were errors in 3 steps. The algorithm could not identify the phases from the fourth hemiplegic subject gait, which the investigators believed was related to the use of crutches. It is also mentioned that the average time between heel contact (as measured by a foot switch) and the heel strike detection by the algorithm was 30 ms.

The authors also evaluated the result of using a single accelerometer closely below the knee and found similar detection accuracy. Based on this result, they suggested the possibility of incorporating the sensor into the stimulator unit, with the resultant elimination of the sensor lead.

Figure 3.6 Positioning of accelerometers on the subject. Four accelerometers represented by arrows are attached to a bracket at positions 1 and 2. There are two accelerometers at each location, one oriented tangentially to the bracket and the other oriented radial to the bracket [Willemsen et al. 1990].

Mansfield and Lyons [2003] used accelerometers to detect heel contact events and considered the possibility of using the sensor for FES systems. The accelerometer was placed on the trunk and the detection was based on the examination of the anterior-posterior horizontal acceleration signal. Comparing the detection using foot switches, for four adult subjects, the detection using accelerometer signal showed an average delay of $147 \pm 91$ ms. The difference between detections was consistent for different velocities but different for different subjects. The authors proposed to use this delay, experimentally determined, to predict heel contact events. When manually accounting
for errors in detecting the heel contact event, the foot switch correctly detected heel contact in a range of 92.4% to 98.7% (for different subjects), while the accelerometer correctly detected in a range from 98.2% to 99.8% (although it diminished slightly when the subjects simulated an hemiplegic gait). The detection of successive heel contact events could provide with walking speed data which could provide extra information for the stimulator (as proposed by Lyons et al. [2001]). However, another event should be used in order to control the trigger of stimulation, which has not been reported in this study. Also, in this study, information from the foot switch was used to process the accelerometer data in order to detect events. Future work should determine if that dependency could be eliminated or the control system would imply both sensors.

Williamson and Andrews [2000a] used a cluster of accelerometers placed on the shank to detect five phases of normal gait using a rule based algorithm. The system was evaluated in three able-bodied subjects and the gait phase detection presented an accuracy greater than 80%. The authors concluded that if the controller were used to initiate a FES walking system that stimulated at 33 Hz, the error would correspond to initiating or delaying the controller by a single sample interval. And, for this reason, the accuracy of the detector, although not ideal, could be considered sufficient to be tested in a FES system. In a follow up paper [Williamson and Andrews 2000b], they compared three different methods for processing the accelerometer signals (rule based algorithm, an adaptive logic network and a threshold algorithm) and found an overall accuracy (for all three unimpaired subjects and all phases detected) of 89% for rules based algorithm, 93% for the adaptive logic network and 92.1% for the threshold algorithm (for the threshold algorithm, only the accuracy for stance-swing detection was calculated).

Tong and Granat [1999] investigated the signal from two gyroscopes placed on the shank and thigh segments of one healthy and one hemiplegic subject. Segment inclination and knee angle were derived from segment angular velocities and compared to the one obtain with a motion analysis system. The correlation between derived angular data from gyroscope signal and angular data from kinematic analysis
was calculated and the results showed a coefficient of correlation between 0.90 and 0.94. Although it was not the main objective of the investigation the authors reported that, from visually inspecting the data obtained from gyroscopes and from the four foot switches placed under the foot, they could see a relation between the events detected by the footswitches and certain features in the gyroscope signal placed on the shank. The authors concluded that a single gyroscope on the shank segment could provide useful kinematic information such as segment inclination range and cadence, and that it is possible to identify different gait events.

Sagawa et al. [2000] used a gyroscope placed on the toe of eight subjects to estimate the beginning and end of the swing phase of gait, using a threshold algorithm. As this was part of a system aimed at measuring vertical and horizontal walking distances outside, results on event detection were not reported. Instead, results of the predicted distance and the actual distance were reported and showed an error of 5.3% for horizontal distance and 11% for vertical distance. A purely threshold algorithm may not be enough to account for differences in gait patterns, so the authors added time constraints to account for those differences. Unfortunately, no results were reported on the reliability of the algorithm.

Ghoussayni et al. [2001] evaluated a gyroscope as a sensor for foot-drop correction systems. Detection of heel contact, foot flat, heel rise and toe off using the gyroscope signal was compared with foot switch detection and kinematic detection (used as gold standard) for five able body subjects and three patients with foot drop.

Each of the unimpaired subjects performed six trials walking on a level floor, up and down a ramp and up and down stairs. The subjects with foot drop performed two trials one with and one without stimulation. The absolute mean differences obtained between the gyroscope and foot switches were 38 ms for HC and 118 ms for TO, for unimpaired subjects on level walking. The absolute mean differences for the patient group were 48 ms for HC without stimulation, 32 ms with stimulation, and 98 ms for TO without stimulation and 144 ms with stimulation. In a follow up work [Ghoussayni 2004], the author concentrated on the HC and Heel Rise events in an online detection system and found that the gyroscope had similar, although slightly
better performance accuracy with respect to the FSR (95.9% for able bodied and 93.8% for patients, for the gyroscope and 93.8% for able bodied and 91.2% for patients when using the foot switches).

Aminian et al. [2002] described an ambulatory system for estimation of spatio-temporal parameters during long periods of walking. The system used three gyroscopes on both shanks and one thigh, but used the gyroscopes at the shanks to detect left and right heel strikes and toe off and, using wavelet analysis, they estimated heel contact and toe off for 9 young adults and 11 elderly subjects. The detection was compared with that from the foot switches detection (one placed under the heel and another under the toe), and the results showed that 95% of the difference in HC were in the range of [7; 13] ms (gyroscope occurred later than FSR) whereas 95% of the TO detections were in the range of [-5 ; 4] ms.

Henty [2003] used a gyroscope on the foot to detect four events (heel contact, foot flat, heel rise and toe off) during gait and evaluated the possibility of using the sensor as part of a foot drop stimulator. Five unimpaired subject walked on level ground, ramp and stairs, while four hemiplegic subjects walked on level ground with and without stimulation. The absolute mean differences between kinematic data (manually analyzed) and the gyroscope showed a difference of 63 ms for all events and the differences between gyroscope and foot switch were 108 ms for all events and all terrains for unimpaired subjects. For hemiplegic subjects, the average of the absolute mean differences for all events between the gyroscope and foot switch was 82 ms without stimulation and 111 ms with stimulation; no data from a gold standard method was available when comparing the sensors performance in hemiplegic patients, which the author considered limiting at the time of analyzing the results.

Monaghan et al. [2004] proposed the use of a gyroscope on the shank in order to use it as part of a stimulator to stimulate during push-off. The algorithm integrates the angular velocity and uses values of change in angle to detect the time of stimulation. Although no specific results were shown, the authors reported that the gyroscope
algorithm probed to be more reliable in five stroke patients than the heel switch previously used.

Jasiewicz et al [2006] used accelerometers and gyroscopes to detect initial and end of contact. The authors compared detection using foot linear acceleration, foot angular velocity and shank angular velocity to foot switches placed under the heel and under the toe. The comparison was undertaken on 19 healthy volunteers and 13 spinal cord injured subjects. The results showed that for normal footfall patterns all three methods were equally accurate in comparison with foot switches. However, for pathological gait, the authors found that increased leg instability showed by considerable shank movement delayed the event detection in the patient group.

Pappas et al. [1999b] presented a combination of gyroscope and force sensitive resistors placed in the insole, as shown in figure 3.7, to be used as a control sensor for functional electrical stimulators. The angular data obtained from the integration of the gyroscope signal, together with the signals from the three FSR were used to detect four gait phases: stance, heel off, swing and heel strike. They compared the detection using this system with the detection using kinematic data from an optical measurement system. They evaluated the system in ten able body subjects and three incomplete spinal cord injured and found that the reliability was 99% and the accuracy (time delay) was smaller than 70 ms for all phases. In subsequent studies, they evaluated the sensor over a variety of terrains (slope, stairs, different surfaces) and found similar reliability rate [Pappas et al. 2001]. The also evaluated the sensor as part of an electrical stimulator (the Compex 2 system mentioned above) and found that the gait of two patients who presented foot drop improved in angle of dorsiflexion during swing and became more symmetrical with stimulation when compared to the without stimulation condition [Pappas et al. 2002; Pappas et al. 2004].

In this case, the design of the multisensor system is such that its placement does not necessarily represent extra inconvenience with respect to the placement of only one sensor. And, as the results of the research suggest, the reliability of the sensor is high even when used in different terrains. However, the combination still has limitations...
regarding cosmesis (as there will be wires connecting the insole with the stimulator),
the whole system will still be exposed to adverse conditions which could damage
some of the components; the change of the resistance in the case of FSR will still be
affected by age and use; its potential for further improvement (in terms of size and
implantation) would still be limited and the subject still needs to be shod with
appropriate shoes in order to use the device.

Figure 3.7 Placement of force sensitive resistors and gyroscope proposed by Pappas et al
[Pappas et al. 1999a].

The sensor – stimulator wire link issue could be addressed by implementation of a
wireless link from the foot switch to the stimulator (the idea has already been
developed for switches incorporated in crutches for voluntary control of stimulation
[Fiedler et al. 1995; Ott 1999] and for foot switches incorporated in insoles
[Vodovnik et al. 1978]). However, researchers in Ljubljana who implemented the idea
in the '70 as part of foot drop stimulators reported that the design never reached the
expected levels of practicality, reliability and costs as to be considered a widely
marketable solution [Kralj et al. 1995]. Also, the reports on switch changes of
behaviour due to age and use, the propensity to breakage and the need for the subject
to be shod remain to be solved.

Fisekovic and Popovic [2001] used a combination of goniometers at the knee and hip
joint, force sensing resistors built into the shoe insole and accelerometers at the hip as
part of a general purpose FES system (for standing, walking, reaching and grasping).
The system was tested for controlling stimulation on one paraplegic subject, who
walked faster, and with less physiological effort, when compared with hand control.
Cikajlo and Bajd [2001] used gyroscopes and accelerometer data to detect the onset of stance and swing. Both sensors were part of a multisensor system, which also included goniometers, for walking assessment and provision of cognitive feedback during re-education period. When the system was used in an incomplete SCI patient [Cikajlo and Bajd 2003], providing peroneal nerve stimulation, gait could be voluntarily improved (using information about the performance of the previous swing phase) and the duration of FES assistance during the swing could be decreased.

Sabatini et al [2005] also used a gyroscope and one biaxial accelerometer, both placed in the instep of the foot to measure the sagittal position and orientation of the foot and also estimate temporal gait parameters for example the stride time, and the relative stance. The gyroscope was used to detect gait events (stance, heel off, foot off and heel contact) in five unimpaired adults and the detection was compared to that from foot switches, in different inclinations (ramp down, level ground and ramp up) using a treadmill. The results showed that the gyroscope on the foot detected foot off earlier (35 ms average) than foot switches and detected heel contact with a mean difference of –2 ms.

3.6.3 Summary of Review

Table 3.2 provides with a summary of the sensors reviewed in the last sections. Only those that reported on the accuracy or reliability of the sensors in detection of events with respect to a reference are presented here.

The literature review shows that there are several different open lines of investigation regarding controlling options for FES. Most of those lines have been evaluated in unimpaired adults walking on level ground.

Fewer investigations involved different terrains and different speeds of walking, although it has been pointed that a sensor should perform reliably in a variety of terrains and at different speed to be able to control stimulation in a desirable manner.

Even fewer included a third gold standard (such as kinematic evaluation) that could provide a better understanding of the sensors capabilities respect to the foot switch.
Table 3.2. Summary of sensors reviewed in this chapter for detection of gait events.

<table>
<thead>
<tr>
<th>Researcher</th>
<th>Subjects included</th>
<th>Sensor evaluated</th>
<th>Events detected</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lauer et al [2004; 2005b]</td>
<td>8 children</td>
<td>CP EMG from quadriceps muscle</td>
<td>Weight Acceptance, Mid stance, Terminal Stance and Initial Swing</td>
<td>Within 30 ms from kinematic detection</td>
</tr>
<tr>
<td>Upshaw et al [1995]</td>
<td>1 adult with MS</td>
<td>Afferent signal from the calcaneal nerve</td>
<td>Heel Contact</td>
<td>85% of the HC were detected, with 8% of false detections</td>
</tr>
<tr>
<td>Haugland and Sinjkaer [1995], Kostov et al [1999], Hansen et al [2002]</td>
<td>1 adult with foot drop</td>
<td>Afferent signal from the sural nerve</td>
<td>Heel Contact and Foot Off</td>
<td>95% of HC detection fell within 60 ms of the FSR, 95% of FO within 130 ms</td>
</tr>
<tr>
<td>Hansen et al [Hansen et al. 2003]</td>
<td>2 adults with foot drop</td>
<td>Afferent signal from the peroneal nerve</td>
<td>Heel Contact and Foot Off</td>
<td>If the signal to noise ratio was 6 dB or higher, the results were similar to those obtained from sural nerve.</td>
</tr>
<tr>
<td>Dai [1996]</td>
<td>1 unimpaired adult and 2 adults with foot drop</td>
<td>Tilt sensor</td>
<td>Heel off and heel on</td>
<td>For one post-stroke patient, tilt sensor detected heel off 0.17 ± 0.15 ms before FSR and HC 0.05 ± 0.04 ms later than the FSR</td>
</tr>
<tr>
<td>Willemsen [1990]</td>
<td>4 unimpaired adults and 4 hemiplegic adults</td>
<td>4 Accelerometers on the shank</td>
<td>Push off, swing, foot down and stance</td>
<td>HC in unimpaired = -30 ± 60 ms. Identification of the phases from the data from one of the hemiplegic adults could not be done.</td>
</tr>
<tr>
<td>Mansfield and Lyons [2003]</td>
<td>4 unimpaired adults</td>
<td>1 accelerometer on the trunk</td>
<td>Heel Contact</td>
<td>Average delay of 147 ± 91 ms respect to FSR</td>
</tr>
<tr>
<td>Williamson and Andrews [2000a; 2000b]</td>
<td>3 unimpaired adults</td>
<td>3 accelerometers on the shank</td>
<td>Loading response, Mid-stance, terminal stance, pre-swing, swing</td>
<td>Overall accuracy of 93% when compared with FSR</td>
</tr>
</tbody>
</table>
### Chapter 3. Functional Electrical Stimulation

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Sensors</th>
<th>Events</th>
<th>Absolute mean difference for HC</th>
<th>Absolute mean difference for FO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ghoussayni [2001; 2004]</td>
<td>5 unimpaired adults and 3 patients with foot drop</td>
<td>1 gyroscope on the shank</td>
<td>Heel Contact, foot flat, heel rise, toe off</td>
<td>Mean difference for HC: 38 ms for unimp, 48 ms for patients</td>
<td>Absolute mean difference for FO: 118 ms for unimp, 98 ms for patients</td>
</tr>
<tr>
<td>Aminian [2002]</td>
<td>9 unimpaired young adults, 11 unimpaired elders</td>
<td>1 gyroscope on the shank</td>
<td>Heel Contact and Toe Off</td>
<td>95% of the differences with respect to FSR: [7; 13] ms for HC and [-5; 4] ms for TO</td>
<td></td>
</tr>
<tr>
<td>Henty [2003]</td>
<td>5 unimpaired adults, and four adults with foot drop</td>
<td>1 gyroscope of the foot</td>
<td>Heel Contact, Foot flat, Heel Rise, Toe Off</td>
<td>Absolute mean difference for all events respect to FSR: 108 ms for unimp and 82 ms for patients</td>
<td></td>
</tr>
<tr>
<td>Pappas et al [1999b; 2001; 2002; 2004]</td>
<td>10 unimpaired adults and 3 ISCI adults</td>
<td>Combination of 1 gyroscope and 3 FSR on the foot</td>
<td>Stance, Heel off, Swing and Heel Strike</td>
<td>Compared to kinematic data: reliability = 99% and mean difference smaller than 70 ms</td>
<td></td>
</tr>
<tr>
<td>Sabatini et al [2005]</td>
<td>5 unimpaired adults</td>
<td>One gyroscope on the foot</td>
<td>Stance, heel off, foot off and heel contact</td>
<td>Compared to FSR, FO was detected on average 35 ms earlier and HC 2 ms earlier.</td>
<td></td>
</tr>
</tbody>
</table>

Of the studies that included patients, almost all focused on adults and the number of patients was limited. Only the EMG has been evaluated in children Lauer et al [2004; 2005b]. These studies involved 8 children, of which one showed such a variable muscle activation pattern that had to be excluded. Also, the system was only evaluated on level ground. Further work would be required to evaluate whether the system is successful in a larger number of patients and if it remains valid when walking in different terrains.

To conclude, the literature shows that there are several lines of investigation open and that further work is needed to clarify their applicability in different situations (terrains, speeds) and in a wider patient population. There is no clear evidence than any of these alternatives would provide better detection than others when applied to children.

At this point, the author of this project decided to follow the approach of evaluating one of the sensors already reviewed but in the population under investigation, that is
to say in children with CP. This evaluation would imply a step forward in the general scheme of sensor evaluations.

Due to the promising results that the gyroscope has presented in the adult population and taking advantage of the in-house experience with the sensor, it was decided to further develop the work undertaken with gyroscope. Extending the research in this direction and if the results of this study showed that it is a good alternative for children, then a gyroscope based stimulator system could be implemented for both adults and paediatric populations.

3.6.3.1 Definition of “Acceptable Results”

As mentioned before, the FSR based foot switch is the most common sensor used in FES systems to improve gait. Given the positive results with such systems, when developing an alternative sensor it could be argued that the new sensor should detect gait events with at least the same accuracy and reliability as the FSR. However, it may be that improving the absolute accuracy of detection could lead to an improvement in stimulation timing and therefore benefit to the patient.

Unfortunately, although different sensors have been evaluated for FES, the author of this project found a lack of studies investigating the effect of a change in the timing of stimulation with respect to the events derived from the FSR.

The only reference found in this respect was Ott et al [1998]. These authors reported on two cases of adult patients using FES for drop foot correction and compared the effects on stimulation of manual triggering against triggering with an FSR under the heel. For one of the patients, the hand switch was pressed, on average, 400 ms after heel rise (standard deviation of 200 ms) and released, on average, 100 ms after initial contact (standard deviation of 200 ms), and no significant difference was found in the basic gait parameters measured (stride time, stride length, speed and cadence). For the other patient the differences in triggering were larger (hand switch was pressed, on average, 1100 ms after heel rise with a standard deviation of 300 ms, and released, on average 200 ms after initial contact, with a standard deviation of 100 ms) and significant differences in the basic gait parameters were found (in fact, the subject walked faster, with increase stride length).
Chapter 3. Functional Electrical Stimulation

From this report some conclusions can be drawn:

➤ For one of the patients, a difference of 400 ± 200 ms in heel rise and 100 ± 200 ms in heel contact did not cause differences in the basic kinematic measured from the walking pattern.

➤ For the patient where more differences were seen, the change in walking pattern represented an improvement. So, an actual difference in the timing of stimulation does not necessarily imply a detriment in the overall result of the treatment.

Unfortunately, although these results provide a starting point for the analysis, they are from two adult patients and cannot be generalized. Also, it is the opinion of the author of this project that the effect of a change in the stimulation timing will depend on several variables. These include:

➤ The “condition” of the neuromuscular system (for both the stimulated muscle and also the antagonist). This could affect the stimulation parameters chosen. For example, different authors used different ramp up times (Pierce et al. [2004b] used 0 ms, Postans and Granat [2005] used 100 to 200 ms, Carmick [1993a] and Comeaux et al [1997] used 500ms). A ramp up may be used to increase the comfort of stimulation and avoid evoking a clonus contraction of an antagonist. If a longer ramp is needed then, it is crucial that the stimulation starts as soon as possible, otherwise, the desired response could occur too late.

➤ The actual problem that the patient presents. It is possible that a child presents with sufficient clearance of the foot with the floor, but that the initial contact is with the toe. Then the main objective of the stimulation will be to correct the initial contact, in which case a delayed response (in mid-swing) may be acceptable.

➤ The speed of walking. If the patient walks fast, an inaccurate determination of events may have more noticeable results (in terms of error in percent of stance, for example) than if the patient walks more slowly.

➤ The differences between the new sensor and the FSR will also depend on the position of the FSR. Although in adults the FSR is normally placed under the heel, in the case of children with CP, as they may not present a consistent heel
strike, the FSR is often placed under the toe or first metatarsal head (see Table 4.1).

To conclude, there are no clear guidelines with respect to the effect of a difference in the stimulation timing on the results of the stimulation and it is possible that the effect varies, for example, with the patient condition. Further investigations are needed to clearly establish this effect.

However, for the scope of this project, the values presented by Ott et al. were taken as very crude guidelines. Therefore as a first approach, the author of this project considered that an absolute average difference between gyroscope and foot switch of $400 \pm 200$ ms in foot off and $100 \pm 200$ ms in for initial contact would be acceptable.

Future work should establish the real effect of the differences in patients with CP and they are considered here only on the basis of the lack of more appropriate evidence.

### 3.7 Conclusion

Functional Electrical Stimulation has been presented as a treatment option for improving the gait of children with cerebral palsy. As is the case with other clinical interventions, the results of studies are not unequivocal. However, it is possible to conclude that some of the children receive benefit from this treatment. Most of the researchers involved in these studies agree that, together with improving selection criteria, there is a need to improve current systems, in terms of cosmesis, adaptability to gait patterns and terrains, and easy of use.

The foot switch is the most commonly used sensor to trigger and stop stimulation. Six of the seven commercial devices presented make use of a foot switch to control stimulation and it is the most widely reported sensor used in studies involving FES in children with CP. However, it presents limitations in terms of cosmesis, easy of use and behaviour.

Several other sensors have been studied to replace or augment the use of foot switches, although the main focus of those evaluations have been in adults with foot drop and less literature has focussed on children with CP. The literature shows that there are several lines of investigation open and that further work is needed to clarify
the applicability of different sensors in different situations (terrains, speeds) and in a wider patient population.

Previous studies done at this Centre have shown promising results when using the gyroscope in the adult population. The small size and mass of the gyroscope used suggest that it could be possible to include it in the same enclosure as the stimulator. If a small stimulator were designed, then the whole system could be placed on the shank, near the position of the electrodes. In this case, much of the inconvenience of wires would be diminished, providing a more cosmetically acceptable system.

It was decided then to extend the research already done with the gyroscope into the paediatric population. If results of this study showed that it is a good alternative for children, then a stimulator system could be available for both adults and paediatric populations.

It was also decided, as very crude guidelines, that the difference between the gyroscope and the foot switches should be less than (mean absolute difference ± one standard deviation) 400 ± 200 ms for foot off and 100 ± 200 ms in for initial contact. These are considered to be only very crude guidelines, future work should establish the real effect of the differences in the patients with CP and these values are used here only on the basis of the lack of more appropriate evidence. Also, the reliability (in number of correctly detected events) of the new sensor should be at least as good as (or better) than the FSR.
4.1 Introduction

In Chapter 3 the use of FES in children with CP and the equipment routinely used for application of the treatment was reviewed. The main limitations of these systems discussed and, from the literature review, two main areas for improvement identified of which the one related to the sensor used to control the stimulation was selected for this project.

The next stage was to evaluate an alternative sensor that could be used to initiate and stop stimulation in children with CP. This chapter focuses on the description of the methods and sensors used for such an evaluation.

Initially, the contact events that could be utilized to control FES in this patient population were studied and a discussion is presented in section 4.2.

Then, as the alternative sensor would replace the FSR, the performance of both sensors needed to be compared. A description of the FSR and the algorithms used for detection of events is presented in Section 4.3.

Section 4.4 deals with the gyroscope, the sensor selected for evaluation as an alternative to FSR. Reasons for its selection, and a description of the algorithm used for detection are presented. The final section describes the hardware used for acquisition of the FSR and gyroscopes signals.

4.2 Events Detected

Drop foot stimulators using single foot switches generally detect two events. Depending on the position of the switch these are heel contact (HC) and heel rise (HR), or toe contact (TC) and toe off (TO).

In the case of children with CP, as explained in Chapter 3, two different approaches have been investigated for correction of Toe Walking. One is the stimulation of
tibialis anterior during swing and the other is the stimulation of gastrocnemius – soleus muscles during stance.

A mature and physiological pattern of tibialis anterior muscle activation normally shows an onset just before toe-off and full swing-phase activity continuing to approximately 40% of stance phase [Sutherland et al. 1988]. This activity of the muscle during this time allows for toe clearance during swing, correct positioning of the foot at the time of contact (so that it would result heel contact) and a controlled plantarflexion until toe contact. In order to obtain similar function in pathological cases, stimulation of tibialis anterior could start when the foot leaves the floor (either at HR or TO) and stopped when the foot lands on the floor (either at HC or TC) or an extension and / or ramp could be added from this point.

The mature pattern of gastrocnemius and soleus activity shows an onset during loading response (approximately, 20% of stance phase) until just before toe off (approximately, 80% of stance phase) [Sutherland et al. 1988]. This action controls the advancement of the tibia during mid stance, prevents hyperextension of the knee at the time of forefoot rocker and initiates knee flexion during terminal stance. To provide with similar function, stimulation could be started at the time of initial contact (or be delayed with an extension or ramp) and finished when the foot leaves the floor.

Different authors have used different activation times to start and stop stimulation. Table 4.1 summarizes the muscles stimulated and the timing of stimulation for the studies involving CP children and described in Chapter 3.

Half of the studies described in Table 4.1, use Initial Contact (which in unimpaired children and some CP children would be heel contact) and Toe Off as reference events and detecting these events would allow for stimulation of the two muscle groups. However, there are cases in which researchers have started or stopped stimulation “just before” one of these events or used the previous event (such as the use of Heel Rise instead of TO) and, with the information available, it is unclear whether starting or stopping at the time of the event would represent an unacceptable delay. Something similar occurs when starting or stopping “just after” an event. In these cases, however, it may be possible to use a fixed extension time or a falling ramp; which, although not necessarily ideal solution, it could provide with better timing of stimulation.
Table 4.1 Muscles stimulated and stimulation times reported in the literature used for children with CP. G-S: gastrocnemius and soleus; TA: tibialis anterior; GA: gastrocnemius; FSR: force sensitive resistors.

<table>
<thead>
<tr>
<th>Author</th>
<th>Sensor used for stimulation</th>
<th>Muscle stimulated</th>
<th>Time stimulation on</th>
<th>Time stimulation off</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carmick [1995]</td>
<td>Hand switch remotely triggered by physiotherapist</td>
<td>G-S during stance phase</td>
<td>Not specified</td>
<td>Not specified</td>
</tr>
<tr>
<td>Pierce [2002; 2004a]</td>
<td>FSR</td>
<td>TA during swing</td>
<td>Terminal Stance</td>
<td>Initial Contact</td>
</tr>
<tr>
<td></td>
<td></td>
<td>GA during push off</td>
<td>Mid - Stance</td>
<td>Terminal Stance</td>
</tr>
<tr>
<td>Pierce, Orlin et al. [2004b]</td>
<td>Foot Switch</td>
<td>TA during swing</td>
<td>Heel Rise</td>
<td>Heel Contact</td>
</tr>
<tr>
<td>Comeaux et al [1997]</td>
<td>Hand Switch remotely triggered by physiotherapist</td>
<td>GA</td>
<td>Just before Heel Contact</td>
<td>Just after Toe Off</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TA</td>
<td>Just after Toe Off</td>
<td>Just before Heel Contact</td>
</tr>
<tr>
<td>Stevens et al. [2001; 2002; 2003]</td>
<td>FSR</td>
<td>TA</td>
<td>Toe Off</td>
<td>Toe Contact</td>
</tr>
<tr>
<td>Durham et al. [2004]</td>
<td>FSR</td>
<td>TA</td>
<td>Toe Off</td>
<td>Toe Contact</td>
</tr>
<tr>
<td>Postans and Granat [2002; 2005]</td>
<td>FSR</td>
<td>TA</td>
<td>Toe Off or contralateral Initial Contact</td>
<td>Initial Contact</td>
</tr>
<tr>
<td></td>
<td></td>
<td>G-S</td>
<td>Fixed delay after Initial Contact</td>
<td>Toe Off</td>
</tr>
</tbody>
</table>

However, as described in Chapter 2, CP children could present an initial contact (IC) of the foot in the form of heel contact (the heel is the first clear contact point), or foot flat (here, it could be most of the sole of the foot or it could be the heel which starts the contact, but the foot is almost parallel to the floor) or toe contact (the toe is the first and sometimes the only, clear contact point). So, some of these children would not present a normal heel contact – toe on – heel rise – toe off pattern. Some of these events may be absent or delayed. However, in all cases, there will be an Initial Contact and Foot Off.
In the case of stimulation being applied to the adult population, normally the events used are HC and Heel Rise, however, this is not necessarily the case for children. In the first place, the heel may not be the first part of the foot contacting the floor. Secondly, in terms of heel rise, only one of the studies of table 4.1 used HR, while four of them used TO. IC and FO will be present in all pathological cases and they would provide timing for stimulation of both muscle groups. It was decided then that, as a first approach, this project would involve the detection of IC and FO. The use of an earlier event (such as HR) to start stimulation would allow for a longer ramp to be used (and in this case, avoid a clonus reaction in the antagonist muscle), which may be an advantage is some patients. As described in 8.7, future work, should explore the possibility of detecting HR. Previous work in adults [Ghoussayni 2004] demonstrated that it is possible to detect HR from the shank angular velocity, using a gyroscope. So, it is this author's opinion that detection may be possible in children, provided the event is present in the gait cycle.

4.3 Foot Switches

Foot switches are the most common used sensors in the clinical practice for control of the start and end of electrical stimulation in children with cerebral palsy. It was considered essential that if a new sensor was to replace the foot switch, their performances needed to be compared.

Early drop foot stimulators used an open-close mechanical type of switch. The main problems with these were deformation of the contacts with use leading to failure, breakage of the solder joints and sticking of the contacts [Lyons et al. 2002]. More recent systems use force sensitive resistors (FSR).

Force Sensor Resistors are devices that exhibit a decrease in resistance with an increase in the applied force. At the low force end of the force – resistance profile, the response is switch-like and after that the response, in general, follows an inverse power law characteristic (see figure 4.13 for typical responses, using different circuit configurations). It is the switch-like characteristic which is exploited to determine when pressure has been applied to it by the foot and when it is removed.
Chapter 4. Sensors Used for Detection of Gait Events

The sensors used in this project were purchased from the Department of Medical Physics and Biomedical Engineering of the Salisbury District Hospital\textsuperscript{1} [Swain and Taylor 2003].

4.3.1 Signal Processing for Foot Switch Event Detection

Different approaches have been reported in the literature for event detection using force sensitive resistors.

Aminian et al. [2002] suggested to first calculate the derivative of the switch signals and then to apply a threshold to it. The main limitation of this approach is that spurious forces applied to the switch during, for example, the swing phase could cause a spike in the derivative, with an amplitude of the same order as that from an actual heel strike, such that both spikes would be detected as HC events. In the case of Toe Off, as the unloading phase is more gradual, the derivative of the signal does not necessarily present the “one spike per event” pattern, and as noted by other authors [Housdorff et al. 1995] an algorithm relying on changes in the derivative, is less effective in distinguishing toe off.

The ODFS stimulator uses a tracking comparator as a method for detecting changes in the FSR due to foot contact and foot lift. In this case, the voltage at the non-inverting input of the comparator follows the voltage at the inverting input (which is the output of the voltage divider itself) but with a delay. This allows for gradual changes in the resistance of the foot switch as a result of, for example wear, but it will change state in response to a sudden change [Swain and Taylor 2003]. The tracking comparator algorithm represents a better option with respect to a fixed threshold algorithm for online detection as the selection of a fixed threshold would be difficult to implement online due to the effect that many variables, such as temperature, loading force and use of the foot switch have on the actual value of the resistance. However, as spurious forces also represent sudden changes, it is possible that those would create false detections. It was decided then to analyse this in the data collected for this project.

\textsuperscript{1} Department of Medical Physics and Biomedical Engineering of the Salisbury District Hospital Salisbury, Wiltshire, SP2 8BJ, UK. Web page: www.salisburyfes.com
The comparator approach was simulated off line by calculating a “comparing output signal” \( x_o(n) = x_i(n+1) - x_i(n-1) \) for the foot switch signal, where, \( x_i \) is the foot switch signal, and \( n \) is the sample number. If the signal in \( n+1 \) and \( n-1 \) is the same (has not suffered sudden changes) then, the output \( x_o \) value will be almost zero. If the signal has suddenly changed between those values, then it will be shown in the output as a high value. Figure 4.1 shows the metatarsal switch signal (from the FSR placed under the first metatarsal head) for subject 1 (S1 of the children who participated in the indoor evaluation of the gyroscope, described in Chapter 6) and the calculated comparing output signal, that is to say, the output of the comparison.

The figure shows that whenever there is a change in the switch signal from being loaded to unloaded, which occurs only once per cycle, there is a corresponding peak in the comparing output signal.

However, when calculating the comparing output signal for other children, it was clear that there were cases in which sudden changes of loading in the switch signals occurred that did not relate to the actual stance loading and unloading events. Figure 4.2, for example, show the heel switch signal and the comparing output signal calculated for subject 2 (of the children who participated in the indoor evaluation of the gyroscope, as described in chapter 6). In this case, it is possible to see that sudden changes in the heel switch also occurred during swing producing peaks similar in magnitude to the ones caused by real events. A similar behaviour can be seen in figure 4.3, which represents the heel switch signal of subject 3 (of the children who participated in the indoor evaluation of the gyroscope, as described in chapter 6).
Chapter 4. Sensors Used for Detection of Gait Events

Figure 4.1 Metatarsal switch and comparing output signal for the metatarsal switch, for subject 1 (of the children who participated in the indoor evaluation of the gyroscope, Chapter 6). It is possible to see that whenever there is a rapid change in the metatarsal switch signal, there is a corresponding peak in the comparing signal.

Figure 4.2 Heel switch and comparing output signal for the metatarsal switch, for subject 2 (of the children who participated in the indoor evaluation of the gyroscope, Chapter 6). It is possible to see that sudden changes in the heel switch occurring mainly during swing produce peaks similar in magnitude to the ones caused by real events. If all positive peaks were considered sudden changes due to heel off, then real and false events would be detected. This is also the case for negative peaks being considered sudden changes due to heel contact.
Figure 4.3 Heel switch and comparing output signal for the metatarsal switch, for subject 3 of the children who participated in the indoor evaluation of the gyroscope, as described in chapter 6. It is possible to see again (as in figure 4.2) that sudden changes in the heel switch occurring mainly during swing produce peaks similar in magnitude to the ones caused by real events. If all positive peaks were considered sudden changes due to heel off, then real and false events would be detected. This is also the case for negative peaks being considered sudden changes due to heel contact.

Another approach applies a threshold to the switch signal itself [Housdorff et al. 1995; Pierce et al. 2002; Smith et al. 2002; Mansfield and Lyons 2003]. Again with this approach, spurious forces applied during for example the swing phase could produce a false detection, however the amplitude of both spikes are not usually of the same order. In order to avoid detection of spurious forces as events, the threshold for detection needs to be high enough. Mansfield and Lyons [2003] used a threshold of 97.5% of the maximum value of the signal for HC, whereas Smith et al. [2002] used a threshold which was “midway” between the minimum and the maximum. Housdorff et al. [1995] calculated first the switch derivative, then found a local minimum in the area of the rising and falling edges of the switch signal and finally, the threshold was calculated as an arbitrary offset taken from that local minimum.

As this project involved off line detection only, it was decided to use a threshold on the switch signal itself as it was considered the best alternative to avoid false detections (and, as it was an off-line detection, the selection of an appropriate
threshold does not need to make assumptions regarding the value of the resistance or the magnitude of the change). The threshold was chosen, following the approach presented by Smith et al [2002], to be the mean value of the signal as it proved to be high enough to avoid false detections and the nearest possible to the beginning of the event. The algorithm for detection (see Appendix C) was written using the mathematical program Matlab®.

Other advantages of using the range between the value when no force is applied and the maximum response, regardless of the actual value of the resistance, is that it allows for gradual changes in the exact value of resistance (for example, due to age or wear) or baseline pressures being applied to the switch due to, for example, tied shoelaces.

For unimpaired and CP children, the Initial Contact would be considered the first contact (either HC or Toe Contact) and Foot Off would be the last break of contact (either Heel Off or TO).

In Figures 4.4 and 4.5, the signals from the heel switch and metatarsal switch from a CP child are shown (data was collected as part of this project).

![Figure 4.4 Heel switch signal from a CP child (subject 7) who participated of the indoor evaluation of the gyroscope, explained in Chapter 6. The red line represents the threshold used for detection. The frame at which the signal was below the threshold was considered HC, as indicated in the figure.](image-url)
4.4 Gyroscope

As explained in Chapter 3, there is very limited literature regarding the evaluation of sensors to control electrical stimulation in the children population. The decision to start by evaluating a gyroscope was based on previous work at Surrey [Henty et al. 1999; Ghoussayni 2000; Ghoussayni et al. 2001; Henty 2003; Ghoussayni 2004; Ghoussayni et al. 2004], in which use of a gyroscope in the adult population had shown promising results, and it was decided to extend such an evaluation to children.

The working principle of the gyroscope was reviewed and is presented in Appendix D.

Several gyroscopes are available in the market (see Table 4.2). In order to select which of these sensors to use, the following factors were taken into account:

- Measurement range: previous work [Staerck 2002] on the angular velocity of children with CP, calculated from kinematic data suggested that the range of angular velocity of the shank in CP children does not exceed $\pm 280$ deg/s; however, the angular velocity in normal children during swing phase could...
exceed this value. A minimum range of angular velocity was taken to be ± 300 deg/s.

➤ Weight and size: these two parameters should be minimised to avoid encumbrance to the subject while walking and to allow for an appropriate design of the whole system. The FSR used in this project and also used with the ODSF III stimulator, weighs 2.2 g and measures approximately 52 x 32 x 1 mm and this was the comparison point.

➤ Cost and availability.

The next step was to evaluate the commercially available gyroscopes against these specifications. Table 4.2 lists the gyroscopes found that were sold as components rather than part of other systems (the data presented in the table was checked in February 2006 and that was the last access date for the web pages mentioned).

From the gyroscopes listed above, a quotation was requested from those with a measurement range equal to or greater than ± 300 deg/s and weights and sizes at least half the size of the smaller stimulators mentioned in chapter 3. The prices (February 2006) are listed in Table 4.3. Unfortunately, although quotations were requested several times, they could not be obtained for the Nec Tokin CG L53 gyroscope, therefore it was not considered further.

Of the available Murata gyroscopes models, the ENC 03M was released in 2002 and although it was available at the time of starting this project, the price of it was double that of the ENC 03J (which at the time of buying cost £18). It can be seen from table 4.3, the prices reverted by February 2006. As both have the same technical specifications but different size (the difference in size between both was considered irrelevant for the purpose of this project), it was decided to use the 03J.

Similarly, considering the size / price relationship between the ENC 03J and the ADXRS300, from Analog Devices, given that the range of measurement was the same, the difference in size was again considered irrelevant for the purpose of this project and it was decided to use the ENC 03J, which was the cheapest option.

The sensor is a vibrating gyroscope that uses the Coriolis effect to measure angular velocity and whose performance has been tested and evaluated by Henty [2003] and Ghoussayni [2000] comparing the gyroscope output to angular velocities obtained using a optical motion system.
Table 4.2 Commercial gyroscopes that are available in the market as single components.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Part number or name</th>
<th>Mass (g)</th>
<th>Dimensions (mm)</th>
<th>Range (deg/s)</th>
<th>Scale factor (mV/deg/Sr)</th>
<th>Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Murata²</td>
<td>ENC-03M</td>
<td>0.4</td>
<td>12.2 x 7.0 x 2.6</td>
<td>±300</td>
<td>0.67</td>
<td>SR 500g</td>
</tr>
<tr>
<td></td>
<td>ENC-03J</td>
<td>1.0 (max)</td>
<td>15.5 x 4.3 x 8.0</td>
<td>±300</td>
<td>0.67</td>
<td>VR at frequency 10-55 Hz, amplitude 1.5 mm p-p duration 2 hours.</td>
</tr>
<tr>
<td></td>
<td>ENC-05E</td>
<td>2.7</td>
<td>21.5 x 8.5 x 7.1</td>
<td>±90</td>
<td>1.1</td>
<td></td>
</tr>
<tr>
<td>Watson Ind.³</td>
<td>ARS-10E</td>
<td>50</td>
<td>76.2 x 28.7 x 52.3</td>
<td>±700</td>
<td>3 – 30 deg/s/V</td>
<td>SR 200 g</td>
</tr>
<tr>
<td></td>
<td>VSG-100</td>
<td>138</td>
<td>75.2 x 42.5 x 39.6</td>
<td>±200</td>
<td>10 – 40 deg/s/V</td>
<td>MTF 50000 hours.</td>
</tr>
<tr>
<td>Analog Devices⁴</td>
<td>ADXR S 150</td>
<td>0.5</td>
<td>7 x 7 x 3</td>
<td>±150</td>
<td>12.5</td>
<td>SR 2000g powered shock</td>
</tr>
<tr>
<td></td>
<td>ADXR S 300</td>
<td>0.5</td>
<td>7 x 7 x 3</td>
<td>±300</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ADXR S 401</td>
<td>0.5</td>
<td>7 x 7 x 3</td>
<td>±75</td>
<td>15</td>
<td></td>
</tr>
<tr>
<td>Micro Sensors⁵</td>
<td>MicroRing Gyro</td>
<td></td>
<td>±60</td>
<td>25</td>
<td></td>
<td>SR 1500 g</td>
</tr>
<tr>
<td></td>
<td>CRS03</td>
<td>18 (max)</td>
<td>29 x 29 x 18.4</td>
<td>±200</td>
<td>10 – 20</td>
<td>Under development.</td>
</tr>
<tr>
<td></td>
<td>CRS03-11</td>
<td>10</td>
<td>27 x 27 x 10.6</td>
<td>±573</td>
<td>3.5</td>
<td>SR 200 g, VR 2g rms (20 Hz to 2 KHz, random)</td>
</tr>
<tr>
<td></td>
<td>CRS05</td>
<td>11</td>
<td>19 x 45 x 11.3</td>
<td>±50 to ±200</td>
<td>10 - 40</td>
<td>SR 200 g, VR 2g rms (20 Hz to 2 KHz, random)</td>
</tr>
<tr>
<td></td>
<td>SiRRS01</td>
<td>35</td>
<td>31.6 x 31.6 x 17.3</td>
<td>±110</td>
<td>18.2</td>
<td>SR: 60g, 30 ms, half sine wave. VR: 10g rms (20 Hz to 2 kHz). MTF: 300000 hours</td>
</tr>
</tbody>
</table>

² Murata Manufacturing Co., Ltd. [www.murata.com](http://www.murata.com)
⁴ Analog Devices: [http://www.analog.com](http://www.analog.com)
⁵ MicroSensors Inc., [http://www.microsensors.com](http://www.microsensors.com)
⁶ SiliconSensor, [http://www.siliconsensing.com](http://www.siliconsensing.com)
<table>
<thead>
<tr>
<th>Sensor Type</th>
<th>Brand/Model</th>
<th>Dimensions (mm)</th>
<th>Active Area (mm²)</th>
<th>Operating Voltage (V)</th>
<th>Operating Temperature (°C)</th>
<th>SR (g)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRS07</td>
<td>ATA</td>
<td>10 (max)</td>
<td>21 x 22 x 11.5</td>
<td>± 573</td>
<td>3.5</td>
<td>200</td>
<td></td>
</tr>
<tr>
<td>ARS-01</td>
<td>ATA</td>
<td>50 (max)</td>
<td>Ø 22.0 x 28.0 high</td>
<td>± 11500</td>
<td>0.87</td>
<td></td>
<td>New release.</td>
</tr>
<tr>
<td>ARS-06</td>
<td>ATA</td>
<td>35 (max)</td>
<td>Ø 18.0 x 27.5 high</td>
<td>± 11500</td>
<td>0.87</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ARS-09</td>
<td>ATA</td>
<td>50 (max)</td>
<td>Ø 30.5 x 21.3 high</td>
<td>± 100</td>
<td>100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ARS-12</td>
<td>ATA</td>
<td>300 (max)</td>
<td>38.0 x 38.0 x 40.6</td>
<td>± 57</td>
<td>0.17-1.7-17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SAR 10</td>
<td>JAE</td>
<td>11.1 x 7.9 x 4.3</td>
<td>± 250</td>
<td></td>
<td>SR: 5000g (0.3 ms half sine wave)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>JG - 108FA</td>
<td>JAE</td>
<td>80 x 80 x 45</td>
<td>± 100</td>
<td>0.05</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>JG - 108FD</td>
<td>JAE</td>
<td>82 x 82 x 71</td>
<td>± 180</td>
<td>0.01</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GyroPack</td>
<td>O-Navi LLC</td>
<td>20 x 20 x 6</td>
<td>± 200 and ± 400</td>
<td>12.5</td>
<td>SR: 500g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CG L43</td>
<td>NEC Tokin</td>
<td>8 x 15.5 x 5</td>
<td>± 90</td>
<td>0.66</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CG L53</td>
<td>BEI Technol</td>
<td>6 x 10 x 2.5</td>
<td>± 1500</td>
<td>0.66</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QRS100</td>
<td>BEI Technol</td>
<td>60 (max)</td>
<td>Ø 41.3, 16.4 high</td>
<td>± 1000 (max)</td>
<td>SR: 200g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>QRS 14</td>
<td>BEI Technol</td>
<td>50 (max)</td>
<td>68.6 x 25.6 x 25.6</td>
<td>± 1000 (max)</td>
<td>SR: 200g</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Horizon Series</td>
<td></td>
<td>60 (max)</td>
<td>58.0 x 25.9 x 25.4</td>
<td>± 200 (max)</td>
<td>SR: 200g (2g rms (20 Hz to 20 KHz random), 5 minutes)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LCG 50</td>
<td>BEI Technol</td>
<td>12</td>
<td>29.4 x 29.4 x 10.7</td>
<td>± 250 (max)</td>
<td>SR: 500g (half sine wav, 2 ms) VR: 10g rms</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

8 Infineon Technologies SensoNor SA, [http://smi.nextframe.net](http://smi.nextframe.net)
9 Japan Aviation Electronics Industry, Ltd., [http://www.jae.co.jp/e-top](http://www.jae.co.jp/e-top)
10 ONavi LLC, [http://www.o-navi.com](http://www.o-navi.com)
11 NEC Tokin Corporation
### Table 4.3 Prices of gyroscopes.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Part number or name</th>
<th>Mass (g)</th>
<th>Dimensions (mm)</th>
<th>Range (deg/s)</th>
<th>Price (02-2006)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Murata</td>
<td>ENC-03M</td>
<td>0.4</td>
<td>12.2 x 7.0 x 2.6</td>
<td>± 300</td>
<td>£ 18.3 (£36.0 at the time of buying)</td>
</tr>
<tr>
<td></td>
<td>ENC-03J</td>
<td>1.0 (max)</td>
<td>15.5 x 4.3 x 8.0</td>
<td>± 300</td>
<td>£ 32.7 (£18.5 at the time of buying)</td>
</tr>
<tr>
<td>Analog Devices</td>
<td>ADXRS 300</td>
<td>0.5</td>
<td>7 x 7 x 3</td>
<td>±300</td>
<td>£ 32.4</td>
</tr>
<tr>
<td>Silicon Sensor</td>
<td>CRS03 - 11</td>
<td>10</td>
<td>27 x 27 x 10.6</td>
<td>±573</td>
<td>£57 (1-5)</td>
</tr>
<tr>
<td></td>
<td>CRS07</td>
<td>10 (max)</td>
<td>21 x 22 x 11.5</td>
<td>±573</td>
<td>£66 (1-5)</td>
</tr>
<tr>
<td>ATA</td>
<td>ARS - 01</td>
<td>50 (max)</td>
<td>Ø 22.0 x 28.0 high</td>
<td>±11500</td>
<td>Became obsolete</td>
</tr>
<tr>
<td></td>
<td>ARS - 06</td>
<td>35 (max)</td>
<td>Ø 18.0 x 27.5 high</td>
<td>±11500</td>
<td>£1220.05 (each, buying 5 to 9)</td>
</tr>
<tr>
<td>O-Navi LLC</td>
<td>GyroPack</td>
<td>1.75</td>
<td>20 x 20 x 6</td>
<td>±200 and ±400</td>
<td>£ 86 Price (as listed in the web page from 09/2004 USA dollars $150 for approx 400)</td>
</tr>
<tr>
<td>Nec Tokin</td>
<td>CG L53</td>
<td></td>
<td>6 x 10 x 2.5</td>
<td>±1500</td>
<td>No price provided</td>
</tr>
<tr>
<td>BEI Technologies</td>
<td>QRS100</td>
<td>60 (max)</td>
<td>Ø 41.3, 16.4 high</td>
<td>±500</td>
<td>£ 570.5 (USA dollars $995, each for 5-10 units)</td>
</tr>
<tr>
<td></td>
<td>QRS 14</td>
<td>50 (max)</td>
<td>68.6 x 25.6 x 25.6</td>
<td>±500</td>
<td>£ 120.4 (USA dollars $210, each for 5-10 units)</td>
</tr>
</tbody>
</table>

---

13 Murata Manufacturing Co., Ltd. [www.murata.com](http://www.murata.com)
14 Analog Devices: [http://www.analog.com](http://www.analog.com)
15 SiliconSensor, [http://www.siliconsensing.com](http://www.siliconsensing.com)
17 ONavi LLC, [http://www.o-navi.com](http://www.o-navi.com)
18 Nec Tokin Corporation, [http://www.nec-tokin.com](http://www.nec-tokin.com)
4.4.1 Evaluation of the Sensor

From the literature review in Chapter 3, some specifications for a sensor to be used to trigger and stop electrical stimulation for correction of toe walking were identified. Those specifications and the evaluation of the Murata ENC 03J (M) gyroscope against them follows:

- The sensor should be robust and able to work in the environment and under the general conditions to which it would be exposed, minimizing the variations in its behaviour due to age or use, and with minimal propensity for breakage. The ENC 03 sensor has been tested by the manufacturers in terms of the shock and vibration withstanding capabilities, which ensures its working capabilities over a wide range of situations. However, there is no information in its technical notes about mean time to failure, which should be evaluated in the actual conditions on which the sensor will be used.

- The encumbrance represented by the sensor to the patient should be minimised together with the need for wires (increasing cosmesis) and it should be possible to use the sensor bare feet. The size of the ENJ 03 produced by Murata is 15.5 x 8.0 x 4.3 mm and its mass is 1 gram. Due to its small size, it would be possible to house it in the same enclosure as the stimulator. In this case, it would represent minimum encumbrance for the patient by itself and the cosmetrical acceptability would be improved with respect to an external sensor. Also, this position would minimise lead and solder joint breakage because no external wires would be used for communication between sensor and stimulator.

- The price of the sensor should be low: equal or less than £23, which is the current price of a foot switch (as published in the Salisbury FES Newsletter, October 2004). At the time of buying the gyroscope, the price of the ENC 03-J was £18. At February 2006, there are fewer 03-J series on the market as it is being replaced by the 03 M, which has the same technical specifications and its price is £18.3.
Regarding the detection, the system (sensor and detection algorithm) should be:

- Accurate for the detection of events.
- Reliable for different walking patterns for different patients.
- Reliable for changes in the walking pattern for the same patient, due to, for example, changes of contact pattern or differences in terrain (for example stairs and ramps).

This specifications need to be evaluated, as no literature regarding the detection of gait events using a gyroscope in children has been found. Chapter 6 and 7 describe the evaluation of accuracy and reliability of the sensor.

4.4.2 Placement of the Sensor

Previous studies into the evaluation of gyroscopes for gait event detection in adults evaluated different locations of the sensor on the lower limb. After comparing the signals obtained when the sensor was mounted on the anterior part of the thigh, anterior part of the shank and above the metatarsals of the foot, Henty [2003] favoured the foot mounted location, while Ghoussayni [2000] favoured the shank, considering it a "trade of between the thigh and the foot position" in terms of convenience and repeatability. Comparing the signals from a gyroscope mounted on the thigh and one on the shank to those generated from an optical system, Tong and Granat [1999] concluded that the signal from the gyroscope on the shank showed a higher correlation to the signals from the motion analysis system than the gyroscope on the thigh and suggested the reason for this was the greater amount of skin and muscle movements on the thigh during walking. In a study that investigated the thigh, shank and foot angular velocity, the latter represented the most variable between subjects [Wu 1995].

For correction of toe walking using FES, the electrodes are placed on the shank. So, mounting the sensor on the same segment would maximise repeatability between subjects with respect to the placement on the foot (which is advantageous for an automatic detection algorithm independent of the subject characteristics), minimise the signal due to movement of the skin and muscles with respect to the placement on the thing and possibly maximise convenience by placing it in the same segment as the electrodes.
4.4.3 Gyroscope Detection Algorithm

4.4.3.1 Angular Velocity of the Shank

The movement of the shank in the sagittal plane during a gait cycle is primarily anticlockwise during swing and clockwise during stance (figure 4.6).

The knee extends during swing and the lower leg moves anticlockwise. Just before HC, the knee flexes and the shank changes rotation to the clockwise direction so that at the time of contact, the knee is flexed approximately 5 degrees [Perry 1992] and the angular velocity of the shank presents the first negative peak (figure 4.7). Figure 4.7 represents the angular velocity for one of the unimpaired children who participated in the study described in Chapter 6.

Figure 4.6 Position of the leg in the sagittal plane at 40 ms intervals during a single gait cycle [Whittle 1991].

Just after HC the angular velocity signal presents a peak less negative than HC and later, another peak more negative (in some cases, even more negative than the one of HC). This double peak representing a rapid decreased (less negative) and increased (more negative) of the rate of movement could be related to the events happening during the first rocker. Perry [1992] describes that after HC there is a short time when the foot is in “free fall”, following an almost free plantarflexion movement towards the floor. However, shortly after, there is a very fast response of dorsiflexors that decelerate the plantarflexion of the foot and, at the same time, makes the tibia move quickly forward. It is possible then, that just after HC the rate of movement of the shank decreases slightly in the forward movement until the dorsiflexors introduce a quick movement that accelerates it again.
From the end of this first rocker and until TO the shank rotates clockwise, decreased (less negative) rate first and increased (more negative) rate later. This increased rate starts at HR [Ghoussayni 2004], when the rapid flexion of the knee (from 7 degrees at the beginning of pre-swing to 40 degrees at the end of it [Perry 1992]) occurs, reaching another negative maximum at TO. It continues the negative movement until the knee reaches its maximum flexion (further 20 degrees) and then, as the knee starts the extension, the shank changes once again to an anticlockwise movement. The occurrence of HC and TO during unimpaired gait can then be correlated to two negative peaks in the shank angular velocity signal [Morris 1973; Wu and Ladin 1996] and these features are used for event detection.

![Angular velocity signal](image)

Figure 4.7 Angular velocity signal from an unimpaired child who participated of the indoor evaluation of the gyroscope, explained in Chapter 6 (particularly, subject 1). The child is walking at self-selected normal speed. Features of the signal that were used for event detection are indicated together with the event they were related to.

As it was described in Chapter 2, children with CP may present an initial contact, which is not HC but could be toe contact or foot flat. The detection of Initial Contact and Foot Off using a gyroscope could rely on the same features described in the shank angular velocity signal if they are also present in CP gait. Staerck [2002] studied the shank angular velocity of CP children, calculating it from marker data from an optical system and found the same features (two negatives peaks) that could be associated
with Initial Contact and Foot Off. An evaluation of these features from a gyroscope signal is presented in Chapter 6 for CP children.

4.4.3.2 Filtering

When data was collected (as part of this project), it was evident that the angular velocity of the shank contained oscillations other than the peaks mentioned earlier (and specially during stance phase) that would complicate the automatic detection of events. In order to improve this situation, it was decided to filter the signal.

For the processing of the gyroscope signal, a digital low pass filter was used in order to reject noise and improve the automatic detection of events.

Data was filtered with a second order Butterworth low pass filter (applied backwards and forwards, so that effectively it became a 4th order filter).

The frequency content of gait has been studied in the literature. It is a key factor in selecting filters and, particularly, cut off frequency such that high frequency noise is rejected with least attenuation of the actual kinematic data.

Tong and Granat [1999] used a low pass filter with frequency cut off of 4 Hz while Mayagoitia et al. [2002] used a cut off frequency of 3 Hz, and Nene et al. [1999] used 5Hz, although none of these researchers used the signal to detect events. When studying the spectrum of the signal, Ghoussayni [2000], found a significant component at around 0.8 Hz and less significant harmonics up to 12 Hz, but did not use a filter in the final set up when detecting events. Henty [2003] used a cut off frequency of 31 Hz when using the angular velocity of the foot for gait event detection. However, none of these researchers had investigated the influence of the cut off frequency in the detection of gait events and therefore this was investigated further.

This project involves determining if features present in normal walking and used for detection of events are still present in pathological gait and on different terrains and, if they are present, to determine whether they are still related to the events (as described in the introductions of chapter 6 and 7). Because determining such an association is of high priority for this project, the effect of the filter should be minimised. It was decided that an acceptable effect would be one, which results in a difference no greater than one sample or 10ms, which would be comparable to the timing error
introduced through the sampling process itself, and at worst a tenth of the ‘acceptable’ accuracy window defined in section 3.6.3.1.

In order to determine the effect of cut off frequencies, the following analysis was performed. Gyroscope data from one unimpaired and one CP children were used. Initial Contact and Toe / Foot Off were manually (by visually inspecting the signal) determined from the raw gyroscope data and from filtered gyroscope signals at 9 different cut off frequencies (40, 35, 30, 25, 20, 15, 12, 10 and 5 Hz). It was the opinion of the author of the present project that frequencies below 5 Hz would limit the information carried in the signal, especially at the time of the rapid loading events and that this would have an effect on the detection, so evaluation of frequencies lower than 5 Hz were not considered. A total of 34 HC events and 32 TO events were detected from the unimpaired child data, while 15 IC and 13 FO events were detected from the CP child data. The difference between the detection using raw data and each of the filters for IC and both children is shown in Table 4.4 and for FO in Table 4.5 and shown graphically in figures 4.8 and 4.9.

Table 4.4 Absolute mean difference ± one standard deviation in detection of the Initial Contact (IC) using raw data and data low pass filtered from an unimpaired child and one child with CP. The cut off frequencies used were 5, 10, 12, 15, 20, 25, 30, 35 and 40 Hz. Results expressed as mean ± standard deviation, in ms. N= 34 for unimpaired child and 15 for child with CP.

<table>
<thead>
<tr>
<th></th>
<th>5 Hz</th>
<th>10 Hz</th>
<th>12 Hz</th>
<th>15 Hz</th>
<th>20 Hz</th>
<th>25 Hz</th>
<th>30 Hz</th>
<th>35 Hz</th>
<th>40 Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>IC</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unimpaired child</td>
<td>60.3 ± 5.6</td>
<td>26.5 ± 3.3</td>
<td>15.6 ± 2.5</td>
<td>12.0 ± 3.3</td>
<td>5.60 ± 3.3</td>
<td>4.7 ± 3.3</td>
<td>2.9 ± 3.3</td>
<td>2.3 ± 3.3</td>
<td>0.6 ± 3.3</td>
</tr>
<tr>
<td>CP child</td>
<td>34.3</td>
<td>25.0</td>
<td>20.0</td>
<td>17.7</td>
<td>7.0</td>
<td>6.1</td>
<td>4.6</td>
<td>4.3</td>
<td>2.4</td>
</tr>
<tr>
<td><strong>IC</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unimpaired child</td>
<td>11.3 ± 3.3</td>
<td>3.3 ± 3.3</td>
<td>3.3 ± 3.3</td>
<td>3.3 ± 3.3</td>
<td>2.7 ± 3.3</td>
<td>4.0 ± 3.3</td>
<td>0.6 ± 3.3</td>
<td>0.59</td>
<td>0.91</td>
</tr>
<tr>
<td>CP child</td>
<td>5.2</td>
<td>4.9</td>
<td>4.6</td>
<td>0.62</td>
<td>0.62</td>
<td>0.62</td>
<td>0.59</td>
<td>0.91</td>
<td></td>
</tr>
</tbody>
</table>
Chapter 4. Sensors Used for Detection of Gait Events

Figure 4.8 Absolute mean difference (expressed in ms) in detection of the Initial Contact (IC) for different cut off frequencies for one unimpaired child (n = 34) and one child with CP (n = 15).

Table 4.5 Absolute mean difference in detection of the Foot Off (FO) using raw data and using data low pass filtered from an unimpaired child and one child with CP. The cut off frequencies used were 5, 10, 12, 15, 20, 25, 30, 35 and 40 Hz. Results expressed as mean ± standard deviation, in ms. N= 32 for unimpaired child and 13 for child with CP.

<table>
<thead>
<tr>
<th>FO</th>
<th>5 Hz</th>
<th>10 Hz</th>
<th>12 Hz</th>
<th>15 Hz</th>
<th>20 Hz</th>
<th>25 Hz</th>
<th>30 Hz</th>
<th>35 Hz</th>
<th>40 Hz</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unimpaired child</td>
<td>10.9±</td>
<td>5.6±</td>
<td>4.1±</td>
<td>3.7±</td>
<td>2.5±</td>
<td>2.2±</td>
<td>1.8±</td>
<td>1.8±</td>
<td>2.2±</td>
</tr>
<tr>
<td>CP child</td>
<td>8.2</td>
<td>6.2</td>
<td>4.9</td>
<td>5.5</td>
<td>4.4</td>
<td>4.2</td>
<td>4.0</td>
<td>4.7</td>
<td>6.6</td>
</tr>
<tr>
<td>CP child</td>
<td>4.6±</td>
<td>3.8±</td>
<td>3.8±</td>
<td>3.8±</td>
<td>3.1±</td>
<td>2.3±</td>
<td>1.5±</td>
<td>2.3±</td>
<td>2.3±</td>
</tr>
<tr>
<td>CP child</td>
<td>6.6</td>
<td>5.0</td>
<td>5.0</td>
<td>5.0</td>
<td>0.48</td>
<td>4.3</td>
<td>3.7</td>
<td>4.4</td>
<td>6.0</td>
</tr>
</tbody>
</table>

Figure 4.9 Absolute mean difference (expressed in ms) in detection of the Foot Off (FO) for different cut off frequencies for one unimpaired child (n = 32) and one child with CP (n = 13).
From figures 4.8 and 4.9, it is possible to see that the biggest differences are seen in the case of IC detection for unimpaired children. It is necessary to emphasise here that the signals were filtered with an effectively zero-phase-shift filter, so that these differences are due to the magnitude change of the signal due to filtering. The differences are thought to be mainly due to a characteristic double peak of the signal at that point in normal gait, which has been suggested in the previous section, could be related to the actions taking place during the first rocker.

Figure 4.10 and 4.11 show the gyroscope signal from one of the unimpaired children (subject 1) who participated in the indoor study of the gyroscope (described in Chapter 6) and whose data was used for calculating the effect of filtering. In particular figure 4.10 shows the gyroscope signals from a complete gait cycle, without and with filtering, while figure 4.11 shows the time around the IC, where the differences in the signal due to the cut off frequencies are more noticeable.

![Figure 4.10](image)

Figure 4.10 The effect of filtering using different cut off frequencies on the gyroscope signal from an unimpaired child (subject 1 – indoor evaluation study). The effect was more noticeable at the time of IC (which is shown in figure 4.11).

Due to weakness and/or poor control of dorsiflexors in CP children, it can be expected that the first rocker is missing in their data so that this feature does not appear and its absence in the original signal clearly diminishes the differences in the detection between raw data and any cut off frequency.
Figure 4.11 The effect of different cut off frequencies on the detection of IC. This figure shows the effect of some of the evaluated frequencies on the signal. The data corresponds to an unimpaired child (subject 1 – indoor evaluation study). In this particular case, the detection of IC (shown in the graph) would be (erroneously) at the time of the second peak for frequencies lower than 25 Hz (see text for discussion).

However, as the gyroscope signal is going to be used in a functional electrical stimulator, it is possible that children being stimulated present a gait pattern more similar to that of normal children. Also, this project involves the detection in unimpaired children, in order to compare with the results from CP children. For these reasons, the filter needs to be selected so that minimal differences occur due to filter effects.

The selection of the cut off filter implies a compromise. On one hand, a lower cut off frequency will provide a reduction in oscillations that will improve automatic detection. On the other hand, the higher frequency will provide the smallest filter effect. From figures 4.8 and 4.9, it is possible to see that the event most affected by the filter is IC; any cut off frequency equal or higher than 10 Hz will produce a delay in FO detection, which is less than 1 sample (10 ms, sample rate 100 Hz). In terms of IC, it could be inferred that cut off frequencies greater than 20 Hz, produce minor changes in the overall delay. However, a frequency of 20 Hz produced delays of up to 30 ms for some IC events, instead a cut off frequency of 35 Hz produced maximum error of 10 ms for all the steps analysed and for both children. This was the cut off
frequency used, at the expense of adding extra rules in the algorithm to avoid false detections due to noise.

4.4.3.3 Detection Algorithm

As explained in section 4.4.3.1, the determination of IC and FO events was based on detection of two negative peaks in the shank angular velocity signal. A rule-based algorithm for detection was written for this project using the mathematical program Matlab® (Student Version 6.5, The Mathworks, Inc.) and the routine is in Appendix C. Similar rules were applied in previous work done at Surrey [Henty 2003; Ghoussayni 2004]; however, Henty used the angular velocity of the foot and, as such, the same rules would not be applicable to the shank angular velocity and Ghoussayni used an on-line algorithm for detection in adults with foot drop that required stronger rules and included seven parameters to be used to allow for subject-dependent variations. The algorithm used here was for off line evaluation, so simpler rules could be applied and no subject dependent parameters were needed. The rules that constituted this algorithm and the algorithm presented in figure 4.12 were developed for this particular project.

Figure 4.12 is a flowchart of the algorithm used for detection, which was empirically derived using data from three unimpaired children and one CP child. Figure 4.12 also shows a characteristic gyroscope signal from the shank movement of an unimpaired child while walking. The parameters chosen were empirically determined. Initially, the signal is filtered with a low pass filter as described in the previous section. Then, using information from the trigger signal, the start time (frame) of the reference system is established and the detection algorithm started at that particular sample.

From that frame, the first negative part of the signal (\(V< 0\), if exists) and the first positive part of the signal are detected. Initial Contact is defined as the first minimum after the positive wave (which represents the swing phase of gait). Around the time of IC, the signal tends to have high frequency components that may be due to the impact of the foot with the floor and are not removed by filtering. In order to avoid false detections of Foot Off during that time, a “wait time” is set during which no determination of Foot Off is carried out. The waiting time is set to be 50% of the
duration of the last stance (if this is not the first step) or 50% of the duration of the "positive wave", which is a rough estimation of the duration of swing phase.

Figure 4.12 Flowchart of the algorithm developed by the author for detection of Initial Contact and Foot Off using the gyroscope signal, together with a shank angular velocity data set from an unimpaired child while walking (subject 1 of Chapter 6), as measured by the gyroscope. V(n) is the output signal of the acquisition algorithm; n: the sample being considered; n + 1: the sample following the sample being considered; n-1: the previous sample to the one being considered.
Once the wait time is over, every sample is evaluated as a possible FO. FO is defined as the sample that represents a minimum in a window, which includes 10 samples before and 15 samples after, that is preceded by a "decreasing tendency" in the signal and that is followed by an "increasing tendency" in the signal.

4.5 Acquisition System

Two approaches were used for collection of foot switch and gyroscope data. Initially, an acquisition card connected to a portable computer in a previously designed configuration was used. Later, a commercially available datalogger replaced the computer, as it was needed for outside trials and it was considered less cumbersome, eliminating umbilical cables going to the computer during the walking trials.

The acquisition card (a DAQCard – 700, produced by National Instruments Corporation\(^\text{20}\)) has 16 analogue channels, with a 12 bit analogue to digital converter, an input voltage range of ± 10 V and a maximum sampling frequency of 100000 samples per second. Software using National Instrument LabVIEW that had already been written for a previous project was used for collection and storage of data. The processing was performed using purpose written routines using Matlab® (Student Version 6.5, Release 13, The Mathworks, Inc\(^\text{21}\)), written especially for this project.

A commercially available data logger, the AD128C (Omega Engineering Inc\(^\text{22}\)), was used later. This datalogger has 8 analogue channels, with an 8 bits analogue to digital converter, an input voltage range of 0 to 5 V, a maximum sampling frequency of 500 Hz and capability to storage 130000 samples. Once data had been collected and

\(^{20}\) National Instruments Corporation, 11500 N Mopac Expwy Austin, TX 78759-3504. Web page: www.ni.com

\(^{21}\) The MathWorks, Inc., 3 Apple Hill Drive Natick, MA 01760-2098 UNITED STATES. Web page: www.mathworks.com

\(^{22}\) Omega Engineering Inc, One Omega Drive, Stamford, Connecticut 06907-0047, P.O. Box 4047 Web page: www.omega.com
storage, it was downloaded into a PC and it was processed using the same purpose written routines as above.

The datalogger was considered appropriate for this data collection, as the requirements for it were:

- Maximum of 4 channels at any time (two for foot switches, one for gyroscope and one for synchronization purposes);
- 100 Hz as minimum sampling frequency (see next section of this chapter and chapter 5). The minimum sampling frequency option from the datalogger was 125 Hz, so this was the frequency used when the datalogger was used.
- With that sampling frequency, and 4 channels being used, a total time of 4 minutes and 20 seconds were available for collection, which was considered enough for inside trials (10 m trials). For outside trials, as foot switches were not used, the channels in used were only two so that the time for data collection doubled (8 minutes 40 seconds), which again was considered enough time, as each trial would involve a walk of approximately 100 m walk.

4.5.1 Foot Switch Measurement System

Each FSR was connected in a voltage divider configuration, as suggested in the Force Sensing Resistor® Integration Guide and Evaluation Parts Catalogue, published by Interlink Electronics\(^\text{23}\) (figure 4.13).

The guidelines suggest to use either the configuration shown in figure 4.13 or to swap RM and RFSR so that the output increases when the force decreases. This latter was used for this project.

In figure 4.13, there are some representative curves for output voltage versus force applied to the switch, for different values of the resistor RM. From the graphs it is possible to see that a resistor higher than 47kΩ will produce a change of 90% of the output with a 1 kg force (9.8 N) applied to the switch. For this project, an RM of 100

\(^{23}\) Interlink Electronics, Inc, 546 Flynn Road, Camarillo, CA 93012, USA. Web page: www.interlinkelec.com
kΩ was used, so that the switch like response was maximise, within stated values of RM.

Figure 4.13 Suggested electrical interface for a force sensing resistor by its manufacturer (Interlink Electronics).

The voltage dividers were powered with a 5 V output from the acquisition card (DAC) or from a 9 V battery, regulated to 5 V by a voltage regulator (LM78L05\textsuperscript{24}), when using the datalogger. The outputs were connected to respective analogue channels of the DAC or datalogger.

4.5.2 Gyroscope Measurement System

In order to adapt the output of the gyroscope to the input ranges of the DAC, a circuit for offset adjustment and amplification was designed. The same circuit was used when the datalogger replaced the computer, but the values of gain and offset were modified to fit within the datalogger ranges. Appendix B contains a diagram of the circuit together with gyroscope data sheet.

The gyroscope output and reference output were connected to the non-inverting and inverting inputs respectively of an instrumentation amplifier (INA101, Burr-Brown

\textsuperscript{24} National Semiconductors Corporation, 2900 Semiconductor Dr., P.O. Box 58090 Santa Clara, California USA. Web page: www.national.com
Products for Texas Instrument Incorporated25). The gain of the instrumentation amplifier was set to 21 when the DAC was used and changed to 5 for the datalogger configuration, to accommodate for the differences in input range (the input range of the DAC is ±10 V, whereas the datalogger range is from 0 V to 5 V).

The specification of the gyroscope states that the output at zero angular velocity changes with temperature and that the difference is unique to any sample, but the variations are greater in the range from 0 to 20°C and stabilize in a range from 20 to 40°C. In order to evaluate the effect of this variation in the gyroscope used, data was collected at different temperatures. The measurements were performed inside and outside the gait laboratory building, at different times of the day, in a range of temperatures that was considered to be similar to those to be used at the time of the measurements (Table 4.6). Each measurement was performed 3 times, once every 5 minutes.

It was established that the difference across the range of temperatures was 5 mV. These variations were taken into account in the detection algorithm and when the trials involved inside and outside walking (chapter 7), the null output of the circuit was measured in both cases.

As the datalogger has an input range from 0 V to 5 V, a fixed offset was added to the signal, using an operational amplifier (OPAM 121, Burr-Brown Products for Texas Instrument) in a summation configuration so that the output at zero angular velocity (null output) was set to 2.5 V.

The final stage before the datalogger itself was another operational amplifier (OPAM 121, Burr-Brown Products for Texas Instrument), in a non-inverting configuration, used to ensure that the input to the datalogger was within the prescribed range.

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25 Texas Instrument Incorporated, Texas Instruments Incorporated 12500 TI Boulevard Dallas, TX 75243-4136 http://www.ti.com
Table 4.6. Effect of temperature on the output voltage of the gyroscope at zero angular velocity (null output). The measurements are expressed as mean ± equipment resolution. N=3.

<table>
<thead>
<tr>
<th>Temperature [°C]</th>
<th>Null output [V]</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 ± 0.1</td>
<td>1.295 ± 0.001</td>
</tr>
<tr>
<td>7.5 ± 0.1</td>
<td>1.3 ± 0.001</td>
</tr>
<tr>
<td>16.5 ± 0.1</td>
<td>1.3 ± 0.001</td>
</tr>
<tr>
<td>18.8 ± 0.1</td>
<td>1.3 ± 0.001</td>
</tr>
<tr>
<td>24 ± 0.1</td>
<td>1.3 ± 0.001</td>
</tr>
</tbody>
</table>

The gyroscope was housed in an enclosure (32 x 22 x 17 mm), which was placed on the anterior aspect of the shank of the subjects.

The circuitry for offset and gain was housed in a 114 x 67 x 25 mm enclosure, which also enclosed the 9 V battery used for power supply and the voltage divider used for foot switches. This box, together with the datalogger, were placed either inside a bag worn on the belt or in rucksack. Figure 4.14 shows the datalogger, the signal conditioning box (containing circuits for offset and gain) and the trigger button.

The experiments involved the data collection from two sensors (gyroscope and foot switch) and one of the two gold standard reference systems (kinematic or plantar pressure systems). For each combination, the data collection was synchronized. The synchronization between different systems was arranged as followed:

- For kinematic, foot switch and gyroscope data collection at the Gait Laboratory, Queen Mary’s Hospital, Roehampton, the synchronization output from the kinematic system that changes from 1 V to 0 V when the system is triggered, was recorded using one of the analogue channels of the DAC or datalogger.

- For kinematic, foot switch and gyroscope data collection at the Gait Laboratory, University of Surrey, a double pole push button switch (18545CD from Apern Components Limited26) was used. Terminals from one pole were connected with a 1.5 V battery to create a signal that changed from 1.5 to 0 V.

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26Apern Components Limited, 55, avenue Edouard Herriot BP1 82303 Caussade cedex Web page: [www.apem.co.uk](http://www.apem.co.uk)
when the switch was pressed and which was recorded by one of the analogue channels of the datalogger or DAC. The other pole was used to trigger the kinematic data, through the control port of the master camera.

- For pressure measurements and gyroscope data collection, a push button switch was also used. Terminals from one pole were connected in order to create a signal that changed from 1.5 V to 0 V when the switch was pressed and was received by one of the analogue channels of the datalogger (no DAC card was used for these experiments). The other pole was used to trigger the pressure measurement system, through the input trigger.

![Figure 4.14 Datalogger, conditioning box and trigger button used for data collection. The datalogger and conditioning box were either in a bag worn on the belt or inside a rucksack.](image)

**4.6 Conclusions**

This chapter has described the methods and sensors that were used in the project with the objective of finding an alternative sensor to use as a control for FES, instead of the commonly used foot switches.

Initially, the most appropriate gait events to control such stimulation had to be selected. From the pool of events used by researchers to start and stop stimulation to correct toe-walking in children with CP, Initial Contact and Foot Off (in general in the form of Toe Off) are often preferred to activate TA (stimulation being started at Foot Off and terminated at IC) and also the gastrocnemius and soleus complex (in this case, the stimulation begins at IC and finishes at FO). As these two events would invariably be present in the walking pattern (which may not be the case for heel rise, for
example) and because they allow for activation of both muscle groups, they were selected for detection in this project.

If an alternative sensor is to replace the FSR as part of an electrical stimulation system, its performance should be compared to that of the FSR itself. For the evaluation of the “alternative” sensor, the same FSRs used as part of the ODFS stimulator were used in this project. A threshold algorithm was used for detection of events. The threshold was chosen to be the mean of the signal for each trial. This approach avoided false detections due to spurious pressure being applied during swing phase and, by taking into account the range of changes rather than actual values for the resistance, it allowed for changes due to age and wear as well as for constant pressure being applied to the switch (even during swing).

As an alternative sensor, the gyroscope was selected for evaluation. The choice of evaluating this sensor was mainly due to the fact that previous studies at Surrey had already evaluated it in the adult population with encouraging results. If the same sensor could be used for children with CP, then a stimulator available to adults and children could be produced.

From the gyroscopes available on the market, the Murata ENC-03J was chosen on the basis of cost, availability, size, weight and range. It was decided to evaluate the sensor when positioned on the shank, as this is the segment where electrodes would also be placed (then encumbrance due to wires would be minimised) and, from the literature review, this is the most reliable signal (when compared to thigh and foot) for different subjects.

The algorithm for event detection mainly focuses on detection of two negative peaks. One peak that occurs just after the swing phase, represents Initial Contact, while the one just before the swing phase, represents Foot Off.

In terms of the hardware used for data collection, initially a portable computer was used for collection. However, this was inconvenient due to the presence of wires connecting the sensors to the computer and it was inappropriate for outside trials. For this reason, a datalogger was used later on, allowing for a completely portable system that could be worn around the waist or carried in a rucksack.
Chapter 5
Evaluation of Kinematic and Pressure Sensor System Detections.

5.1 Introduction

As discussed earlier, it was considered necessary to relate the performance of the gyroscope to that of foot switches, as the latter are in current use as part of FES systems. Once approach could have been the direct comparison between gyroscope and foot switches only. However, although this comparison is important, given that foot switches may change their behaviour with different terrains or with the time of use, it was also considered important to compare the gyroscope performance against a reference method. This reference should provide appropriately accurate data at all times, so that in the case that the foot switch does not provide accurate or reliable data, the reference could still be used in order to evaluate the gyroscope.

In order for the reference method to be accepted as such, it should comply with the following specifications:

- Accurate in time detection of IC and FO (which were the events selected). The reference system could be a well-established gold standard (as is the conventional force platform) or, another system that compared favourably with the force platforms. Taking into account that IC in unimpaired subjects has been defined by Perry [1992] as a phase lasting approximately 2% of gait cycle or 3.3% of stance phase (taking data from Whittle [1991], in adults, this would represent a difference of approximately 25 ms), it would be expected that the reference would not differ more than this in detection of both events when compared to a force platform.

- Non-encumbrance for walking.

- Information of the position of the foot during the gait cycle would be sufficient, but additional information of other segments (shank, thigh, hip) could add further possibilities for analysis.
Detection of several consecutive events during one trial (so for each trial a series of gait cycles could be used for detection).

A wide detection area in order to be able to capture gait cycles even if the subject is not walking in a straight line.

The last requirement excludes systems such as force platforms or pressure sensitive walkways. The use of conventional force platforms, despite its known accuracy and reliability, is also restrained by the following issues:

- Only one step can be measured per trial (which would not comply with one of the requirements listed above).
- The common need to have several training trials before starting the experiment to find a good starting point, to avoid missing the platform either partially or completely or stepping on the same platform with two feet.
- Aiming or targeting the platform (that is to say, to change the walking pattern in order to hit it) [Orlin and McPoil 2000].
- In the case of having a long platform, the patient still needs to walk in a straight line, keeping both feet in separate platforms.

Two alternative options were evaluated. The use of kinematic data would comply with the last four requirements (including additional information of other segments rather than foot only, as well as information about the unaffected side). Its limitation is that its use is confined to indoor trials, but its advantage is that real foot switches could also be used during these trials.

The second option was to use pressure sensitive insoles. In this case, trials outside the gait laboratory could be done, but data from the foot only could be recorded and virtual footswitches would need to be used instead, as preliminary studies showed that the presence of a footswitch inside the shoe would change the measurement of the pressure insoles around the footswitch area.
It was decided that provided the kinematic and pressure measurement systems were accurate for detection, kinematic detection would be used for indoor trials and the pressure sensitive insoles would be used for outdoor trials.

The literature review showed that kinematic detection, through different approaches, has been used before for event detection. The results presented in the literature so far would indicate that it is an accurate system for event detection; however, the results differ according to the method used. The methods were evaluated but it was considered that none was appropriate for the application in this particular study so a new approach (based on those presented in the literature) was developed.

The literature review also showed that pressure sensors have been used for detection of maximum and minimum forces, that they have been evaluated in terms of accuracy and reliability in force measurements but not as a method for event detection.

It was considered, then, than both methods needed to be evaluated for the purposes of this study.

Ideally, this evaluation should have been performed in the population under investigation (unimpaired children and children with CP), should have included alternative contact and brake of contact events (specifically, Heel Off and Toe Contact) and be performed in the actual setting where experiments were going to take place, which in the case of the pressure measurement system would include stairs and ramps. However, due to difficulties experienced when recruiting children for the studies (in terms of ethical proposals and actual recruitment) and limitations regarding available equipment, the experiments were performed in adults and on level ground terrain, both issues represent the main limitations of this study.

This chapter presents a review of the use of both systems in sections 5.2 and 5.3, the methods used to evaluate the reference systems in section 5.4; the results of the evaluations in section 5.5 and 5.6 and ends with a closing discussion in 5.7.

5.2 Literature Review: Kinematic Detection

Several researchers have investigated the accuracy and reliability of kinematic detection of gait events. The methods for detecting events generally use either marker displacement, or some of the derivatives from displacement or a combination. Recent
Chapter 5. Evaluation of Kinematic and Pressure Sensor System Detection

and representative studies using different methods and the results obtained are presented below, together with the evaluation of the methods to be used as part of this study.

Stanhope et al. [1990] used a subject-defined kinematic pattern (kinematic based model) defined by the trajectory of a point (marker), fixed to the lateral malleoli of the subject, at the time at which an event occurred. The times at which subsequent occurrences of the same gait event takes place are determined by identifying the best fit for the model previously defined using a sensing (or testing) device, which could be a force platform or a pressure-sensitive pad. The results of kinematic detection of initial foot-to-floor contact and terminal foot-to-floor contact were compared with detection by kinetic data of the same events. The results showed that for 78% of the 300 steps collected from one normal walker and one pathological walker, the differences were less than 20 ms.

The method required the definition of a kinematic model (based on kinematic and kinetic data) for each subject, in order to detect the events. As mentioned before, the use of force platforms (kinetic data) has its limitations and a method that would not require the use of them for detection of events, particularly in pathological cases would be preferred. Also, it would be necessary to evaluate the performance of the method for CP children perhaps on an individual basis, who could potentially change their initial contact among different patterns such as heel contact, foot flat or toe on.

Mickelborough et al. [2000] compared kinematic detection with kinetic detection of four gait events. For kinematic detection, the position and velocity in the vertical direction of markers placed on the heel and toe were used. Different raters visually tracked these variables and determined four events, named heel off, swing toe off, heel contact and stance toe off. Of the events, swing heel contact and stance toe off were determined using a clear step onto and off the platform. The kinetic detection was performed automatically, using the force platforms data and a threshold criteria. Their results show that between 78% and 97% of all ratings (for the four events) were within 20 ms of kinetic values, which was ±1 sample for the kinematic data (78.1% for swing heel contact and 97.3% for stance toe off). They concluded that a protocol
based on foot marker kinematics for determining timing of foot contact events was valid and reliable.

Their method used a visual (manual) method for detection using the vertical displacement and velocity of the heel and toe marker. Raters were given instructions for the detection of the events, from the signals being displayed on a computer screen. For this study, though, which would involve the analysis of several steps, the use of an automatic method for detection was preferred.

Hreljac and Marshall [2000] compared kinematic detection with the kinetic detection for two events of gait (HC and TO), at different speeds (selected by the participants). For the kinematic algorithm they used the third derivative of the vertical position of the heel and forward position of the toe markers. The kinetic detection was also performed automatically using force platforms data. The absolute mean differences between the methods was 4.7 ms for HC and 5.6 ms for TO, with a maximum of 13.9 ms for HC detection. No significant differences were found between kinematic and kinetic detection, and no noticeable differences were recorded for the different velocities.

The method the authors proposed used the third derivative of the vertical (Z) displacement of the heel marker for detection of heel contact and the third derivative of the anterior posterior (X) displacement of the toe marker for TO detection. Similar principle was used for detection of HC and TO. The heel contact was estimated to occur at the time of a local maximum in the vertical component of the acceleration of the heel marker and the actual maximum value of acceleration occurred when the derivative of acceleration (which was called jerk) was equal to zero. Toe off was estimated to occur at the time of a local maximum of the acceleration of the toe marker in the X direction and this maximum occurred at the time when the derivative of acceleration was equal to zero.

It was decided to repeat the calculations for evaluation of the method for the heel contact detection, as example figures were provided in the original paper. When the calculations were repeated with data from one normal adult collected as part of this study, it was possible to see the apparent relationship between the time when the vertical heel marker displacement reached a stable value (meaning that the heel is on
Chapter 5. Evaluation of Kinematic and Pressure Sensor System Detection

the floor without further movement), the time when the vertical acceleration had a local maximum and the time when the jerk had a zero crossing (figure 5.1).

However, from figure 5.2 that shows the displacement and jerk signal for a trial containing three heel contacts, it is possible to see that the jerk signal has several zero crossings in that period of time (and even within one stride) and defining the HC seems very difficult from just the detection of zero crossing.

![Figure 5.1 Evaluation of Hreljac and Marshall [2000] method for detection of HC. As part of this project, the method was reproduced using data from one unimpaired adult collected for this project (Subject 1 of the subjects who participated in Study A – see section 5.4.1). The graph represents the displacement, acceleration and jerk (third derivative of the displacement) of the heel marker. The vertical blue line indicates the time when HC is estimated by this method, that is when the acceleration signal presents a local maximum and the jerk signal presents a zero crossing. The signals were scaled to fit on the same graphs (acceleration was divided by 100 and jerk by 1000).

There are some possible explanations for this. Firstly, although in both studies the signals were filtered with a low pass Butterworth filter, Hreljac and Marshall used the residual method for determining the optimal cut off frequency of the filter, which was different and unique for each coordinate of each marker, while in this study, the cut off frequency was fixed at 20 Hz (for reasons explained in section 5.4.5.1). The use of
a lower cut off frequency would eliminate more signal content that in turn will reduce the frequency content of the differentiated signals.

Secondly, it is possible that the authors used extra constraints (for example, using the displacement signal itself to help locate the local maximum of the acceleration that would correspond to heel contact) that were not mentioned in the article.

After evaluation of the method, it was considered not feasible to implement the method using similar conditions to those described in the article and the filter used for this project.

Figure 5.2 As part of this project, the method of Hre1jac and Marshall was reproduced using data from one unimpaired adult collected for this project (Subject 1 of the subjects who participated in Study A –see section 5.4.1). The graph represents the displacement and jerk signal (third derivative of the displacement) of heel marker in the vertical (Z) direction for an entire trial. The red vertical line shows the estimation of the first HC (showed in detail in figure 5.1). It is possible to see that the jerk signal presents several zero crossing during each stride. For this reason the estimation of HC by the detection of zero crossing of the jerk signal seems extremely difficult, under the described conditions.

Ghoussayni et al. [2003] compared kinematic to kinetic detection for four events of gait (HC, TO, Heel Off and Toe Contact). The kinetic detection was automatically performed, whereas the kinematic detection was done through visual inspection (displacements of the markers in the vertical and progression direction were used) and automatic detection (in this case, the velocity of the markers in the sagittal plane was
used). Their results show that for heel and toe contact the difference between the three methods were within 1.5 frames (25 ms). For heel off and toe off, the differences between the kinematic method (both, automatic and visual) and the kinetic method were higher and more varied (up to 175 ms). Statistically significant differences were found between kinetic and automatic kinematic detection but no statistically significant differences were found between the manual and automatic methods.

This automatic method for event detection used the sagittal velocity of the markers (heel marker for heel contact and heel off and toe marker for toe contact and toe off). The sagittal velocity for this study would be the component of the velocity in plane XZ, calculated as the square root of the sum of the squares of the velocities in X (the direction in which the subject was asked to walk along) and Z (vertical direction).

In order to evaluate this method, it was decided to calculate the velocity in the X (figure 5.3) and Z directions (figure 5.4) using data collected for this study from a healthy adult. Also shown is the kinetic detection of heel contact.

It is possible to see that the velocity in the Z direction has some oscillations at the time of heel contact.

After analysing the graphs for 5 of subjects who participated in this study, it was concluded that the velocity in the X direction around the time of HC resulted in more repetitive pattern than the velocity in the Z direction. The data checked was from subjects 2, 4, 7, 9 and 10, who participated in Study A. The subjects were randomly selected from the total set, with the idea of establishing whether there was a repetitive pattern for the velocities. It was considered that 5 subjects (which represents half of total number of subjects) would provide a good representation of the total sample. Analysing the data for those subjects, it became clear that the velocity in the X direction presented a repetitive pattern, whereas the velocity in the Z direction had intra and inter subject variability.

Figures 5.5 and 5.6 show the velocities in the X and Z direction for a subject different from figures 5.3 and 5.4, which illustrates this point.

From the analysis it was concluded that, although the velocity on both direction (X and Z) provide information about beginning and end of stance phase, at HC the velocity of the marker in the Z direction presents greater oscillations, which may not
be related to the movement of the heel but to marker movements due to the high impact that the contact represents.

Therefore, for this study, it was preferred to use only the X component of the velocity of the heel marker to detect HC.

The method proposed by Ghoussayni et al [2003] uses also the sagittal velocity of the toe for TO detection. In the case of CP children, they could present poor clearance of the foot during swing phase, in which case, the toe could even be in contact with the floor at some point during that phase. Although it not evaluated, it was considered then that the velocity in the X direction (the direction of progression) would represent a better indicator of the actual movement of the toe than the Z direction. So, for the purposes of this study, it was preferred to use only the X component of the velocity of the toe marker in order to detect TO.

![Velocity in the X direction](image)

Figure 5.3 The velocity of the heel marker in the X direction was calculated and is shown for a healthy adult who participated in this study (Subject 2 who participated in Study A, Section 5.4.1). Also, the time for the first HC (as detected using the force platform data) is shown as a vertical red line.
Figure 5.4 The velocity of the heel marker in the Z direction was calculated and is shown for the healthy adult who participated in this study (Subject 2 who participated in Study A, Section 5.4.1) and same trial as fig 5.3. Also shown is the first HC (as detected using the force platform data).

Figure 5.5 The velocity of the heel marker in the X direction was calculated and is shown for a healthy adult who participated in this study, explained in Section 5.4 (Subject 1 of the subjects who participated in Study A). The time for the first HC (as detected using the force platform data) is shown as a vertical red line.
Figure 5.6 The velocity of the heel marker in the Z direction was calculated and is shown for a healthy adult who participated in this study, explained in Section 5.4 (Subject 1 of the subjects who participated in Study A). The time for the first HC (as detected using the force platform data) is shown as a vertical red line. From figures 5.4 and 5.6 it is possible to see that at HC the velocity has slight oscillations that present intra subject variability (also some inter subject variability can be noted). These may not be related with the movement of the heel but to the movement of the marker because of the impact of the heel with the floor.

The literature review showed that kinematic data has been proved to be accurate (differences smaller than 25 ms) to use for gait event detection, however the results differ according to the method used for detection. Further, the methods presented in the literature were considered not to be entirely appropriate for use in the experiments designed to evaluate the gyroscope. The reasons for this are that either the methods:

- used manual detection, which is considered time consuming when data from several subjects and several steps is expected to be collected, (this was the case for the method proposed by Mickelborough;

- or they required force platform data, which has its limitations as expressed in section 5.1 (in terms of number of steps used per trial, the need to step in different platforms and in a straight line when long platforms are used). This was the case for the method proposed by Stanhope;
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➢ or they use a model for each subject that is constructed using the first event in the trial, however in the case of CP children, it is possible that they change their contact pattern during the trial (this was also the case for the method proposed by Stanhope);

➢ or, when the method was reproduced using data collected for this project, it was not possible to obtain a clear event recognition (this was the case for the method proposed by Hreljac and Marshall);

➢ or, when reproduced with data collected for this project, it was considered that it would be more appropriate to use part of the data used for that method (as it was the case for the method proposed by Ghoussayni);

A method derived from the ones presented in the literature was proposed for further evaluation. In particular, the method uses the velocity in the direction of progression (X direction) from the heel and toe marker. A threshold algorithm was applied to detect HC and TO. The algorithm is further described in section 5.4.5.

5.3 Literature Review: Pressure Sensor System

In the area of gait analysis, pressure measurement systems are mainly used when information regarding the loading of the plantar surface of the foot is needed [Orlin and McPoil 2000]. Several companies (for example, Novel¹, Tekscan Inc², Paromed³ and Rsscan⁴) produce pressure measurement systems in the forms of mats or insoles.

Some of these systems have been used to determine plantar pressure distribution of unimpaired and hemiplegic children. Henning et al. [1994] analysed the foot loading behaviour of young school children between 6 and 10 years of age in comparison to adults, using a capacitive pressure distribution platform (EMED, system F01 pedography analyzer, Novel GmbH). Kellis [2001] examined the pressure distribution

1 Novel GmbH, Ismaninger Strasse 51, 81675 Munich, Germany, www.novel.de
2 Tekscan Inc, 307 West First Street, South Boston, MA, USA, www.tekscan.com
3 Paromed Vertriebs GmbH and Co. KG, Hubertushof, Heft 8D-83115, Neubeuern, www.paromed.de
under the feet in preschool boys during standing, landing and walking tasks, using a pressure platform system (Musgrave WM Automation and Preston Communication Ltd, North Wales, United Kingdom). Femery et al. [2002] used pressure insoles (Parotec, Paromed GmbH) to compare the plantar pressure distribution in hemiplegic children with a healthy control group and, in this way, illustrate the link between the changing dynamics during the stance phase and the degree of deficiency.

An F-Scan® Mobile system (Tekscan Inc.) is part of the gait laboratory equipment at Surrey. It consists of two insoles with 960 different pressure-sensing locations, with a spatial resolution of 4 sensors per cm². Each sensor consists of two polyester sheets whose inner surfaces are printed with electrical circuits. Between the circuits there is semiconductive ink whose electrical resistance change inversely proportional to the pressure applied.

Although the primary focus of the system has been reported to be the peak pressure distribution over time [Young 1993], as part of research directed at analysing pressure distribution, it was considered an option for the experiments in this study as:

1. The insoles are light, thin and unobtrusive in the shoe.
2. The total weight of the complete portable equipment is approximately 1.5 kg.
3. Using the portable system would avoid the need of wires from the patient to a computer and allow data to be collected outside the laboratory.
4. The system allows for an external trigger that could provide an easy way of synchronizing the system with another system.

Several researchers have studied the accuracy and reliability of pressure measurements using the F-Scan® system but none of them have considered the performance in terms of timing of events.

A number of key conclusions may be drawn from the literature review regarding the use of F-Scan® pressure measurement system:

1) Calibration of the insoles is an important issue to achieve accuracy in the measurement of pressure. It is recommended;
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a. To calibrate the system, at least, 5 minutes after the insoles are fitted in the shoes to allow for temperature equilibration of the sensor [Randolph et al. 2000].

b. To calibrate using pressure which is in the same range as the applied pressure [Hsiao et al. 2002]. In this case, if the person is not able to perform a calibration, another person, whose weight is similar to the first, could be involved in the calibration instead.

2) It has also been recommended to leave the protecting backing of the insoles in order to increase durability of the sensors [Randolph et al. 2000].

3) It has been suggested that the system is not suitable for hard surfaces [Luo et al. 1998], so soft surfaces should be used instead (in the work by Luo et al., foam insoles were considered the soft surface and 1 mm thick rigid plastic sheets were considered the hard surface).

4) There is conflicting information in the literature regarding the accuracy and precision of the system as well as its variability within and between sensors for pressure/force measurements [Woodburn and Helliwell 1996; Woodburn and Helliwell 1997; Randolph et al. 2000]. Because of this, absolute values of force or pressure were not used for event detection. Instead, the area of the sensor being pressed at any time was the selected variable.

5) It has been reported that high temperatures (above 30°C) could affect the measurements of force/pressure [Luo et al. 1998]. It is this author opinion that it is possible for the temperature inside the shoe to reach values of 30°C. This represents another factor that encourages the use of an area loaded instead of pressure measured.

6) The measurement of force by the sensors drifts with time. This is the reason for the manufacture to suggest that the calibration of the sensors needs to be performed including a time for loading which should be similar to the time of loading during the actual walking (and which could be different for different walking speeds). If a person is standing and the total force under their feet is being monitored on line, it is possible to see this drift as an increase of the force with time. As it was mentioned before, instead of using the force or pressure measurement, for this project, the area loaded was the variable.
selected, hence the drift in the measurement of force does not affect the detection algorithm.

7) It has also being found that the F-Scan® presented delays in detection of times for the maximum and minimum forces respect to the force platform detection [Sumiya et al. 1998; Chen and Bates 2000]. Suggested reasons for this included the response of the sensor (time response), the presence of the shoe, the measurement of shear force together with vertical forces in the case of F-Scan or the techniques used for triggering. Some of these reasons could also affect the detection of events.

Only two studies involved the timing of forces events using F-Scan system [Sumiya et al. 1998; Chen and Bates 2000], but in both cases the events measured were the peaks of the force during stance phase. The study by Sumiya et al found that F-Scan detected the first peak of force during a stance from 11 to 17 % of stance later than the force platform, but detected the second peak almost at the same time. In the study by Chen and Bates, F-Scan® showed a significant delay in the times of occurrence of the peak forces during stance when compared against force platforms detection. Some possible reasons for such delays suggested by the authors were:

- The F-Scan insole measures the ground reaction force between the foot and shoe while the force platform measures the ground reaction force between the support surface and shoe. The shoe may have delayed the peak due to shock absorbing characteristics of the shoe.
- A slow dynamic response of the F-Scan sensor.
- And/or limitations of the synchronisation technique.

As there are no studies that have evaluated the system for event detection, it was considered necessary to undertake an evaluation by comparing it with force platform detection.
5.4 Method

In order to evaluate the use of kinematic and pressure measurement systems as reference methods, the study consisted of two parts:

A) Comparison of the proposed reference methods with kinematic detection in ten healthy adults.

B) Evaluation of the effects of using different sensors and the repeatability of the measurements in two different days in the detection using the pressure measurement detection in one healthy adult.

5.4.1 Subjects

Ten healthy adults, 9 males and 1 female, mean age 28.75 ± 5.9 years (range 25 – 42) and mean weight 82.6 ± 18.9 kg participated in Study A and one unimpaired adult (female, 29 years old) participated in the Study B.

In all cases, the subjects wore their own leisure shoes. All shoes included soft insoles, which were considered to be more similar, concerning hardness, to foam insoles than to rigid plastic sheets.

5.4.2 Data Collected

Kinetic data was obtained using two AMTI platforms (model 400600HF-2000, Advanced Mechanical Technology, Inc., Watertown, Massachusetts, U. S.) and were used as the gold standard to which the other two systems were compared.

Kinematic data was obtained using a ProReflex MCU system (Qualisys Medical AB, Gothenburg, Sweden), which consisting of seven digital infrared cameras. Retroreflective markers were placed on both heels (posterior of the calcaneus) and toes (between the second and third metatarsal head). Prior to data collection, calibration was performed according to the instructions provided by the manufacturer.

Pressure distribution under the feet was measured using a F-Scan® Mobile system (Tekscan, Inc. South Boston, M.A., U.S.).

The subjects were first fitted with the insoles (F-Scan sensor, number 3000), which were trimmed to their shoe size, together with the rest of the equipment (figure 5.7).
They were asked to report if they felt any discomfort caused by the insoles, in which case, the insoles were repositioned. After that, the subjects were asked to walk for at least five minutes, for temperature equilibration and to become familiar with the equipment.

The system was connected to the computer and a real time acquisition was performed to inspect for high pressure areas near the edge of the insole, which would indicate the presence of crinkles in the insoles. In order to check for these, the subject was asked to sit down and lift both feet. If there were any high pressure area, either the sensor was repositioned or under-trimmed.

For calibration of the insoles, the subjects were first weighed using one of the force platforms and this measurement was the “applied force” used for calibration. In order to calibrate, the subject was asked to stand still, then put all his weight on the contralateral leg to that being calibrated and then, when asked to, change the leg of support.

The same procedure was repeated for the other leg and the recordings began.

Figure 5.7. Equipment used for data collection in one of the subjects who participated in this study (in particular, the subject who participated in Study B). The subjects were fitted with markers on heels and toes and also with insoles inside the shoes and a portable datalogger on their waist for capturing and temporal storage of pressure measurement data.
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i) Study A

Two pairs of sensors were used for data acquisition, each pair was used by five subjects.

The subject was asked to walk for 30 m, 3 times on a walkway of 10 m, with the forceplatform placed in the middle of it. This was repeated 6 times, with a 3 to 5 minutes break between measurement.

Data was then processed and algorithms were used for the detection of HC and TO for each method. The time of detection was, then, compared between the methods in order to evaluate accuracy.

ii) Study B

As explained before, it has been noted in the literature that different sensors differ in the measurement of pressure. Although the variable measured to detect events was contact area rather than pressure, it was thought that it was still possible that different sensors would measure the contact area in different ways. The extent of such variability needed to be studied.

Finally, repeatability is relevant to the study of method comparison because the repeatability of two methods of measurement limit the amount of agreement which is possible [Bland and Altman 1986].

The aim of this part of the study was to evaluate:

1. the repeatability of the measurements, repeating each measurement twice, on different days one week apart (during that week, the sensors were not used), once the sensors had been used for study A (so, comprising the worst case in terms of the use of the sensor).

2. the effect of using different sensors, repeating each measurement with two different pair of sensors.

The protocol for walking and data acquisition was repeated as for the first part of the study in one healthy adult who did not participate of the first part. Data was also processed as described for the first part of the study (see next section).
5.4.3 Data Processing

All data was collected at a sampling frequency of 200 Hz and the systems were triggered by the same push button.

Those steps for which the foot contact was not clearly inside the platform were excluded from analysis. For Study A, the maximum number of valid steps available for all subjects was 21, so 21 steps per subject were analysed (total of 210 steps). For Study B, the maximum number of steps for every condition was 32, so 32 steps for each condition (2 sensor and 2 days) were analysed, which makes a total of 128 steps.

The methods used for detection of HC and TO using the different data set are described below. They were applied off line and were performed using routines written using Matlab® (MathWorks, Natick, MA, U.S.), which are presented in Appendix C.

5.4.4 Detection of HC and TO Using Kinetic Data

The detection was done using the force data, in particular, the vertical component of the force.

The three components of the force were considered for detection. However, it was clear that both the anterior – posterior and the medial – lateral forces (figure 5.8) presented oscillations at the time of heel contact (and some times at the time of toe off, as well). The oscillations confused the exact moment of contact (or break of contact). The vertical component of the force, however, represented a suitable option (figure 5.9).

HC was determined as the time when the vertical force exceeded the set threshold (10 N). In the same way, TO was determined as the time when the force fell below the same threshold (fig 5.9).

Different authors who used force platform data for gait event detection have used different thresholds when detecting event from force data. While Hansen et al. [2002] used a threshold of zero, Stanhope et al. [1990] used a threshold equal to two standard deviations above the mean unloaded baseline, measured during an unloaded phase of each trial. Kollmitzer et al. [1995] used 1/10 of body weight as threshold, Wall and
Crosbie [1996] used 2.5 N, Housdorff et al. [1995] used a threshold of 10 N for Initial Contact and 5 N for Foot Off, while Mickelborough et al. [2000], Hreljac et al. [2000] and Ghoussayni [2003] used a 10 N threshold for both events.

In this study, 10 N was considered to be high enough as to avoid false detections due to noise (which were not avoided using lower thresholds), but low enough as to detect the initial contact time and the end of the break of contact (figure 5.9).

Figure 5.8 Anterior Posterior and medial lateral forces for Subject 1 (of the subjects who participated in Study A). It can be seen that at the time of HC, the oscillations could make it difficult to detect the exact point of contact. These oscillations were variable (in amplitude and timing) between subjects.

Figure 5.9 Vertical component of the force obtained from force platform for Subject 1, (of the subjects who participated in Study A). In this signal, there is a clear time for contact and break of contact, without oscillations. As a result, this component was used for detection. The red line represents the threshold used for detection. The intersection between the line and the signal was considered Heel Contact if the signal was increasing and Toe Off if signal was decreasing.
5.4.5 Detection of HC and TO Using Kinematic Data

5.4.5.1 Filtering

As explained in Chapter 4, the frequency content of gait has been studied in the literature. In terms of kinematic filtering, Winter suggested filtering at 4 Hz to 6 Hz [Winter et al. 1974]. Later on, Angeloni et al. [1994] analysed kinematic data from a motion system consisting of two cameras and arrays of infrared emitting diodes, mounted over soft tissue of different body segments (foot, shank, thigh, pelvis, trunk, upper arm and head). The amplitude distribution of the signal frequency spectrum was computed. It was determined that the optimum cut off frequency (calculated using the residual analysis method proposed by Winter [Winter 2004]) for the kinematic data ranged from 5.5 Hz to 9.8 Hz for different segments, with 9.72 Hz for the foot.

Antonsson and Mann [1985], under the assumption that kinematic accelerations are directly related to forces, used force platforms data to evaluate the “portion of the gait cycle where the most abrupt and rapid position changes with time occur, thereby encompassing the worst case accelerations in the biomechanical system”. Those accelerations occur at the foot during heel strike. Their results showed that 98% of the total power of the signal is contained below 10 Hz and 99% below 15 Hz.

These studies suggest that 15 Hz cut off frequency would be appropriate for an ideal filter. However, because of the characteristics of signal attenuation of a non-ideal Butterworth filter and in order to maintained any components of the signal at or below 15 Hz, the cut off frequency used was 20 Hz.

To maintain the correct cutoff frequency when using multiple passes of a filter (as it is the case when applying the filter backwards and forwards to avoid phase delays), the cutoff frequencies must be adjusted [Winter 2004]. The coefficient used for adjusting the frequency was 1.246 [Robertson and Dowling 2003].

So, after collection, kinematic data was filtered using a Butterworth filter of second order and cut off frequency of 24.92 Hz, which was applied backwards and forwards.
5.4.5.2 Algorithm for Detection

Consideration of the methods proposed in the literature for kinematic detection of HC and TO (section 5.2) revealed that they were not entirely appropriate for use in this study, as it was explained before. In this particular study, the detection of HC and TO was accomplished using the velocity of the markers (heel and toe marker, respectively) in the X direction (direction of progression).

A threshold had to be set in order to accommodate low-level movement of the markers during contact periods and errors due to the inherent noise of the measuring system [Ghoussayni et al. 2003]. The threshold was empirically set by visually inspecting data from two of the subjects. The events were visually detected and for that particular frame, the velocity was noted. For the HC events detected from the two subjects, the corresponding velocity at that frame was in all cases in the range between 750 and 850 mm/s. As a compromise and to avoid systematic errors (if the threshold was chosen as 750, all the events would have been detected at the time or later than the actual event), the value of the threshold was set to 800 mm/s (accepting that in this case, events would be detected at the time of, earlier or later than the actual event).

HC was determined every time the velocity of the marker in that direction dropped below that threshold. Figure 5.10 shows the velocity of the heel marker in the direction of progression for one of the subjects who participated in the study.

A threshold was also set empirically for TO detection. The threshold was set after visually analysing the data for two subjects and noting the velocity when the movement of the marker started to be continuous in the direction of progression. For the TO detected from the two subjects, the corresponding velocity at that frame was in all cases between 750 and 850 mm/s. As a compromise and to avoid systematic errors (if the threshold was chosen as 850, all the events would have been detected at the time or later than the actual event), the value of the threshold was set to 800 mm/s (accepting that in this case, events would be detected at the time of, earlier or later than the actual event).

The velocity of the toe marker in the direction of progression for one of the subjects who participated in this study is shown in figure 5.11.
Figure 5.10 Velocity of the heel marker in the direction of progression for the subject who participated in Study B – section 5.4. The red line represents the threshold set for the detection of HC. The frame at which the signal exceeded the threshold was considered Heel Contact (HC) event.

Figure 5.11 Velocity of the toe marker in the X direction for the subject who participated in Study B – section 5.4. The red line represents the threshold used for detection. The frame at which the signal exceeded the threshold was considered Toe Off (TO) event.
5.4.6 HC and TO Detection Using Pressure Measurement System

The software accompanying the F-Scan system provides not only the pressure and force data during the recording but also the area loaded of the sensor (defined as the area of only the sensels that have some—greater than zero—pressure applied to them).

As the accuracy in the measurement of pressure depends on a number of factors including suitable calibration, the hardness of the surfaces against the insoles and the level of input force, it was considered that the loaded area could provide a better option for time detection as it considers each sensor as an on-off sensor.

When the foot contacts the floor, there is a rapid increase in the loaded area. The area loaded increases until the foot is completely on the floor, decreases after heel off and has another maximum when the anterior part of the foot is the contact surface and then decreases as the foot is lifted, until toe off (figure 5.12).

![Right Foot Area and Threshold Used for Detection](image)

Figure 5.12 Area of contact for the right foot of one of the subjects that participated in the study (Subject 1, who participated in Study A). The red line represents the threshold used for detection of HC and TO. The time at which the signal exceeded the threshold was considered as the event time shown in the figure.

To detect the time when the area starts to increase and the time when it decreases as the foot is lifted, an estimation of the area loaded when the foot was not in contact...
with the floor (area loaded during swing phase, ALSw) and of the area loaded during
stance, ALSt, were calculated. Although normally, ALSw would be zero, it is possible
that during the trial some areas of the insole become constantly loaded (for example,
if the insoles move, crinkles could appear near the edge). The selection of an ALSw
would help identify this residual area, if existed.

The algorithm for estimation of both, ALSw and ALSt, was empirically determined
analysing data from two subjects.

First, in order to calculate ALSw, a histogram was used to calculate the distribution of
values in the signal below 2000 mm², in 100 mm² divisions. The lowest area that
presented the highest frequency of occurrence was considered ALSw. Figure 5.13
represents the distribution of the values between 0 and 2000 mm² for the trial shown
in figure 5.12, and the ALSw was set at 1000 mm².

![Distribution of area signal](image)

Figure 5.13 Distribution of the area signal in the range from 0 to 2000 mm². The lowest area
that presented the highest frequency of occurrence was considered the "area loaded during
swing" (ALSw), in this case, ALSw was chosen as 1000 mm².

Then a histogram was used to calculate the distribution of values above 2000 mm²,
and up to the maximum in the signal, again in 100 mm² divisions. The lowest area
that presented the highest frequency of occurrence was considered ALSt. Figure 5.14 shows the distribution of the values above 2000 mm$^2$ for the trial shown in figure 5.12, and the ALSt was set at 6900 mm$^2$. ALSt represents the most frequent value of area loaded during the stance phases.

Now, the total area was calculated by the difference between these maximum and minimum values. In this example, the estimation gave a value of 5900 mm$^2$.

A threshold had to be set in order to accommodate low-level of remaining loaded area and variations in the loaded area during swing. The thresholds for HC and TO were again empirically set by visually inspecting data from two of the subjects and stating the minimum area that represented the change from swing phase to stance phase. This threshold was set as 5% of the estimated total area of contact for each trial and it was added to the minimum area calculated. In the example, 5% of 5900 resulted in a value of 295 mm$^2$, which were added to the 1000 mm$^2$ of the minimum value. The threshold was then set to 1295 mm$^2$.

The total area was calculated for each trial and the threshold was the same for all the steps in one trial.

![Figure 5.14 Distribution of the area signal in the range from 2000 mm$^2$ to the maximum of the signal. The lowest area that presented the highest frequency of occurrence was considered the “area loaded during stance” (ALSt), in this case, ALSt was chosen as 6900 mm$^2$.](image-url)
5.4.7 Data Analysis for Study A

5.4.7.1 Time Difference

Once the events were determined for each method, the comparison between the methods was carried out by calculating the difference in time (ms) between the detections for each step analysed.

First, for each step analysed, the differences in the detection of events were calculated as:

a) KN-KD = kinetic detection (KN) – kinematic detection (KD),

b) KN-CA = kinetic detection (KN) – contact area (CA),

c) KD-CA = kinematic detection (KD) – contact area (CA).

Second, in order to avoid misleading results due to cancellation of positive and negative values when averaging, the absolute value of the difference was calculated for each step.

Later, the absolute differences of all the steps for each subject were averaged so that a single value was obtained for each subject and each pair of methods.

Finally, the mean absolute differences for the ten subjects were averaged (and are reported in Section 5.5.1). These values were calculated in order to compare the results with the ones previously reported in the literature (in particular, with the results of Hreljac and Marshall [2000] and Ghoussayni et al [2003], which were the two automatic algorithms considered for this project and reproduced using data collected for this project).

However, for data that is not normally distributed (and specially, when the data is skewed), the median value represents a better option to represent the central tendency. Therefore, values of the median, together with the 95% confidence interval, expressed as percentage of stance phase (for easy understanding with the sample distribution as shown in figure 5.5.3), have been included.
5.4.7.2 Distribution of the Time Differences

In order to evaluate whether there was a tendency for any of the methods to detect an event systematically earlier or later than others, an analysis of the distribution of the differences was performed.

The number of positive, negative and zero differences for each of the methods and each subject was calculated. As the differences were calculated as “first method – second method”, a positive difference means that the first method detected the event later than the second, a negative difference means that the first method detected the event earlier than the second, and a zero difference means that both detected it at the same time. This analysis would show if there is a bias in the detection across subjects.

5.4.7.3 Time Difference as a Percentage of Stance Phase

In order to evaluate the real significance of the time differences in the context of gait, the absolute mean differences were expressed as a percentage of the stance phase of gait, with the duration of the stance phase calculated using the force platform data as the time elapsed between the detection of HC and TO for every step. These results are presented in Section 5.5.2.

Also the distribution of the differences in the form of histograms are presented in the same section. The histograms of the number of steps versus the time difference as a percentage of stance phase (in the range of -20% to 20%, divided in 1% interval) was calculated for the differences between each pair of methods.

5.4.7.4 Statistical Analysis

Statistical analysis was performed in order to evaluate the statistical significance of the differences. For this, the differences as a percent of stance phase for each subject were averaged so a total of 10 values were used for the analysis. Nonparametric Wilcoxon signed rank test was used, using GraphPad InStat software, Version 3.05 (GraphPad Software Inc., San Diego, CA, USA).

The result of this analysis should be used only as indicatives as the sample size (ten subjects) was small for statistical purposes. The number of subjects was limited as it
was decided to use only two pair of sensors, which were trimmed downwards to the appropriate shoe size.

5.4.8 Data Analysis for Study B

5.4.8.1 Time Difference

In this study, the differences in the detection of events were calculated only between kinetic and contact area as before:

\[ \text{KN-CA} = \text{kinetic detection (KN)} - \text{contact area (CA)}, \]

Then, the absolute value of the difference was calculated for each step and the absolute differences of all the steps for each condition were averaged so that a single value was obtained for each condition and each pair of method. These results are presented in Section 6.

5.5 Results for Study A

5.5.1 Median and Absolute Mean Difference

The median of the differences and the 95% interval, together with the absolute mean differences are shown in Table 5.1.

Table 5.1 Median [95% interval] in percentage of stance phase (Absolute mean difference ± one standard deviation, expressed in ms), for heel contact (HC) and toe off (TO). The differences were calculated between kinetic and kinematic (KN-KD), kinetic and contact area (KN – CA) and kinematic and contact area (KD-CA).

<table>
<thead>
<tr>
<th>Event Detected</th>
<th>KN – KD</th>
<th>KN – CA</th>
<th>KD – CA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heel Contact</td>
<td>0.8 [-3.5]</td>
<td>-2.9 [-7.0]</td>
<td>-4.0 [-8.0]</td>
</tr>
<tr>
<td></td>
<td>(11 ± 9)</td>
<td>(23 ± 11)</td>
<td>(30 ± 16)</td>
</tr>
<tr>
<td>Toe Off</td>
<td>2.2 [0.5]</td>
<td>-0.7 [-5, 3]</td>
<td>-2.8 [-6, 1]</td>
</tr>
<tr>
<td></td>
<td>(16 ± 8)</td>
<td>(11 ± 12)</td>
<td>(21 ± 13)</td>
</tr>
</tbody>
</table>
Differences as a Percentage of Stance Phase of Gait

The results expressed as a percentage of stance phase are shown in figure 5.15.

Figure 5.15 Mean differences as a percentage of stance phase for HC (red bars) and TO (blue bars). The mean differences are represented as solid bars and the line in the bar represents two standard deviations.

5.5.3 Distribution of the Differences

Figure 5.16 shows the number of steps for which the difference between methods was positive, negative or null for HC and TO detection.

The distribution of the differences are shown in figure 5.17 for HC and figure 5.18 for TO. For the HC event, the differences in the -4.0% to 4.0% range represented 99.5% of the steps for KN-KD, 79.0% for KN-CA and 50.0% for KD-CA. In the case of the TO event and using the same range (-4.0% to 4.0%), it represented 98.6% of the steps for KN-KD, 94.8% for KN-CA and 70.5% for KD-CA.
Figure 5.16 The number of steps for which the differences between the methods were positive, negative or null. For example, for HC, the differences between KN and KD presented 138 positive values which implies that KN detected HC later than KD, 42 negative values, which implies that KN detected HC earlier than KD and 30 null values, in which both methods detected the event at the same sample.

Figure 5.17 Distribution of the differences between the methods for detection of HC. In each figure the differences are shown (from top to bottom): between kinetic and kinematic methods (KN-KD), kinetic and contact area (KN-CA) and kinematic and contact area (KD-CA). n= 210, bar with 1% of stance phase.
5.5.4 Statistical Analysis

The results of the Wilcoxon tests are shown in table 5.2.

Table 5.2 Results of the statistical analysis applied to the differences between the methods. P values shown, p > 0.05 no statistical significance (ns), p < 0.05 statistical significance between the methods (*).

<table>
<thead>
<tr>
<th></th>
<th>KN-KD</th>
<th>KN-CA</th>
<th>KD-CA</th>
</tr>
</thead>
<tbody>
<tr>
<td>HC</td>
<td>P = 0.23 (ns)</td>
<td>P = 0.02 (*)</td>
<td>P = 0.02 (*)</td>
</tr>
<tr>
<td>TO</td>
<td>P = 0.02 (*)</td>
<td>P = 0.13 (ns)</td>
<td>P = 0.04 (*)</td>
</tr>
</tbody>
</table>

Figure 5.18 Distribution of the differences between the methods for detection of TO. In each figure the differences are shown (from top to bottom): between kinetic and kinematic methods (KN-KD), kinetic and contact area (KN-CA) and kinematic and contact area (KD-CA). n=210, bar with 1% of stance phase.
5.6 Results for Study B

Table 5.3 shows the results for study B. In this case the absolute mean differences in time were calculated only between CA and KN to evaluate the change in those differences when the stated condition changed.

Table 5.3 Differences ± one standard deviation between KN – CA (expressed in ms) in the HC and TO detection for two different sensors and two different days of data collection. N=32 steps for each condition.

<table>
<thead>
<tr>
<th>Day</th>
<th>Sensor</th>
<th>HC</th>
<th>TO</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>S1</td>
<td>22 ± 6</td>
<td>20 ± 7</td>
</tr>
<tr>
<td></td>
<td>S2</td>
<td>22 ± 7</td>
<td>20 ± 6</td>
</tr>
<tr>
<td>2</td>
<td>S1</td>
<td>22 ± 5</td>
<td>20 ± 5</td>
</tr>
<tr>
<td></td>
<td>S2</td>
<td>24 ± 5</td>
<td>21 ± 7</td>
</tr>
</tbody>
</table>

From this data it is possible to calculate the absolute difference between the sensors and between days. Those differences are presented in table 5.4.

Table 5.4. Absolute difference (ms) when using different sensors and for different days of data collection respect to the reference system

<table>
<thead>
<tr>
<th></th>
<th>HC</th>
<th>TO</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1-D2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Sensor 2</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>S1-S2</td>
<td>Day 1</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Day 2</td>
<td>2</td>
</tr>
</tbody>
</table>

It is possible to see that the absolute difference in detection of events with respect to the reference between the means of the two days of data collection was equal or less than 2 ms. The results were similar for the absolute difference in detection with respect to the reference of the means of detections using the two sensors.
5.7 Discussion

5.7.1 Study A

5.7.1.1 Absolute Mean Differences and Differences Relative to Stance Phase.

The median value of the differences for the healthy adults group between each of the proposed reference methods (kinematic and contact area) and the force platforms were in all cases between −3% and 3% of stance phase for both events. The absolute mean differences were in all cases less than 25 ms. Considering these mean differences relative to stance phase duration, they were less than 3.5% of stance.

Perry [1992] describes the Initial Contact as a phase lasting 2% of the gait cycle (with stance phase representing approximately 60% of gait cycle, the phase would last 3.3% of stance), while the unloading phase (from the contact of the other foot on the floor until TO) represents 10% of gait cycle (17% of stance phase, considering that the stance phase represents 60% of gait cycle). Taking into account this values, the differences between the methods were in the order of the duration of IC (the shortest of both events).

These differences between KN and KD are comparable to the ones presented in the literature. Hansen et al. [2002] compared kinetic detection of HC and TO with a method that combined kinematic data (an ankle marker) and the centre of pressure of the body during the stride and found that the mean differences (not absolute) between methods were 8.33 ms for HC and 18.3 ms for TO.

Ghoussayni et al [2003] found that the mean of absolute differences were within 25 ms for HC, whereas for TO, the differences were higher and more varied (up to 175 ms).

Stanhope [1990], using a kinematic pattern defined by the trajectory of a marker and comparing those with kinetic detection found that 78% of the steps had a difference less than 20 ms for both, initial contact and end contact.

It is necessary also to take into account that due to the sampling frequency used in this experiment (200 Hz), there may be a delay of up to 5 ms between the actual event happening and the detection happening. The synchronization was performed by starting the three systems using the same pushbutton, and Tekscan starts the data.
collection up to 0.5 ms after receiving the signal. The maximum delay produced by both, sampling frequency and synchronization, between detection and real event happening, is 5.5 ms.

5.7.1.2 General Distribution of Differences

For HC detection, the KD method detected earlier than KN for the majority of the steps (65%), whereas CA method detected later than KN for the majority of the steps (98%).

The results are similar for TO detection. KD detection was earlier than KN in 94% of the steps, while CA detection was later than KN in 63% of the steps.

This partly explains the higher absolute mean differences between KD and CA (30 ms was the absolute mean difference for HC and 21 ms for TO).

As with this study, Hansen et al. [2002] found that kinematic detection occurred earlier than the kinetic in the majority of the steps and for both events, while Ghoussayni et al. [2003] found that KD detection was earlier than KN only for TO detection, but later for HC detection. The different distribution found between the latter study and the present study in terms of HC detection may be explained by the use of different thresholds for detection. Ghoussayni et al. used a lower threshold (100 mm/s) than the one used in this study (800 mm/s).

5.7.1.3 Distribution of the Differences for HC

Although the KD detection occurred earlier than KN in the majority of the steps, the median difference was 0.8% of stance phase, the absolute mean difference between the methods was 11 ms (1.5% of stance phase), the differences were distributed around zero than for CA (99.5% of the differences were in the range from -4 to 4% of stance, figure 5.20) and the statistical analysis proved the differences between the methods were not statistically significant.

The median difference between KN and CA was -2.9% of stance phase, the absolute mean difference was 23 ms (3.1% stance phase), being the CA detection later in 98% of the steps.
Several factors that could have influenced in the later detection of HC were evaluated. They are described below.

Influence of selected threshold

As mentioned before when describing the method used for contact area detection, a threshold had to be set in order to accommodate low-level of remaining loaded area and variations in the loaded area during swing. This threshold should be high enough as to avoid false event detections. The threshold was chosen as 5% of the estimated total area.

Changing the threshold may have an effect on the results. In order to evaluate the influence of the chosen threshold, a lower threshold (2% of estimated total area) was used and results were recalculated. In this case, it was sometimes necessary to visually detect the events. In those cases the following rule was applied for detection:

"HC is the first frame number after which the area signal, having exceeded the threshold, keeps an steady increase into stance phase".

The results showed that the difference in HC between KN and CA methods diminished from $23 \pm 11.0$ with a 5% threshold to $16 \pm 10$ with a 2% threshold. And in terms of the distribution of the difference, the negative differences (the number of steps for which CA detection of HC occurred later than the KN detection) diminished from 98% (207 steps) with a 5% threshold to 90% (190) with a 2% threshold (figure 5.20).
From these results, it is possible to see that although there is an influence of the threshold in the results, it does not seem to explain the differences seen in the study.

**Influence of the shoe**

Taking into account that the insoles measure contact between the foot and the shoe whereas the force platform measures contact between the shoe and the platform, it was suggested in the literature [Chen and Bates 2000] that this might have an effect on the detection of time related variables.

In order to evaluate this effect, a pair of insoles was used so that one of them was placed inside the shoe while the other was taped to the outside sole of the same shoe. Only one subject participated in this study. The same protocol used for the rest of the study was used and the subject walked along the walkway.

The detection of HC was then performed using the outside insole, the inside insole and the kinetic data. A total of 14 steps were analysed.

The results showed an absolute mean difference between KN and CA-I (contact area, inside shoe) of $15 \pm 3$ ms, while the absolute mean difference between KN and CA-O (contact area, outside shoe) was of $10 \pm 3$ ms. The difference between inside and outside detection was $5$ ms.

![Positive, Negative and Null Differences](image)

Figure 5.20 Number of steps for which the differences between the methods (kinetic, contact area with insole inside the shoe and contact area with insole outside the shoe) were positive, negative or null. It is possible to see that the differences between KN and CA (both, inside and outside) were in all cases negative, indicating that CA detection occurred later than KN. At the same time, the differences between CAI and CAO showed that for the majority of the steps the difference was positive, indicating that CAO detected earlier than CAI.
Chapter 5. Evaluation of Kinematic and Pressure Sensor System Detection

The distribution of these differences showed that for the 14 steps CA (both, inside and outside the shoe) detection occurred later than KN. The distribution of the differences between CA-I and CA-O showed that for 12 steps CA-O detected earlier than CA-I and the difference was null for the other two steps (figure 5.21).

Again, it is clear that the presence of the shoe had an influence on the results but it does not seem to explain on its own the differences seen in the study.

Combined effect of threshold and shoe

The results from the previous section (influence of the shoe) were recalculated using a 2% threshold. The absolute mean differences are shown in table 4 and the distribution of those differences in figure 5.22.

From those results it is possible to see that in this case there is a combined effect of threshold and shoe in the distribution of the differences between KN and CA methods.

When the threshold is selected as 2% of estimated total area and the detection is done with an insole outside the shoe (which would be more similar to the actual detection done by the platforms), the distribution of the differences changes from all the 14 events being detected earlier by the KN method to 9 steps being detected earlier by the CA method and 4 being detected at the same time by both methods and the remaining 1 being detected earlier by the KN.

Although the sample size of only one subject and 14 steps in this study is not sufficient to conclude the extend of the effect, the results could imply that the selection of the threshold and the presence of the shoes has some influence on the HC detection, by the CA method.

Table 5.5 Absolute mean differences between methods for HC contact detection, expressed in ms.

<table>
<thead>
<tr>
<th>Method Comparison</th>
<th>5%</th>
<th>5%</th>
<th>2%</th>
<th>2%</th>
</tr>
</thead>
<tbody>
<tr>
<td>KN – CAI</td>
<td>15</td>
<td>10</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>KN – CAO</td>
<td>3</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>
Figure 5.21 Number of steps for which the differences between the methods (kinetic, contact area with insole inside the shoe and contact area with insole outside the shoe) and for different thresholds (2% or 5%) were positive, negative or null.

5.7.1.4 Distribution of the Differences for TO

In this case CA detection occurred later than KN in the majority of the steps (133 out of 210), the median value of the differences was –0.7% of stance phase, the absolute mean difference between the methods was 11 ms (1.6 % of stance phase), 94.8% of the differences were in the range of – 4% to 4% of stance, (figure 5.21) and the statistical analysis proved that the differences between the methods were not statistically significant.

KD detected earlier than the other two methods, which coincides with previous studies as already mentioned. One of the possible causes for these is the fact that the toe marker starts moving before the actual breaking of contact, so, as it has already being suggested in the literature [Ghoussayni et al. 2003] KD method would be more related to the start of the TO phase when KN would be more related to the end of the same phase.

5.7.2 Study B

The results from the detection on two different days and on two difference sensors showed a difference of up to 2 ms.

In the experiments to evaluate the gyroscope, the sampling frequency had to be reduced to allow for long data collection, and the sampling frequency was 125 Hz. This would also be the sampling frequency for the channel that would detect the...
synchronization pulse. In this case, there is a maximum possible delay of 8 ms. Compared to this, the difference between days and between sensors was considered negligible.

The two sensors used had already been used five times each, so that the repeatability seems to be acceptable even after that number of applications. This supported the idea of reusing the sensors.

5.7.3 Final Discussion

The results for unimpaired adults showed that there are differences between the methods of detection and this was reflected in the statistical analysis. Having said so, the median values for the differences for the healthy adults group between the methods being studied (kinematic and contact area) and the force platforms were between −3% and 3% of stance phase for both events, the absolute mean differences were in all cases less than 25 ms (less than 3.3 % of stance phase), which was within the range of “accepted differences”, as defined on section 5.1. The difference between the studied methods (KD and CA) was higher (up to 4.1% of stance phase), as they detected events earlier and later than KN, respectively.

The results may have been influenced by the threshold selected for detection and the presence of the shoes.

As mentioned before, the KD thresholds were selected conservatively to ensure that the beginning of the HC and end of TO were detected.

The effect of using different sensors and repeating the experiments on different days was considered negligible with respect to the maximum possible delay in detection of the synchronization pulse due to sampling frequency.

As mentioned earlier, the main limitations of this study are:

- It involved unimpaired adults, instead of children. However, Sutherland [1988; 1997] found that by 4 years of age the inter-relationships between the time-distance parameters are fixed and by the age of 5, the kinematic variables and most of the timing of muscle activity have reached adult values. It was also mentioned in that study that in terms of timing of events measuring from IC, the
opposite IC appears to have the least variability of all the gait events, occurring regularly at around 50% of gait cycle in all children from 2 years old, whereas the timing of FO reaches adult values (approximately 62% of gait cycle) by 5 years of age. These results encourage the applicability of the results from adults in children.

➢ There was no evaluation of the systems in pathological gait (where IC could be either HC or TC) and there was no evaluation of other events, such as Heel Off and Toe Contact. In this respect, researchers have found that there are similarities between the loading events (HC and TC) and between the unloading events (HO and TO) when using algorithms to detect them. Ghoussayni et al [2003], for example, determined that the differences between an algorithm using sagittal velocities of the markers at heel and toe and force platforms were similar for HC and TC, being less than 2% of gait cycle for both events, and also similar for HO and TO, being less than 10% of gait cycle for both events. Mickelborough et al. [2000] also found similar results for the event detection between HO and TO (80.3% of HO detection and 78.2% of TO detection occurred within 20 ms of force platform algorithm).

➢ There was no evaluation of the pressure measurement system in stairs and ramps, which are features that are going to be used in the evaluation of the gyroscope. In terms of the pressure measurement system, the detection is made using the whole area of the sole of the foot. This would allow for different areas of the foot to be the first area of contact or the last area of contact during a stance, which permits certain variability to occur in different terrains. However, the exact variability in event detection for different terrains is unknown and should have being tested.

Another limitation of the study is the relatively small sample size, which does not allow for generalizations to be made.

5.8 Conclusion

To conclude:
The median differences between KD and the gold standard (KN) were in both cases (HC and TO) less 2.5% of stance phase, the absolute mean difference was less than 20 ms (and less than 2.5% of stance phase) and, in general, KD detected earlier than KN.

For both events, the median of the differences between contact area method (CA) and the gold standard (KN) was less than –3%, the absolute mean differences were less than 25 ms (and less than 3.5% of stance) and, in general, CA detected later than KN.

The effect of collecting contact area data on different days and using different sensors was considered negligible with respect to the maximum possible delay in detection of the synchronization pulse due to sampling frequency.

Although there were differences between the methods of detection, in view that they showed differences comparable to the duration of IC (the shortest of the events), they were considered to be useful as references for event detection.

The main limitations of this study are that it involved unimpaired adults, instead of children; there was no evaluation of the systems on pathological gait; and there was no evaluation of the pressure measurement system in stairs and ramps.
Chapter 6
Evaluation of Gyroscope Indoors

6.1 Introduction

As stated in Chapter 1, this project is part of an overall project at the University of Surrey, towards the design and development of a stimulator that would be more appropriate for routine use in children with cerebral palsy.

The main objective of this project is to evaluate the gyroscope as a possible sensor to be used as part of an electrical stimulator aimed at improving the position of the foot during gait in children with CP. For that, it was necessary to develop hardware and software that would allow gyroscope and foot switch data collection and analysis (presented in Chapter 4) and it was also necessary to chose and evaluate reference detection systems that could provide accurate timing of events for comparison with the gyroscope (presented in Chapter 5). As discussed in section 5.1, the reference systems were used since it was considered that they may provide information about the detection that would make the analysis of the behaviour of the sensors, more complete, e.g. in the case where foot switch data became unreliable. The next step is to evaluate the detection from the gyroscope in unimpaired and cerebral palsy children on level ground.

This Chapter describes the evaluation of the gyroscope in unimpaired and CP children, when comparing its performance with foot switches and kinematic detection.

The evaluation involved level ground trials for six unimpaired and two CP children.

The evaluation had two objectives:

1) To determine if the features from the shank angular velocity signal as measured from one gyroscope on the shank associated to IC and FO in unimpaired adult gait, are still related to those events in children and CP gait.
2) And, if they are, then the accuracy of event detection (as compared to kinematics, as the reference system, and to foot switches) should be determined to evaluate whether it is possible to use this sensor to control functional electrical stimulation in CP children.

Section 6.2 describes the methods chosen for the study, and the results are presented in section 6.3. In section 6.4 there is a discussion of those results taking into account a review of the results already obtained by other researchers regarding the evaluation of sensors for gait event detection.

6.2 Method

6.2.1 Subjects

Six unimpaired children (mean age 9.5 ± 3.2 years old) and two children with cerebral palsy (both aged 9), whose data is summarized in table 6.1, participated in this study. A limited number of CP participants were recruited due to limited number of CP children attending regular sessions at the hospital. Further recruitment was planned at a later stage (Chapter 7), but new issues regarding ethical approval, moving of the facilities and continuing recruitment issues limited the total number of participants (as explained in Section 7.2.1).

Table 6.1 Age, gender and condition of children who participated in the study

<table>
<thead>
<tr>
<th>Participant</th>
<th>Age</th>
<th>Gender</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1</td>
<td>13</td>
<td>F</td>
<td>Unimpaired</td>
</tr>
<tr>
<td>S2</td>
<td>14</td>
<td>M</td>
<td>Unimpaired</td>
</tr>
<tr>
<td>S3</td>
<td>7</td>
<td>F</td>
<td>Unimpaired</td>
</tr>
<tr>
<td>S4</td>
<td>7</td>
<td>M</td>
<td>Unimpaired</td>
</tr>
<tr>
<td>S5</td>
<td>7</td>
<td>F</td>
<td>Unimpaired</td>
</tr>
<tr>
<td>S6</td>
<td>9</td>
<td>M</td>
<td>Unimpaired</td>
</tr>
<tr>
<td>S7</td>
<td>9</td>
<td>F</td>
<td>Mild Diplegia (left side more affected)</td>
</tr>
<tr>
<td>S8</td>
<td>9</td>
<td>M</td>
<td>Mild Left Hemiplegia</td>
</tr>
</tbody>
</table>

Both children with CP were foot flat walkers, with the foot landing almost parallel to the floor at the time of IC and none used any walking aid for the trials.
An Information Sheet was provided for parents and children and a consent form was signed by every parent/carer and each child.

The study was reviewed and obtained ethical approval from the Wandsworth Local Research Ethics Committee.

6.2.2 Set Up and Protocol

For each child, data was collected from the self selected leg of unimpaired children and for the most affected leg in the case of CP children. The set up (see figure 6.1) consisted of:

- A gyroscope placed on the anterior aspect of the shank, the position of which was maintained using a Velcro strap wrapped around the shank.
- Two foot switches placed inside the shoe: one placed underneath the heel and the other under the first metatarsal head, both attached with double-sided tape onto the surface of the shoe insole.
- Retroreflective markers placed on the heel and on the toe (between the second and third metatarsal head). In all cases, markers on the shank and on the contralateral side were added in order to have extra visual information about the movement.

Each child wore the shoes they normally used for daily activities.

Kinematic data was collected using the ProReflex and MacReflex MCU systems (Qualisys Medical AB, Gothenburg, Sweden\(^1\)), consisting of 7 and 6 infrared cameras, respectively. When the ProReflex system was used, the chosen sampling frequency was 100 Hz, while when the MacReflex system was used, the sampling frequency was set to the maximum sampling frequency of the equipment which is 60 Hz.

\(^1\) Qualysis AB, [http://www.qualisys.se](http://www.qualisys.se)
Chapter 6. Evaluation of Gyroscope Indoors

Figure 6.1 The set up being worn by a CP child. A gyroscope was situated on the anterior aspect of the shank, two foot switches were placed underneath the heel and first metatarsal head and small retroreflective markers were placed in prescribed different anatomical points.

As explained in Chapter 4, gyroscope and FSR data were collected using either a portable laptop (in which case, there were cables connecting the devices to the computer and a sampling frequency of 100 Hz was used) or a portable datalogger (with a sampling frequency of 125 Hz).

The children were asked to walk at a comfortable speed, from a determined mark on the floor to the opposite wall. Data collection started approximately 2 steps after the start of the walk and finished at least 2 steps before the child stopped, with a total distance of 10 m. Six walking trials were recorded for unimpaired children and three for CP children.

6.2.3 Data Analysis

6.2.3.1 Events Detection

For each child and for each trial, kinematic data was analysed using the algorithm explained in Chapter 5, while gyroscope and FSR data were analysed using the algorithms explained in Chapter 4. All routines are included in Appendix C.
Chapter 6. Evaluation of Gyroscope Indoors

The detection time for Initial Contact (IC) and Foot Off (FO) were determined for each trial and each method. Figures 6.2 and 6.3 illustrate the kinematic detection of IC (in this case HC) and FO (in this case TO) for one unimpaired child. Figures 6.4 and 6.5 show the signals from heel and toe switches respectively and the corresponding event detection. Figure 6.6 shows the gyroscope signal and detection of HC and TO. All the figures correspond to the signals from the same trial and the same unimpaired child.

Figure 6.2 Speed of the heel marker in the X direction (which is the direction of progression) and (in red) threshold used for detection for an unimpaired child. The sample at which the descending signal had a value below the threshold was defined as HC. Threshold = 800 mm/s.
Figure 6.3 Speed of the toe marker in the X direction (direction of progression) and (in red) threshold used for detection of TO for an unimpaired child. The sample at which the ascending signal exceeded the threshold was defined as TO. Threshold = 800 mm/s.

Figure 6.4 Heel Switch signal and (in red) threshold used for detection of HC for an unimpaired child. The sample at which the descending signal was below the threshold was defined as HC. Threshold used= mean value of the signal.
Chapter 6. Evaluation of Gyroscope Indoors

Figure 6.5 Toe Switch signal and (in red) threshold used for detection of TO for an unimpaired child. The sample at which the ascending signal exceeded the threshold was defined as TO. Threshold used = mean value of the signal.

Figure 6.6 Gyroscope signal and detection of HC (in red) and TO (in black) for an unimpaired child. A rule-based algorithm (detailed in Chapter 4) determined the samples at which HC an TO would be determined.
The same analysis was performed for CP children. In this case, however, it was necessary to analyse the type of contact and break of contact that occurred. In order to determined whether IC was HC or Toe Contact (TC), both were calculated using the Heel and Toe marker respectively, using identical algorithm, and the first to occur was considered IC. The same procedure was repeated for FO (by calculating TO and Heel Off, using identical algorithm, and choosing the last of these events to occur).

The results of this analysis showed that both CP children were foot flat walkers, that is to say that HC and Toe Contact occurred approximately at the same time (figures 6.7 and 6.8) and that, in both cases, TO occurred later than Heel Off.

Further analysing the kinematic detection of IC event, from the 9 events analysed for subject 7 (figure 6.7), toe contact was detected at the same sample as HC for 7 events while it was detected later for the remaining 2. Similarly, from the 11 events analysed for subject 8, toe contact was detected at the same sample as HC for 7 events while it was detected later for the remaining 4. This information would indicate that HC occurred either at the same time or earlier than Toe Contact for both children.

Figure 6.7 Heel and toe marker speed for S7 (CP child). The first of the signals to go down below the threshold was considered for IC detection, while the last of the signals to exceed the threshold was considered for FO detection. Threshold = 800 mm/s
Figure 6.8. Heel and toe marker speed for S8 (CP child). The first of the signals to go down below the threshold was considered for IC detection, while the last of the signals to exceed the threshold was considered for FO detection. Threshold = 800 mm/s

The same analysis was repeated with the foot switch signals. Figures 6.9 and 6.10 show the foot switches signals for subject 7 and 8 respectively. From figure 6.9, it is possible to see that in the case of subject 7, for some steps the heel and toe foot switch signals diminish almost at the same time (in the used configuration the output voltage goes down when the switches are pressed and goes up when they are released), meaning that pressure was applied almost at the same time, coinciding with the kinematic information. For other steps, however, (in figure 6.9, the second and third steps) the toe switch signal goes down before the heel signal.

On the other hand, for S8 (figure 6.10), all IC are HC (the heel switch being pressed before the toe switch, showed by the heel switch signal going down before the toe switch signal).

In terms of FO, for both children the toe switch was released later than the heel switch indicating TO rather than Heel Off.
Chapter 6. Evaluation of Gyroscope Indoors

Figure 6.9 Signals from the foot switch for S7. When the switches are pressed, the output voltage decreases. In some cases (second and third step) the toe switch (red trace) is pressed earlier than the heel switch, for other steps they are pressed almost simultaneously.

Figure 6.10 Signals from the foot switch for S8. Heel switch being pressed earlier than toe switch for all steps.

Taking into account the definition of Initial Contact as the first contact of the foot with the floor, it was decided that such definition should be kept independent for each
method and each step, so that kinematic detection of IC was performed using the heel marker velocity for both children while the foot switch detection was performed using the first switch being pressed.

Foot off, defined as the last contact of the foot with the floor, was determined using the toe marker velocity and the toe switch for both children.

6.2.3.2 Time Difference

Once the events were determined for each method, the comparison between the methods was carried out by calculating the difference in time (ms) between the detections for each step analysed.

First, for each step analysed, the differences in the detection of events were calculated as:

a) KD-FS = kinematic detection (KD) - foot switch detection (FS),
b) KD-GD = kinematic detection (KD) - gyroscope detection (GD),
c) FS-GD = foot switch detection (FS) - gyroscope detection (GD).

Second, in order to avoid misleading results due to cancellation of positive and negative values when averaging, the absolute value of the difference was calculated for each step.

Later, the absolute differences of all the steps for one subject were averaged so that a single value was obtained for each subject and each method.

Finally, the mean absolute values for the six unimpaired children were averaged (and are reported in Section 6.3.1) and the mean absolute values for the two CP children were averaged (and are reported in Section 6.3.2). These values were calculated in order to compare the results with the ones previously reported in the literature (in particular, with the results reported in table 6.5).

However, for data that is not normally distributed (and specially, when the data is skewed), the median value represents a better option to represent the central tendency. Values of the median, together with the 95% confidence interval, are also provided in Section 6.3.1 for unimpaired children and in Section 6.3.2 for CP children.
6.2.3.3 Distribution of the Differences

In order to evaluate whether there was a tendency for the any of the methods to detect an event systematically earlier or later than others, an analysis of the distribution of the differences was performed.

The distribution of the differences for each method was analysed in two different ways.

First, all the events analysed for each child were taken into account and the number of positive, negative and null differences for each of the methods and each child was calculated. As the differences were calculated as "first method – second method", a positive difference means that the first method detected the event later than the second, a negative difference means that the first method detected the event earlier than the second, and a null difference means that both detected it at the same sample. This analysis would show if there is a bias in the detection in one subject and across subjects. In Section 6.3.3 the number of positive, negative and null events registered for each unimpaired child is presented, while Section 6.3.4 presents the same information for each of the CP children.

The other way used to analyse the differences was to construct a histogram of the number of steps versus the time difference (in the range of −200 to 200 ms, divided in 10 ms interval) calculated for each pair of methods. For example, the number of events analysed for which the difference was from −205 to −195 was assigned to the −200 bar, and so on up to 195 to 205 ms interval. Each histogram represents the distribution of differences for one of KD-FS, KD-GD, FS-GD for one of the group of children. In order to avoid bias of the results due to different number of events analysed for different children, a fixed number of steps was selected for each event and each group. The fixed number was the maximum available steps for all subject. This analysis would provide general information regarding the group and an idea of the variability in detection.
6.2.3.4 Time Difference as a Percentage of Stance Phase

The differences were also calculated as a percentage of the stance phase in order to put them in the context of gait timings. The differences for IC and TO for all subjects are presented in Section 6.3.5.

6.3 Results

6.3.1 Median and Absolute Mean Differences for Unimpaired Children

For unimpaired children, a total of 81 HC events and 70 TO events were analysed (normally, more HC events than TO events were analysed since the detections on the trial were started by the first HC and, by the end of the trial, it is likely that the software will loose the tracking of the makers for the end part of the last gait cycle, as the subject goes near the edge of the capture volume). The median of the differences between the methods (expressed in ms) for all the unimpaired children and the absolute mean differences are shown in Table 6.2, while the absolute mean difference for each child and each method is shown in figure 6.11 for HC detection and in figure 6.12 for TO detection.

<table>
<thead>
<tr>
<th>Event Detected</th>
<th>KD-FS</th>
<th>KD-GD</th>
<th>FS-GD</th>
</tr>
</thead>
<tbody>
<tr>
<td>HC</td>
<td>0 [-30, 40]</td>
<td>10 [-20, 40]</td>
<td>0 [20, 20]</td>
</tr>
<tr>
<td></td>
<td>(17 ± 5)</td>
<td>(17 ± 3)</td>
<td>(9 ± 4)</td>
</tr>
<tr>
<td>TO</td>
<td>20 [0, 60]</td>
<td>60 [10, 100]</td>
<td>30 [10, 60]</td>
</tr>
<tr>
<td></td>
<td>(20 ± 8)</td>
<td>(50 ± 9)</td>
<td>(34 ± 7)</td>
</tr>
</tbody>
</table>
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Figure 6.11. Absolute mean difference (ms) for the Heel Contact (HC) event for each of the unimpaired children who participated in the study. The differences were calculated between kinematic and foot switch detection (blue bar), kinematic and gyroscope detection (green bar) and foot switch and gyroscope detection (red bar). The black lines represent one standard deviation. n = 81.

Figure 6.12 Absolute mean difference (ms) for the Toe Off (TO) event for each of the unimpaired children who participated in the study. The differences were calculated between KD-FS (blue bar), KD-GD (green bar) and FS-GD (red bar). The black lines represent one standard deviation. n = 70.
6.3.2 Median and Absolute Mean Differences for CP Children

For CP children, a total of 20 IC events and 18 FO events were analysed for both children. The median and 95% interval of the differences between the methods (expressed in ms) for the CP children and the absolute mean differences are shown in Table 6.3, while the absolute mean difference for each child and each method is shown in figure 6.13 for IC detection and in figure 6.14 for FO detection.

Table 6.3 Median [95% interval] of the differences and (absolute mean difference ± one standard deviation), all expressed in ms for IC and FO for CP children. The differences were calculated between kinematic and foot switch detection (KD-FS), kinematic and gyroscope detection (KD – GD) and foot switch and gyroscope detection (FS -GD). n = 20 IC and n = 18 FO

<table>
<thead>
<tr>
<th>Event Detected</th>
<th>KD-FS</th>
<th>KD-GD</th>
<th>FS-GD</th>
</tr>
</thead>
<tbody>
<tr>
<td>IC</td>
<td>15 [-20, 30]</td>
<td>15 [-10, 30]</td>
<td>0 [-20, 20]</td>
</tr>
<tr>
<td></td>
<td>(15 ± 1)</td>
<td>(16 ± 1)</td>
<td>(11 ± 7)</td>
</tr>
<tr>
<td>FO</td>
<td>95 [40, 150]</td>
<td>100 [50, 150]</td>
<td>10 [-40, 40]</td>
</tr>
<tr>
<td></td>
<td>(106 ± 67)</td>
<td>(112 ± 32)</td>
<td>26 ± 7</td>
</tr>
</tbody>
</table>
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Figure 6.13 Absolute mean difference (ms) for IC event for each of the CP children who participated in the study. The differences were calculated between kinematic and foot switch detection (blue bar), kinematic and gyroscope detection (green bar) and foot switch and gyroscope detection (red bar). The black lines represent one standard deviation.

Figure 6.14 Absolute mean difference (ms) for FO event for each of the CP children who participated in the study. The differences were calculated between KD-FS (blue bar), KD-GD (green bar) and FS-GD (red bar). The black lines represent one standard deviation.
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6.3.3 Distribution of the Differences for Unimpaired Children

Figure 6.15 shows the distribution for each child in HC detection, while figure 6.16 shows the distribution for each child in TO detection. A group of three columns is associated with each subject. The first column, represents the differences between KD-FS, the second column the differences between KD-GD and the third column the differences between FS-GD. For example, in figure 6.15 (HC events) for subject 1 (S1), the differences between KD and FS (represented in the first column) presented 2 positive values (showed in the graph as the lavender part of the bar), 3 negative values (showed as the pink part of the bar) and 0 null values (which would have been showed in yellow).

Figures 6.17 and 6.18 show the histograms of the differences between the methods in detection of HC and TO, respectively, for all the unimpaired children. In order to construct the histograms, 7 HC events and 8 TO events for each child were considered, so that the total number of events were 42 HC and 48 TO.

Although the distribution was calculated in the range of -200 to 200 ms, the x axis was scaled for each histogram to a smaller range without loosing any component.

![Figure 6.15](image_url)
Figure 6.16. Distribution of the differences for the TO event detection for each of the six unimpaired subjects. Each group of three columns represent the differences for that particular subject, where the first column, represents the differences between KD-FS, the second column the differences between KD-GD and the third column the differences between FS-GD. $n=70$.

Figure 6.17. Histograms representing the distribution of the differences in HC detection for the unimpaired children group. Each bar represents the number of events analysed for which the value of the difference was in the interval considered for that particular bar. $n=42$.
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6.3.4 Distribution of the Differences for CP children

Figures 6.19 and 6.20 show the distribution of the differences for IC and FO, respectively, for the CP children group.

Figure 6.19. Distribution of the differences for IC event detection for each of the two CP subjects. Each group of three columns represent the differences for that particular subject, and in each group, the first column represents the differences between KD-FS, the second column the differences between KD-GD and the third column the differences between FS-GD.

Figures 6.21 and 6.22 show the histograms of the differences between the methods in detection of IC and FO, respectively, for the CP children. In order to construct the
histograms, 9 IC and 8 TO events were considered for each child, which made a total of 18 IC and 16 TO events.

Figure 6.20. Distribution of the differences for FO event detection for each of the two CP subjects. Each group of three columns represent the differences for that particular subject, where the first column represents the differences between KD-FS, the second column the differences between KD-GD and the third column the differences between FS-GD.

Figure 6.21 Histograms representing the distribution of the differences for IC event detection for CP children. n=18
Figure 6.22 Histogram representing the distribution of the differences for FO event for CP children. n= 16

6.3.5 Differences as a Percentage of Stance Phase

Table 6.4 shows the absolute mean differences between the methods (now, expressed as a percentage of stance phase) for the two groups.

Table 6.4. Absolute mean difference ± one standard deviation (% of Stance Phase) for Initial Contact (IC) and Foot Off (FO) event detection, for both groups of children.

<table>
<thead>
<tr>
<th>Event</th>
<th>Group</th>
<th>KD-FS</th>
<th>KD-GD</th>
<th>FS-GD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Unimpaired</td>
<td>2.8 ± 1.6</td>
<td>2.9 ± 1.2</td>
<td>1.4 ± 0.5</td>
</tr>
<tr>
<td></td>
<td>CP</td>
<td>2.1 ± 0.1</td>
<td>2.2 ± 0.1</td>
<td>1.6 ± 1.0</td>
</tr>
<tr>
<td>IC</td>
<td>Unimpaired</td>
<td>3.2 ± 1.2</td>
<td>8.5 ± 2.0</td>
<td>4.9 ± 2.2</td>
</tr>
<tr>
<td>FO</td>
<td>CP</td>
<td>14.1 ± 8.4</td>
<td>14.9 ± 3.1</td>
<td>3.7 ± 1.1</td>
</tr>
</tbody>
</table>
6.4 Discussion

6.4.1 Initial Contact Detection Using Kinematic and Foot Switches

In Section 6.2.3.1 it was explained that when determining the type of IC event (whether heel contact, foot flat or toe contact) the results obtained using kinematic detection were different to those using foot switches detection for one CP child. In particular, when analysing the IC for subject 7, kinematic detection showed that IC was always either heel contact or foot flat, whereas the foot switch detection showed that some IC were toe contacts followed by the contact of the heel (occurring up to 30 ms later).

In order to explain this disagreement between the methods it may be necessary to elaborate on the actual detection that each method reports.

In the literature, methods detecting foot contact and foot off using kinematic or force variables have been used almost interchangeably, and Chapter 5 of this project showed that the detection using kinematic method was close enough to the detection using force platforms as to use it as a reference method.

However, the basic mechanisms of detection are slightly different for both methods. In this particular case (using velocities), the kinematic detection uses progression as indicator (detects "start of progression", when the toe marker starts moving forward and "end of progression", when the heel marker stops moving forward). On the other hand, the foot switches detect the contact of the foot with the floor and the break of contact, which the actual definition of foot contact and foot off relates to. This difference in the principles may have influenced the issue of defining the type of foot contact for the gait pattern of S7.

It was expected then that the other reference system evaluated (pressure measurement system), which used contact rather than progression information for detection of events, would avoid this particular difference with the foot switch.

6.4.2 Median and Absolute Mean Differences

6.4.2.1 Comparison with Other Studies

Table 6.5 and 6.6 summarize those studies mentioned in Chapter 3 that report on the accuracy of sensors when compared with a reference method in the detection of gait.
events. As mainly two reference methods were used, table 6.5 shows all the studies that reported the results when compared with foot switches and table 6.6 shows those studies that reported results against a motion analysis system. The results presented in the tables correspond to level ground walking or treadmill walking (with 0° inclination); however, some of those studies varied the speed of walking but reported the overall results (for all speeds). Also the results from this study are shown.

Although results have been reported in various ways, the tables provide a general idea of the range of differences that have been achieved so far. It is worth noting that some of the studies reported the difference as mean difference rather than absolute mean difference. In this way, an underestimation of the actual value of the differences might occur by cancellation of positive and negative values.

To avoid such underestimation, the results in this study are reported as absolute mean differences only.

For HC detection compared with FSR, the reported results range between an average of -2 ms to a 147 ± 91 ms. For this study the largest differences were seen for CP children and they were 11 ± 7 ms.

For TO detection compared with FSR, the 95% of foot off were in the [-5, 4] ms range as reported by Aminian et al, and in a 220 ms window as reported by Hansen et al. For this study, 95% of TO were in the range [10, 60] ms in a 50 ms window.

In terms of HC detection compared with kinematic detections using motion analysis systems, a mean difference of 70 ms was reported by Pappas et al. whereas an absolute mean difference of 28 ms was reported by Ghoussayni et al. In this study, the absolute mean difference was smaller than 20 ms for both groups (17 for unimpaired children and 16 for CP).

Finally, in terms of the TO detection compared with kinematic detection, a mean difference of 35 ms was reported by Pappas et al, whereas an absolute mean difference of 58 ms was reported by Ghoussayni et al. In this study, the absolute mean difference for the unimpaired group was 50 ms whereas for the CP group it was 112 ms.

These comparisons show that, most of the results of this study are well within (and towards the bottom of) the range of results reported in the literature.
Table 6.5 Time differences (mean time ± standard deviation –sd–, when provided) reported by between evaluating sensor and FSR. Speeds: ss = self-selected, nm = normal, sl = slow, ft = fast.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Participants and protocol</th>
<th>Sensor Used</th>
<th>Reference used</th>
<th>Mean Time Difference ± one sd [ms]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Willemsen et al [1990]</td>
<td>4 unimpaired and 4 hemiplegic adults (of which only the data of 3 could be analysed). Speeds: ss nm, ss sl, ss ft</td>
<td>Four accelerometers placed on the heel and toe</td>
<td>FSR (under the heel and toe)</td>
<td>HC unimpaired = -30 ± 60</td>
</tr>
<tr>
<td>Mansfield and Lyons [2003]</td>
<td>Four unimpaired adults</td>
<td>One accelerometer placed on the trunk</td>
<td>FSR (under the heel).</td>
<td>For HC = 147 ± 91</td>
</tr>
<tr>
<td>Ghoussayni et al [2001]</td>
<td>Five unimpaired and three hemiplegic adults. Speeds: ss nm, ss sl</td>
<td>One gyroscope placed on the shank</td>
<td>FSR under the heel and first metatarsal head.</td>
<td>(Absolute mean difference): HC unimp= 38 TO unimp= 118 HC hem =48 TO hem= 98</td>
</tr>
<tr>
<td>Aminian et al [2002]</td>
<td>unimpaired: 9 young adults and 11 elderly subjects Speeds: ss nm, ss sl, ss ft</td>
<td>One gyroscope on the shank</td>
<td>FSR under the heel and toe</td>
<td>95 % of HC = [7, 13] 95% of TO = [-5, 4]</td>
</tr>
<tr>
<td>This study</td>
<td>6 unimpaired children and 2 CP children. Speeds: ss nm.</td>
<td>One gyroscope placed on the shank</td>
<td>FSR (one under the heel and one under the first metatarsal head)</td>
<td>(Absolute mean difference): HC unimp = 9 ± 4 TO unimp = 34 ± 7 HC CP =11 ± 7 TO = 26 ± 7</td>
</tr>
</tbody>
</table>
Table 6.6. Time differences reported between evaluating sensor and motion analysis system.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Participants and protocol</th>
<th>Sensor Used</th>
<th>Reference used</th>
<th>Mean Time Difference [ms]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lauer, Smith et al. [2005]</td>
<td>8 CP children Speeds: ss nm.</td>
<td>EMG of quadriceps</td>
<td>Motion Analysis System</td>
<td>IC = 4 ± 40 (Range for diff. subjects [-29, 50]) FO = -5 ± 31 (Range for diff subjects [-52,24])</td>
</tr>
<tr>
<td>Pappas, Popovic et al. [2001]</td>
<td>3 unimpaired adults Speeds: fixed at 3 and 5 km/h</td>
<td>Three FSR and a gyroscope in an insole</td>
<td>Motion Analysis System</td>
<td>HC = 70 TO = 35</td>
</tr>
<tr>
<td>Ghoussayni, Henty et al. [2001]</td>
<td>Five unimpaired and three hemiplegic adults. Speeds: ss nm, ss sl.</td>
<td>One gyroscope placed on the shank</td>
<td>Motion Analysis System</td>
<td>(Absolute mean difference): HC unimp=28 TO unimp=58</td>
</tr>
<tr>
<td>This study</td>
<td>6 unimpaired children and 3 CP children. Speeds: ss nm.</td>
<td>One gyroscope placed on the shank</td>
<td>Motion Analysis System</td>
<td>(Absolute mean difference): HC unimp = 17 ± 3 TO unimp = 50 ± 9 HC CP = 16 ± 1 TO = 112 ± 32</td>
</tr>
</tbody>
</table>

6.4.2.2 Median and Absolute Mean Differences in this Study

The differences between FS and GD for this study were similar between groups for the HC event (the median was 0 ms for both groups, while the absolute mean difference was 9 ± 4 ms for unimpaired and 11 ± 7 ms for CP children) and TO event
(median 30 ms and absolute mean difference was $34 \pm 7$ ms for unimpaired and
median was 10 ms and absolute mean difference $26 \pm 7$ ms for CP children) which
seems to indicate that the relationship between the methods in the detection of events
in unimpaired children is maintained for the gait pattern of the two CP children who
participated in the study. Also, taking into account the absolute mean difference as a
percentage of stance phase, the differences between FS and GD are within 5% of
stance for both groups and both events.

As mentioned in Chapter 3, stimulation frequencies in the range between 30 to 40 Hz
are commonly used for functional electrical stimulation in children. Considering that a
frequency of 40 Hz is used, the differences seen between the gyroscope and foot
switch would represent stimulation starting or stopping 2 pulses before or after
stimulation started by foot switch.

When considering the kinematic detection, differences between KD-FS and KD-GD
were similar for HC detection in the unimpaired group (median 0 ms and 10 ms,
absolute mean differences 17 ms in both cases) and in the CP group (median 15 for
both groups, absolute mean difference 15 ms and 16 ms respectively) and also in the
TO detection for CP children (median 95 ms and 100 ms respectively, absolute mean
difference 106 ms and 112 ms, respectively). However, in TO detection in unimpaired
children, the FS and KD detection were closer than the GD and KD (median 20 ms
and 60 ms respectively, absolute mean differences 20 ms and 50 ms respectively).

For both groups and all methods, the absolute mean differences expressed as a
percentage of stance phase in the detection of IC were below 3.0% of stance phase,
and particularly below 2% of stance phase for the FS-GD. For FO detection, for both
groups and all methods, the absolute mean differences expressed as a percentage of
stance phase, were below 15% and particularly below 5% for FS-GD.

As explained in Chapter 5, Perry [1992] describes the Initial Contact in unimpaired
gait as a phase lasting 2% of the gait cycle (if we assume that stance phase represents
approximately 60% of gait cycle, the phase would last 3.3% of stance), while the
unloading phase (from the contact of the other foot on the floor until TO) represents
10% of gait cycle (17% of stance phase, considering that the stance phase represents
60% of gait cycle).
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Taking these values into account all the differences were within the duration of the events, which could indicate that the differences are due to the methods detecting different times of the same event.

6.4.3 Distribution of the Differences

Analysing now the distribution of the differences, it is possible to see that in terms of KD-FS differences for HC detection, for 3 out of six unimpaired children (figure 6.15) and both CP children (figure 6.19), that is subjects 3, 4, 5, 7 and 8, the differences were mainly positive meaning that the FS detected IC earlier than KD. The histograms show that for unimpaired children, 95% of HC were in the range from -30 to 40 ms (figure 6.17), whereas for CP children the range was from -20 to 30 ms (figure 6.21).

Again, this is the pattern for GD for which 4 of the unimpaired children (figure 6.15) and both CP children (figure 6.19), that is subjects 1, 3, 4, 5, 7 and 8, most of the differences are positives, meaning that GD detected IC earlier than KD. The histograms show that for unimpaired children, 95% of HC were in the range from -20 to 40 ms (figure 6.17), whereas for CP children the range was from -10 to 30 ms (figure 6.21).

For FS-GD the detections are more equally distributed between positive, negative and null values, which is also shown by the histograms (both unimpaired and CP groups) centred in zero. Both histograms show that 100% of the values are in the range of -20 to 20 ms.

So, in general, there is a tendency for FS and GD to detect IC before KD and close to one another, with 100% of the detections presenting a difference in the -20, 20 ms range.

In terms of TO, the GD detection occur clearly earlier than KD (most of the detections were positive for all the subjects, as seen in figures 6.16 and 6.20) and also earlier than FS for seven of the eight subjects (except subject 7). There is a tendency for the FS detection to occur earlier than KD although it is less strong than for the GD.

Considering now the histograms (figure 6.18 for unimpaired children and figure 6.22 for children with CP), they show greater variability for FO detection than for IC. The
distribution of the differences between KD and FS for unimpaired children presents 96% of differences in the range from 0 to 60 ms. For CP children, the variability increases, and the distribution differ for each subject. For S8, the differences are in the range of 20 to 80 ms, whereas for S7, all the differences are larger than 110 ms.

Similarly, for the distribution of the differences between KD and GD, for unimpaired children, 95% of the differences are in the range of 10 to 100 ms, whereas for CP children, all the differences are in the range from 50 to 100 ms for S8, but from 100 to 150 for S7.

For the differences between FS and GD, 98% of those differences are in the range from 10 to 60 ms in the unimpaired group, and in the – 40 to 40 ms for the CP children, in this case the differences are distributed for both children.

The differences for FO present greater variability than the ones for IC for both groups. The KD detection seems to be particularly affected by the gait pattern of each CP child (as it shows from the differences between KD-FS and KD-GD).

6.4.4 Final Considerations

6.4.4.1 Foot Off Detection

The Foot Off detection deserves further analysis, especially when taking into account the kinematic detection, in particular:

1) The bigger differences between KD and both other methods for CP children (KD-FS and KD-GD);

2) The fact that FS detection seems to be nearer KD for unimpaired children than GD but that close relationship seems to be lost in the case of CP children.

Two considerations should be taken into account.

Researchers [Ghoussayni et al. 2003] have suggested to consider the “take – off” or unloading events (heel off and toe off), as phases rather than events. While Initial Contact in unimpaired gait has being described as a phase lasting 2% of the gait cycle, the unloading phase has being described as 10% of gait cycle [Perry 1992].
In the particular case of the CP children, there could be a need of extending the double support phase of gait to improve stability. It would be reasonable to believe, then, that the advancement of the foot may not start until the other foot has been loaded or, in other words, that the limb that will start the swing will be partially unloaded first (by loading the contralateral) before any forward movement starts.

This could account, though to an unknown extent, for the larger differences seen in CP detection using FS with respect to KD and for the difference between unimpaired and CP detection (FS detection being closer to KD in unimpaired children than in CP children).

From the results, it seems that GD detection remains close to the FS detection even in this cases.

6.4.4.2 Other Considerations

The differences found between the methods could also be influenced by:

1) the sampling frequency. When, for example, the kinematic sampling frequency was 60 Hz (which was the lowest sampling frequency used), the KD detection may have detected the event approximately 16.7 ms later than the actual event happened.

2) The sampling frequency in the detection of the synchronization. In the worst case, the synchronizing pulse was detected by a channel of the acquisition card, sampled at 100 Hz. So the detection could have occurred 10 ms later than the actual start of the kinematic method and a systematic delay of 10 ms would have occur in all the detections for that trial.

The maximum error caused by both, the sampling frequency and the detection of synchronizing pulse, is 27 ms.

Also, the number of children who participated in this study does not allow for generalizations to be made. However, the results show a tendency that should be confirmed by analysing the gait event detections in more participants.

Finally, there was no evaluation of children using stimulation, which would change their walking pattern. However, when stimulation is applied, it would be expected that the gait pattern of children with CP would change towards the gait pattern of
unimpaired children. It would then, be expected that the sensor detection would become closer to the detection in unimpaired children.

6.5 Conclusion

This study has allowed reaching some conclusions, which are summarized below.

The differences obtained in this study between the GD and both other methods for both groups of children were within the ranges of differences reported in the literature when using a variety of sensors.

When using kinematic information (and particularly the use of velocities) and foot switch information, different standpoints are being used for event detection. Kinematic uses information of progression whether foot switches uses contacts. This may have affected the determination of the type of initial contact. Due to this disagreement, the use of another reference, which also uses contact information for event detection, would be an advantage for the comparisons.

The median of the differences between GD and FS for IC detection and for both set of children was 0 ms. The absolute mean differences were below 15 ms (less than 2% of stance phase of gait and, under the assumptions explained in Section 6.4.2.2, less than the actual duration of the unimpaired IC as defined by Perry [1992]) and 100% of events were in the range of -20 to 20 ms.

The median of the differences between GD and FS, for FO detection were below 30 ms. The absolute mean differences were below 35 ms (less than 5% of stance phase which is one third of the duration of the unloading phase, as described under the same assumptions by Perry [1992]). The distribution was wider, with 98% of TO for unimpaired children found in a 50 ms window, from 10 to 60 ms, and the 100% of FO for CP children in the range from -40 to 40 ms.

In terms of the differences expressed before between FS and KD detection methods, these results suggest that GD would be closer to FS detection than to KD, even when the gait pattern changes (as the changes seen in the two children who participated in this study).
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Considering a stimulation frequency of 40 Hz, the differences between gyroscope and foot switch would represent less than 2 pulses of stimulation.

With respect to the objectives described in the Introduction of this chapter, the conclusions are:

1) The differences seen in FS-GD for the unimpaired group were similar to those seen in the CP group for both events, which would indicate that the features chosen from the shank angular velocity to detect the events are still present in the case of these two CP children. Due to the small sample size, it is not possible to generalize these results; however they show a tendency that should be confirmed with further analysis in more participants.

2) The gyroscope detected IC in a ± 20 ms window with respect to the foot switch detection for all steps analysed (from unimpaired and CP children) and FO in a ± 40 ms window in CP children, and in a 0 to 50 ms window for unimpaired children.

Comparing with the reference system, both sensors seem to be equally accurate for IC detection (median, 0 ms for FS and 10 ms for gyroscope for unimpaired children and 15 ms for both sensors for CP children – less than 1 sample); the FS seems to be slightly more accurate (closer to the reference) than the gyroscope for FO detection (the medians for the FS were 20 ms for unimpaired children and 95 ms for children with CP while the medians for the gyroscope were 60 for unimpaired children and 100 ms for children with CP).

Finally, taking into account that in Chapter 5 it was shown that KD detection was earlier than the gold standard (KN) (absolute mean difference of 20 ms) and that the sensors detected the events earlier than KD, the errors are adding up and the differences between both sensors and the gold standard could be higher (mean 20 ms higher).
Chapter 7
Evaluation of Gyroscope Outdoors

7.1 Introduction

This chapter describes the evaluation of the gyroscope detection outdoors, which included walking trials on level ground, stairs and ramp for seven unimpaired children.

The reason behind this evaluation is that an electrical stimulator for walking should provide accurate and reliable stimulation in the environment where the child will ambulate during daily activities, and this may include ramp and stairs.

Researchers have investigated the gait pattern when subjects walk up and down stairs and ramps and have found that the kinematics of the lower limb changes.

Kuster et al [1995], for example, evaluated kinematic data collected from 12 unimpaired adults while they walked both downhill and at level ground at a controlled cadence. On the basis of the differences in ankle, knee and hip joint kinematics, the authors found that movement adjustments occurred primarily at the knee joint during the stance phase and at the ankle and hip joints during the swing phase. The average difference in hip angle found at heel strike was 12° (less flexed when walking downhill), and that of knee and ankle angle at toe off was 10° (the knee being more flexed and the ankle less plantarflexed when walking downhill).

Prentice et al. [2004] studied kinematic changes that occur at the transition of walking from level ground onto different inclined surfaces (slopes 3°, 6°, 9° and 12°). They focused the study in the TO – HC interval, where TO occurred on level ground and HC on the inclined surface. Their results showed an increased flexion at the hip, knee and ankle joints beginning approximately at TO which continued until foot contact. The initial changes of increased flexion did not differ among the different non zero ramp inclinations; however, as the limb approached mid-swing the hip, knee and ankle angles showed further increases in flexion that were scaled to the slope of the ramp.
Lay et al [2005] investigated the effects of up and down slope walking on the lower limb kinematics of 9 healthy adults. Their results showed that for upslope walking the hip, knee and ankle flexed more at heel strike and extended more during midstance compared to level walking, which is consistent with the need to raise the limb for toe clearance and heel strike and then to propel the body up the incline. For downslope walking, the angle changes were inconsistent across the joint (and similar to Kuster's findings), although overall they correspond to a controlled descent of the body during stance.

In terms of stairs, Riener et al [2002] investigated the gait patterns of staircase in 10 unimpaired adults using a five step staircase at three different inclinations. They also compared the data with that of level ground walking. The results showed considerable differences between staircase and level ground walking to the point of suggesting that they are different gait patterns, rather than an evolution. In particular, they found that all 10 unimpaired subjects studied contacted the step with the forefoot, in both climbing directions and in all inclinations. At foot contact (IC) of stair ascent, the hip and knee were more flexed than during level walking and the ankle dorsiflexed (instead of neutral). At foot contact of stair descent, on the other hand, the hip was only slightly flexed (less than for level ground walking), the knee was almost fully extended (similar to level walking values) and the ankle joint was plantarflexed instead of neutral. At foot off the joint angles between stair ascent and level walking were similar, but for stair descent the hip and knee were more flexed than in level walking and the ankle was around neutral (rather than plantarflexed).

The results for stair ascent were similar to those of Nadeau et al [2003] for a group of 11 unimpaired subjects over the age of 40 years and those for stair descent were similar to those of Mian et al [2006] for a group of 23 unimpaired adults.

The results of these studies show that, in unimpaired adults, the angle of the ankle, knee and hip and even the position of the foot at landing change when walking in ramps and staircases with respect to level ground walking. These changes may have an effect on the position and velocity of the shank, and this in turn may result in a different angular velocity pattern.
Therefore, this evaluation had the objective of evaluating the gyroscope detection in a
more natural environment and comparing its behaviour with that of the FS. The
particular objectives of the study were:

1) To determine if the features from the shank angular velocity signal previously
associated to IC and FO on unimpaired level ground gait are still related to IC
and FO in unimpaired ramp and stairs gait.

2) To determine the accuracy of the association.

3) To determine the reliability of the gyroscope for a path that comprised level
ground walking, ramps and stairs and compare it with the reliability of Virtual
Foot Switches (VFS).

The sensors were evaluated by comparing the detection of events using three
methods: gyroscope (GD), virtual foot switches (VFS) and a reference system, in this
case a pressure measurement system (CA). Then, the accuracy (as the time difference
in detection between each sensor and the reference) and the reliability (as the number
of events correctly detected by each sensor over the total number of events detected
by the reference system) were calculated and the performance of the sensors were
compared.

Section 7.2 describes the methods chosen for the study and the results are presented in
section 7.3. Section 7.4 is a discussion of those results and section 7.5 summarizes the
results in conclusion.

7.2 Method

7.2.1 Subjects and Protocol

Initially, this study was designed so that 10 unimpaired children and 10 children with
CP would participate. However, there were issues regarding the time that it took for
the ethical approval to be finalized (in total, it took 8 months until approval was
given), when that was finished, there was a window of 3 months for recruitment
before the gait laboratory where the experiments were going to take place moved to a
new location. It would have been possible to re-apply for ethical approval on a new
site, but also a new set of stairs and ramp should have been used. Also there were very limited number of CP children attending regular session at hospital and recruitment was an extra issue. Recruitment of only unimpaired children was possible.

Seven children (five girls and two boys) without motor impairments participated in the study. The mean age of the group was 11.7 years old (range between 8 and 16), the mean height was 153.2 ± 17.1 cm (range between 138 and 187.3) and the mean body mass was 44.5 ± 13.1 kg (range between 33.3 and 65.3).

Each child was equipped with:

- A gyroscope placed on the anterior aspect of the shank, the position of which was maintained using a Velcro strap wrapped around the shank.
- A pressure measurement insole inside each shoe (F-Scan® Mobile system, Tekscan Inc., South Boston, M.A., U.S.) that had been trimmed to shoe size just before data collection.

The conditioning box for the gyroscope sensor, the datalogger for collection of gyroscope and synchronization data and the datalogger for the pressure measurement system were placed inside a rucksack that was carried on the back, as explained in Chapter 4.

Each child wore the shoes they normally used for daily activities.

Gyroscope and pressure sensor data were collected at a sampling frequency of 125 Hz.

The protocol for walking was explained to the children, who were asked to walk at a comfortable speed. The walking circuit started inside the gait lab, then they walking outside where they went down a ramp (figure 7.1). After the ramp, they walked on level ground (pavement), shown in figure 7.1 and finally going up six steps of the stairs (figure 7.2) before going inside the gait laboratory. The level ground path included a 90-degree turn.

For clarity, to be able to separate the data into the different terrains and to measure the output of the gyroscope at zero angular velocity, the child was asked to stop and stand still just before and after every different terrain. In this way, they would stop for
approximately 5 seconds before the ramp, after the ramp and before starting walking on level ground, before the stairs and after the last step had been reached.

The total distance walked for each circuit was approximately 200 m, followed by a 5 to 10 minutes rest and repeating the circuit in the other direction.

The ramp had a total length of 7 m, with an inclination of approximately 8.6°. The stairs consisted of six steps, each with a 25 cm tread and 15 cm height, and the final step that lead to level ground was also considered a step for data analysis.

Figure 7.1 Part of the path used in the study, which included a ramp and level ground walking.

An Information Sheet was provided for parents and children and a consent form was signed by every parent/career and each child (an example is shown Appendix E).

The study was reviewed and obtained the ethical approval from the Wandsworth Local Research Ethics Committee.
7.2.2 Events Detection

7.2.2.1 Gyroscope Event Detection

The gyroscope detection algorithm was as presented in Chapter 4. However, due to the slight differences in the signal pattern when walking on ramps or on stairs, some restriction rules were added.

These extra restrictions had to compensate for two differences that the angular velocity signal presented in these cases:

- the angular velocity of the shank during stance phase becomes positive (which occurred in all stair ascent stances and in some of the stair descent)
- the pattern of the signal at toe off becomes more irregular in ramps and stairs.

Figure 7.2 Stairs leading to the Gait Laboratory that were part of the walking path used in the study.
Low Pass Filtering

Detects the trigger signal and moves to frame.

Detects and skips first negative wave (stance phase), if exists.

1) Detects zero crossing.

2) Detects and counts samples where $g(n) > 0.2$.

3) Detects zero crossing.

4) If the samples where $g(n) > 0.2$ are $= 5$, it detects IC as the first minimum after zero crossing [$g(n-2) > g(n-1) > g(n) < g(n+1)$]

5) After IC detection, there is a waiting time (wt). wt is 50% of the last stance (time from last IC to last FO) or 50% of the time between 1) and 3).

6) Foot Off detection. n would be considered the time for FO if a) AND b) AND c) AND d) are true OR if b) AND e) are true, where:
   a) $g(n) < -0.2$
   b) $g(n)$ is the minimum in the window $[n-10 : n+15]$
   c) In the window $[n-10 : n]$, at least 5 samples are smaller than the previous one (showing a “decreasing pattern”).
   d) In the window $[n:n+15]$, at least 10 samples are larger than the previous one (showing an “increasing pattern”).
   e) $g(n+15) - g(n) > 0.2$

Figure 7.3 Flowchart of the algorithm used for detection of Initial Contact and Foot Off using the gyroscope signal in trials including ramps and stairs. Changes (shown in red) were introduced respect to the algorithm presented in chapter 4. The diagram is data of two gait cycles from one of the children who participated when going up the stairs.
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The restriction added was a threshold (empirically set at 0.2 V). It was used so that an IC would only be looked for after the signal has been larger than 0.2 V for at least five samples. This is used to differentiate the positive part of stance phase from a proper swing phase.

Also, FO would be detected only if the signal at that point is below the threshold of -0.2 V or if the signal shows a rapid change into “less negative” (indicating the start of swing). This was used to make stronger rules for FO and avoid false detections.

So, taking into account the algorithm presented in Chapter 4 with the new introductions, the new algorithm is presented in Figure 7.3, together with data collected from one of the children when walking up the stairs, and was used for all data, including level walking (where added restriction rules are shown in red). The routine is included in Appendix C.

7.2.2.2 Contact Area Event Detection

The data from the pressure measurement system was processed and analysed as described in Chapter 5 for detection of IC and FO (see appendix C).

7.2.2.3 Virtual Foot Switch Event Detection

Extra analysis was performed to the pressure measurement data, as a form of “Virtual Foot Switches” (VFS). The algorithm for detection was written using the mathematical program Matlab® (Student Version 6.5, The Mathworks, Inc.) and the routine is included in Appendix C.

As expressed before, if the gyroscope will be used to control a functional electrical stimulator, its performance should at least be compared against that from a foot switch as the literature review has shown that this is the most commonly used sensor for FES control. However, test trials performed using both pressure measurement insoles and foot switches inside the shoe demonstrated that pressure and area data were affected by the presence of the foot switches in a way that could compromise the data obtained by the insole.
The test trials consisted of the data collection on a volunteer first without and then with an FSR placed on the heel of the shoes, and on top of it, the pressure measurement insole.

Figures 7.4 to 7.6 illustrate the type of problems that occurred when collecting pressure or area data with an FSR inside the shoes, against the same situations without FSR. Figure 7.4 shows an insole during the swing phase of gait with and without FSR inside the shoes. It is clear that no area were being pressed for the no FSR condition, whereas there was an area with some pressure on it, when the FSR is in placed, which is variable during the swing phase.

Figure 7.4 Data collected from a volunteer to evaluate the possibility of using a pressure measurement system and FSR at the same time. The first figure on the left shows a common swing phase, with no pressure being applied to any area of the insole. The two figures on the right show different frames during a single swing phase, when an FSR was placed inside the shoes. It is possible to see that there is some area being pressed because of the FSR (while the foot is not on the floor) and from the difference between both pictures, it is possible to see that the amount of area being pressed changes during the same swing phase.
This area being pressed during swing phase would affect the area detection algorithm. Figure 7.5 shows the area signal collected with no foot switch inside the shoe, while figure 7.6 shows the area signal with the foot switch inside the shoe. It is possible to see again that the area loaded during swing is zero if no foot switch is placed (figure 7.5), but there is a remaining area loaded during switch (which is also variable) if there is a foot switch inside (figure 7.6), which could lead to false detections.

![Figure 7.5 Area loaded and threshold data collected from a volunteer to evaluate the possibility of using a pressure measurement system and FSR at the same time. In this particular case, no FSR was placed inside the shoe and the total area reaches zero (no area loaded) during swing.](image)

This discouraged the use of both systems at the same time.

It was decided instead to use data from predefined areas of the insole as virtual foot switches, as the relationship between the pressure measurement system and foot switches has been used by researchers to investigate the pressure pattern of patients during walking and determine optimum positioning areas for foot switches [Smith et al. 2002; Johnston et al. 2004; Pierce et al. 2004a; Pierce et al. 2004b].
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Figure 7.6 Area loaded and threshold data collected from a volunteer to evaluate the possibility of using a pressure measurement system and FSR at the same time. In this particular case, an FSR was placed inside the shoe, under the heel and it is possible to see that there is a remaining loaded area during swing that may lead to false detections.

Tekscan software allows creating polygons inside the data collected from insoles, so that information from that area can be separated from the rest and exported. The foot switches used in the previous study (described in Chapter 6) were of circular shape and of 28 mm diameter. As the software does not allow building circles but only polygons, an octagon was constructed with an internal radius of 14.5 mm, in order to make the area as similar to the foot switch as possible.

Figure 7.7 shows the insole with the polygon used in the heel. The maximum area of the octagon was of 619 mm$^2$, which was considered closed enough to the 615.7 mm$^2$ that a perfect circle would have provided.

The same size octagon was placed at the heel and under the first metatarsal head.

The circuit configuration used for FSR was such that the sensor was used as an “on-off switch” that detected pressure being applied rather than measuring it. The closest way found to simulate this output from the pressure measurement insoles was to use the “contact area” inside the octagons. In this way, each sensor within the VFR would
produce an on-off response, but no actual measurement of force. So, the contact area was calculated for the heel VFS and also for the toe VFS.

![Image: Figure 7.7. Pressure being applied to the heel area, near the time of heel contact, while walking on level ground, for one of the participants. Also, it is possible to see the VFS (virtual foot switch) as a green octagon.](image)

Finally, as it was done with the FSR signal, a threshold was chosen as the mean of the signal used for detection. However, because these trials involved times when the subject was standing that could have influenced the threshold, and previously making sure that in each case the signal would go from 0 to maximum during walking, the threshold was fixed as half the maximum area of the octagon (so equal to 309.5 mm²) rather than calculated as the mean of the signal (figure 7.8).

Using the heel area signal, HC was detected as the first frame in which the signal exceeded the threshold and HO (heel off) was detected as the first frame in which the signal went below the threshold. Using the toe area signal, TC (toe contact) was detected as the first frame in which the signal exceeded the threshold and TO (toe off) was detected as the first frame in which the signal went below the threshold. IC was determined as the first of HC and TC and FO as the last of HO and TO. HO and TC were calculated as well because, although during level ground walking, as the study involved only unimpaired subjects, the IC would be expected to be HC and FO would
be TO, evidence has been presented that when going up and down stairs, a toe contact pattern occurred in unimpaired adults [Riener et al. 2002].

As explained before it was considered not appropriate to use pressure insoles and real foot switches at the same time, as the use of this latter would have changed the use of the insole. So, in order to compare the performance of the virtual foot switches and the real foot switches, an indirect comparison was performed. The differences between real FSR and gyroscope obtained from 6 unimpaired children on level ground walking (and presented in chapter 6) were statistically compared to differences between virtual FS and gyroscope obtained from 7 unimpaired children on level ground walking (and presented in this chapter). The tests used for the comparison are explained in Section 7.2.3.4, while the results of such comparison are presented in section 7.3.4 (table 7.5).
7.2.3 Data Analysis

7.2.3.1 Time Difference

Once the events were determined for each method, the comparison between the methods was carried out by calculating the difference in time between the detections for each step analysed.

The analysis was performed separately for each type of terrain: level walking, ramp and stairs. Seven children completed the trial going down the stairs, walking on level ground and going up the ramp and six completed the trial going down the ramp, walking on level ground and going up the stairs.

First, for each step analysed, the differences in the detection of events were calculated as:

a) CA-VFS = contact area detection (CA) - virtual foot switch detection (VFS),

b) CA-GD = contact area detection (CA) - gyroscope detection (GD),

c) VFS-GD = virtual foot switch detection (VFS) - gyroscope detection (GD).

Second, in order to avoid misleading results due to cancellation of positive and negative values when averaging, the absolute value of the difference was calculated for each step.

Later, the absolute differences of all the steps for one subject were averaged so that a single value was obtained for each subject and each pair of method.

Finally, the mean absolute values for the seven children were averaged. These values were calculated in order to compare the results with the ones previously reported in the literature (in particular, with the results reported by Henty [2003]).

However, for data that is not normally distributed (and specially, when the data is skewed), the median value represents a better option to represent the central tendency. Values of the median, together with the 95% confidence interval, are also included.
7.2.3.2 Distribution of the Differences

As previously done for the indoor evaluation study, and in order to determine whether there was a tendency for any of the methods to detect an event systematically earlier or later than others, an analysis of the distribution of the differences was performed.

Histograms of the number of steps versus the time difference (in the range of -1000 to 1000 ms, divided in 10 ms interval) were calculated for each pair of method. Each histogram represents the distribution of differences for one of CA-VFS, CA-GD, VFS-GD. In order to avoid bias of the results due to different number of events analysed for different children, a fixed number of steps was selected for each event and each group, which corresponded to the maximum number of events available for every child. This analysis would provide general information regarding the group and an idea of the variability in detection.

7.2.3.3 Rate of Success in Detection

One way of measuring the reliability of the system is by measuring the rate of correctly detected events as a percentage of the total events (as detected by the contact area method). In order to compare the reliability of gyroscope with VFS, the rate of success was calculated for both.

An error in detection was considered if the event was missed or wrongly detected or if there is a wrong, extra event in a gait cycle when another (correct) event was detected.

7.2.3.4 Further Analysis of the Results

The absolute mean differences between the methods for each child were statistically compared.

Initially, the differences between the CA – GD method obtained in this study during level walking was compared with the KM – GD differences obtained for indoor evaluation (results presented in Chapter 6). Also, the differences between FS – GD for indoor evaluation were compared with the results from VFS – GD for outdoor evaluation, during level walking. A comparison using the Mann – Whitney test, (with a significance level of p< 0.05) was performed to the groups.
Then, the differences between CA – VFS, CA – GD and VFS – GD for each stair and ramp conditions were compared with the level ground walking using a Friedman test (level of significance \( p < 0.05 \)), with a Dunn post test in case the differences were significant.

### 7.3 Results

#### 7.3.1 Detection on Level Ground

#### 7.3.1.1 Median and Absolute Mean Differences

For level ground detection, a total of 455 IC and 438 FO were analysed. The median of the differences between the methods (expressed in ms) for all the children and the absolute mean differences (also in ms) are shown in Table 7.1, while the absolute mean difference for each child and each method is shown in figure 7.9 for IC detection and in figure 7.10 for FO detection.

Table 7.1. Median [95% interval] and (absolute mean differences ± one standard deviation) all expressed in ms, for Initial Contact (IC, \( n = 455 \)) and Foot Off (FO, \( n = 438 \)) event detection for level ground walking.

<table>
<thead>
<tr>
<th>Event Detected</th>
<th>CA - VFS</th>
<th>CA-GD</th>
<th>VFS-GD</th>
</tr>
</thead>
<tbody>
<tr>
<td>IC</td>
<td>-24 [-50, -10]</td>
<td>-8 [-50, -30]</td>
<td>8 [-20, 60]</td>
</tr>
<tr>
<td></td>
<td>(24 ± 8)</td>
<td>(15 ± 6)</td>
<td>(20 ± 14)</td>
</tr>
<tr>
<td>FO</td>
<td>24 [10, 60]</td>
<td>48 [20, 90]</td>
<td>24 [-30, 60]</td>
</tr>
<tr>
<td></td>
<td>(31 ± 15)</td>
<td>(53 ± 16)</td>
<td>(31 ± 12)</td>
</tr>
</tbody>
</table>
Figure 7.9. Absolute mean differences (ms) for Initial Contact (IC, n = 455) event for level walking detection and for each of the children who participated in the study. The differences were calculated between CA and VFS (blue bar), CA and GD (green bar) and VFS and GD (red bar). One black line represents one standard deviation.

Figure 7.10. Absolute mean differences (ms) for Foot Off (FO, n = 438) event for level walking detection and for each of the children who participated in the study. The differences were calculated between CA-VFS (blue bar), between CA-GD (green bar) and between VFS-GD (red bar). One black line represents one standard deviation.
7.3.1.2 Distribution of the Differences

Figures 7.11 and 7.12 show the histograms of the differences between the methods in detection of IC and FO, respectively, for all the children. In order to construct the histograms, avoiding any bias in the histogram due to different number of events from each child, the maximum amount of steps available for all children was considered. Therefore, 39 IC events and 38 FO events of the first trial available (as one of the children did not complete the second trial) were considered, so that the total number of events was 273 IC and 266 FO.

![Histograms representing the distribution of the differences in IC detection for level ground walking trial. n=273.](image)
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Figure 7.12 Histograms representing the distribution of the differences for FO detection for level ground walking. n = 266.

7.3.1.3 General Comments on Detection and Reliability Measure

For the level ground walking trials, FO was detected using in all cases data from the VFS placed under the first metatarsal head. The IC was mostly detected using the data from the VFS placed under the heel, except for one particular case in which the child, to avoid an obstacle (water on the floor), jumped using the right as the leading leg. In this case, the initial contact was determined by the metatarsal VFS. Figure 7.13 shows the gyroscope signal for the gait cycle where the jumping took place and the previous and following gait cycles. Figure 7.14 shows the area signal from the heel VFS and metatarsal VFS for the same gait cycles. The detection time using the metatarsal VFS was included in the data set.

Considering all the IC (either HC or TC) and all FO, a total of 893 events were detected by the contact area method. Of those, the gyroscope detected correctly 889 and missed/wrongly detected 4 (all FO). The correct detected events represented 99.5% events.
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The VFS method correctly detected 891 and missed 2 (one IC and one FO). The correct detected events represented 99.8% of the total events.

It is worth mentioning that the VFS detection presented issues at the time of standing still. The children were asked to stand still before and after finishing walking on each different terrain. During this time, small body movements (for example, shifting weight from one foot to the other) were almost unnoticeable in the gyroscope signal (as seen in figure 7.15), so that the gyroscope detection routine did not consider them as walking events.

However, the same movements caused the pressure measurement system to be loaded and unloaded, so that the area of the virtual foot switches changed from below to above the threshold (and vice versa) so that the VFS detection algorithm repeatedly considered those movements as events (in figure 7.16, several HC and HO events were detected at the time when the subject was standing still). The "errors" in the VFS detection were not considered when calculating the rate of success or failure of the detection, as only events that occurred during each walk were considered.

![Gyroscope signal](image)

Figure 7.15 Gyroscope signal. When the person is standing still, the angular velocity of the shank remains almost unchanged so that the detection algorithm does not detect any walking events.
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7.3.2 Detection on Ramps

7.3.2.1 Median and Absolute Mean Differences

Seven children completed the ramp up trial, with a total of 77 IC and 70 FO, while six children completed the ramp down trial, with a total of 51 IC and 48 FO. The median of the differences and the absolute mean differences between the methods (expressed in ms) for all the children are shown in Table 7.2, while the absolute mean difference for each child and each method is shown in figure 7.17 for IC detection and in figure 7.18 for FO detection.

Figure 7.16. Heel and metatarsal VFS. When the person is standing still, movements of the body repeatedly loaded and unloaded the heel VFS. This caused the detection algorithm to wrongly detect several HC and HO events.
Table 7.2. Median [95% interval] and (absolute mean differences ± one standard deviation), all expressed in ms for Initial Contact (IC, n= 77 for ramp up and 51 ramp down) and Foot Off (FO, n = 70 for ramp up and 48 for ramp down) event detection for ramp walking. R: ramp.

<table>
<thead>
<tr>
<th>Event Detected</th>
<th>CA-VFS</th>
<th>CA-GD</th>
<th>VFS-GD</th>
</tr>
</thead>
<tbody>
<tr>
<td>IC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R Up</td>
<td>-24 [-10, -40]</td>
<td>-24 [-60, 20]</td>
<td>0 [-40, 40]</td>
</tr>
<tr>
<td></td>
<td>(25 ± 7)</td>
<td>(24 ± 12)</td>
<td>(17 ± 8)</td>
</tr>
<tr>
<td>R Down</td>
<td>-24 [-10, 50]</td>
<td>-8 [-60, 30]</td>
<td>16 [-10, 60]</td>
</tr>
<tr>
<td></td>
<td>(27 ± 8)</td>
<td>(20 ±11)</td>
<td>(25 ± 14)</td>
</tr>
<tr>
<td>FO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>R Up</td>
<td>24 [20, 60]</td>
<td>40 [20, 70]</td>
<td>8 [-30, 50]</td>
</tr>
<tr>
<td></td>
<td>(31 ± 10)</td>
<td>(43 ± 10)</td>
<td>(18 ± 8)</td>
</tr>
<tr>
<td>R Down</td>
<td>24 [20, 70]</td>
<td>72 [40, 100]</td>
<td>48 [-20, 80]</td>
</tr>
<tr>
<td></td>
<td>34 ± 12</td>
<td>73 ± 12</td>
<td>42 ± 10</td>
</tr>
</tbody>
</table>

7.3.2.2 Distribution of the Differences

Figures 7.19 shows the histogram of the differences between the methods for the IC event for the walking down the ramp trial and figure 7.20 shows the histogram for FO. In both cases, 6 events were considered for each subject (which was the maximum number of events available for all subjects), with a total of 36 IC and 36 FO, for the six subjects who participated.

Figures 7.21 and 7.22 show the histograms of the differences between the methods for the IC and FO event, respectively, for the ramp up walking. In both cases, 9 (which was the maximum number of events available for all subjects) events were considered, which makes a total of 63 IC and 63 FO.
Figure 7.17. Absolute mean differences (ms) for Initial Contact (IC) event detection during ramp up and ramp down walking for each of the children who participated in the study. The differences were calculated between the different methods (CA and VFS, CA and GD and VFS and GD) and for both conditions (ramp up and ramp down). One black line represents one standard deviation. Total n= 77 for ramp up and 51 for ramp down.

Figure 7.18 Absolute mean differences (ms) for Foot Off (FO) event detection during ramp up and ramp down walking for each of the children who participated in the study. One black line represents one standard deviation. n = 70 for ramp up and 48 for ramp down.
Figure 7.19 Histograms representing the distribution of the differences in IC detection for ramp down walking trial. Each bar represents the number of events analysed for which the value of the difference was in the interval considered for that particular bar. n = 51.

Figure 7.20 Histograms representing the distribution of the differences in FO detection for ramp down walking trial. Each bar represents the number of events analysed for which the value of the difference was in the interval considered for that particular bar. n = 48
Figure 7.21 Histograms representing the distribution of the differences in IC detection for ramp up walking trial. Each bar represents the number of events analysed for which the value of the difference was in the interval considered for that particular bar. \( n = 77 \).

Figure 7.22 Histograms representing the distribution of the differences in FO detection for ramp up walking trial. Each bar represents the number of events analysed for which the value of the difference was in the interval considered for that particular bar. \( n = 70 \).
7.3.2.3 Reliability Measure

The total number of events detected during ramp down walking was 99 (51 of which were IC and 48 FO). The gyroscope missed one event (FO), which means that the rate of correct events detected was 99%. The VFS, on the other hand, missed two events (both IC) and detected two extra ones (both FO), so that the rate of correct events detected was 96%.

In the case of ramp up walking, the total number of events detected was 147 (77 IC and 70 FO). The gyroscope missed one event (FO), so that the rate of correct events detected was 99.3%. The VFS missed one event (FO) and detected one extra (IC), which makes the rate of correct events detected to be 98.6%.

Both systems presented high rate of success in the detection. However, an analysis of the causes of these errors may add some insight into the performance of the systems.

The events missed through the gyroscope detection, were mainly due to the lack of enough or appropriate information available for the algorithm to "estimate" the occurrence of the next event. In particular, the algorithm makes use of a "waiting time" after IC has occurred to look for a FO. The waiting time is calculated using information about either the previous stance, if this is available, or part of the previous swing. As shown in figure 7.23 for the first step, no information of the previous stance is available and the previous swing phase may be slightly shorter than it would normally be during walking. If this is the case, then the waiting time is short and this combined with a "noisy" stance phase may end in an error in the detection of FO.

A similar effect could be seen if the previous stance is shorter than the following one (in fact, of the two missed FO, one was the first step as shown in figure 7.23 and the other was due to discrepancies in the stance phases).

The missed detections in the VFS method were mainly due to a change in the contact pattern of the foot with the floor. In some cases, the initial contact was performed using the lateral side of the foot and no pressure was put on the heel area (in which cases, a missed IC would occur) or the pressure was mainly in the posterior area of the foot and no pressure was on the metatarsal heads (figure 7.24). The extra detections were due to a loading and unloading pattern, similar to the one seen in figure 7.31 for stairs ascent, in which one of the VFS is loaded, unloaded and reloaded during one stance phase.
Figure 7.23. Gyroscope signal during ramp down walking. The first FO after stance was detected wrongly.

7.3.3 Detection on Stairs

7.3.3.1 Median and Absolute Mean Differences

Seven children completed the stairs down trial, with a total of 31 IC and 27 FO, while six children completed the stairs up trial, with a total of 24 IC and 20 FO. The median of the differences between the methods (expressed in ms) for all the children and the absolute mean differences are shown in Table 7.3, while the absolute mean differences for each child and each pair of method are shown in figure 7.25 for IC detection and in figure 7.26 for FO detection.
Figure 7.24. Heel and metatarsal VFS areas during ramp up walking. It is possible to see a redistribution of the contact pressure so that the metatarsal VFS is not pressed during the stance (or not pressed enough as to reach the threshold).

Table 7.3. Median [95% interval] and (absolute mean differences ± standard deviation), all expressed in ms, for Initial Contact (IC, n= 31 for stairs down and 24 for stairs up) and Foot Off (FO, n = 27 for stairs down and 20 for stairs up) event detection for stairs walking. S: stairs.

<table>
<thead>
<tr>
<th>Event Detected</th>
<th>CA-VFS</th>
<th>CA-GD</th>
<th>VFS-GD</th>
</tr>
</thead>
<tbody>
<tr>
<td>IC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S Up</td>
<td>-40 [-210, -20]</td>
<td>-8 [-60, 50]</td>
<td>48 [-50, 210]</td>
</tr>
<tr>
<td></td>
<td>(71 ± 76)</td>
<td>(23 ± 7)</td>
<td>(68 ± 75)</td>
</tr>
<tr>
<td>S Down</td>
<td>-40 [-100, 0]</td>
<td>4 [-30, 100]</td>
<td>40 [10, 200]</td>
</tr>
<tr>
<td></td>
<td>(42 ± 14)</td>
<td>(38 ± 36)</td>
<td>(61 ± 49)</td>
</tr>
<tr>
<td>FO</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>S Up</td>
<td>40 [10, 60]</td>
<td>-32 [-60, 0]</td>
<td>-80 [-90, -50]</td>
</tr>
<tr>
<td></td>
<td>(41 ± 14)</td>
<td>(40 ± 13)</td>
<td>(76 ± 12)</td>
</tr>
<tr>
<td></td>
<td>50 ± 28</td>
<td>132 ± 44</td>
<td>94 ± 54</td>
</tr>
</tbody>
</table>
Figure 7.25. Absolute mean differences (ms) for Initial Contact (IC) event detection during stairs up (n = 24) and stairs down walking (n = 31) for each of the children who participated in the study. One black line represents one standard deviation.

Figure 7.26. Absolute mean differences (ms) for Foot Off (FO) event detection during stairs walking (n = 27 for stairs down and 20 for stairs) for each of the children who participated in the study. One black line represents one standard deviation.
7.3.3.2 Distribution of the Differences

Figures 7.27 shows the histogram of the differences between the methods for the IC event for walking up the stairs and figure 7.28 shows the histogram for FO. As before, and to avoid bias of the histogram due to the different amount of events detected for each child, a fixed number of events was considered for every child (in this case, 4 IC which made a total of 24 IC events for stairs up and 2 FO events, which made a total of 12 for the six children who completed this trial).

Figures 7.29 and 7.30 show the histograms of the differences between the methods for the IC and FO event, respectively, during walking down the stairs. For this trial, 4 IC events were considered from each child, which made a total of 28 events for the seven children who completed this part of the study and 2 FO for each child, which made a total of 14 events.

7.3.3.3 General Comments on Stairs Ascent and Descent Detection and Reliability Measure

The total number of events detected during stairs up walking was 44 (24 of which were IC and 20 FO). Of these, the gyroscope missed two FO events, which means that the rate of correct events detected was 95.5%. The VFS, on the other hand, detected two extra events (one IC and one FO), so that the rate of correct events detected was also 95.5%.

The total number of events detected during stairs down was 58, of which the gyroscope missed 4 FO (rate of correct events detected 93.1%) and the VFS detected six extra events (4 IC and 2 FO) and missed one IC (rate of correct events detected 87.9%).

The stair walking proved to be the most challenging terrain for the algorithms to detect the events.

From figure 7.25 it is possible to see that two of the children (subjects 6 and 7) showed higher differences than the others for IC detection in stairs. In particular, subject 6 showed higher differences between the VFS and the other two systems (CA and GD) for the stairs up walking. A possible reason for this is the particular walking pattern that the subject had, as the initial contact while walking up the stairs was made
with the lateral part of the mid-foot and forefoot. The loading pattern moved to the whole forefront only by mid-stance. As the VFS of the forefront was placed under the first metatarsal head (medial part of the forefoot), the detection from VFS was done later than the other two systems and later than for the other subjects.

In terms of subject 7, for which only data for walking down stairs was available, it is possible to see that while the differences between CA and VFS remained as for the other subjects, the differences with the GD were larger (in particular, the GD detected IC earlier than the other systems). As explained in Chapter 4, the feature of the gyroscope signal used to detect IC is the first negative peak after swing. At the end of the swing phase, there is a rapid flexion of the knee, followed by IC and after that, there is a controlled advancement of the tibia. The negative peak is taken to represent the point just after the flexion of the knee and just before the controlled advancement of the tibia. However, during walking up and down the stairs, this pattern may change (as explained in section 7.4.2). If the flexion of the knee is followed by a further preparation for movement (for example, reaching) and this is then followed by IC, then the detection made by the gyroscope will be earlier than the actual event happen. This may have been the cause of the bigger differences for subject 7, although the exact cause is unknown as there were no data of the movement of the shank apart from the data from the gyroscope.

In particular, for the VFS, and unlike all other trials, the IC was sometimes detected using TC rather than HC, as sometimes the heel was not pressed at all. In fact, of the 24 IC for stairs up walking, 13 were HC and 11 TC, and for the 31 IC for walking down the stairs, 24 were TC and 7 HC. The FO had a more regular pattern, and for both conditions the FO was a TO except in one step during walking up the stairs in which it was HO. Figure 7.31 shows the stairs up part of the trial for Subject 1, it is possible to see that the first IC (the first signal to exceed the threshold) was HC, for the second and fourth HC and TC occurred at the same time, for the third TC occurred slightly earlier.
Figure 7.27 Histograms representing the distribution of the differences in IC detection for walking up the stairs. Each bar represents the number of events analysed for which the value of the difference was in the interval considered for that particular bar. n = 24.

Figure 7.28 Histograms representing the distribution of the differences in FO detection for walking up the stairs. Each bar represents the number of events analysed for which the value of the difference was in the interval considered for that particular bar. n = 20
Figure 7.29 Histograms representing the distribution of the differences in IC detection for walking down the stairs. Each bar represents the number of events analysed for which the value of the difference was in the interval considered for that particular bar. \( n = 31 \)

Figure 7.30 Histograms representing the distribution of the differences in FO detection for walking down the stairs. Each bar represents the number of events analysed for which the value of the difference was in the interval considered for that particular bar. \( n = 27 \)
Figure 7.31. Walking up the stairs for subject 1. The different IC as detected by the VFS method can be seen. The first IC (from the left) was a HC, the second and fourth HC and TC occurred at the same time and the third was TC.

Figure 7.32 shows the walking down the stairs also for subject 1. In this case, for two of the three steps the heel VFS is not pressed so that IC and FO are detected using the metatarsal VFS.

The change in the shank movement pattern while walking up and down stairs compared with level walking was also noticeable from the gyroscope signal. Also a greater variability in the pattern was seen between different children.

Figure 7.33 shows the stairs up trial for Subject 1, with a shank angular velocity signal similar to the one presented during level walking and ramp, but the signal reaches positive values during stance phase (indicating a temporal counterclockwise movement of the shank), which was also noted in the gyroscope signal by other researchers [Coley et al. 2005] and in the movement of the leg by other authors [McFadyen and Winter 1988].
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Figure 7.32. Walking down the stairs for Subject 1. For the second and third stances, the heel VFS was not pressed.

Figure 7.33. Gyroscope signal for S1 while walking up the stairs. It presents a pattern similar to the one presented at level ground walking, but the signal reaches positive values during the stance phase.
In particular McFadyen and Winter observed that during up stairs walking, during a phase that they called “pull up” phase (which extended from beginning of single leg support to approximately mid swing of the contralateral leg) the leg moved backwards, which increased the vertical position of the knee and, in conjunction with knee extension, provided lift to the body. Figure 7.34 shows the stairs up trial for Subject 5, with a more irregular pattern, with more oscillations during the stance phase, for which the algorithm missed the detection of the third FO.

![Gyroscope Signal](image)

Figure 7.34. Gyroscope signal for S5 while walking up the stairs. In this case, not only the signal reaches positive values but also presents more oscillations during stance phase.

7.3.4 Further Analysis of Results

Table 7.4 presents the results from the comparison between the indoor evaluation and outdoor evaluation in the use of KM and CA methods as references for detection of events, comparisons being measured in the differences between KM-GD and CA-GD. Table 7.5 presents the results for similar comparison between FS-GD and VFS-GD. Statistical errors type II (concluding that the populations do not differ when in fact they do) could have occurred due to the small number of samples and the use of non
parametric statistical tests. In this sense, the analysis is only indicative but it provides an extra tool for the analysis.

Table 7.4. Comparison between the differences obtained between KM-GD in level ground walking indoors (n = 6 subjects) and the differences between CA-GD in level ground walking outdoors (n = 7 subjects). (ns: no statistically significant).

<table>
<thead>
<tr>
<th></th>
<th>KM-GD (indoor trial)</th>
<th>CA-GD (outdoor trial)</th>
<th>P value (in–out)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (ms)</td>
<td>Distribution</td>
<td>Mean (ms)</td>
</tr>
<tr>
<td>IC</td>
<td>17</td>
<td>95% [20; 40]</td>
<td>15</td>
</tr>
<tr>
<td>FO</td>
<td>50</td>
<td>95% [10; 100]</td>
<td>53</td>
</tr>
</tbody>
</table>

Table 7.5. Comparison between the differences obtained between FS-GD for level ground indoor walking (n = 6 subjects) with the differences obtained between VFS-GD with level ground outdoors walking (n = 7 subjects). (ns: not statistically significant).

<table>
<thead>
<tr>
<th></th>
<th>FS-GD (indoor trial)</th>
<th>VFS-GD (outdoor trial)</th>
<th>P value (in–out)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (ms)</td>
<td>Distribution</td>
<td>Mean (ms)</td>
</tr>
<tr>
<td>IC</td>
<td>9</td>
<td>100% [-20; 20]</td>
<td>20</td>
</tr>
<tr>
<td>FO</td>
<td>34</td>
<td>98% [-40; 100]</td>
<td>31</td>
</tr>
</tbody>
</table>

Table 7.6. Analysis of the mean differences between methods, comparing each ramp and stair condition (RU: ramp up, RD: ramp down; SU: stairs up; SD: stairs down, LW: level walking) with level ground walking condition for both events detected (IC: initial contact, FO: foot off). The results of the test could be ns (no significant, p > 0.05) or * (significant, p < 0.05).

<table>
<thead>
<tr>
<th>Significance (p &lt; 0.05)</th>
<th>LW-RU</th>
<th>LW-RD</th>
<th>LW-SU</th>
<th>LW-SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA - IC VFS FO</td>
<td>ns</td>
<td>ns</td>
<td>*</td>
<td>ns</td>
</tr>
<tr>
<td>CA - IC GD FO</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
</tr>
<tr>
<td>VFS IC FO</td>
<td>ns</td>
<td>ns</td>
<td>*</td>
<td>ns</td>
</tr>
<tr>
<td>VFS - GD FO</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
<td>ns</td>
</tr>
</tbody>
</table>
7.3.5 Summary of Results

In tables 7.7 and 7.8 a summary of the results for the IC and FO event detection respectively have been presented and in table 7.9 a summary of the reliability results is presented.

Table 7.7 Summary of results for IC detection using the three different methods. AMD: absolute mean difference (ms); Distribution of the diff: distribution of the difference (percentage in a [-50; 50] ms interval); sign: the sign of the majority of the differences. * : results that showed statistical significance respect to level walking.

<table>
<thead>
<tr>
<th>Method</th>
<th>Level Walking</th>
<th>Ramp Up</th>
<th>Ramp Down</th>
<th>Stairs Up</th>
<th>Stairs Down</th>
</tr>
</thead>
<tbody>
<tr>
<td>CA - VFS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (ms)</td>
<td>-24</td>
<td>-24</td>
<td>-24</td>
<td>-40*</td>
<td>-40*</td>
</tr>
<tr>
<td>A. M. D. (ms)</td>
<td>24</td>
<td>25</td>
<td>27</td>
<td>71</td>
<td>42</td>
</tr>
<tr>
<td>Distribution of the diff</td>
<td>98.5%</td>
<td>100%</td>
<td>97%</td>
<td>70.8%</td>
<td>78.6%</td>
</tr>
<tr>
<td>Sign</td>
<td>100% Negative</td>
<td>100% Negative</td>
<td>100% Negative</td>
<td>100% Negative</td>
<td>100% Negative</td>
</tr>
<tr>
<td>CA - GD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (ms)</td>
<td>-8</td>
<td>-24</td>
<td>-8</td>
<td>-8</td>
<td>4</td>
</tr>
<tr>
<td>A. M. D. (ms)</td>
<td>15</td>
<td>24</td>
<td>20</td>
<td>23</td>
<td>38</td>
</tr>
<tr>
<td>Distribution of the diff</td>
<td>96.7%</td>
<td>88.8%</td>
<td>86.1%</td>
<td>91.7%</td>
<td>82.1%</td>
</tr>
<tr>
<td>Sign</td>
<td>61.5% Negative</td>
<td>77.9% Negative</td>
<td>56.8% Neg. 25.5 % Pos.</td>
<td>58.3% Neg. 29.2% Pos.</td>
<td>41.9% Neg.</td>
</tr>
<tr>
<td>VFS - GD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (ms)</td>
<td>8</td>
<td>0</td>
<td>16</td>
<td>48*</td>
<td>40</td>
</tr>
<tr>
<td>A. M. D. (ms)</td>
<td>20</td>
<td>17</td>
<td>25</td>
<td>68</td>
<td>61</td>
</tr>
<tr>
<td>Distribution of the diff</td>
<td>94.5%</td>
<td>98.4%</td>
<td>86.1%</td>
<td>58.3%</td>
<td>79.2%</td>
</tr>
<tr>
<td>Sign</td>
<td>76.5% Positive</td>
<td>40.0% Pos.</td>
<td>76.5% Positive</td>
<td>87.5% Positive</td>
<td>96.8 % Positive</td>
</tr>
</tbody>
</table>
Table 7.8 Summary of results for FO detection using the three different methods. AMD: absolute mean difference (ms); Distribution of the diff: distribution of the difference (percentage in the [-20; 70] ms interval, unless otherwise stated); sign: the sign of the majority of the differences; *: results that showed statistical difference respect to level walking.

<table>
<thead>
<tr>
<th></th>
<th>Level Walking</th>
<th>Ramp Up</th>
<th>Ramp Down</th>
<th>Stairs Up</th>
<th>Stairs Down</th>
</tr>
</thead>
<tbody>
<tr>
<td>FO CA - VFS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (ms)</td>
<td>24</td>
<td>24</td>
<td>24</td>
<td>40</td>
<td>32*</td>
</tr>
<tr>
<td>A. M. D. (ms)</td>
<td>31</td>
<td>31</td>
<td>34</td>
<td>41</td>
<td>50</td>
</tr>
<tr>
<td>Distribution of the diff.</td>
<td>100%</td>
<td>98.4%</td>
<td>94.4%</td>
<td>91.7%</td>
<td>92.8%</td>
</tr>
<tr>
<td>Sign</td>
<td>100% Positive</td>
<td>100% Positive</td>
<td>100% Positive</td>
<td>100% Positive</td>
<td>100% Positive</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Level Walking</th>
<th>Ramp Up</th>
<th>Ramp Down</th>
<th>Stairs Up</th>
<th>Stairs Down</th>
</tr>
</thead>
<tbody>
<tr>
<td>FO CA - GD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (ms)</td>
<td>48</td>
<td>40</td>
<td>72</td>
<td>-32</td>
<td>116</td>
</tr>
<tr>
<td>A. M. D. (ms)</td>
<td>53</td>
<td>43</td>
<td>73</td>
<td>40</td>
<td>132</td>
</tr>
<tr>
<td>Distribution of the diff.</td>
<td>84.6%</td>
<td>98.4%</td>
<td>55.5%</td>
<td>91.7% in [-90; 0]</td>
<td>85.7% in [60; 160]</td>
</tr>
<tr>
<td>Sign</td>
<td>100% Positive</td>
<td>100% Positive</td>
<td>100% Positive</td>
<td>88.9% Negative</td>
<td>100% Positive</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Level Walking</th>
<th>Ramp Up</th>
<th>Ramp Down</th>
<th>Stairs Up</th>
<th>Stairs Down</th>
</tr>
</thead>
<tbody>
<tr>
<td>FO VFS - GD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median (ms)</td>
<td>24</td>
<td>8</td>
<td>48</td>
<td>-80</td>
<td>68</td>
</tr>
<tr>
<td>A. M. D. (ms)</td>
<td>31</td>
<td>18</td>
<td>42</td>
<td>76</td>
<td>94</td>
</tr>
<tr>
<td>Distribution of the diff.</td>
<td>94.7%</td>
<td>95.2%</td>
<td>88.9%</td>
<td>100% in [-90; -50]</td>
<td>57.1%</td>
</tr>
<tr>
<td>Sign</td>
<td>76.9% Positive</td>
<td>60.3% Positive</td>
<td>95.8% Positive</td>
<td>100% Negative</td>
<td>95.6% Positive</td>
</tr>
</tbody>
</table>

Table 7.9 Summary of results for reliability measure (% of correct event detected) for all the steps analysed and for the different terrains.

<table>
<thead>
<tr>
<th>Reliability measure (%)</th>
<th>Level Walking</th>
<th>Ramp Up</th>
<th>Ramp Down</th>
<th>Stairs Up</th>
<th>Stairs Down</th>
</tr>
</thead>
<tbody>
<tr>
<td>VFS</td>
<td>99.8</td>
<td>98.6</td>
<td>96</td>
<td>95.5</td>
<td>87.9</td>
</tr>
<tr>
<td>GD</td>
<td>99.5</td>
<td>99.3</td>
<td>99</td>
<td>95.5</td>
<td>93.1</td>
</tr>
</tbody>
</table>
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7.4 Discussion

7.4.1 Differences between CA – VFS

Although using the same technology, CA and VFS differed in terms of threshold and area of detection. While the threshold for the CA method was 5% of total area, the threshold for VFS was 50% of a particular area (and in all cases, the 5% of total area was less than the 309 mm²). The area used for detection was also different (in CA case, the area of the entire sole of the foot was considered, while for VFS two octagons with an internal radius of 14.5 mm were considered).

Combining these two facts, it could be expected that a 5% of the total area of the foot whichever area the contact occurs would be at the same time or earlier than a 50% of a particular, limited area. Similarly, it would be reasonable to expect that the remaining 5% of area at FO occurred at the same time or later than the 50% of a particular area. And this was the general tendency for all results for all terrain conditions: the CA method detected IC earlier and FO later than VFS.

This tendency for the differences remained almost unchanged (and no significant differences were found) between ramps and level ground walking for both events, but differed significantly between stairs and level walking (stairs up and down, in the case of IC and stairs down for FO).

In the case of stairs, CA detected IC earlier and FO later than for other terrains. Visual inspection of the insoles pressure distribution, showed that for all of the children the first contact of the foot with the floor was by the lateral forefoot for both stair walking (stairs up and stairs down), rather than the medial forefoot or the heel where the VFSs were placed. For FO different children used different patterns at the time of break of contact, in some cases, the lateral forefoot was involved in the last contact with the ground.

These different contact types would have a direct influence on the contact times. These would suggest that to detect the first contact and the last contact, two foot switches may not be enough to cover the walking patterns of the three terrains evaluated in this study.
7.4.2 Differences between CA and GD

As expected from the results of Chapter 5, the differences between CA and GD for outdoors level ground walking were similar (and not statistically significant) to the differences between GD and KD for level ground walking inside the laboratory.

The IC detection for ramp was similar to that of level walking, being in both cases the GD detection later than CA. For FO, GD detected earlier than CA; the detection for ramp up events was similar to the level walking but for ramp down although the tendency was the same (GD detecting earlier than CA), the differences in detection were larger (and that is the case for all subjects, as seen in figure 7.18) than for ramp up, being the GD earlier than the CA.

For the stairs condition, FO detection changed with respect to the other terrains. For stairs up, GD detected FO generally later than CA, and this was the case for all subjects. In order to understand this change in the pattern, the description of the first part of the swing during walking up the stairs made by McFayden and Winter [1988] will be considered. These authors described the first part of the swing as a phase that involved not only bringing the leg up and over to the next step, but also keeping the foot clear of the intermediate step. According to the authors, this was accomplished in two ways; one way was by contraction of the tibialis anterior which dorsiflexed the foot; the other way was by pulling back the leg through flexion at the knee. The movement backwards of the leg and flexion of the knee is more pronounced that for level walking and several authors agree that the extension of the knee (and consequent anticlockwise movement of the shank) is delayed from the FO with respect to level ground walking [McFadyen and Winter 1988; Riener et al. 2002; Nadeau et al. 2003].

The feature (negative peak) from angular velocity that was used in this and other studies for FO detection represents the time when the movement backwards of the shank slows down to change into a movement in the opposite (forward) direction. If the flexion of the knee prolongs and the extension movement is delayed, then it is possible that this peak is also delayed. This could be an explanation for the delay in detection of the FO of the GD respect to CA in the stairs up detection.

For stairs down, GD detected FO earlier than CA as for other terrains, but the differences were higher and this was again the case for all subjects (figure 7.26). Riener et al [2002] showed that the extension of the knee starts earlier in stair descent.
than on level ground walking and McFadyen and Winter [1988] also noted that the knee flexion during early swing was only slight as foot clearance was not as imperative. Following a similar reasoning as for stairs up, it is possible that the negative peak in the angular velocity that is used to detect FO could happen earlier in stairs descent than in level ground walking and this could explain the larger differences seen in the detection of FO by GD respect to CA for stairs descent.

From the results of Chapter 5, CA showed a tendency to detect the events later (25 ms) than the gold standard (the force platforms) for both events. The results obtained in this chapter, showed that the gyroscope detected IC close to the CA (median 8 ms, which represents one sample), except for ramp down when GD detected later than CA (median 24 ms), in which case the errors are adding up and the real difference between gyroscope and force platform could be higher (50 ms). In terms of FO, the gyroscope detected it earlier than CA (and nearer the gold standard) except for stairs up, when the gyroscope detected later than CA and in this case again the errors would be adding up (and the real difference would be up to 50 ms).

7.4.2.1 The Use of GD Detection for Functional Electrical Stimulation

It was mentioned in Chapter 3 that the use of FES for improving the position of the foot during the gait cycle is applied either to the dorsiflexors of the foot during the swing phase of gait or to plantarflexors of the foot during the stance phase. Also in Chapter 4 a summary of the events used for stimulation of each muscle group was presented and from that summary, it was concluded that FO and IC were the most used events to start and stop stimulation and that the detection of both would roughly cover for stimulation of both muscle groups.

The mature pattern of activity of both muscles groups during level walking approximately coincides with those events. TA (dorsiflexor muscle) are normally active from before toe off until after IC (40% of stance phase), while the gastro-soleus complex (plantarflexor muscles) shows an onset of activity after IC (during loading response, approximately 20% of stance phase) until just before TO (approximately 80% of stance phase) [Sutherland et al. 1988]. Tokuhiro et al [1985] found similar patterns during ramp up and ramp down walking.
So, for ramps and level walking and if the unimpaired muscle activation patterns is
used, FES applied to TA could start at FO and finish at or after IC and FES applied to
soleus and gastrocnemius could start at or after IC and finish at FO. As said before,
these are not the exact timing of average normal activity, but an approximation. The
fact that the gyroscope has a tendency to detect FO earlier than the actual event occurs
could be an advantage if taking into account the physiological activation of both
muscles (although to an unknown extent). The detection of the IC by the gyroscope is
less than 25 ms later than the actual event occurred and an extension could be used for
starting or finishing the activation even later.

In terms of the activation of these muscles during stairs ascent and descent,
researchers [Townsend et al. 1978; Andriacchi et al. 1980; McFadyen and Winter
1988; Nerin Ballabriga et al. 1999] have investigated the muscle activation and agree
in terms of activation of TA and gastrocnemius and soleus for level walking and stairs
ascent. These studies show that during stairs ascent, the primary pattern of TA activity
starts before TO until IC (McFadyen and Winter found that some basal activity is
still present during stance phase while Andriacchi found that activation finishes
before IC), similar to ground level walking, to ensure foot clearance over the next step
and suitable placement.

For descending stairs, however, McFayden and Winter and Townsend suggested that
the weight acceptance occurs from IC to the contralateral FO and during this time,
the TA is active, then the activity increases again until after ipsilateral FO. McFayden
and Winter proposed that the continuous activity, especially around the time of
contralateral foot off could be to stabilize the ankle during single support.

It is well known that TA does not only provide clearance of the foot during swing but
also decelerates plantarflexion and provides a forward movement of the tibia after IC.
Townsend et al [1978] proposed that, similarly, during the second double support of
ascending of stairs (before FO) and the first half of the stance during descending the
stairs, the body is moved forward and that part of the forward movement is provided
by the tibialis anterior muscle rotating the lower leg.

Activity of the gastro-soleus complex during stair ascent was similar to level ground
walking (activity starting after IC until before FO, although Ballabriga et al [1999]
found some activity during swing phase as well). However, during stairs descent the
soleus muscle presents levels of activity during the whole gait cycle while the gastrocnemius presents activity from after FO until after contralateral FO. Townsed et al [1978] regarded the function of these muscles during stance to provide balance when the centre of pressure is forward, which is clear during the single support phases of level ground and ascending walking patterns. And the activity of the gastro-soleus after FO seems to have contributed to augment the plantarflexion at FO, to control the foot for weight acceptance and during the first part of stance, together with TA, to support the ankle of the single supported leg.

So, considering the use functional electrical stimulation is applied to the dorsiflexors during swing and to the plantarflexors during stance, this is still the physiological pattern of activation for stairs ascent. In this case, the gyroscope would detect FO later than the actual event happens, but still detects IC with a difference of 25 ms to the actual occurrence. The effect of the delay in detection of FO would need to be studied when stimulation is applied.

For stairs descent, the physiological activation of the muscles is different. A method to detect that stairs descent would be necessary to apply the stimulation accordingly.

### 7.4.3 Differences between VFS and GD

As the differences between real FS and GD were similar to the ones between VFS and GD (also, there was no statistical significant difference), the results from the indirect comparison between VFS and real FSRs supports the resemblance of behaviour between them both and encourages the use of the virtual foot switches as an alternative.

The differences for detection of the events on ramp are similar to those for level ground walking (and not statistically significant), with a tendency for GD to detect both events earlier.

The differences were larger in the case of both events when evaluating the stairs detection (and statistically significant for IC detection between stairs up and level ground). The fact that the detection of the VFS may have been influenced by the type of initial contact and foot off, could have affected the differences between the VFS and GD.
The reliability measured showed that GD and VFS were close and it was better than 96% for level walking and ramps.

Smith et al [2002] found similar reliability for real foot switches detection. They used two or three (depending on the child contact pattern) foot switches for the detection of five events, including IC and FO and tested them on seven children with cerebral palsy (age range between 7 and 13). Then they evaluated the reliability of the FSR when compared with a kinematic detection, while the children walked on level ground and found a reliability of 94.5% in detection of events.

In this study the reliability of both, VFS and GD diminished in the case of stairs walking, particularly for walking down the stairs, being the GD slightly better than the VFS.

For all terrains, the reliability of GD was better than 90%.

7.4.4 Final Comments on Detection

The results from the level walking part of this study resemble the results from the indoor study, as expected, supporting the use of CA and KD as similar reference methods for detection of events in unimpaired subjects and the possibility of using VFS rather than FSR.

The differences between the “outdoor level ground walking” study and the “indoor level walking” study presented in Chapter 6 are mainly in terms of the environment which was less “controlled”. Outdoors, the subjects were not asked to walk in a straight line but in fact, half way between the ramp and the stairs, they needed to performed a 90° turn; also, sometimes, they needed to avoid small obstacles, like water on the floor; finally, the path was approximately twice as long as the indoor path.

Two considerations about VFS should be noted. The first is that, from the “jumping” gait cycle, small changes in the walking pattern that affects the foot contact type (from HC to TC) would affect the detection of a one foot switch system. The second consideration is that the VFS would give false detections (extra events) due to changes in the loading of the feet (which has been mentioned by users of stimulators with FSR).
The results also show that there are no significant differences between ramp up, ramp down and level walking for the ramp inclination used in this study and that detection on stairs is the most challenging for both types of sensors.

Finally, it should be noted that the sampling frequency used for this experiment was 125 Hz for data collection and the same frequency was used to sample the synchronization pulse. This means there could exist a delay of up to 8 ms between the occurrence of the actual event and the detection (due to the sampling frequency) and there could also exist a delay of up to 8 ms in the detection of the synchronization pulse, which would delay the detection of all the events in the trial. The worst-case scenario, would represent a delay of 16 ms between the actual occurrences of the event and its detection.

7.5 Conclusion

The conclusions of this part of the study could be summarized as follows:

The use of a reference system that uses contact rather than movement (in this case, a pressure measurement system) provided useful insight into the type of contact produced in each terrain and this proved helpful in understanding the results.

Although a direct comparison between the performances of VFS and FSR was not viable as the presence of the FSR inside the shoe would have affected the performance of the CA, they had a similar performance for level ground walking, which supports the idea of using VFS as an alternative system when studying FSR behaviour.

Some commercial stimulators mentioned in chapter 3 make use of one FSR for detection of events. In this study, it was shown that a small change in the contact pattern (for example, jumping over an obstacle) would make a one-sensor system miss or alter the detection. The gyroscope did not present problems detecting the previous FO or the following IC.

Also, if the VFS were placed under the heel (which is recommended if there is enough heel contact on level ground walking), most of the stairs detection would be either missed or erroneous. The use of two FSR would improve the reliability of the system.
but also has limitations in terms of detecting the very first contact during stair walking.

It was also noticed that while the subjects were standing still, the VFS detected false events that would affect the performance of a stimulator or require the subject to turn it off. This did not affect the gyroscope detection.

With respect to the objectives described in the Introduction of this chapter, the conclusions are:

1) The detection of both events during ramp up and down was similar to that of level walking, with the same tendency of detecting IC later than the reference (CA) and FO earlier than the reference (and there were no statistical significant differences), which would suggest that the relationship between the features used for detection and the events, persists. In terms of the stairs walking, the detection of IC was similar to that for level walking, with same tendency as described above (and there were no statistical significance when compared with level walking). Again, this would suggest that the features are related to the events. For detection of FO during stairs, it is possible that the feature is delayed with respect to the event during stairs ascent and precedes the event during stairs descent. The effect of these differences considering the physiological activation of muscles needs further investigation.

2) The absolute median of the difference in the detection between gyroscope and reference system (CA) was less than 25 ms for IC (all terrains) and les than 75 ms, except for stairs down when it was 116. The absolute mean difference was less than 40 ms for IC (for all terrains) and less than 75 ms for FO for all terrains except walking down the stairs, for which it was 135 ms.

The absolute median of the differences between gyroscope and virtual foot switches was less than 50 ms for IC and less than 80 ms for FO. The absolute mean difference between the gyroscope and the virtual foot switches was less than 70 ms for IC and less than 100 ms for FO for all terrains.

To put this numbers into perspective, if we consider using a stimulation frequency of 40 Hz, there would be a difference of up to 2 stimulus for level walking and ramp and up to 4 stimulus in the starting or stopping of
stimulation with respect to a foot switch in stairs. The significance of such difference has yet to be established

3) The reliability of the VFS was better than 95% in all terrains except walking down the stairs, when the reliability dropped to 87.9%. The reliability of the gyroscope was similar to that of the VFS, but slightly better; it was in all cases better than 95% except for stairs down when it was 93%.
8.1 Introduction

This chapter presents the summary of the project and the conclusions drawn from it. Initially, the summary and conclusions from the literature review are presented. The results and conclusions from the experimental studies follow, together with the limitations of this work and the proposed future work.

8.2 Summary and Conclusions from the Literature Review

Cerebral Palsy (CP) refers to a disorder of motor function resulting from non-progressive damage occurring before the brain is fully mature. A common outcome is an imbalance in the muscles that control the ankle resulting in increased effort for walking, risks of falls and possibilities for permanent contracture and deformations.

One of the proposed treatments is functional electrical stimulation (FES). Its aim is to improve the gait of children with CP, mainly by applying it to the muscles governing the movement of the ankle to help correct or improve the positioning of the joint during the gait cycle.

The electrical stimulators used for adults are also used in children. From the literature review it was possible to see that these stimulators present issues, such as positioning of the electrodes, the sensation produced by the stimulation and the use of a foot switch as a sensor to control stimulation, that limit its acceptability and its widespread use in the adult population. It is thought that these issues would represent difficulties also for the use of FES in children. In addition, researchers and clinicians working with children have noted that the stimulators should be improved in terms of cosmesis, and easy of use and functionality, to increase acceptability among children and their carers.
Chapter 8. Conclusions and Future Work

As part of an overall project at the University of Surrey aimed at designing and developing a stimulator more appropriate for use in children, this project concentrated on the sensor to control the stimulation.

Several other sensors have been reported in the literature with the aim of finding an appropriate one to control the timing of FES, although the main focus of those evaluations has been in adults with a foot drop problem and less literature has focussed on children with CP. The literature demonstrates that further work is needed to clarify the applicability of different options in different situations (terrains, speeds) and in a wider patient population, which would include children.

Previous studies done at this Centre have shown promising results when using the gyroscope in the adult population. It was decided then to extend the research already done with the gyroscope to the paediatric population.

8.3 Evaluation of Kinematic and Pressure Sensor System Detection

It was considered necessary to select appropriate reference systems to evaluate the accuracy of the gyroscope detection. Kinematic data and data from a pressure measurement system were evaluated against force platforms to determine the accuracy of the systems to detect HC and TO in eleven healthy unimpaired adults.

The results showed that the mean absolute differences between kinematic and kinetic detection were less than 20 ms for both events and the differences between contact area and kinetic detection were less than 25 ms for both events. For both events and both systems, the absolute mean differences were within 3.5% of stance phase (approximately the duration of IC), which was considered accurate enough for detection of events.

8.4 Evaluation of Gyroscope Indoors

This study compared the gyroscope detection against kinematic and force sensitive resistor detection. It involved indoor, level ground trials for six unimpaired and two CP children.
Chapter 8. Conclusions and Future Work

The results showed that the differences seen between foot switch and gyroscope (FS-GD) for the unimpaired group were similar to those seen in the CP group for both events, which would indicate that the features chosen from the shank angular velocity to detect the events are still present in the case of these two CP children.

The results also showed that the absolute mean difference between the gyroscope and the reference system was less than 20 ms (3% of stance phase) for IC and less than 115 ms (15% of stance phase) for FO for both groups of children. Taking into account that the reference detected events earlier than the gold standard in up to 20 ms, an extra 20 ms should be added to both results for comparison of the gyroscope with the gold standard (force platforms). The gyroscope detection remained closer to that from the FSR than to that from the reference system, the absolute mean differences for IC was less than 15 ms (2% of stance phase) and for FO less than 35 ms (5% of stance phase) for both groups of children.

8.5 Evaluation of the Gyroscope Outdoors

This study compared the gyroscope detection against contact area and virtual foot switch detection. It involved the evaluation of the gyroscope in seven unimpaired children who walked on a path that included level ground walking, a ramp and stairs outside the gait laboratory.

The results showed that the differences between contact area and gyroscope for ramps and stairs were not statistically significant with respect to level ground walking for both events. It was possible to note, however, that FO detection during stair walking seemed different with respect to the other terrains, which may be related to the particular pattern of movement of the knee.

The results also showed that the absolute mean difference of detection between gyroscope and reference system (CA) was less than 40 ms for IC (for all terrains) and less than 135 ms for FO. Taking into account that CA detected events later than the gold standard (force platforms) in up to 25 ms, the gyroscope could have detected the events 25 ms nearer the gold standard than CA.

The absolute mean difference between the gyroscope and the virtual foot switches (VFS) was less than 70 ms for IC and less than 100 ms for FO for all terrains.
In terms of reliability, both sensors behaved similarly for level ground walking (VFS: 99.8% and gyroscope 99.5%), and stairs down (reliability of both 95.5%). The gyroscope was slightly better for ramps (VFS for ramp up 98.6% and 96% for ramp down, gyroscope for ramp up: 99.3% and 99% for ramp down). Stairs descent was the most challenging task for both sensors; the reliability of gyroscope was 93.1% and 87.9% for VFS.

This study also showed that the gyroscope presented some advantages with respect to the VFS method, and potentially to the foot switch method, in terms of avoiding false detections when standing still and being robust to small changes of the walking pattern.

8.6 Contribution and Final Conclusions

The present work represents the first evaluation of a pressure measurement system for detection of gait events. It is also the first evaluation of the gyroscope as a method to detect initial contact and foot off in unimpaired and CP children and it is the first evaluation of the performance of the gyroscope to detect those events while the subjects walk on ramps and stair, when placed on the shank.

Overall, the results of such evaluation showed a tendency for the gyroscope to be more accurate (closer to the reference systems) for IC detection than foot switches, and a tendency for the foot switch to be more accurate for FO detection.

The difference between the gyroscope and foot switch would represent 2 electrical pulses (with a frequency of stimulation of 40 Hz) for all children studied on level ground walking and for unimpaired children walking on ramps, and a difference of up to 4 pulses for unimpaired walk on stairs. Taking into account that although there are clear guidelines as to how to apply stimulation, but that the effect of stimulating earlier or later than an actual event (or an event as detected by the foot switch) is still unknown, further work is needed to establish the clinical significance of the mentioned differences between the gyroscope and the foot switch.

The differences found could have been affected by the sampling frequency and synchronization detection between equipments. In the worst-case scenario (chapter 6,
where the sampling frequency was the lowest used, 60 Hz and synchronization pulse was sampled at 100 Hz), the error due to these factors could have been up to 27 ms.

The gyroscope proved to be slightly more reliable in ramps and stairs; also it demonstrated advantages with respect to a one foot switch system for changes in contact pattern (for example changing the IC from HC to TC) and false detections during standing, and potential benefits from a cosmetic point of view.

Although the sample size does not allow for generalizations of these results, the gyroscope showed promising results as a sensor for detecting IC and FO in unimpaired and CP children.

Going back to the hypothesis of this project and the very crude guidelines that were considered: the overall hypothesis of the complete project, was that “a gyroscope can be used effectively as part of a functional electrical stimulator dedicated for gait assist in children with CP”. And as very crude guidelines for this particular project, it was said that it would be expected for the differences between the gyroscope and foot switch to be smaller than (absolute mean difference ± one standard deviation) 400 ms ± 200 ms for foot off and 100 ± 200 ms for initial contact. These were considered to be only very crude guidelines, future work should establish the real effect of the differences in the patients with CP and they are considered here only on the basis of the lack of more appropriate guidelines. For FO, the absolute mean differences for both groups of children and under all terrains, were smaller than 100 ms (± 55 ms) and for IC, they were smaller than 70 ms (± 50 ms). So, the differences were indeed smaller than the crude guidelines accepted.

Also, the reliability (in terms of the number of correctly detected events) of the new sensor should be at least as good as (or better than) the foot switch. In this respect, as mentioned before, the reliability of the gyroscope was similar to or better than the foot switch, especially going down ramps and stairs. So again the guidelines were met.

The results from this project provided information that would encourage the use of a gyroscope for FES. Now, further work should allow for complete acceptance of the hypothesis.
8.7 Limitations of this Study

The present study does suffer from a number of limitations. Of particular note:

- The reference systems used (kinematic and contact area) were not experimentally tested in children or in pathological gait or in different terrains. However, as discussed in Chapter 5, confidence as to use those results comes from different sources. First, it is accepted that the inter-relationships between the time-distance parameters is fixed and that the kinematic variables and most of the timing of muscle activity reach adult values by the age of 5. As this project involved children older than 6, it could be assumed that they have reached an adult gait pattern. In terms of the using the reference systems in pathological gait, especially when the IC may not be HC but TC, previous research on detection of events has shown that the methods tend to behave similarly for loading events and also for unloading events. Assuming this, it would be expected that the differences between the references and the gold standard would be similar for TC as those establish for HC. Finally, the pressure measurement system allows for different areas of the sole of the foot to be involved in any of the events, allowing for certain variability to occur in different terrains.

- The kinematic detection was not tested for Heel Off and Toe Contact detection. However, as mentioned before and discussed in Chapter 5, previous research on detection algorithms have shown a tendency for the algorithms to performed similarly for the loading events (HC and TC) and also perform similarly for the unloading events (TO and HO). In this respect, researchers have found that there are similarities between the loading events (HC and TC) and between the unloading events (HO and TO) when using algorithms to detect them. Ghoussayni et al [2003], for example, determined that the differences between an algorithm using sagittal velocities of the markers at heel and toe and force platforms were similar for HC and TC, being less than 2% of gait cycle for both events, and also similar for HO and TO, being less than 10% of gait cycle for both events. Mickelborough et al. [2000] also found similar results for the event detection between HO and TO (80.3% of HO detection and 78.2% of TO detection occurred within 20 ms of force platform algorithm). Although it has not been demonstrated for the algorithms used in this study, taking into account those results and the similarities in IC and TC as loading events and HO and TO as unloading events, it
could be expected that the differences between the references and the gold standard would be similar for TC as those establish for HC and for HO as establish for TO.

➢ As it is the case when one foot switch is used under the metatarsal head, instead of the heel, the approach taken in this project was to detect FO rather than Heel Off. This may represent a disadvantage in some patients, as the use of an earlier event (such as HR) to start stimulation could have allowed for a longer ramp to be used and could have prevented a clonus reaction in the antagonist muscle).

➢ The limited number of patients that participated in the evaluation of the sensor.

The following section will address these limitations and present main areas for future work.

8.8 Future Work

8.8.1 Reference Systems

A similar protocol used for evaluating the reference systems in adults could be used with a paediatric population (both unimpaired and children with CP).

In order to evaluate the kinematic system for detection of other gait events such as heel off or toe contact, an approach where the subject contacts one platform with the heel and another platform with the toe could be used. Such a protocol has been used already in unimpaired adults [Ghoussayni et al. 2003] and could be repeated for unimpaired children. However, it does require the foot to land in the intersection between the platforms, which would require sufficient training and adjusting of the initial starting point, and it may prove especially difficult for children with walking impairments.

For evaluation of the contact area detection (provided by the pressure measurement system) in ramp and stairs, instrumented ramps and stairs could be used.

In the case of ramps, a treadmill incorporating a force platform (for example, the Advanced Mechanical Technology Inc. instrumented treadmill, AMTI, Watertown, MA, USA,) could be use to simulate ramps. Another approach, as used in [Kuster et al. 1995] is to construct a ramp, in the middle of which there is an aluminium plate,
with surface dimensions the same as the force platform. The plate was independently supported upon a rigid aluminium scaffold that bolted to the four corners of the Kistler force platform directly located below. Other researchers embedded commercial force platforms into custom designed ramps [Redfern and Di Pasquale 1997; Lay et al. 2005]

In terms of stairs, embedded force platforms in the steps could be used or force transducers could be placed in the corners of each step as used by Riener et al. [2002]. Other researchers [Nadeau et al. 2003] used one force platforms placed on the floor and constructed a stair case, such that the first step was directly above the force platform and another force platform was mounted on a solid frame that served as the second step of the stairs.

8.8.2 Gyroscope Evaluation

With the objective of implementing the gyroscope as part of a clinical electrical stimulator, proposed further work should include:

➢ The evaluation of gyroscope versus force sensitive resistors should be performed in a larger patient population with mild and moderate degrees of involvement and with different types of initial contact patterns. For this study, a contact reference system such as a pressure mat would be an advantage with respect to the use of kinematic data as expressed before. Although the results are not expected to be different, the additional data could reinforce the conclusions of this study.

➢ The evaluation of the gyroscope in cerebral palsy children when walking in different terrains. In this case, a similar protocol to the one used in chapter 7 could be applied, moderating the total length of the walk (especially the stairs) to the abilities of the patient group.

➢ Further evaluation of the gyroscope with changes of footwear (and barefoot) and speed should be performed to evaluate the robustness of the detection. If evaluating the barefoot condition, a contact reference system such as a pressure mat would be an advantage. The evaluation could provide information about the possibility of using the system for running tasks for example.

➢ Further work in the detection algorithm for additional gait events could provide more flexibility for children who present a heel-toe pattern (this being the natural
pattern of walk or induced by electrical stimulation). In this case, the data collected could be used to detect heel rise and toe contact, for example.

➢ If the evaluations support the findings of this study, then an on line detection algorithm should be implemented and evaluated. Initially a microcontroller could be programmed with the detection algorithm and a datalogger could be used to store the gyroscope signal and the output of the detection algorithm. Then an evaluation of the algorithm should be performed to check its applicability during on line detection.

➢ The gyroscope detection should also be evaluated when stimulation is being applied. The above mentioned on line system could be used in combination with a stimulator triggered by a foot switch, to compare the output from the gyroscope to the one from the foot switch, when stimulation is being applied.

➢ Later, a prototype system including the new sensor and the stimulator could be designed to apply the stimulation, with the gyroscope replacing the foot switch (or even using both as triggers for different trials to see whether the user notices any differences between the systems). If the system proves to be useful and accepted in these children, then a miniaturized version of the stimulator could be designed and developed. The overall design should be for a stimulator mounted on the shank. The specifications regarding colours and shape should be addressed toward the paediatric market, for which it would be desirable to perform a survey in children who are FES users and their parents to consider their preferences.


References


Ref -2


Ref -3


References


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References


Ref -16


Appendix A

Functional Electrical Stimulation

A.1 Stimulation Parameters

The different stimulus parameters that could be varied in order to achieve the desired contraction are described below, together with some values normally used for transcutaneous stimulation.

A.1.1 Pulse Amplitude and Duration

The amplitude, or intensity, of the current pulse and its duration must be adequate to meet or exceed the threshold of excitability of the stimulated tissue. The relationship between both is reciprocal: incrementing any of them would result in an increment in the total current generated during the pulse. This in turn, within certain limits, would increase the force response of the muscles by increasing the number of motor units recruited (figure A.1).

The threshold needed to produce contraction and the maximum intensity (such that supramaximal levels result in no additional force response) both depend on the muscle being stimulated. Different authors have suggested pulse width range up to 500 μs for surface stimulation is enough in terms of variation of torque, although, in general, pulses longer than 400 μs means no savings in current amplitude level [Peasgood et al. 1995; Baker et al. 2000].

In terms of current values, it could go up to 100 mA (taking an impedance of 1 kΩ in parallel with 100 nF, which are the values of a simplified model of the skin impedance [van Boxtel 1977; Dorgan and Reilly 1999]).

The greater the current level, the deeper and broader the stimulus penetrates. However, this also means loss of specificity and more sensory information travelling that could help to the uncomfortable sensation accompanying stimulation. This has been mentioned as more of a limiting factor with children than adults, under the assumption that adults may be willing to accept more discomfort to achieve an anticipated benefit [Reed 1997].
A. Functional Electrical Stimulation

Figure A.1 Effect of the amplitude of the stimulus on the recruitment of nerve fibers. A stimulus pulse at an amplitude and duration just above threshold will excite the closest and largest fibers. Increasing the intensity will excite smaller fibers close to the electrode, as well as larger fibers further from the electrode.

A. 1.2 Frequency

The frequency of the stimulation determines the rate at which nerves fire action potentials and therefore it influences the strength and quality of the evoked motor response. For FES programs, a smooth tetanic muscle contraction is desirable, for which frequencies should be in the range of 25 to 50 Hz (figure A.2). The stimulated muscle will fatigue if the current is applied continuously because all of the motor units are recruited simultaneously and in the reverse order of physiologic recruitment. This effect can be reduced if the stimulation is applied during a period of time and turn off for another period (ON:OFF). The recommended ON:OFF ratio is 1:3 [Baker et al. 2000].

Again, Baker et al [2000] stated that frequencies necessary to cause a tetanic contraction will vary from 15 Hz to 50 Hz, depending on the muscle. And, although in general, frequencies between 30 to 35 Hz are enough, patients will “feel” a smooth contraction around the 50 Hz and prefer even higher [Baker et al. 1988]. However, it
should be borne in mind that there is a compromise in this sense between comfort and fatigue.

![Graph showing muscle tension over time for different motor units with varying firing frequencies.](image)

Figure A.2 a) Physiologically achieved tetany: the summation of all the muscle fibers results in a smooth tetanic contraction with relatively low firing frequency requirements of each individual muscle fiber; b) electrically elicited tetany: as the frequency of the stimulus increases, the muscle does not return to its resting tension and the summating contractions fuse. Pps: pulses per second, it refers to the frequency of stimulation. [Baker et al. 2000].

A.1.3 Waveforms

The electrical pulses delivered could be monophasic (current moving in one direction only—from the active to the indifferent electrode) or biphasic, (in this case, during half of the cycle one electrode is the active one and it becomes the indifferent during the other half). The biphasic waveform is balanced if the charge in both directions is the same and they can be symmetrical or asymmetrical.

A rapid onset and offset avoids nerve accommodation and minimal stimulation amplitude can be used [Baker et al. 2000]. While monophasic waveforms (Figure A.3) facilitate ion accumulation and skin irritation, the asymmetric balanced biphasic waveforms (Figure A.4) not also provide similar specificity but also minimize skin irritation (balanced means that the charge in both directions is the same). The symmetric biphasic (Figure A.5) produces even less skin irritation but less specificity and even the antagonist could be stimulated [Baker et al. 2000].
Peasgood et al. [1995] tried different waveforms in surface stimulation of the tibialis anterior of two unimpaired patients (aged not specified). The waveforms evaluated were monophasic and biphasic rectangular and monophasic and biphasic sinusoid. The most efficient waveform was defined as the highest peak force measured when stimulating using a pulse width of 300 µsec and a frequency of 30 Hz. The results showed that the rectangular biphasic was the most efficient waveform.

Baker et al. [1988] evaluated different waveforms in the wrist flexors and extensors (as example of small muscles) and in the quadriceps muscles (as example of large muscles). They evaluated several symmetric and asymmetric waveforms and the results of the comparison showed that there is little difference between the comfort of a symmetric biphasic and an asymmetric biphasic in the small muscles of the forearm. But the authors observed more antagonist recruitment with the symmetric, so they suggested the use of the asymmetric for small muscles.
Figure A.5 Symmetric Biphasic Waveform. Also in this case, if the charge of the positive and negative parts of the signal is equal, the signal is called balanced. This type of waveform will reduce skin irritation even more than the other two but some specificity will be lost and muscles other than the target may be recruited.

Also, there was clear preference of biphasic over the monophasic waveforms, in both small and large muscles.
Appendix B

Gyroscope Circuit and Datasheet

B.1 Enc 03J Gyroscope Datasheet

Ultra-Small angular velocity sensor with Murata's unique ceramic bimorph vibrating unit.

This product is an angular velocity sensor that uses the phenomenon of Coriolis force, which is generated when a rotational angular velocity is applied to the detecting body. To achieve its ultra-small size, ultra-lightweight, and quick-response capability, the circuitry has been converted to a custom IC in addition to a sensor element using a Murata's original, ultra-small, ceramic bimorph vibrating unit. This product offers many excellent features such as a quick-response feature when detecting a moving object or the increased flexibility of installation because of its small and lightweight design.

FEATURES
1. Ultra-small and ultra-lightweight
2. Quick response
3. Low driving voltage; low current consumption
4. Reliable features achieved by a built-in AGC circuit

APPLICATIONS
1. Detecting hand movements involved in video and still cameras
2. Detecting vibrations in various vibration-free tables and isolators
3. Detecting the own movement

RATINGS

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<td>Current consumption (mA max.)</td>
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<td>Max. angular velocity (%)</td>
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<td>Output (at angular velocity=0 Vdc)</td>
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<td>Scale factor (pV/deg.)</td>
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<td>Temp. coefficient of scale factor (%)</td>
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<tr>
<td>Linearity (% FS)</td>
<td>±5</td>
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<tr>
<td>Response (Hz max.)</td>
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<tr>
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<td>Storage temperature range (°C)</td>
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<td>Weight (g max.)</td>
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TERMINAL DESCRIPTIONS

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<td>(3)</td>
<td>Ground (GND)</td>
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Appendix B. Gyroscope Circuit and Datasheet
B.2 Circuit used for Gyroscope Conditioning

Gyro Conditioning Circuit
Appendix C
Routines Used for Events Detection

C.1 Routines Included in CD

The CD contains the routines used for event detection explained in different chapters.

From Chapter 4:

➢ Routine Gyro.m: it is the routine for detection of IC and FO using the gyroscope signal for level walking unimpaired and CP gait.

➢ Routine Footswitches.m: it is the algorithm used to detect HC, HO, TC and TO using real force sensitive resistors placed under the heel and toe.

From Chapter 5:

➢ Routine Platform.m: it is the routine that detected IC and FO in each of the force platforms, using kinetic data.

➢ Routine Kinematic.m: it is the algorithm used to detect IC, FO, HO and TC using kinematic data from two markers placed on the heel and between the second and third metatarsal head.

➢ Routine Ca.m: it is the routine used to detect IC and FO using contact area reported from a pressure measurement system from the insoles placed inside the shoes.

From Chapter 7:

➢ Routine Virtualfsr.m: this is the routine that used data from two areas of an insole placed inside the shoe. One area was under the heel and another under the first metatarsal head.

➢ Routine Gyrot terrain.m: it is similar to the routine Gyro.m but modified to account for changes in the signal pattern for ramps and stairs.
Appendix D

The Coriolis Principle and the Vibratory Gyroscope

The Coriolis Principle involves the generation of a force composed of two separate physical effects. In order to explain it, the following example of a rotating disc containing a slot in which a particle may slide, as shown in figure D.1 will be used.

Let the disc in the figure rotate with a constant angular velocity \( \omega \) and the particle A move inside the slot with a constant speed \( v \). Under these conditions, the velocity of A will have two components \( v \) (the linear movement relative to the slot) and \( r \omega \) (the rotational movement due to the disc motion).

![Figure D.1 Representation of a sliding particle in a rotating disk to illustrate the Coriolis acceleration. Adapted from [Meriam and Kraige 1998], page 395.](image)

If the disk rotates by an angle \( d\theta \), the a-b axes will rotate to a new position a' - b', as shown in figure D.2.

The velocity increment due to the change in direction (due to disk rotation) of \( v \) is \( vd\theta \) and the velocity increment due to the change in magnitude of \( r \omega \) (due to the increase in the distance \( r \)) is \( d(r \omega) = \omega dr + r d\omega \), but as \( \omega \) is constant \( rd\omega \) is zero, so the change in velocity due to the change in magnitude is \( \omega dr \).

Dividing each increment by \( dt \), \( vd\theta \) becomes \( v \omega \) and \( \omega dr \) becomes \( \omega v \). Adding the two produces \( 2 \omega v \) which is the Coriolis acceleration.
Appendix D. The Coriolis Principle and the Vibratory Gyroscope

The direction of the Coriolis acceleration is always normal to \( v \), in the \( b \)-direction normal to the slot. The Coriolis force may be written as:

\[
F = 2 \, m \, v \, \omega
\]

Figure D.2 Movement of the disc will produce rotation of the frame.

Given that the mass of the particle is constant and that ideally the velocity \( v \) is also constant, the force \( F \) will be dependent only upon the angular velocity \( \omega \). However, since it is not actually possible for the particle to continue travelling in one direction for any length of time, the particle must instead move backwards and forwards through the slot and the velocity sampled when the particle is at the same distance from the centre of the disc.

The ENC 03 vibratory gyroscope produced by Murata Manufacturing, makes use of the Coriolis principle to measure angular velocity [Ebara et al. 1998]. It consists of a vibrating body (a triangular prism) and three piezoelectric elements attached to the side faces of the prism, as shown in figure D.3. An oscillation circuit is connected between the piezoelectric elements, so that a bending movement of the prism is produced and also two of the elements are used for detection.
When the prism is rotated about the Z plane, a Coriolis force is produced and transmitted to the detection elements:

\[ F = 2mv \omega \]

While the mass is constant, the velocity is not since the piezoelectric elements oscillate. However, by sampling the peak of the velocity amplitude, the value appears to be constant, in which case the force becomes dependant only upon the angular velocity.

Figure D.4 Detection of angular velocity and noise cancellation in the ENJ 03 Murata gyroscope.
By mounting the detecting elements 60 degrees to each other, the response of each of them will be opposite to the other, so that the difference between the two is proportional to the angular velocity. The advantage of this arrangement is that noise components are cancelled out by subtraction (see Figure D.4).
Appendix E

Ethical Submission

The documents submitted to be considered by the ethical committee included a protocol for the study, information sheets for the parents or guardians of the participants (one for children with cerebral palsy and one for unimpaired volunteers), information sheets for the participants (one for each group of children), a consent form for the parents and a consent form for the children.

Below, a copy of the protocol is presented together with a sample information sheet for parents of participants with CP and parents consent form. All the has been included in the enclosed CD (in a folder called Appendix E Ethical Submission, the four copies of the information sheets and two copies of the consent form, together with the protocol).
Evaluation of a Gyroscope for Detection of Gait Events in Children with Cerebral Palsy to be Used as Part of a Functional Electrical Stimulator.

Dr David Ewins, Supervisor

Ms Paola Catalfamo, PhD Student.

Project Protocol

Summary

The aim of this project is to evaluate a sensor (gyroscope) to detect gait (walking) events in children with cerebral palsy (CP). The events to be detected are the initial and final contact of the foot with the floor during the stance phase of the walking cycle.

The gyroscope detection will be compared with two reference detection systems and virtual foot switches. The reference detection will be provided by the movement of the foot (taken from kinematic data) and a pressure measurement system, which measures the pressure being applied under the foot during walking. Part of the data from the pressure measurement system will be used as a virtual foot switch.

The research participant will be asked to walk inside and around the gait laboratory. The path outside the lab has a ramp and some steps so allowing the sensor to be evaluated over a range of terrains.

Each participant will be asked to walk three times (one inside the lab, two outside the lab) in one session lasting approximately 60 minutes. No further sessions will be required. A total of 20 research participants (10 healthy and 10 cerebral palsy volunteers) will be recruited for this study.
1. Background

Cerebral Palsy (CP) refers to a disorder of motor function resulting from non-progressive damage occurring before the brain is fully mature [Gelber and Jeffery 2002]. A common feature of CP is toe-walking [Perry 1975], in which the first contact of the foot with the floor is made essentially by the toe, instead of the heel. This may result in unstable gait and consequently frequent falls.

One possible treatment for toe walking correction is the use of Functional Electrical Stimulation (FES). FES refers to the application of electrical pulses to neural pathways or muscles in order to achieve an effective muscle contraction with the aim of restoring a lost or impaired function. Research carried out on the effects of FES when used as an orthotic device in CP children suggests that FES could provide improvements in gait for that population [Carmick 1995; Johnson et al. 2002; Pierce et al. 2002; Postans and Granat 2002; Stevens 2003]. However, most of the researchers agree with Wright [2001] in that the convenience and cosmesis of the commonly used electrical stimulator should be improved to encourage use and increase acceptability from children and parents.

The idea of applying electrical stimulation for improving gait in CP children is based on the assumption that the selective activation of muscles during different phases of gait is possible. In order to activate the muscles at the appropriate time, a sensor needs to be used to detect the correct start and stop time for stimulation.

Currently, the sensor used is a foot switch, usually attached to an insole worn inside the shoe. Some researchers have indicated that the heel switch is cosmetically undesirable and is exposed to adverse conditions (high temperatures and humidity), causing frequent failures [Kostov et al. 1999; Munih and Ichie 2001]. Also, it has been reported that variation in both gait style and footwear can lead to occasional failure of the sensor or different detection patterns [Wall and Crosbie 1996; Henty et al. 1999; Ott 1999] and that the reliability is diminished due to their tendency to detect heel contact during the swing phase of gait as small forces are exerted on the heel during swing [Mansfield and Lyons 2003].

Several different sensors have been evaluated for detection of gait events and possible use in electrical stimulation. Some of the evaluated sensors are electromyograms...
Appendix E. Ethical Submission

[Coiro et al. 2001; Kamono et al. 2001], tilt sensors [Dai et al. 1996], accelerometers [Mansfield and Lyons 2003] and gyroscopes [Tong and Granat 1999; Sagawa et al. 2000; Ghoussayni et al. 2001; Aminian et al. 2002]. From those, the gyroscope has been evaluated at Surrey University and it has shown promising results for event detection. However, the evaluation has been done in adults. An evaluation of the sensor in children is now proposed.

This project focuses on the evaluation of the gyroscope as a sensor to detect events in CP gait. If the gyroscope proves to be a reliable and accurate sensor for detection in children, it would be possible to include it as part of a functional electrical stimulator.

2. Objective

The objective of this study is the evaluation of the gyroscope in terms of accuracy and reliability for detection of events (in particular, the initial contact of the foot with the floor and the end of contact of the foot with the floor).

Each research participant will be equipped with reflective markers, pressure measurement insoles (inside the shoes) and a gyroscope at the shank. The data from the pressure measurement (it provides data of the pressure under the entire sole of the foot) and from the markers (kinematic data) will be used as reference.

It has been shown in the literature [Ghoussayni et al. 2003] that systems measuring movement (kinematic data) and forces (kinetic data) provide different information regarding the event (while one of them provides information about the beginning of the event, the other provides information about the end of the same event). Using both references inside the laboratory will provide information about the accuracy of the gyroscope but also it will provide some extra information about when, during the event, the detection by the gyroscope occurs.

Part of the pressure measurement data will be used as “virtual foot switches” (as if two foot switches, one under the heel and one under the first metatarsal head, are being used for detection).
Each research participant will be asked then to walk inside the gait laboratory (level ground) to provide a base measurement. The walk will be recorded by video cameras. Afterwards they will be asked to walk outside the gait laboratory, where they will be asked to use ramp and a few steps. The purpose of changing the terrain, from level ground to ramp and steps, is to evaluate the reliability of the gyroscope in a more “realistic environment”, which will be similar to the actual terrain the children will use in the community.

3. Criteria for the selection of participants

Two groups will be included in this study, healthy and CP participants will be recruited. The inclusion criteria for healthy children is as follow:

- Children of 6 to 17 years old.
- Without known motor impairments.

The inclusion criteria for CP children is as follow:

- Children of 6 to 17 years old.
- Diagnosis of spastic or mixed CP.
- Present 90 degrees of passive dorsiflexion with knee extended.
- Able to walk up and down stairs and ramps (with or without aids).

The CP research participants that meet the criteria mentioned above will be recruited from the patients attending physiotherapy sessions at the Physiotherapist Department, and from patients attending the Gait Analysis Laboratory, both at Queen Mary’s Hospital.

The healthy research participants will be recruited from children known by physiotherapist and clinicians from the Physiotherapist Department and from the Gait Analysis Laboratory.
Each possible research participant will be approached by their physiotherapist in either department. If they are interested in participating, a copy of the information sheet, consent form and contact details of the researchers will be provided.

4. Experimental Design

On arrival, a copy of the information sheet and consent form will be provided (in case the participant has not one with them). The research participants and their parents or guardians will be encouraged to ask questions after reading the information sheet and discussion will follow.

Then, in case they are still interested in participating, the parent or guardian and the research participant will be invited to complete the consent form.

The research participants will be asked to change into appropriate clothes (shorts and comfortable shoes). Then they will be equipped with pressure measurement insoles (inside the shoes), reflective markers (small lightweight balls) and a gyroscope on the shank. The pressure measurement system and the gyroscope have associate dataloggers (boxes that record and store the data), which will be placed inside a rucksack worn on the back.

Each research participant will then be asked to perform three walks, all of them at their self selected speed and using the aids normally used for walking.

The first walk will be carried out inside the gait lab, walking 20 metres (twice on a 10 metres walkway). The walk will also be recorded by video cameras.

The second walk will be carried out outside, around the lab. For this, the research participant will need to go down a ramp, walk on level ground, go up a few steps and walk again on level ground inside the laboratory. The total length of the walk will be approximately 200 metres.

The third walk will be a repetition of the second, but going down the steps and up the ramp. Again, the total length will be approximately 200 metres.

Resting time will be provided between walks.

Digital photographs will be taken at the end of the test in order to record the position of the gyroscope and markers.
5. Security and Confidentiality

The consent form, video data and experimental data (marker, pressure measurements and gyroscope data) will be kept in locked filing cabinets. Participants will be referenced by a code, and this will be the only means of identifying the experimental data with the participants. This code will be kept in separate, locked, filing cabinet. Unless prior permission is given (see below), only the experimental data will be used in any published material. For this anonymity will be preserved.

A clause has been included in the consent form, following the anonymity clause that seeks participants' consent for their video and photographs to be used in seminars, publications or publicity. Only media relating to those participants who indicate that they were so willing would be considered for such use. If such media were used no other details, such as their names, would be disclosed.

6. Data Collection Timescale

The data will be collected from 1st October 2005 to 1st October 2006.
6. References


Appendix E. Ethical Submission

Wandsworth NHS
Primary Care Trust

Clinical Biomedical Engineering Centre (CBEC)
Roehampton Rehabilitation Centre
Queen Mary’s Hospital
London SW15 5PN
Tel: 020 8355 2175
Fax: 020 8355 2952
email: p.catalfamo@surrey.ac.uk

PARENTS / GUARDIANS INFORMATION

SHEET

Evaluation of a sensor for detection of events during walking

Your child is being invited to take part in a research study being conducted by the University of Surrey and Queen Mary’s Hospital. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and if you wish, discuss it with relatives and your physiotherapist. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish your child to take part. Thank you for reading this.

What is the purpose of the study?

This study is being undertaken as part of a PhD at the University of Surrey. The purpose of the study is to evaluate a new system that will work as part of a Functional Electrical Stimulator.

Functional Electrical Stimulation (FES) is a technique that uses small electrical pulses to activate muscles and produce useful movement. One of its applications is to
stimulate some of the muscles of the lower leg in order to improve walking. It is essential, in this case, to activate the muscles at the correct time during walking.

Currently, most of the devices that provide stimulation use a system inside the shoe (figure 1) to start and end the stimulation and the same system is used for adults and children. However, patients and clinicians have reported problems with this system, for example, stimulation starting at the wrong time, and practical issues associated with the wires connecting it with the stimulator normally worn on the waist.

The aim of this study is to investigate the possibility of replacing this inside-the-shoe system by another one which could be placed on the leg. For this study, we will evaluate how well the new system works. The evaluation will not involve any stimulation.

Previous work with adults at the University/Queen Mary’s Hospital has suggested good results when using this new system to measure the time when the foot contacts the floor and when the foot is lifted while walking. Now, we would like to evaluate it in children. If the results indicate that it is as good as expected, it could be part of a new stimulator for adults and children.

Figure 1. System placed underneath the foot, either under the heel or the toes, to measure the time when the foot hits the floor and the time when it leaves the floor while walking.
Why has your child been chosen?

Your child is suitable for inclusion in the trial if you wish, as she/he fulfill the selection criteria:

- All volunteers must have been diagnosed with spastic or mixed cerebral palsy.
- They have 90 degrees of passive dorsiflexion with knee extended.
- They are able to walk up and down stairs and ramps (with or without aids).
- They are between 6 and 17 years old.

We would like to recruit ten volunteers for this study.

Does your child have to take part?

Taking part is entirely voluntary. It is up to you to decide whether or not your child will take part. If you do decide your child to take part you will be given this information sheet to keep and then be invited to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. This will not affect the standard of care your child receives.

What will happen to your child in case of taking part?

Your child involvement in the study will require one visit to Queen Mary’s Hospital (Gait Laboratory), which will take approximately 60 minutes.

At the visit he/she will be asked to walk, first inside the laboratory and then going outside the laboratory where she/he will need to go down a ramp and up a few steps. This will be repeated going down the steps and up the ramp. Breaks between each walk will be provided.

What does your child have to do?

The way in which the new system behaves will be evaluated while you walk. For this, different types of information will be collected:
a) The movement of the foot and leg will be collected using markers (small reflective balls) placed on legs and hips. The movement of these markers will be monitored by six cameras.
b) The force applied on the floor while walking will be measured using a thin insole worn inside the shoe (figure 2).
c) A small box will be placed on the leg and kept in place with a Velcro strap. This will provide information about the movement of the lower leg. This will be connected to two boxes (to store the signals), which will be inside a small rucksack.
d) Video. While your child is walking inside the gait lab, the walk will also be recorded by video cameras.
e) A photographic record of the position of the boxes and markers will be made. Photographs will be kept for reference and will be securely stored on a locked computer.

In order for the box on the leg and markers to be attached effectively, we will first ask your child to change into appropriate clothing (cycling shorts and comfortable shoes). We can provide lycra shorts if you do not have these available.

Figure 2. Insoles used for measurement of foot pressure.

Afterwards she/he will be asked to do the following:
Appendix E. Ethical Submission

- Walk at comfortable speed inside the gait lab.
- Then, walk outside the lab where there will be a ramp and a few steps, back into the lab.
- Finally, repeat the above going down the steps and up the ramp.

In total, the distance walked will be approximately 450 m and rests will be given between each part of the test. The whole procedure will take approximately 60 minutes.

If your child normally uses an aid for walking (walker, cane or crutches) please bring all of them to the assessment.

Dr Soori, Consultant in Rehabilitation Medicine at Queen Mary’s Hospital, has agreed to overview the project to ensure that we do not make unreasonable demands of you. His details follow.

Dr Soori
Consultant in Rehabilitation Medicine
Queen Mary’s Hospital
Roehampton
London
Tel: 020 8355 2724
Email: ssoori@swlondon.nhs.uk

What is what is being tested?
The purpose of this work is to evaluate how well the new system works to measure the time when the foot contacts the floor and the time when the contact ends.

What are the alternatives to the testing device?
The alternative to this system used in the leg is another system worn inside the shoe. However, we believe that the new one will improve appearance and convenience of use.

**What are the side effects of any treatment received when taking part?**

There are no side effects that we are aware of. During the study, we will be collecting different information to describe the way in which your child walks, but the treatment will not be altered in any form.

**What are the possible inconveniences and risks of taking part?**

As the test will be carried out in the gait laboratory at Queen Mary’s Hospital, you will need either to travel to the hospital or extend your time at hospital any day your child has a physiotherapy session (we could make an appointment before your physiotherapy session starts).

**What are the possible benefits of taking part?**

There will be no direct benefit to your child from taking part in the study. However, we hope that the work will result in an improved version of electrical stimulators, which may become commercially available at a later date.

**What if new information becomes available?**

Sometimes during the course of a research project, new information becomes available. If this happens, we will tell you and your child about it and discuss with you whether you want your child to participate in the study or not. If you decide that your child will participate in the study you will be invited to sign an updated consent form.

**What if something goes wrong?**
Appendix E. Ethical Submission

The University of Surrey has two types of insurance to cover claims arising from its involvement in clinical research. One covers the University when something goes wrong and the University is at fault. The other one provides compensation to subjects if they suffer a significant and enduring injury (including illness or disease), which may be directly attributable to their involvement in the trial.

If your child is harmed due to negligence from a member of NHS staff, then you may have grounds for a legal action, but you may have to pay for it.

Regardless of this, if you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service and University of Surrey complaints mechanisms will be available to you.

**Will your child taking part in the study be kept confidential?**

We may, with your consent, like to use photographs or video records for teaching or research presentation purposes. There is a consent form for you to give your permission or not for this.

All other information that is collected about your child during the course of the research will be kept strictly confidential. Any information about your child that leaves the hospital will have the name and address removed so that your child cannot be recognised from it.

**What will happen to the results of the research study?**

The results of the work may be submitted for publication in a peer review journal and will also be included in the final thesis of the PhD project, which will be available at the University of Surrey library for public access.

**Who is organising and funding the research?**

a. Investigators
Appendix E. Ethical Submission

Miss Paola Catalfamo, Centre for Biomedical Engineering, School of Engineering, University of Surrey.
Dr David Ewins, Clinical Scientist, Queen Mary’s Hospital and Senior Lecturer, University of Surrey

b. Funding Bodies

No payment is being made directly to the investigators for running this study.

Contact for further information

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School of Engineering
University of Surrey
GU2 7TE
Tel: 01483-684575
Email: p.catalfamo@surrey.ac.uk

If you require any further information please do not hesitate to contact us.
If you decide to allow your child to take part in this study you will be given a copy of this information sheet, your child will get another copy of the information sheet and a signed consent form to keep.

Thank you for your time spent in considering your child participation in the study.
PARENTS/GUARDIANS CONSENT FORM

Title of Project: Evaluation of a sensor for detection of events during walking
Name of Researcher: Paola Catalfamo

1. I confirm that I have read and understand the information sheet dated for the above study and have had the opportunity to ask questions.

2. I understand that my child participation is voluntary and that I am free to withdraw him/her at any time without giving any reason, without her/his present or future medical care or legal rights being affected.

3. I understand that sections of any of my medical notes may be looked at by responsible individuals from Queen Mary’s Hospital or the University of Surrey or from regulatory authorities where it is relevant to my child taking part in research. I give permission for these individuals to have access to her/his records.

4. I understand that all data recorded including photographs and videos will be securely stored for a minimum of 10 years at the end of the study.

5. I understand that there is a separate consent form regarding the use of the photographs taken/videos recorded of my child for teaching and research presentation purposes.

6. I agree my child to take part in the above study.

Name of Participant ___________________________ Date _____________ Signature ___________________________

Name of Researcher ___________________________ Date _____________ Signature ___________________________

Name of Witness ______________________________ Date _____________ Signature ___________________________