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Bioengineering Unit

Design and Evaluation of the Performance of a New Type of Reciprocal Gait Orthosis

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Abbreviation list:

AFO	Ankle Foot Orthosis
A_ GO	Advanced Reciprocal Gait Orthosis with no cable
AP	Anteroposterior
ARGO	Advanced Reciprocal Gait Orthosis
ASIA	American Spinal Injury Association
BMD	Bone Mineral Density
BW	Body Weight
C	Cervical
COG	Centre of Gravity
COM	Centre of Mass
COP	Centre of Pressure
DGO	Driven Gait Orthosis
FES	Functional Electrical Stimulation
FIM	Functional Independence Measure
GF	Gauge Factor
GRF	Ground Reaction Force
H	Height
HALO	Hip Ankle Linkage Orthosis
HGO	Hip Guidance Orthosis
HKAFO	Hip Knee Ankle Foot Orthosis

HRGO	Hydraulic Reciprocating Gait Orthosis
IRGO	Isocentric Reciprocal Gait Orthosis
KAFO	Knee Ankle Foot Orthosis
L	Lumbar
LSU RGO	Louisiana State University Reciprocal Gait Orthosis
MAS	Mobile Arm Support
ML	Mediolateral
MLO	Medial Linkage Orthosis
MMLO	Moorong Medial Linkage Orthosis
MPa	Mega Pascal
N	Newton
NERSCIC	New England Regional Spinal Cord Injury Centre
NRGO	No Cable Advanced Reciprocal Gait Orthosis
ORLAU	Orthopaedic Research Locomotors Assessment Unit
PAGO	Pneumatic Active Gait Orthosis
PCI	Physiological Cost Index
PGO	Powered Gait Orthosis
S	Sacral
SACH	Solid Ankle Cushion Heel
SBO	Spring Brake Orthosis
SCI	Spinal Cord Injury
T	Thoracic

TLSO	Thoraco Lombo Sacral Orthosis
VRSO	Vannini- Rizzoli Stabilizing Orthosis
W	Weight
WBC	Weight Bearing Control
WSCO	Wrapped Spring Clutch Orthosis

Abstract

Over the years, various types of orthoses have been designed to assist Spinal Cord Injury (SCI) subjects to stand and walk. However, the functional performance of the orthoses has not been adequate; patients experience stability problems, consume excessive energy during ambulation and generally require assistance in donning and doffing the devices.

The aim of this project was to address the shortcomings of currently available orthoses by introducing design modifications based on the Reciprocal Gait Orthosis (RGO), but using the principle of the hip guidance orthosis (HGO) instead of the linking cables of the RGO, for limb advancement. A prototype was designed and manufactured. It is of modular construction incorporating features which allow the alignment of the structure to be adjusted to suit the patient needs. Features have also been introduced to facilitate the donning/doffing procedures, allowing independent use of the device by the patient.

The feasibility and functional performance of the new orthosis was evaluated on three normal subjects under laboratory conditions. Assessment of standing stability was carried out using force plates, and of walking performance using gait analysis and measuring the energy consumption. Following these series of tests the prototype was modified to improve it, and a second series of tests was undertaken in order to compare its function with that of the standard HGO on 5 normal subjects.

The results of the tests indicate that the performance of the normal subjects in standing and walking with the prototype was better than that with the HGO. Moreover, it offers the ability to change the alignment of the orthotic components which is of considerable advantage. For instance, it was found that setting the hip joint of the orthosis in 5 degrees of abduction improved the walking performance of the subjects and the force applied on the elbow crutch decreased significantly.

However, before any definite conclusions on the effectiveness of the orthosis prototype can be made, a trial using paraplegic patients must be undertaken.

During the initial stages of the project, a literature survey showed a lack of information on the loads transmitted by hip-knee-ankle-foot orthoses. Without such data it is very difficult to effectively design any orthoses. This project provided the opportunity to acquire these data from the normal subjects. This was achieved by strain gauging one of the lateral bars connecting the hip to the knee of the orthosis. It is worth noting that the results of this part of the research showed that the loads transmitted through the lateral bar of the orthosis were considerably less than those transmitted through the human lower limb.

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CHAPTER 1: INTRODUCTION

1.1 Background to project

Spinal Cord Injury (SCI) is damage to the spinal cord that results in loss of mobility and sensation below the level of injury. This disorder is characterized according to the amount of functional loss, sensational loss and of the inability to stand and walk (Zampa et al, 2003, Stolov and Clowers, 1981, Capaul et al, 1994). The incidence of SCI varies amongst countries. For example there are 12.7 and 59 new cases per million in France and the United States of America, respectively (Surkin et al, 2000, Sutton, 1973). It may be a result of trauma (especially motor vehicle accident), penetrating injuries, or disease. As a result of this type of disability most SCI individuals rely on a wheelchair for their mobility. They can transport themselves from one place to another using a manual wheelchair with the speed and energy expenditure which is similar to normal subjects (Cerny et al, 1980, Waters and Lunsford, 1985).

Although, wheelchair use provides mobility to those patients, it is not without problems. The main problems are the restriction to mobility from architectural features in the landscape, and a number of health issues due to prolonged sitting. Decubitus ulcers, osteoporosis, joint deformities, especially hip joint adduction contracture can result from prolonged wheelchair use (Douglas et al, 1983). SCI individuals often undergo various rehabilitation programmes for walking and exercises. As expected, walking is a good exercise for paraplegics in order to maintain good health; decrease urinary tract infections; improve cardiovascular, digestive functions and psychological health.

Several types of orthoses have been designed to enable SCI patients to walk however, they are not without problems which include: independent donning and

doffing is difficult, transporting the orthosis from one place to another is difficult, walking speed is reduced compared with 'normal' subjects, cosmesis is poor and the style of walking is abnormal (Whittle et al, 1991, Hawran and Biering, 1996, Waters and Lunsford, 1985). The speed of walking for a SCI individual using an orthosis is significantly lower than that of an able body person and their energy cost of walking is much higher. Independent and convenient use of the orthosis is important in order that the orthosis be used regularly and successfully. Therefore, functional aspects produced by these orthoses such as ease of standing up and sitting down, donning and doffing the orthosis, ease of access and storage, are important and often leave much to be desired.

Several orthoses have been designed for SCI patients to allow walking as a therapeutic exercise however, the problems of slow walking speed, high energy cost and lack of independent donning and doffing remain serious issues to be resolved (Hawran and Biering, 1996, Merkel et al, 1984, Waters and Lunsford, 1985, Nene and Patrick, 1989). Moreover, the cosmesis of available orthoses is poor and structural stiffness is not sufficiently high to withstand the loads applied on the orthoses without serious structural deformities (Ferrarin and Pedotti, 1994, Whittle et al, 1991). Sometimes the mechanical reliability of the orthosis is poor and it is required to be checked regularly. This is a big problem especially for those living far from the rehabilitation centers.

Most SCI patients start walking with orthoses after receiving sufficient treatment to correct the deformities which they have acquired in the knee, ankle and hip joints as a result of prolong sitting in a wheelchair (Douglas et al, 1983). Unfortunately, some patients have knee flexion contracture, which is of more than 10 degrees or knee hyperextension. Since the orthosis cannot be used for the patients with more than 10 degrees flexion contracture in the knee joint, some patients have to undergo special surgical treatment to correct the deformities (Douglas et al, 1983). This delays the relevant treatment and increases the onset of bone osteoporosis.

One of the orthosis which was designed specifically for these patients is the Louisiana State Reciprocal Gait Orthosis (LSU RGO). The original concept of this orthosis was developed by Motloch in 1967 at Ontario Crippled children Centre in Toronto. The original orthosis was made from a couple of KAFOs and a plastic body jacket which were connected to each other by a set of gear mechanism. The mechanical reliability of the orthosis was poor (Woolridge, 1969). The orthosis was modified and further developed by Douglas in conjunction with Carlton Fillaver Company (Fillaver Inc USA). The new generation of this orthosis is more cosmetically appealing than other available orthoses however, the structural stiffness of the orthosis is not high enough to prevent the deformity and collapse of the orthosis during walking, especially for the heavy patients with high level of spinal cord lesion (Whittle et al, 1991, Jefferson and Whittle, 1990). This problem decreases the efficiency of the orthosis during walking and increases the loads applied on the upper limb through sticks. Although the functional performance of the subjects in using this orthosis is not as good as other orthoses, many subjects prefer to use this orthosis because of cosmetic reasons (Whittle et al, 1991, Stallard and Major, 1998).

Another well designed orthosis which was developed for paraplegic subjects is the Hip guidance Orthosis (HGO) designed at the Orthopaedic Research and Locomotor Assessment Unit (ORLAU) in Oswestry. This orthosis consists of three main parts, the hip joints, callipers with shoe plates and knee joints, and a body section. The design of the callipers is the same as the traditional KAFO orthosis made of stainless steel with the knee leather straps. According to the results of various research studies the stiffness of this orthosis is greater than that other available orthoses and its structural deformity during walking is not too much (Jefferson and Whittle, 1990). The functional performance of the HGO orthosis is better in contrast to other well known orthoses however, many subjects prefer to use other orthoses such as LSU RGO instead. They prefer to use an orthosis which is well fitted on the body and is more cosmetically appealing.

Some investigators have tried to design an orthosis which has a structural stiffness similar to that in the HGO orthosis and be as cosmetic as the RGO orthosis. They have tried to use some mechanisms such as using a medial linkage with a couple of KAFOs, using special mechanisms which enable the user to keep both feet parallel to the floor during stance and helping the subjects to move the swinging leg forward (Hip and Ankle Linkage orthosis), using a hydraulic cylinder to transmit the motion from one side to other side (Hydraulic Reciprocal Gait orthosis), and using air muscles which act as human muscles to help the swinging leg to advance (Kirtley and McKay, 1992, Genda et al, 2004, Ozyalcin and Ozbasli, 1992, Belforte et al, 2001). In other orthoses such as in Weight Bearing Control orthosis (WBC) a specific control mechanism was used, this mechanism controlled the performance of the orthosis during walking (Yano et al, 1997). A motor powered mechanism was attached to the hip joint of an RGO orthosis by Ohta et al (2007) to increase the speed of walking.

The results of various research studies have shown that using the above mentioned orthoses did not improve the ability of the subjects. Moreover, they have shown that the HGO orthosis is the best available orthosis for paraplegic subjects. The loads applied on the crutches and the energy consumption during walking with the HGO orthosis are less than these of other orthoses. Moreover, the subjects can walk with this orthosis faster than with other orthoses (Jefferson and Whittle, 1990, Whittle et al, 1991, Stallard and Major, 1998). However, many subjects prefer to not use any orthoses or they select other orthoses instead of the HGO. So designing an orthosis which has a structural stiffness better or the same as the HGO orthosis and be as cosmetic as the RGO orthosis is very important. Designing an orthosis which fulfill these requirements not only improves the performance of the subjects but also, increases their willingness to use the orthosis.

According to results of various research studies, the SCI subjects need to stand and walk regularly and for a long periods of time in order to control bone osteoporosis

(Sabo et al, 2002). Presently it is too difficult for the subjects to donn and doff the orthosis several times a day in order to walk. If the orthosis has this capacity to allow the patients to wear some parts when they are in wheelchair and connect the other parts only for walking, they can walk several times during a day. So it was aimed to design an orthosis to cover all of the aforementioned needs. The new design of an orthosis needs to cover the following requirements:

1) Possess mechanical reliability
2) Has sufficient structural stiffness
3) The cosmetic of the orthosis be the same as in RGO orthosis or better
4) The weight of the orthosis should be less than other available orthoses
5) Donning and doffing the orthosis be easy for the subjects in order to use the orthosis regularly and independently
6) Allow patients with more than 10 degrees of knee flexion contracture to use the device

The first generation of the orthosis under investigation in this thesis was designed by the author in Iran. The orthosis had an open structure similar to that in the Advanced Reciprocal Gait Orthosis (ARGO), i.e. without the medial thigh bar. This orthosis was made of three components, a couple of thermoplastic Ankle Foot Orthoses (AFO), body section (made of thermoplastic material) and lateral bars with traditional knee and hip joints (drop lock). The hip joint of the orthosis has adjustable screws in order to change the range of motion of the hip joint (flexion/extension) (Karimi, 2001).

The AFO parts of the orthosis and the body section were custom moulded and were therefore manufactured specifically for each subject. The components of the orthosis could be attached to each other by the subjects when they were sitting on a wheelchair. They wore the AFO and the body section and attached the lateral bar only for walking. The orthosis was tested on two paraplegic subjects with lesion between T_{12} and L_1. They were trained to walk with the orthosis independently

and using crutches. First they were trained to donn and doff the orthosis independently. Secondly they were skilled to walk in parallel bars and finally they were educated to walk with the crutches independently. The results of their assessment showed that they could wear the orthosis independently. Moreover, they could walk with the orthosis better than other available orthoses. However, there were some problems associated with the first generation which were:

1) The thermoplastic material used for manufacturing the AFO and body sections did not have enough mechanical stiffness
2) The lateral bar of the orthosis was weak and it was necessary that it should be made from a suitable material
3) The knee joint of the orthosis was a drop lock ring type and it was too difficult for the patients to unlock the knee joint for sitting
4) The hip joint locking system was also a drop lock ring type and patients had problems with locking and unlocking the system
5) The alignment of the orthosis could not be changed according to the patients' requirements

In a glance to the relevant literature it was found that aligning the orthosis in some degrees of abduction improved the performance of the subjects and decreased the magnitude of the loads applied on the crutch. Thus, it became apparent that using a component in the orthosis to allow changes in its alignment in a mediolateral direction could improve the performance of the orthosis. So it was aimed to design an orthosis to overcome the aforementioned problems and also to introduce a component which aligns the orthosis in different planes.

Another problem associated with research of SCI patients was related to the methods of analysis which were selected by the investigators. Many of the researchers only used one parameter to evaluate a designed orthosis. They used some gait parameters such as Spatio-temporal parameters to evaluate the performance of the subjects in walking with orthosis. However, other researchers only focused on the stability

analysis during quiet standing or measured the energy consumption or the loads applied on the crutches. Unfortunately, there is no research which has been used all of the above mentioned parameters. So another aim of this research was to evaluate the new design of the orthosis by using gait analysis, stability analysis and by measuring the energy consumption and the loads applied on the crutches.

There is a lack of information regarding the best performance of paraplegic subjects during walking with orthosis. It is not practical to compare the performance of paraplegic subjects with the healthy subjects during normal walking. Although, the orthosis stabilizes the paralyzed joints and help the handicapped subjects to walk again, it restricts other motions, which are necessary for normal walking, such as the pelvic motion. It could be a good idea to compare the functional performance of normal subjects in walking with the orthosis with that of paraplegic subjects. This not only will show the negative effects of using the orthosis on the normal walking but also will show the importance of other motions which are restricted by the orthosis. Moreover, it will represent the best performance that can be achieved by paraplegic subjects in walking with the orthosis which would be the same as the function of normal subjects in using the orthosis. This can show the gap between the normal and handicapped subjects' performance, which can be decreased by designing a suitable orthosis.

In a survey of the relevant literature, it was also found that the loads applied on the orthosis structure during walking were not measured. Having this information not only would help the researchers to design an orthosis properly but also, would answer the following question that is: can an orthosis decrease the bone osteoporosis or not. Designing the orthosis according to absolute values of the loads can help the designer to decrease the size of the orthosis components and help them to select the appropriate materials. As the results, the cosmetic of the orthosis would be improved and the patients would be more interested to use it.

1.2 The aims of this research study

The main aims of this research were:

1) To design an orthosis which has the above mentioned features
2) To evaluate the orthosis on normal subjects by undertaking gait analysis, stability analysis during quiet standing and while performing various hand tasks
3) To measure the loads applied on the crutch
4) To analyze the energy consumption.
5) To measure the absolute values of the load applied on the orthosis by attaching strain gauges on the lateral bar of the orthosis.

1.3 Limitations of the study

There were some limitations that need to be acknowledged regarding the present research study. These included:

1) The facilities in the workshop of Bioengineering Unit of University of Strathclyde were limited and it was difficult to manufacture the complex components. Moreover, the waiting list of the workshop was too long and the investigator had to wait for a long time
2) The time of access to the Gait laboratory was limited and it was difficult to arrange the available time of the Gait lab with the participants and the supervisor
3) There was a lack of facilities to carry out energy consumption tests using oxygen consumption techniques. The investigator of this research project had to undertake energy consumption testing based on heart rate monitoring
4) The sample size of the first part of this research study was small. It was impossible to increase the number of the participants, since it took considerable time and funding to prepare the orthosis specifically for each subject
5) The training and data collection time restricted the possibilities to do the tests with many hip joint configurations
6) Obtaining the ethical approval for undertaking the research was very time consuming

7) It was unadvisable to apply for the ethical approval for conducting tests on the paraplegic subjects prior to testing the orthoses on normal subjects, for safety aspects

1.4Organization of the thesis

The thesis consists of seven chapters which highlights the shortcoming of the available orthoses, describes the design of the new RGO orthosis, evaluates the new orthosis and states the final conclusion.

In the second chapter of the thesis the benefits of walking with orthoses is described in detail and the gait parameters of the normal and paraplegic subjects are compared. Moreover, the advantages and disadvantages of the available orthoses are addressed. The methods which were used for undertaking energy consumption and stability analysis are also described.

The third chapter of the thesis covers the design of the orthosis components. The loads which were necessary to design an orthosis were calculated. Force analysis of different components of the orthosis, mechanical requirements of the material used for this orthosis and manufacturing processes are the other items which are addressed in this chapter.

The forth chapter of the thesis is concerned with testing of the orthosis (first generation) on 3 normal subjects. Gait analysis, stability and energy consumption during standing and walking with the orthosis with different hip joint configurations and without the orthosis are the parameters covered in this chapter. The performance of normal and paraplegic subjects from the literature, are compared and discussed in detail.

The design of the second generation of the orthosis, manufacturing process and the properties of the materials, which were selected for the second orthosis, are described in chapter 5. The performance of the subjects in walking with the second orthosis is compared with that of the first one and is discussed in detail.

The performance of the subjects in walking with the second generation of the new orthosis and the HGO is compared in chapter 6. Determination the magnitude of the loads applied on the orthosis during walking of normal subjects with the orthosis is the other part of this research study which is described in this chapter. The difference between the function of the subjects in using both orthoses is discussed and compared with that of the paraplegic subjects obtained from the literature.

The seventh chapter summarizes the results of the whole research project and provides recommendations for the future studies in this subject.

CHAPTER 2: LITERATURE REVIEW

2.1 Spinal Cord Injury (SCI)

Spinal cord injury (SCI) is damage or trauma to the spinal cord that results in a loss of function, mobility and sensation below the level at which the spinal cord has been injured. This disorder is characterized according to the amount of functional loss, sensation loss and inability of a SCI individual to stand and walk (Capaul et al, 1994, Stolov and Clowers, 1981).

2.1.1 The Annual Incidence of SCI

The annual incidence of SCI differs from one country to another; it varies between 12.7 (France) and 59 (USA) new cases per million each year (Chen et al, 1997, Hammell, 1995, Pickett et al, 2003, Surkin et al, 2000, Sutton, 1973, Wyndaele and Wyndaele, 2006). In Canada, it varies between 37.2 and 46.2 (Pickett et al, 2003). In contrast, it is 40.2, 18, 12.7 and 19.4 new cases per million in Taiwan, Turkey, France and Australia, respectively (Chen et al, 1997, Surkin et al, 2000). According to Surkin (Surkin et al, 2000), the incidence of SCI in the USA is 59 new cases per million. However, Wyndaele (Wyndaele and Wyndaele, 2006) mentioned that the incidence of SCI in the Northern America is 51. According to the results of the research carried out by Wyndaele, the incidence of this disorder is 19.4 in Europe, 16.8 in Australia, and 23.9 in Asia and 14 in the UK.

In the USA, it is estimated that there are 183,000 to 230,000 individuals living with SCI (NSCISC, 2001). This prevalence statistics are estimates which were obtained from several studies carried out by different investigators and is not directly derived from National SCI databases. In contrast, the total population of individuals with SCI in the UK is about 40,000. In 1992 there were 900 to 1000 new cases of SCI in the UK and it was mentioned that the incidence of this disorder was increasing

(Hammell, 1995). In Australia the prevalence of SCI varied from 8096 to 9614 cases in 1985. However, by 1997 it was nearly 10,000 people with SCI in Australia (O'Connor, 2005).

The majority of SCI patients are young, with an age varying between 20 and 40 years (Chen et al, 1997, Surkin et al, 2000, Karacan et al, 2000). Those suffering from SCI in the UK are predominately male (87%) and young (24%, 58% and 72% are teenagers, under 30 and under 40 years old, respectively) (Hammell, 1995, Sutton, 1973). In the USA 82% of those patients are male (NSCISC, 2001). The ratio of male to female with SCI is 5 to 1 in Turkey, however; it is 2.5 to 1 in the rural areas and 5.8 to 1 in Istanbul (Karamehmetoglu et al, 1995, Karacan et al, 2000).

2.1.2 The Main Causes of SCI

The main cause of SCI is trauma, especially road traffic accidents and this is followed by domestic falls, work related accidents and sporting injuries (Hammell, 1995, Sutton, 1973). According to O'Connor and Murray, motor vehicle collisions were the cause of 50%, falling 37%, work related accident 2%, sports injuries 9% and Iatrogenic 2% of all SCIs in Ireland. They also mentioned in their research that the incidence of this injury is the highest in September followed by May (O'Connor and Murray, 2006).

2.1.3 The Types of SCI

There are different kinds of SCI that are named as complete and incomplete according to the types of dysfunction and paraplegia and quadriplegia according to the level of the lesions. According to Maharaj (Maharaj, 1996) the percentage of complete spinal cord lesion in Fiji is 52% of all cases and nearly 69% of them are paraplegia. In contrast, Karacan stated that nearly 57% of SCI in Turkey have incomplete lesions and 54% of them are paraplegia (Karacan et al, 2000).

2.2 THE ANATOMY OF THE SPINE

The human spinal cord is protected by the bony spinal column, which is made of the bones called vertebrae. These bones are connected together in a way, which allows some motion between them. The vertebral foramina of all vertebrae stacked one in top of the other forms the vertebral canal. This canal is surrounded by parts of the vertebrae and is protected by vertebral ligaments, menisci, and meninge layers (Marieb, 1989). The spinal column consists of 33 vertebrae; 7 Cervical, 12 Thoracic, 5 Lumbar, 5 Sacral and 4 Coccygeal (Gray et al, 1994). Figure 2.1 shows the anatomy of the vertebral column.

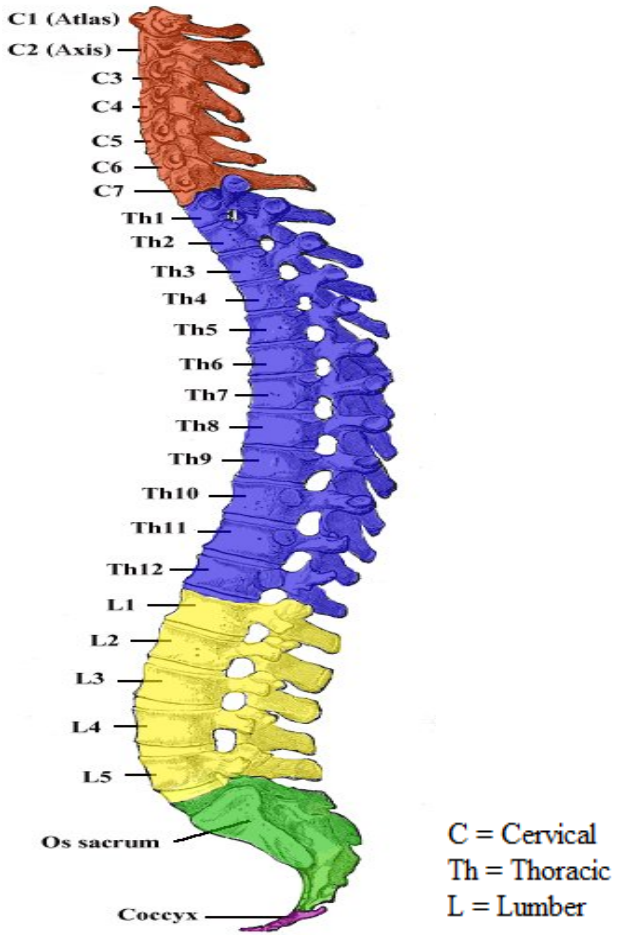


Figure 2.1: The structure of vertebral column (adapted from Gray's anatomy)

Two strong joints connect each two-adjacent vertebra to each other. The first joint, which locates on the anterior aspect, consists of two adjacent vertebra and inter-vertebral disc. The second joint is on the posterior aspect and is made from pedicle

facet joints. The former is actually a weight bearing structure and the later acts as a sliding and gliding joint. Strong ligaments such as the anterior and posterior ligaments, interspinous ligaments and ligamentum flavum support the vertebral column. Some small ligaments such as the dentate ligament also increase the structural stability of the column. Figure 2.2 shows the inter-vertebral joints.

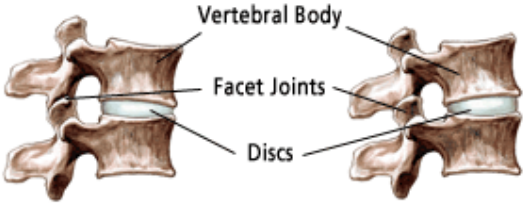


Figure 2.2: The inter-vertebral joints (adapted from Gray's anatomy)

2.2.1 Spinal Cord Nerves and Their Plexus

In total, there are 31 spinal nerves, which originate from different levels of the spinal cord and exit through holes named inter-vertebral foramina. The nerves that exit through the spinal column are named according to the level of the foramina from which they emerge. Except for the thoracic nerves from T_2 to T_{12} other ventral rami of spinal nerves combine with each other to make spinal plexuses. There are four spinal plexuses in the vertebral column, which include: Cervical, Brachial, Lumbar and Sacral plexuses.

The Cervical plexus consists of the ventral rami of the first to fifth Cervical nerves; occasionally a part of the fifth Cervical nerve is also in this plexus. It innervates the

muscles and skin of the neck and a portion of the head and shoulder. It also has an important role in innervation of the diaphragm, by the phrenic nerve.

The Brachial plexus is another spinal plexus, which consists of the anterior rami of the fifth Cervical nerve through to the first Thoracic nerve, figure 2.3. Some peripheral nerves such as Ulnar, Radial, Median and Musculoskeletal nerves, which innervate upper extremity muscles, originate from this plexus.

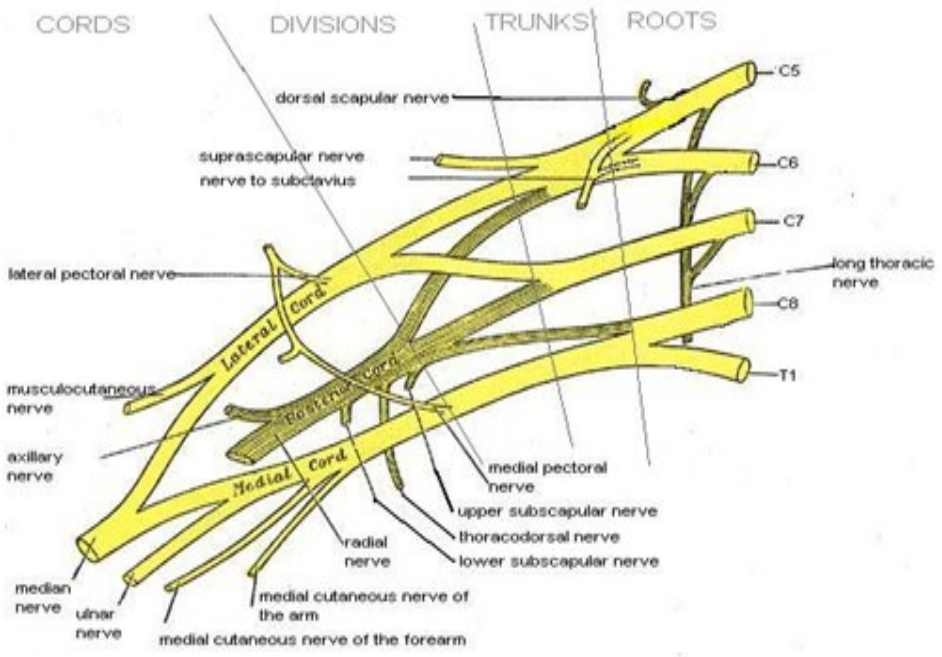


Figure 2.3: Brachial plexus (adopted from Gray's anatomy)

The Lumbar plexus is the spinal plexus which innervates the lower limb muscles. It is formed by the anterior rami of L_1 – L_4 and sometimes a branch from T_{12}. The nerves which arise from it innervate the structures located in the lower part of the abdomen and the anterior and medial portions of the lower extremity. Many muscles of the lower limbs are innervated by the Femoral and Obturator nerves, which originate from the Lumbar plexus, figure 2.4.

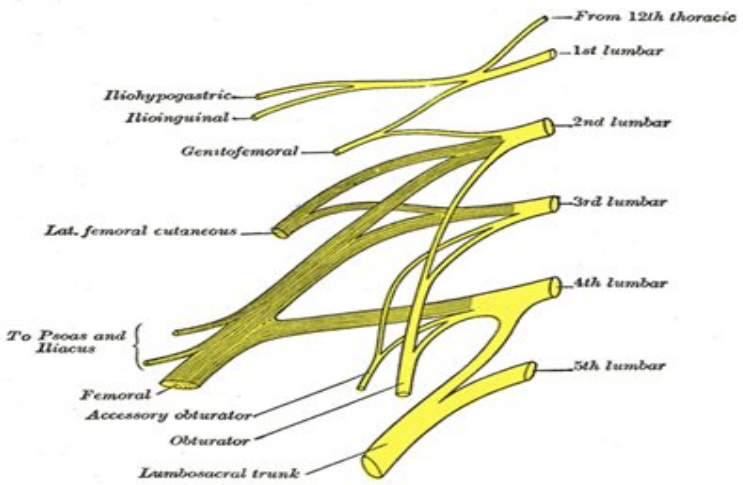


Figure 2.4: Lumbar plexus (adopted from Gray's anatomy)

Finally the Sacral plexus is formed by the anterior rami of the spinal nerves L_4 – L_5 and S_1 through S_4. It innervates the lower back, pelvic, perineum, posterior surface of the thigh and leg and dorsal and plantar surfaces of the foot. The sciatic nerve, which is the largest nerve in the body, arises from the Sacral plexus. It is composed of the tibial and common peroneal nerves, which innervate some muscles of lower limb, figure 2.5.

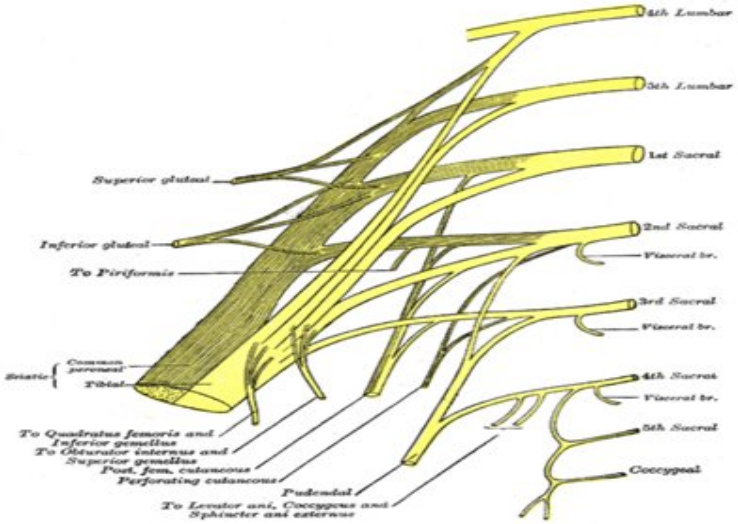


Figure 2.5: Sacral plexus (adopted from Gray's anatomy)

2.3 NEUROLOGICAL PROBLEMS WITH SCI

Neurological problems occur in patients with SCI. Distortion of a small portion of the column produces profound motor and sensory change. In complete SCI all function, sensory and motor, is lost below the level of the lesion. In contrast, in incomplete lesions, there is some sensory and motor function below the level of injury.

Paraplegia, which refers to any impairment or loss of sensory and motor function in the thoracic, lumbar or sacral segments of the spinal cord, is one of the neurological disorders associated with SCI. It does not affect the functions of the arms however, the function of the trunk, legs and pelvic organs, depending on the level of spinal lesion, may be involved (Maynard et al, 1997, Lee, 1991, Liverman, 2005).

Tetraplegia or quadriplegia is the other neurological disorder, which refers to any impairment and loss of function, sensory and motor, resulting from damage to neural elements within the spinal cord in the cervical region. This happens by any damage to neural elements within the spinal cord at that region. As a result, there is loss of function in the arms as well as the trunk, legs and pelvic organs (Liverman, 2005, Lee, 1991, Maynard et al, 1997).

There are five specific clinical syndromes that may be associated with incomplete injuries. The first, which is named the Central cord syndrome, is a very common incomplete injury that is associated with greater loss of upper limb function compared to the lower limbs. The second is named the Brown-Sequard syndrome, which results from a hemi section lesion of the spinal cord. This is characterized by relatively greater ipsilateral proprioseptive and functional loss and in the contralateral side there is loss of sensitivity to pain and temperature (Maynard et al, 1997).

Anterior cord syndrome is defined by a variable loss of motor and sensitivity to pain and temperature, with no effect on proprioception. This lesion occurs as a result of any damage to the anterior two thirds of the spinal cord while the posterior part of the column is intact.

Conus medullaris syndrome results from damage to the sacral cord and lumbar nerve roots within the spinal cord. In this syndrome the sacral reflexes may be preserved. Cauda equina syndrome is as a result of any injuries to the lumbosacral nerve roots, which results in loss of reflexes in bladder, bowl and lower extremities (Maynard et al, 1997).

2.4 STANDARD CLASSIFICATION OF SCI

The Frankel system of SCI classification is generally used for SCI description according to the type of impairment (Capaul et al, 1994). The Frankel system is defined as:

Grade A: complete motor and sensory function disorder

Grade B: motor complete but sensory incomplete function disorder

Grade C: motor and sensory incomplete function disorder

Grade D: useful motor function with or without auxiliary means

Grade E: no motor or sensory function disorder

There is another scale used in grading the degree of impairment of SCI and is actually a modification of the Frankel system. This scale is known as ASIA (American Spinal Injuries Association) system and has one grade for complete injury and three grades for incomplete ones. In this scale the strength of key muscles of the lower limb is used as a factor to determine the grade of injury. Clinicians

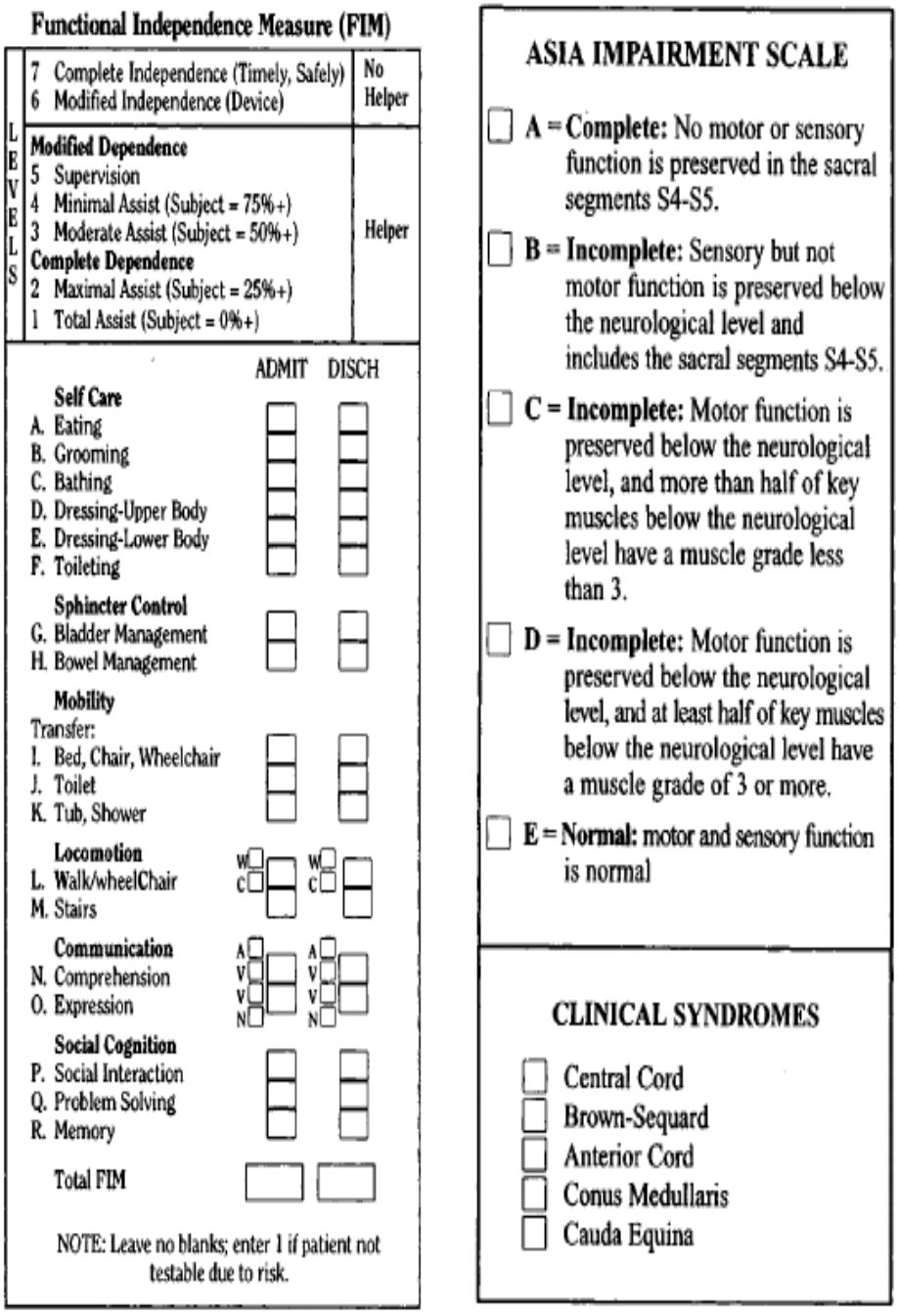
determine the strength of the muscles by using a five scores scale, in which 0 is applied for total paralysis and 5 for action against a full resistance (Maynard et al, 1997). This system is defined as:

Grade A (complete): is defined as absence of any sensory and motor functions in the sacral segments S4-S5

Grade B (incomplete): sensory is intact but there is no motor function below the neurological level and also sacral segments S4 and S5

Grade C (incomplete): more than half of key muscles below the neurological level have a grade less than 3

Grade D (incomplete): the motor function is intact below the lesion level and half of the key muscles have a muscle score, which is greater or more than 3.



Functional Independence Measure (FIM)

LEVELS		
	7 Complete Independence (Timely, Safely) 6 Modified Independence (Device)	No Helper
	Modified Dependence 5 Supervision 4 Minimal Assist (Subject = 75%+) 3 Moderate Assist (Subject = 50%+) **Complete Dependence** 2 Maximal Assist (Subject = 25%+) 1 Total Assist (Subject = 0%+)	Helper

	ADMIT	DISCH
Self Care		
A. Eating		
B. Grooming		
C. Bathing		
D. Dressing-Upper Body		
E. Dressing-Lower Body		
F. Toileting		
Sphincter Control		
G. Bladder Management		
H. Bowel Management		
Mobility		
Transfer:		
I. Bed, Chair, Wheelchair		
J. Toilet		
K. Tub, Shower		
Locomotion		
L. Walk/wheelChair	W C	W C
M. Stairs		
Communication		
N. Comprehension	A V V N	A V V N
O. Expression		
Social Cognition		
P. Social Interaction		
Q. Problem Solving		
R. Memory		
Total FIM		

NOTE: Leave no blanks; enter 1 if patient not testable due to risk.

ASIA IMPAIRMENT SCALE

- ☐ **A = Complete:** No motor or sensory function is preserved in the sacral segments S4-S5.
- ☐ **B = Incomplete:** Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-S5.
- ☐ **C = Incomplete:** Motor function is preserved below the neurological level, and more than half of key muscles below the neurological level have a muscle grade less than 3.
- ☐ **D = Incomplete:** Motor function is preserved below the neurological level, and at least half of key muscles below the neurological level have a muscle grade of 3 or more.
- ☐ **E = Normal:** motor and sensory function is normal

CLINICAL SYNDROMES

- ☐ Central Cord
- ☐ Brown-Sequard
- ☐ Anterior Cord
- ☐ Conus Medullaris
- ☐ Cauda Equina

Table 2.1: Functional Independence Measurement (FIM) adapted from ASIA (Maynard et al, 1997)

2.5 FUNCTIONAL SIGNIFICANCE OF SPINAL CORD LESION LEVELS

The physical limitations of SCI patients in performing daily activities vary greatly depending upon the level of the lesion. Improvement of some activities such as personal hygiene (bathing, shaving and socially acceptable bowel and bladder function), ambulation transfer (from wheelchair to bed and vice versa), dressing and eating can be achieved by using an effective treatment method (Stolov and Clowers, 1981).

During recent years, different scales have been proposed in order to measure the disability however, the Functional Independence Measurement (FIM) is the most commonly used (Zampa et al, 2003). The ASIA also evaluated this scale in assessment of the functional performance of SCI patients and recommended its universal adaptation in 1994. Table 2.1 shows the parameters selected for FIM as mentioned by ASIA (Maynard et al, 1997).

The first attempt to measure the performance of SCI subjects during daily activities, according to the neurological lesion level was done by Long and Lawton in 1955 and the outcome still serves as a guide today (Long and Lawton, 1955).

2.5.1 Functional Significance of a Spinal Cord Lesion Above The C_5 Level

Patients with lesion level above C_5 have significant problems with motion and also with breathing. Some muscles such as pectoralis major, latissimus dorsi, seratus anterior are inactive in those patients. They have no ability to push their wheelchair and their endurance is significantly low. They are completely dependent on others.

Those with C_1-C_3 lesion level have no movement of the upper and lower extremities muscles. They have only movement of the head and neck or shoulder elevation. They are dependant on others for help with almost all of their mobility and self care needs. They may be able to use a powered wheelchair with chin or pneumatic controls. It is possible to use different assistive devices which transmit the signals by means of radio waves, infrared waves to control their environment. They may be able to use a powered wheelchair with a Mobile Arm Support (MAS) orthosis to assist them with feeding and grooming activities (Long and Lawton, 1955, Stolov and Clowers, 1981, Maynard et al, 1997).

SCI subjects with lesion level at C_4 have innervation of the diaphragm, so they may not need ventilatory assistance. However, those between C_1-C_3 injuries have to use long term mechanical ventilatory support as a loss of innervation of the diaphragm.

2.5.2 Functional Significance of a Spinal Cord Lesion at a Level Below C_5

Those patients with a lesion level below C_5 have full innervation of trapezius, sternocleidomastoid and upper cervical paraspinal muscles. Some muscles such as those, which rotate and stabilize the neck, are intact in those patients. Rhomboids, deltoids and all of the major muscles of the rotator cuff have partial innervation. These patients have scapular adduction, shoulder abduction, internal and external rotation. The activity of shoulder flexor, extensor and elbow flexor is partially preserved in those patients.

For those with C_5 tetraplegia, a power wheelchair with hand controls can be very helpful for most of their mobility needs. They have problems in using a manual wheelchair, as a result of their reduced respiratory reserve. They need assistance for most self-care, transfer mobility with a manual wheelchair and for socially

acceptable bowel and bladder functions (Stolov and Clowers, 1981, Long and Lawton, 1955).

2.5.3 Functional Significance of a Spinal Cord Lesion at Level C_6

Rotator cuff muscles are fully innervated however, seratus anterior, latissimus dorsi and pectoralis major muscles have only partial innervation. Extensor Carpi radialis and flexor Carpi radialis are intact at the wrist. Active grasping is not possible in those patients without using an assistive device. Although the respiratory reserve is low, these patients can move their own wheelchair on a smooth level surface. They need assistance with their daily activities, especially for transferring from bed to the wheelchair and vice versa. They need no assistance for some daily activities such as eating and writing.

2.5.4 Functional Significance of a Spinal Cord Lesion at Level C_7, C_8

At this level the patient has power in the triceps, common finger extensors, and long finger flexors. Patients with an injury at this level can propel their wheelchair independently on smooth level surfaces. They can transfer from bed to wheelchair and move about in the sitting position. By using an appropriate orthosis to fix the paralysed joints those patients can ambulate to some extent.

2.5.5 Functional Significance of a Spinal Cord Lesion at Level T_1 - T_6

Patients with a lesion at this level have full innervation of all upper limb muscles. Their grip force is good enough to do all their activities in bed independently. They can achieve functional independence of self-care in bladder and bowel function. They need to receive advance training in order to use a wheelchair to move over uneven surfaces. They lack trunk stability and also require help donning and doffing an orthosis. These patients may be able to use an orthosis, such as an HGO, along with a walker and/ or crutches for standing and ambulation.

2.5.6 Functional Significance of a Spinal Cord Lesion at Level T_6 - T_{12}

Patients with a lesion at this level may have strong and powerful upper extremity muscles. The long muscles of the upper back have good innervations and the intercostal muscles are active, so the individuals have good respiratory function and endurance. They can manage bowel and bladder function independently after appropriate training. The patient can use bilateral Knee Ankle Foot Orthoses (KAFO) or HGO orthosis with a walker or crutches for standing and ambulation. They have better trunk control than patients with a higher injury, so they may be able to walk independently with an orthosis. Independent walking requires energy and time; therefore they usually prefer to use a wheelchair for their mobility.

2.5.7 Functional Significance of a Spinal Cord Lesion at Level T_{12} - L_4

The patients with a spinal cord injury at T_{12} have full innervations of the rectus abdominis, abdominal oblique muscles, transverse abdominis, and all muscles of the thorax. The hip joint hiker (quadratus lumborum) is not active however, some muscles such as the internal and external muscles of the abdomen and latissimus dorsi are active for hiking the hip joint during walking with an orthosis. These patients can attempt to walk up and down stairs with orthoses and crutches. Walking with an orthosis places a considerable energy demand on the patient.

For patients with an injury between L_1 - L_4, bowel, bladder and ambulation function are impaired initially. With treatment, bowel and bladder function can be independently managed. They can also become functionally independent in terms of household and community ambulation. Orthoses such as ankle foot orthoses and knee ankle foot orthoses can be prescribed for these patients in order to help them to stand and ambulate.

2.5.8 Functional Significance of a Spinal Cord Lesion at Level L_4-S_2

Patients with a lesion at level L_4 have good muscle function around the knee joint in order to stabilize it during walking. Some muscles such as quadratus lumborum, lower erector spine and primary hip flexors and quadriceps are intact. However, the major stabilizers of the hip joint are absent and ankles remain frail. The extensors of the knee joint are intact so long leg bracing becomes unnecessary. The ankle joint is frail and the patients need a suitable AFO orthosis to support it. The lack of hamstring and gluteus maximus muscles increases the incidence of hyperextension of the knee joint in these patients. They can stand and walk using a pair of AFO orthoses. The L_4 patient is completely independent in all phases of self care and ambulation (Long and Lawton, 1955, Stolov and Clowers, 1981).

2.6 COMPLICATIONS ASSOCIATED WITH SCI

The most common complication of SCI is the loss of functional mobility and sensation below the level of injury. However, paralysis, whether partial or complete, may lead to development of complications in other parts of the body. The following complications can arise in persons with SCI (Stolov and Clowers, 1981):

Respiratory disorder: this occurs as a result of infection in the lungs or from collapse of all or parts of the lungs in SCI subjects. In patients with a lesion at the upper cervical (above C_6) the breathing pattern is altered and patients have difficulty breathing, therefore they need respiratory assistance (Stolov and Clowers, 1981).

Gastrointestinal disorders: gastrointestinal bleeding caused by a stomach ulcer, which relates to stress developed after the SCI.

Cardiovascular disorders: SCI patients have problems related to fluctuating blood pressure. A sudden increase of blood pressure occurs by overdistention of the bowel or bladder and lowered blood pressure occurs when subjects try to stand or ambulate. In these patients, the blood vessels are not able to accommodate the rapid change in posture and cannot maintain adequate blood pressure. Inflammation of the vein followed by formation of blood clots can lead to vascular disease in some individuals (Stolov and Clowers, 1981).

Skin problems: the most common skin problem seen in SCI patients is skin breakdown, commonly known as pressure sores or decubitus ulcers. This occurs as a result of prolonged pressure over bony prominence due to an absence of pain appreciation and an inability of these patients to lift their weight/ posture. The soft tissues over bony prominences such as the greater trochanter, sacrum, knee joint epicondyles and ankle malleoli can be prone to pressure sores (Stolov and Clowers, 1981).

Musculoskeletal problems: the range of motion of the joints decreases if a therapist or other person does not routinely move these joints. Lack of movement can lead to joint contracture, which happens as a result of the joint being in one constant position. Depending on the level of the lesion, the vertebral column may be unstable and a scoliosis may develop.

In normal subjects bone strength is maintained through regular muscle activity and/ or by applying body weight through them. When the muscle activity or when the load applied through the bone decreases, they begin to lose calcium and phosphorus and become weak and brittle. Fractures of long bones secondary to osteoporosis is one of the most common complications associated with SCI (Sabo et al, 2002, Shields, 2002, Rosenstein et al, 1987).

Neurological problems: abnormal painful sensation may exist below the level of the lesion. Excessive sweating and spasticity are other neurological problems, which can be seen after SCI (Stolov and Clowers, 1981).

Psychological disorders: some factors such as pain, poor sleep, feeling of helplessness, frequent hospitalisation, poor self care and problems with transportation increase the risk of psychological disorders (Stolov and Clowers, 1981).

2.7 THE BENEFITS OF STANDING AND WALKING FOR THE SUBJECTS SUFFERING FROM SCI

Clinical experience has shown that wheelchair users often have complications secondary to their injury and also due to long term sitting (Stolov and Clowers, 1981). Standing and walking brings some benefits for SCI patients, such as decreasing bone osteoporosis, prevention of pressure sores, and improving the function of the digestive system, which increases their performance during daily activities (Rose et al, 1983, Sykes et al, 1995, Dunn et al, 1998).

2.7.1 Decreasing Bone Osteoporosis

Shortly after SCI, the metabolism changes resulting in the body sending a large amount of calcium and other minerals in the urine. This happens independently of the weight, age and sex of the person. The rate of calcium and mineral loss is high during the first 6-16 months after the injury. Osteoporosis also happens due to the reduction of body weight applied to the bones. Due to spinal cord injury these patients cannot stand and apply load to the lower limb bones, the bones become weaker and thus more brittle. In contrast to the lower limbs, more force may be applied on the upper limbs and spine; as a result the percentage of osteoporosis in

the upper limb and spine is significantly less than that in the lower limb bones (Shields, 2002).

In the research carried out by Sabo and his co-workers (Sabo et al, 2002), the Bone Mineral Density (BMD) of the proximal and distal parts of the femur and lumbar spine of 46 male SCI patients, with an average age of 32 years, was monitored regularly. They found a significant difference between the amounts of the BMD of the femur, but not the lumbar spine, between complete and incomplete paraplegic subjects. The level of the BMD of the femur did not show a significant difference between ambulatory and none ambulatory participants. They concluded that the rehabilitation treatment must be for a long time to have a significant impact on the BMD level.

In other research work carried out by Rosenstein (Rosenstein et al, 1987) the BMD of the upper and lower limbs of 80 myelomeningocel patients, with different levels of lesion was measured. The results of this study showed the effects of the lesion level on the bone density was more in the lower limb than that in the upper limb. They concluded that being ambulatory is an effective factor to decrease bone osteoporosis.

Ogilvie and his co-workers (Ogilvie et al, 1993) carried out research to evaluate the effects of ambulation with an orthosis on bone density. They followed a group of paraplegic subjects, who walked with an orthosis for a period of 24 months. They found that the BMD of the femoral neck improved or didn't have any change during this period. Standing with an orthosis or in a frame can increase the BMD in lower limb bones and decrease the amount of osteoporosis, which occur in SCI subjects. Although it seems that there is no difference between standing with orthosis or in a frame, the results of the research carried out by Goemaere (Goemaere et al, 1994) showed that those who stood with an orthosis had more BMD at the proximal femur in contrast to those who stood in a frame. Fifty three complete traumatic paraplegic subjects participated in this study. The results also showed that the BMD of the

paraplegic patients was preserved better in those who stand in contrast to none ambulatory subjects.

It can be concluded that walking and standing increase the BMD of SCI individuals. The effects of standing and walking are more obvious in the lower limb and spine than that in the upper limb. Moreover, standing with an orthosis has a better effect on the BMD than standing in a frame. The effect of standing and walking on the BMD is significant if the rehabilitation programmes were followed for a long time.

2.7.2 Prevention of Pressure Sores

Standing and walking with an orthosis decreases the incidence of skin breakdown in SCI patients (Eng et al, 2001, Dunn et al, 1998, Mazur et al, 1989). The effects of early ambulation with an orthosis on general health were evaluated on 36 patients by Mazur. These patients, who ambulated with the orthosis, had fewer pressure sores and the time of their hospitalisation was less than those using only a wheelchair (Mazur et al, 1989). The subjects, 77% were paraplegic and 23% were quadriplegic, who participated in Dunn et al's work (Dunn et al, 1998), also stated that standing in a frame or an orthosis decreased the number of bedsores and improved their independence.

2.7.3 Improvement of Respiratory Function

It is stated that in the standing position the pelvis tends to tilt more anteriorly than in the sitting position. This increases lumbar lurdosis and establishes a better alignment of the spine in an extended posture. In this posture the force applied on the internal organs decreases and as a result the performance of the respiratory organs increases. During standing, the abdominal organs fall downward and forward, because there is no abdominal muscle function to increase the stability of the abdominal walls anteriorly. As a result the force applied on the diaphragm decreases and respiratory function increases (Rowley and Edwards, 1987, Carroll, 1974). However, the results of the research carried out by Ogilvie (Ogilvie et al, 1993) showed that orthosis

usage and ambulation did not affect the respiratory function of the participants, 24 months after continued use of an orthosis.

2.7.4 Prevention of Joint Deformity

During standing the body weight is applied vertically downward and symmetrically upon both feet. According to Douglas et al (1983), long-term orthosis use and early ambulation after injury decreases the risk of deformity of the lower limb joints, because it limits the distortions caused by gravitational positioning of the flexed joints. In the work done by Kunkel (Kunkel et al, 1993) on a group of SCI subjects, it was found that standing in a frame did not have a significant effect on decreasing muscle spasticity and increasing joint range of motion.

Middleton et al (1997) fitted and trained 25 SCI patients to walk with the 'Walkabout Orthosis' and they were followed up for 2 years. 60% of all participants continued to use the orthosis during their life. Maintained range of motion and prevention of joint deformity were the two most important outcomes, which were mentioned by the researchers (Middleton et al, 1997).

2.7.5 Improving Bowel and Bladder Functions and Decreasing Urinary Tract Infections

Decreasing urinary tract infections and improving the function of the bowel and bladder systems are other benefits achieved from orthosis ambulation. In work done by Dunn and his co-workers on a group of paraplegic and quadriplegic subjects (Dunn et al, 1998), they found that standing in a frame or an orthosis, decreased urinary tract infections in the participants and improved their independency to manage sociable bowel and bladder functions.

2.7.6 Improving Digestive System Function

Another benefit of standing and walking for SCI patients, mentioned in the literature, is the effect on the digestive system function. Eng et al (2001) stated that standing with an orthosis or a frame could regulate and improve the performance of the digestive system. In this research 126 adults with SCI participated. Nearly 30% of them reported that they used their orthoses or frames regularly for prolonged standing, on average 40 minutes per session and for 3 to 4 times per week. They found that standing not only improved the function of the digestive system, but also improved their general health.

2.7.7 Decreasing Muscle Spasm

Standing with an orthosis or in a frame extends the hip and knee joints and stretches the surrounding muscles. Odeen and Knutsson (1981) showed that standing and applying body weight through the legs reduces muscle spasm more efficiently than stretching the muscles only in the supine position (Odeen and Knutsson, 1981).

2.7.8 Improving Independent Living

The degree of independence during the performance of daily activities depends on the level of the lesion. The results of the research by Rose et al (1983) showed that the level of independence of SCI subjects improved after standing and ambulation with an orthosis. In an investigation by Sykes and co-workers, the functional performances of 85 patients who were supplied with a Reciprocal Gait Orthosis (RGO) between 1986 and 1993 were evaluated. They found a significant difference between users and nonusers in terms of their assistance needed to do their daily performances (Sykes et al, 1995).

2.7.9 Improving Psychological Health

Some factors such as poor sleep, problems with transportation, pain and other diseases associated with SCI increase the incidence of psychological health disease

(Stolov and Clowers, 1981). Eng and his co-workers showed that the sleep pattern and general health of the participants, 152 adults with SCI, in their research improved with standing (Eng et al, 2001).

In other work by Kunkel et al (1993), 67% of the participants agreed that standing in a frame had a positive psychological impact on them. Ogilvie et al, in their research mentioned that nearly 33% of the participants were happy with orthosis use and reported a better general health as a consequence of using the orthosis (Ogilvie et al, 1993).

2.7.10 Improving the Function of the Cardiovascular System

Improving the function of the cardiovascular system is a further benefit mentioned in the literature concerning ambulation with orthoses (Douglas et al, 1983) however, there is no evidence in the literature to support this view.

2.8 PROBLEMS ASSOCIATED WITH USING AN ORTHOSIS

The main problem with orthosis use is the high-energy demands it places on the user during ambulation. The walking speed of a SCI patient with an orthosis is significantly less than that of normal walking and also in contrast to mobility with a wheelchair. SCI subjects walk more slowly and less efficiently with an orthosis than moving with a wheelchair (Merati et al, 2000, Cerny et al, 1980).

It is worth considering that the increased energy consumption during ambulation with an orthosis may have a negative effect on the functional performance of SCI subjects during their participation in social activities. Children with SCI as a result of myelomeningocel could participate in the community or in school activities with a wheelchair but not with an orthosis (Franks et al, 1991).

2.9 ORTHOSES USED BY PARAPLEGIC INDIVIDUALS FOR STANDING AND WALKING

Different types of orthoses have been designed to enable SCI individuals to walk and stand. The types of orthoses selected by these patients and the type of mechanisms which are used in those orthoses depend on the abilities of the subjects and their level of spinal cord lesion. The following categories of orthoses are used to stabilize paralyzed limbs during standing and walking:

a) Ankle Foot Orthoses (AFO)

b) Knee Ankle Foot Orthoses (KAFO)

c) Hip Knee Ankle Foot Orthoses (HKAFO)

d) Externally powered orthoses

e) Functional Electrical Stimulation (FES)

e) Hybrid orthoses

2.9.1 Ankle Foot Orthoses (AFO)

Ankle foot orthoses are usually designed to permit safe and effective ambulation of SCI individuals with lesion levels between L_4 and S_2 (Long and Lawton, 1955, Stolov and Clowers, 1981). They also may be used to prevent the development of deformity and to reduce the effect of spasticity at the ankle joint (American Academy of Orthopaedic Surgeons, 1985, Redford, 1986). Using this orthosis during walking may also have significant effects on the knee joint stability (Lehmann, 1979). The AFOs are divided into two subcategories which include conventional orthoses and plastic orthoses (Rose, 1986, Redford, 1986).

2.9.1. 1 Conventional AFOs

They have a leather covered metal calf band with one or two metal side bars or a posterior bar. The shoe or foot attachment anchors the orthosis distally (American Academy of Orthopaedic Surgeons, 1985). The distal part of the orthosis is attached into the shoe by means of a stirrup.

The ankle joint can have four different configurations such as free motion, dorsiflexion and plantar flexion assist, dorsiflexion and plantar flexion fixed, and dorsiflexion assist ankle joint (plantarflexion fixed). In orthoses used for SCI subjects those with dorsiflexion and plantarflexion fixed and dorsiflexion assist ankle joint are used (Redford, 1986).

A plantarflexion stop at the ankle joint prevents toe drag and stumbling during swing phase however, the ankle angle at which plantarflexion of the ankle joint is locked has a significant effect on the magnitude and duration of the moment applied around the knee joint (Redford, 1986). The flexion moment around the knee joint is greater during walking with the orthosis in which the ankle joint is set at slight dorsiflexion in contrast to an orthosis in which the ankle is set in a slight plantar flexion angle. However, toe clearance during swing phase of the paralysed foot is improved with an ankle joint which is set in dorsiflexion (Redford, 1986, Lehmann et al, 1970). Figure 2.6 shows the effect of the ankle joint alignment on the amount of the force required to stabilize the knee joint.

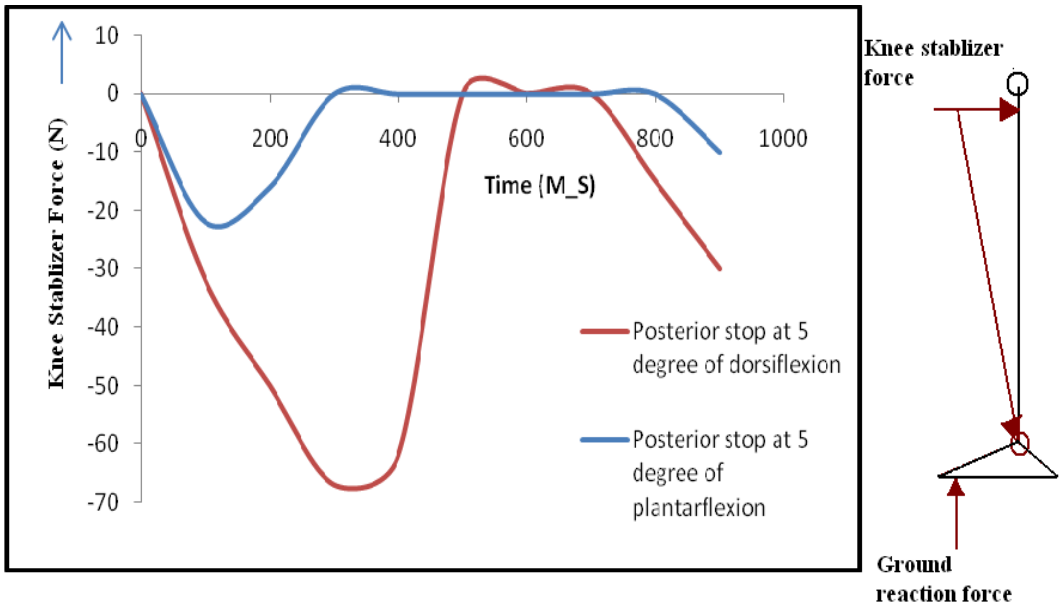


Figure 2.6: The effect of the ankle joint angle on the force required to stabilize the knee joint (Redford, 1986, Lehmann et al, 1970)

Vannini-Rizzoli Stabilizing Orthosis (VRSO) was one of the AFO's designed by the Veterans Affairs Rehabilitation Research and Development Service in 1989, specifically for SCI individuals. It was a new type of below knee orthosis (Boot) which was prescribed for SCI individuals with lesion at T_6 or lower. A full range of motion and stability at all joints of the lower limbs, good function in the upper limbs, good physical abilities with normal pulmonary and cardiovascular status, absence of disease, and having an age of less than 40 were the main criteria for selecting the patients to use this orthosis. The VRSO design immobilized the foot and ankle in approximately 10° to 15° of plantar flexion. The plantar flexion angle of the ankle joint stabilizes the knee joint in extension. There are a lot of contraindications for selection of SCI individuals who can use this orthosis (Kent, 1992). Practically this orthosis cannot be used by most SCI individuals. This orthosis is shown in figure 2.7.

Figure 2.7: Vannini-Rozzoli Stabilizing Orthosis (Kent, 1992)

2.9.1. 2 Plastic AFOs

Compared to conventional types, plastic orthoses are generally more cosmetically appealing. They are lighter and offer greater flexibility. The closer fitting and better distribution of pressure are other advantages of this type of orthosis. Variations in ankle movement and degree of resistance to movement depend on the chemical composition and the thickness of the plastic used (American Academy of Orthopaedic Surgeons, 1985, Rose, 1986). Plastic AFOs are made from a variety of thermoplastic and thermosetting materials; such as polypropylene, polyethylene and laminated thermosetting plastics. After the introduction of thermoplastic materials, there was a significant decline in the use of thermosetting plastics for orthosis manufacture (Redford, 1986).

A rigid AFO is one of the main parts of an RGO orthosis. In order to increase the structural stiffness of the orthosis near the ankle joint, carbon fibre inserts can be used utilizing a vacuum forming technique.

2.9.2 Knee Ankle Foot Orthosis (KAFO) Used by SCI Individuals

KAFOs are prescribed for SCI individuals in order that they can stand and walk particularly for those with a lesion level below T_{10} (Redford, 1986). The main purpose of using a KAFO is to stabilize the ankle and knee joints during stance phase. The main components of this type of orthosis include shoes, stirrups, ankle joints and calf band, the same as a traditional AFO, knee joints and thigh section with an anterior soft closure. In the newer designs of KAFOs a plastic AFO is used. Figure 2.8 shows a KAFO which is used by SCI individuals (American Academy of Orthopaedic Surgeons, 1985), not seen in the newer version of this book.

Different types of knee joints have been designed for KAFOs, such as offset knee joints and knee joints with a ratchet locking mechanism, figure 2.9.

Figure 2.8: Craig-Scott brace design for walking of SCI subjects (American Academy of Orthopaedic Surgeons, 1985)

In the offset knee joint, the axis of rotation is located posterior to the metal uprights.

The knee joint is free to move during the swing phase of the gait cycle. This type of knee joint is used for those patients with quadriceps weakness and is not suitable for patients with SCI because they don't have any muscular power around the knee joints.

The ratchet locking mechanism provides support for a limited range of knee flexion, so it is not necessary for the leg to be extended before locking. The ratchet mechanism allows people to stand up in several stages and permits users with knee contractures to be accommodated more easily.

There is no KAFO orthosis with this type of the knee joint for paraplegic people however, this type of knee joint was used in the Louisiana State University (LSU) RGO orthosis by Solomonow (Solomonow et al, 1989). The mechanical reliability of this joint is not high and shearing of the teeth occurs as a result of applying excessive force on the gear (Douglas et al, 1983).

The mechanism used to lock and unlock the knee joint also depends on the type of the knee joint. The most commonly used locking system for KAFOs is the drop lock mechanism. The ring drops over the knee joint by gravity or manually by the user, when the mechanical knee is completely extended. Patients who have spasm in the muscles around the knee joint cannot use this locking system. Moreover, sometimes it is difficult to lock the knee joint with this mechanism by the effect of gravity. A pawl lock is another locking system which is easier to release than drop lock, especially when a flexing force is applied on knee joint. A bail, which is a semicircular lever placed posterior to the knee joint, unlocks both sides of a knee joint simultaneously by a manual upward pull or by catching the bail on the edge of the chair (American Academy of Orthopaedic Surgeons, 1985). Figure 2.9 shows different types of knee joints and locking systems.

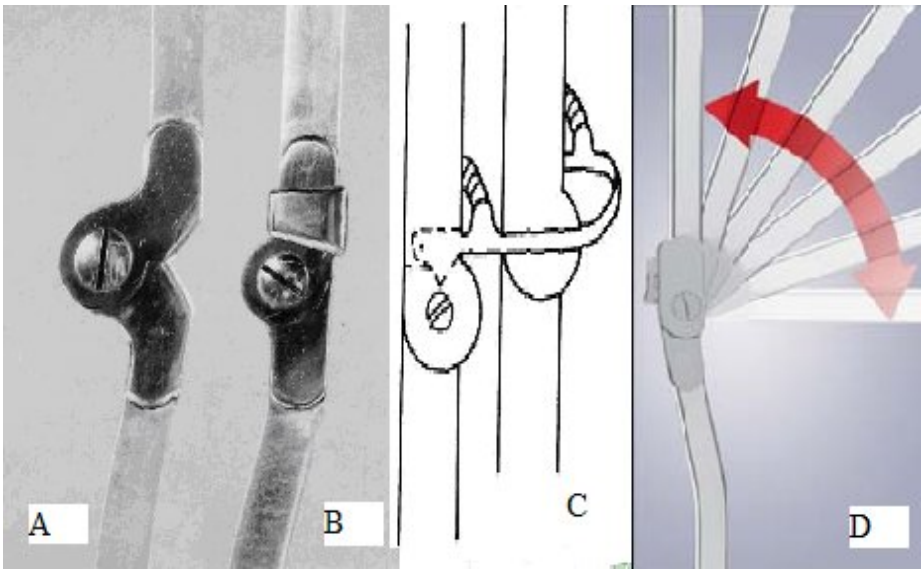


Figure 2.9: Different types of the knee joints, A is an offset knee joint, B is a drop lock, C is a pawl lock knee joint, D is a ratchet knee joint (American Academy of Orthopaedic Surgeons, 1985)

To maintain full extension of the anatomical knee joint during stance phase some accessory pads and straps are required. The location of those straps is very important to secure the safety of the individual and also to decrease the load applied on the limb during walking. There are six different configurations of straps and bands which can be used for KAFO's which are:

a) Supra-patellar Strap with Patellar Tendon Strap
b) Lower Thigh Band with Calf Band Closures
c) Lower Thigh Band Closure with Patellar Tendon Strap
d) Supra-patellar Strap
e) Patellar Tendon Strap
f) Knee Cap Strap

Knee ankle foot orthoses can be divided into two main groups: the traditional KAFO and new developed KAFO orthoses. Figure 2.10 shows different types of KAFO's according to the location of the straps.

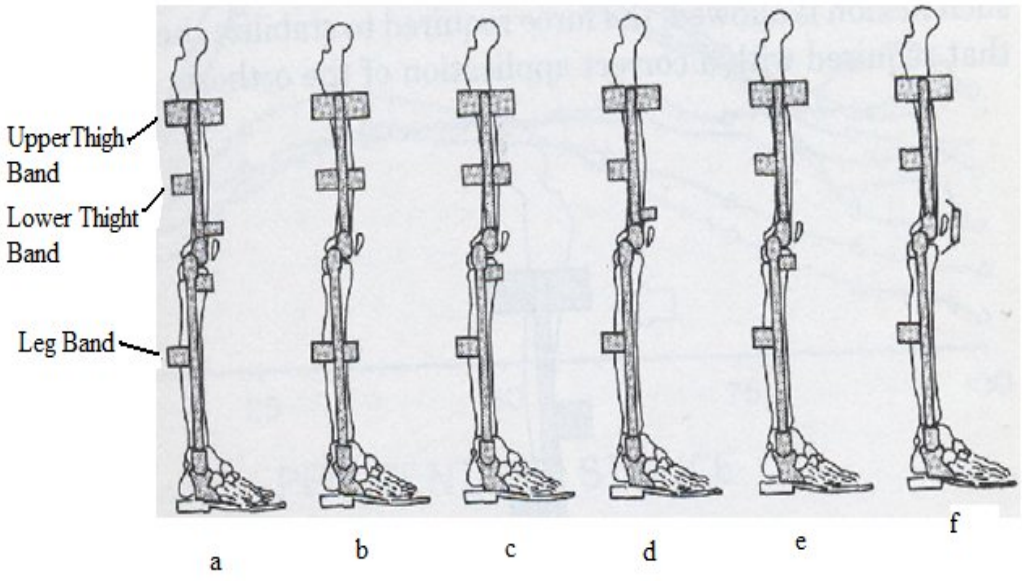


Figure 2.10: Different configurations of the straps that can be used in the Craig Scott KAFO (Redford, 1986)

2.9.2. 1 Traditional KAFO orthoses designed for SCI individuals

One of the best orthosis which was specifically designed for SCI patients was the Craig- Scott orthosis. This orthosis had double uprights, offset knee joints with pawl locks and bail control and thigh and leg bands. The ankle joint of this orthosis had anterior and posterior pin stops. There was a cushion heel in the shoes of this orthosis with especially designed longitudinal and transverse foot plates made of steel (American Academy of Orthopaedic Surgeons, 1985). Figure 2.8 shows Craig-Scott orthosis.

2.9.2. 2 New KAFO orthoses designed for SCI individuals

The same concept is used in the design of a new orthosis for paraplegic subjects. The main difference between the traditional and the new designs of those orthoses relates to the type of materials and knee joint design. One of the new designs of KAFO used for paraplegic subjects was the “New England Regional Spinal Cord Injury Centre” (NERSCIC) KAFO. It was designed by the New England spinal cord

injury centre in 1981; it was lighter and more cosmetically appealing in contrast to Craig Scott orthosis. Its AFO component was made from polypropylene by a vacuum forming technique (Lobley et al, 1985). Figure 2.11 shows this orthosis.

The light weight modular orthosis was another new KAFO orthosis designed for SCI individuals, which was an inexpensive, lightweight, modular orthosis for early standing of patients with paraplegia and quadriplegia. The other advantages of this orthosis were quick fabrication and fitting of the leg frames. It was made from plastic components, AFO and thigh bar, and metal knee joints and assembled with the use of a few tools, straps, and fasteners. The donning and doffing of this orthosis was easier than other traditional KAFO orthoses (Engen, 1989). This orthosis is shown in figure 2.12.

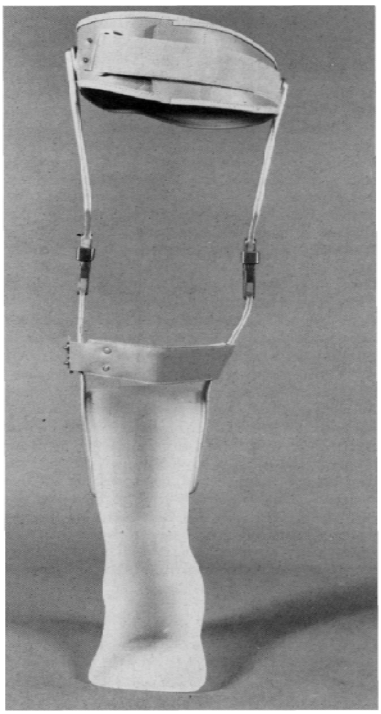


Figure 2.11: NERSCIC KAFO orthosis (Lobley et al, 1985)

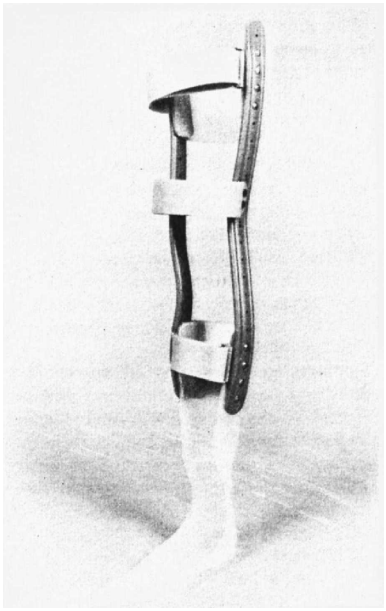


Figure 2.12: The light weight Modular KAFO, suitable for paraplegic subjects (Engen, 1989)

2.9.3 Hip Knee Ankle Foot Orthosis Designed for SCI Subjects

Hip Knee Ankle Foot Orthoses (HKAFO) are used to control selected motions of the hip joint using various types of the hip hinges which are inserted between a pelvic band, or a spinal rigid orthosis, and the KAFO (American Academy of Orthopaedic Surgeons, 1985). The design of these orthoses must provide the following needs (Rose, 1986).

a) A walking style similar to normal walking
b) Control of paralysed joints
c) Increasing independency for walking by improving the energy consumption during walking and by decreasing the assistance for sitting down and standing up and donning and doffing the orthosis
d) Structural integrity
e) Increasing the efficiency of the users during walking with orthoses with simple walking aids

A variety of mechanical HKAFO orthoses have been designed for paraplegic subjects in order to increase their performance during standing and walking. The available HKAFO orthoses can be divided into two main groups which are the traditional and the new orthoses.

2.9.3. 1 Traditional HKAFO orthoses designed for SCI individuals

Similarly to other orthoses, the traditional HKAFO orthoses are manufactured from a combination of metal and leather. The hip joint is locked during walking and unlocked for sitting. The most common type of the joint used is the single axis type. Patients walk with this orthosis with a swing through gait pattern. During standing an extended posture of the trunk stabilizes the hip joints and decreases the load applied on the crutch. The concepts behind the design of the hip joints for these orthoses are prevention of any motion which the patients cannot control adequately and restriction of the motions which cannot be allowed in any circumstance during gait cycles, for example abduction and adduction, (Rose, 1986, American Academy of Orthopaedic Surgeons, 1985). Figure 2.13 shows the traditional orthosis used for SCI subjects.

Figure 2.13: The traditional HKAFO (Leeder Group, 2000)

2.9.3.2 New HKAFO orthoses designed for SCI individuals

Several new designs of HKAFO have entered into the market since 1971. By employing different mechanisms they allow the SCI patients to ambulate with a reciprocal gait. (Butler et al, 1984, Stallard et al, 1986, Douglas et al, 1983, Gilbertson, 1971).

2.9.3. 2.I Reciprocating Brace with polyplanar Hip Hinges

In all previous orthoses designed for paraplegic subjects, pelvic rotation was not permitted during walking. However, pelvic rotation about the vertical axis is important to increase the step length and to decrease rotation between the foot and the ground. In this orthosis the designer tried to achieve rotation about the vertical axis during walking. The most practical way to reach to this goal was to displace the axis of the hinge from the horizontal. By using this method in this orthosis, 15 degrees of flexion was combined with 8 degrees of external rotation and 2 degrees of abduction, because the axis of this hinge passed upward and medially. There was another hinge in this system used for sitting, which was aligned along the horizontal axis of the hip joints. However, the polyplanar axis was inserted below the anatomical hip joints with some deviation from the horizontal and vertical axes; the hinge axis was aligned at 45 degrees to the horizontal (Gilbertson, 1971, Scrutton, 1971).

The stability of the hip joints, mechanical and anatomical, during walking was achieved through using two cable mechanisms. The original concept of this design was from Ontario Crippled Children Centre, Toronto (Scrutton, 1971). The first cable (A) was attached to the rear of the orthosis side members, so any flexion movement of the legs increased the tension in this cable. By using this cable simultaneous left and right hip joints flexion would be prevented. The second cable (B) was attached to the front of the side members of the two orthoses (left and right) so tension in this cable was increased by extension (Gilbertson, 1971, Scrutton,

1971). This orthosis is shown in figure 2.14. The main disadvantages of this system according to the designer were as follows:

a) Cable adjustment was necessary every 6_8 weeks

b) With this arrangement of cables and hinges the mechanism was rather wide

This orthosis was tested on children with myelomeningocel however, it could be used for both adult and child SCI patients.

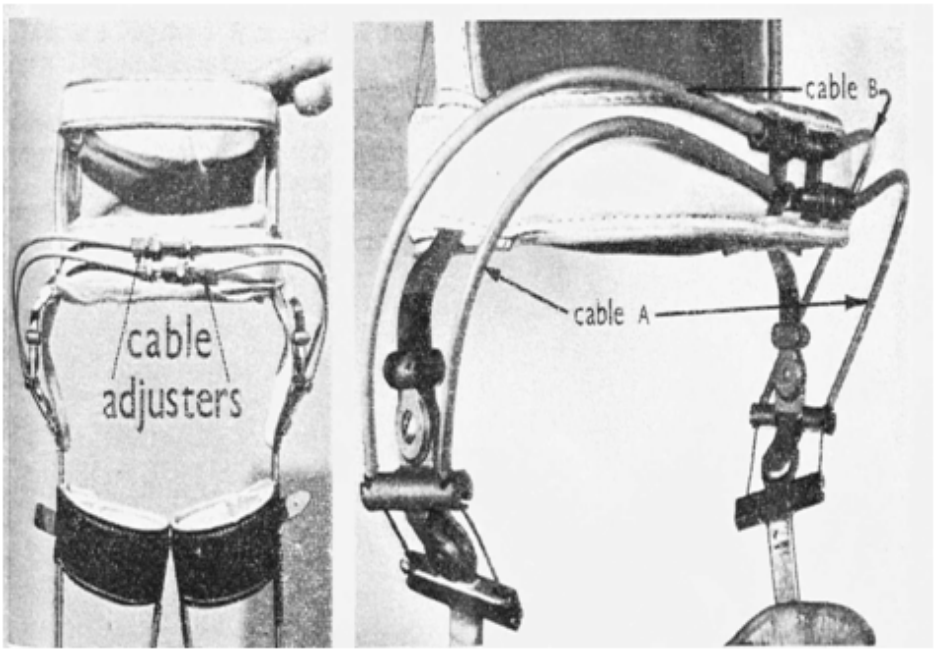


Figure 2.14: Polyplanar reciprocal gait orthosis (Scrutton, 1971)

2.9.3. 2. II Hip Guidance Orthosis (HGO)

According to Stallard, the first communication on this topic was presented in 1974 at the inaugural ISPO world congress in Switzerland (Stallard, 2000). Major et al (1981) described the principle of the HGO orthosis, which was initially designed for spina bifida children. The design was changed so that the orthosis can be used by adult paraplegics, by using new materials and some improvements in the hip joint (Major et al, 1981, Stallard et al, 1986). After some improvements and changes to

the hip joint, the name of this orthosis was changed to ORLAU (Orthopaedic Research and Locomotor Assessment Unit) Parawalker. Today both names are used for this orthosis.

The HGO orthosis consists of three main parts: the hip joints, callipers with shoe plates and knee joints with pawl lock and bail control and a body section. This orthosis is shown in figure 2.15. The specific design of the hip joint in this orthosis, which allows some motion during walking, has the following features (Stallard et al, 1986):

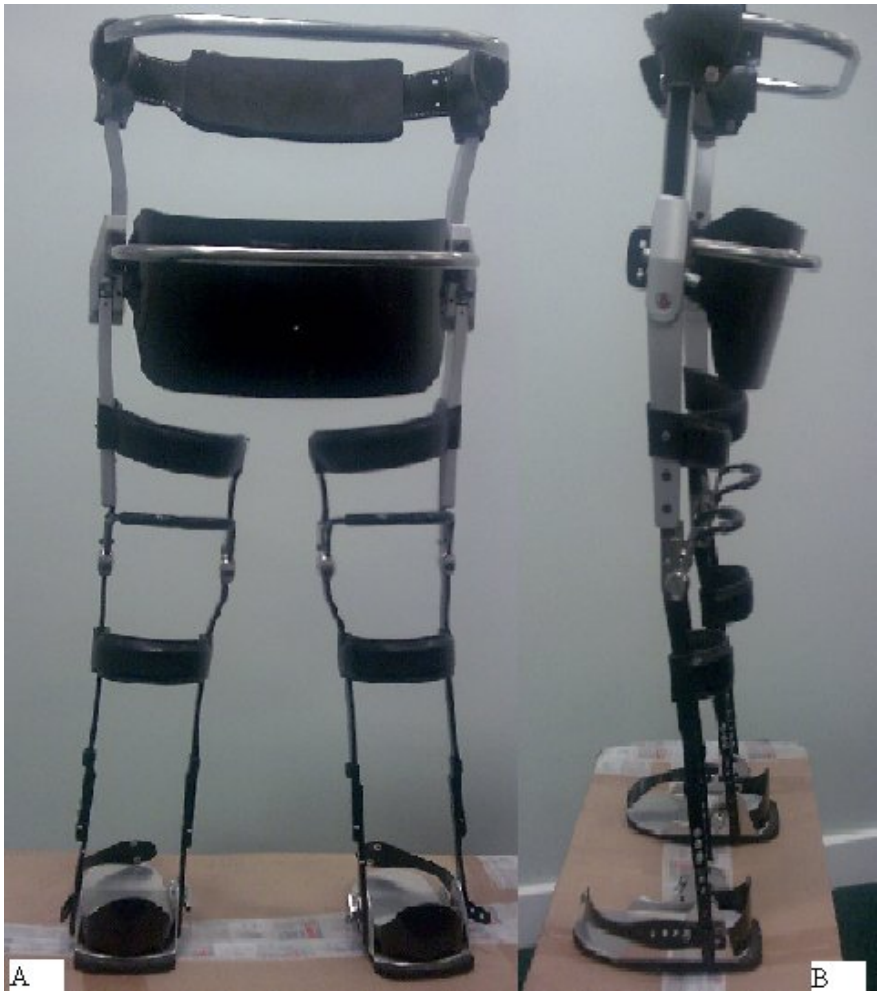


Figure 2.15: Hip Guidance Orthosis from the orthosis supplied by Oswestry
A is the posterior view and B is the lateral view of this orthosis

a) It has greater lateral stiffness in contrast to the available orthoses

b) It has less lateral play in walking in contrast to the available orthoses

c) It is easily assembled

d) It is easy to be used by patients

e) It has greater mechanical reliability in contrast to other orthoses

f) It is of lighter weight than other available orthoses

The first design of the hip joint, figure 2.16, was very simple and contained a stop to control the hip joint range of motion in sitting and walking however, it had some problems such as:

a) The hip joint was cast from aluminium alloy and it was subject to brittle failure
b) The bearing pin was a cantilever and therefore high bending and shear stresses were applied on it
c) The formability of the material was not good and it was difficult to shape the lower bar according to the patient's needs
d) The flexion and extension stops were not adjustable
e) The maximum range of flexion in the sitting position was 90 degrees

A new hip joint was designed to solve the above problems. It was machined from solid aluminum alloy. In this design an adjustable flexion stop was incorporated and the extension stop was omitted. The range of motion during sitting was increased, by changing the shape of the lower bar of the hip joint. After some changes in this design and incorporating an adjustable extension stop again, the new hip joint was introduced in August 1983, figure 2.17.

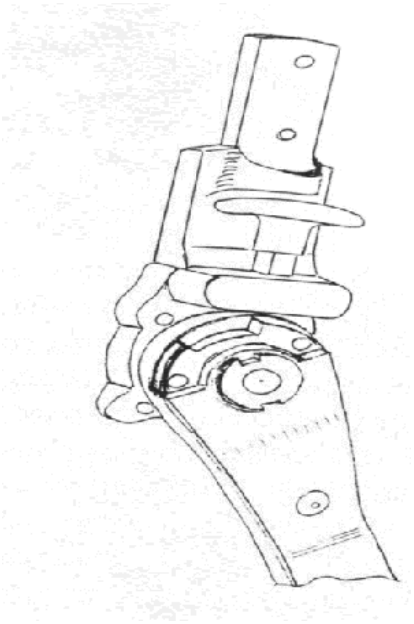


Figure 2.16: The first design of the hip joint used in the HGO (from ORLAU annual report)

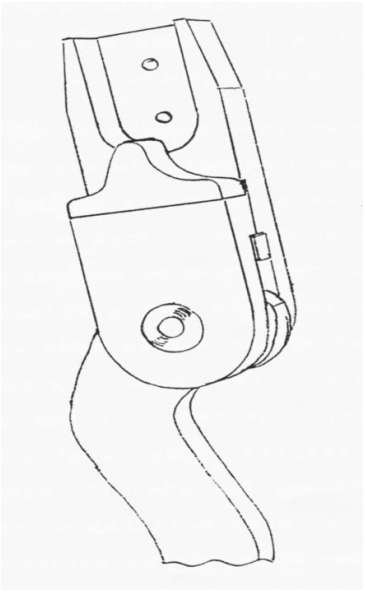


Figure 2.17: The second type of hip joint used in the HGO (from ORLAU annual report)

The third version of the hip joint was designed in order to improve some features of the previous designs. The mechanical performance of the new design was better than the older ones. It was more cosmetic, easier to manufacture and shape than the older joints. The lower bar of the hip joint had the same shape as the first design. The new more rigid hip joint, figure 2.18, provided an overall increase in lateral stiffness and had a noticeable improved effect on the walking performance of paraplegic subjects. It was named as the ORLAU Parawalker 89 hip joint. This new design increased the lateral rigidity of the hip joint by 70%. It was shown that increasing the stiffness of the hip joint increased the total rigidity of the orthosis by 10% (Stallard and Major, 1993).

The main function of the body brace component is to provide a supporting structure for the leg segment and acts as two of three points of fixation to stabilize the hips. The specific design of this part provides the structural stiffness to the orthosis and improves its rigidity against abducting and adducting moments applied about the hip joint during walking. This component was constructed from two lateral bars with a pair of stainless steel tubes. One tube was bolted to the top of the lateral bars and the other was attached directly to the hip joint, figure 2.15.

The tubes were shaped to the patient's body shape and the body brace was secured to the body by two straps (Stallard et al, 1986). In order to improve the cosmesis and rigidity of the body brace several attempts have been made to manufacture it from composite materials (Stallard et al, 2003, Woollam et al, 1999).

The KAFO sections of the HGO orthosis provide the third fixation point for the hip joints. They were manufactured from a machined steel rectangular section. The specific design of the knee joint allows the maximum range of knee flexion in sitting and had a good mechanical reliability. The knee joint of this orthosis had bail lock operation which was easy to use by SCI patients (Stallard et al, 1986).

The shoe plates were attached to the leg segments with approximately 6 degrees of dorsiflexion. It was easy for the patients to don and doff the orthosis and also they could use any shoes they wanted. The security of the ankle was increased by using a polypropylene strap which passed over the mid-foot and fastened via a toggle clamp. The angle between leg segments and shoe plates was fixed and there was no play between them during walking (Stallard et al, 1986).

Figure 2.18: The third type of hip joint used for the HGO
A and B are the lateral views and C is the posterior view

2.9.3. 2.III HGO orthosis with composite material body brace

The designers of the Parawalker orthosis paid a lot of attention to increase the structural rigidity of the orthosis in the frontal plane. The main concept behind this was to help the patient to clear the swing leg easily. Due to the greater weight and height of adult paraplegics relative to children, the deformation of the orthosis

structure is high in this group of patients, especially during single stance, so the material which can be used for those patients needs to have enough strength. A crucial factor which influences initial patient choice in selecting an orthosis is the cosmesis. However, a metal body brace is not sufficiently cosmetic to be selected by all patients. To overcome these problems and to decrease the weight of body brace, a new body brace with composite material was developed. The composite material body brace was produced from a mould of the patient, which was taken in an appropriate position and was manufactured by utilizing a vacuum forming technique. It was constructed from carbon fibres with aramid fibres to increase the structural stiffness of the body segment (the type of resin used was not stated in the references). The new construction was compared with a metal body brace segment with the same size as the composite one. It was shown that the new design had 40% greater lateral stiffness than the metal one. Moreover, it was lighter and was more cosmetically appealing (Stallard et al, 2003, Woollam et al, 1999). The newer version of the hip joint used in the HGO was designed for a metal body brace, so for using body brace made from composite material the other components of the orthosis must be redesigned.

2.9.3. 2.IV Ortho-Walk Pneumatic Orthosis

This pneumatic orthosis was produced by ILC Dover, a division of ILC industries, figure 2.19. This was a new concept in the field of orthotics however, the mechanism of action was the same as a rigid orthosis. It was used to stabilize the paralyzed joints especially the hip and knee joints during walking. It was a light weight garment that fitted the body snugly. There were two anterior and posterior inflatable tubes which were pressurized to 2.25 kg/cm². It provided enough rigidity to support the body in the upright posture (Ragnarsson et al, 1975). The mediolateral stability and toe pick up during walking was achieved by a plastic AFO orthosis or using special boots (Redford, 1986).

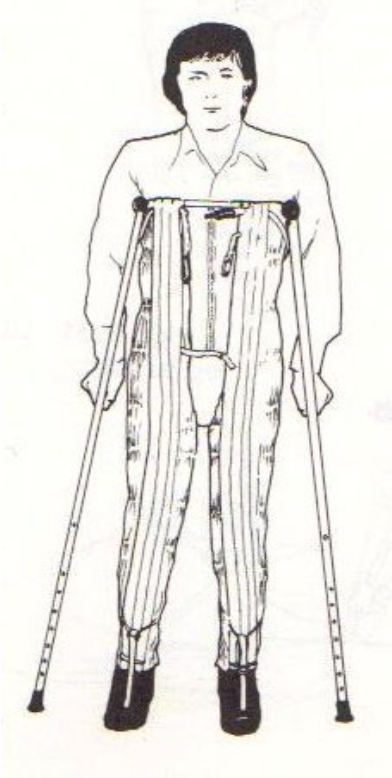


Figure 2.19: Pneumatic orthosis (Redford, 1986)

The pneumatic orthosis was manufactured in 6 sizes and could be easily adjusted for every subject. The weight of this orthosis was significantly lower than a conventional KAFO; the weight of the pneumatic orthosis was 2.27 kg in contrast to a KAFO orthosis which is between 5.45 to 9.07 kg. The walking performance of the SCI individuals during walking with this orthosis could be better if subjects use AFOs as well. It could be used effectively during early mobilization of SCI patients since it could be fitted using a suitable size on the patient's limbs. This orthosis had some disadvantages such as:

a) Discomfort of the orthosis especially excessive sweating in warm weather and having pain or feeling of pressure in the chest
b) Inadequate support, especially around hip and knee joints
c) Air leaks and repeated inflation requirement
d) Zippers: they opened during ambulation

e) The air pressure was high enough to create pressure sores especially in insensitive areas

Because of these problems many paraplegics preferred to use other orthoses, especially for higher rates of ambulation (Redford, 1986).

2.9.3. 2.V Louisiana State University Reciprocal Gait Orthosis (LSU RGO)

The original concept of the reciprocal gait orthosis was developed by Motloch in 1967 at the Ontario Crippled Children's Centre in Toronto, Ontario. He tried to develop an orthosis which could provide stability during standing similar to the Parapodium and also to help the patients in order to walk efficiency. Motloch developed his idea for children with spina bifida. His experimental orthosis was made from a plastic body jacket and a pair of KAFOs which were connected to the body jacket by a set of gears. The orthosis worked, but the mechanical reliability of the gears was inadequate (Woolridge, 1969).

In a development of this orthosis, Christianson replaced the gear mechanism by double steel cables, which were more durable and effective in contrast to the gear mechanism. In this generation the hip joints of the orthosis were coupled together using two Bowden cables, so that the extension of one leg produces flexion in other side. In standing, this coupling provides hip joint stability by preventing simultaneous hip flexion. Subsequently, Douglas et al (1983) from Louisiana State University developed this orthosis in conjunction with Carlton Fillauer at Fillauer Inc, Chattanooga Tennessee, to produce the orthosis components commercially. The new generation of the orthosis was used for patients who suffered from Cerebral Palsy (CP), paraplegia and muscular dystrophy (Douglas et al, 1983, Yongue et al, 1984). This orthosis is shown in figure 2.20.

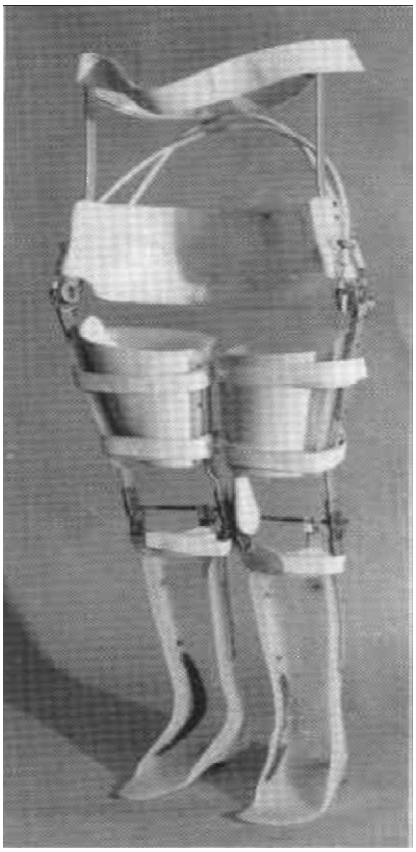


Figure 2.20: The LSU RGO orthosis (Jefferson and Whittle, 1990)

Patient selection criteria included those who have: feet without any contractures, knee joints with no deformity of more than 10 degrees and hip joints with no contracture and no limitation to movement. Those patients with contractures in the lower limb joints and with poor upper extremity strength cannot use this orthosis (Douglas et al, 1983).

The body brace of this orthosis was made of a pelvic band covering the gluteal and sacral areas with two lateral bars and a thoracic extension, which terminated at the level of the xiphoid process. The body brace was secured to the body using two straps. In the new design a custom moulded plastic girdle is used instead of a traditional pelvic band. It helps to distribute the pressure over a greater area and has superior sitting comfort (Douglas et al, 1983).

In the first design, the knee joints were of posteriorly offset type with ring locks on their lateral sides. In the new design other types of knee joints such as swivel knee joints were used. In the orthosis which is designed for children the medial knee joint may be omitted and a drop lock ring knee joint used for the lateral side. The posterior thigh shell was manufactured from polypropylene, which was formed over plaster models of the patient's legs. The AFOs of this orthosis were made from polypropylene and were reinforced in the ankle area with composite inserts (carbon fibre) to assure stability against dorsiflexion. The ankles were placed in the plantigrade position in this orthosis. The Velcro knee control strap was fitted at mid patellar tendon level in order to maintain the knee joint in an extended position (Douglas et al, 1983). The components of the RGO orthosis are produced commercially by Fillauer Inc, USA.

2.9.3. 2. VI Steeper Advanced Reciprocal gait Orthosis (ARGO)

The ARGO orthosis, figure 2.21, was developed by Hugh Steeper Ltd, London, UK and was actually a modified LSU RGO orthosis. In this orthosis only one posterior cable was used and also the hip and knee joints in the same side were connected to each other. This orthosis is commercially available and consists of two moulded polypropylene AFOs with lateral uprights. Those lateral uprights extend from the AFO through the hip joints to chest height. The body brace consists of two lateral bars with a rigid cross bar at the distal end. Jefferson and Whittle (1990) established that the inclusion of a compression mechanism in the ARGO orthosis made sitting and standing easier than other available orthoses. It has benefits to the patients both socially and in terms of energy expenditure at the beginning and ending of walking .The method of walking in the ARGO is the same as that used in the LSU RGO orthosis (Jefferson and Whittle, 1990).

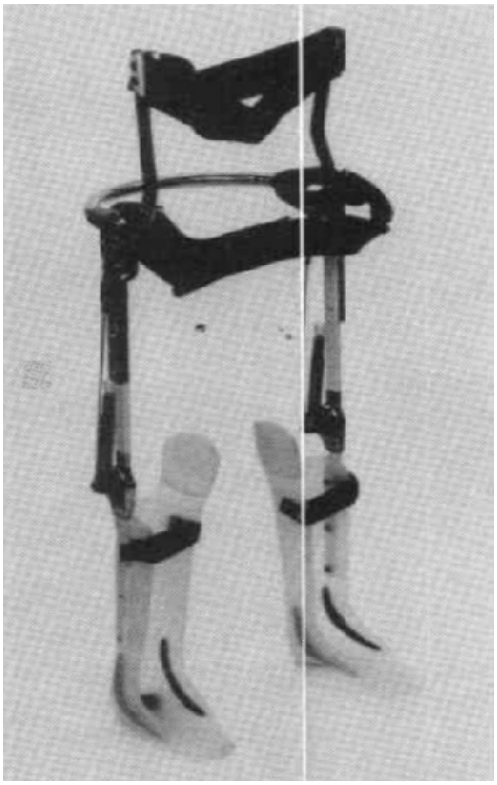


Figure 2.21: ARGO orthosis suitable for walking of paraplegic subjects (Jefferson and Whittle, 1990)

2.9.3. 2. VII Adjustable ARGO orthosis

This orthosis, based on the ARGO orthosis, was modified by Scivoletto et al (2003) in the Catholic University, Italy. The difference between the ARGO orthosis and this orthosis were that the height; distance between ground and hip hinge, and width, the distance between the hip joints of the orthosis, were adjustable according to the size of the patients (Scivoletto et al, 2003). The investigators of this research study tried to change the structure of the ARGO orthosis in order to be used by all patients. After some training in walking with this orthosis, the patients can take the final decision to use the orthosis or withdraw it. As a result they do not need to spend a lot of money to have the orthosis to check their preliminary performance in walking with the orthosis. Figure 2.22 shows this orthosis. This orthosis is no longer in use.

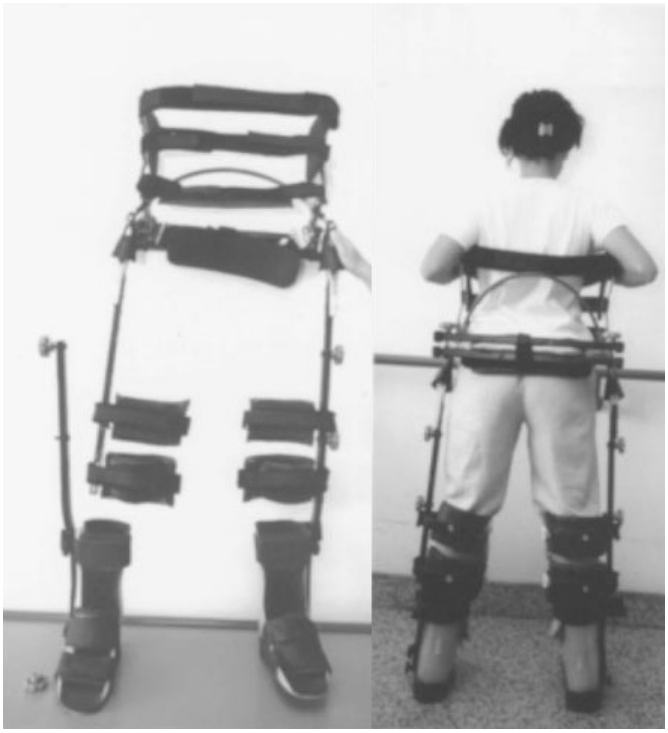


Figure 2.22: Adjustable ARGO orthosis (Scivoletto et al, 2003)

2.9.3. 2.VIII ARGO Orthosis aligned in a slight abduction

The concept of an orthosis which is aligned in abduction to decrease the amount of the lateral sway of the body during walking was investigated by Stallard and Major (1993). It was also expected that alignment of the orthosis in slight abduction decreased the amount of force required to stabilize the stance leg and also yield better utilization of the swing crutch force for propulsion. Some researchers performed calculation of the mechanical stresses at the hip hinge to determine the best mechanical abduction angle which can be used in the hip hinge of the orthosis (Rose, 1979). Rose stated that the best abduction angle for an orthosis is 5 degrees however, the author of this thesis is of the opinion that an optimal abduction angle must be determined for each subject individually. In this orthosis, which was based on an ARGO orthosis, the angle of abduction varied from 0 to 9 degrees and this was achieved by using different 'bent rods' aligned in abduction of 0, 3, 9 degrees (Ijzerman et al, 1997b). Those bent rod are shown in figure 2.23.

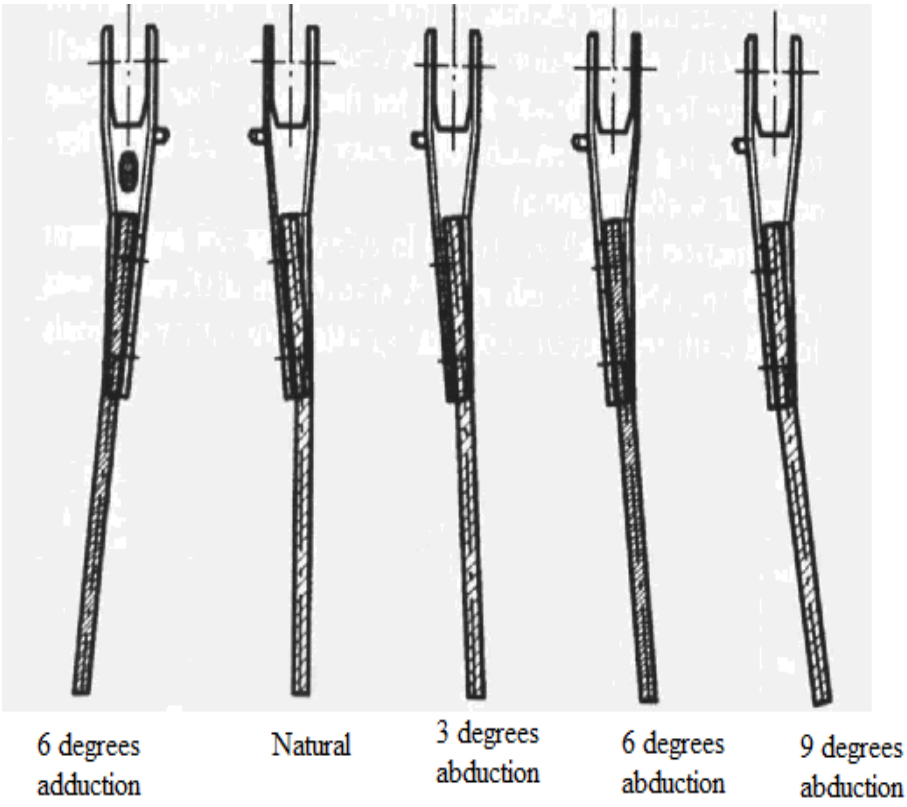


Figure 2.23: The bent rods used for the ARGO (Ijzerman et al, 1997b)

2.9.3. 2.IX Isocentric Reciprocal Gait Orthosis (IRGO)

The IRGO was also a modification of the LSU RGO. In this orthosis, the two crossed Bowden cables were replaced by a centrally pivoting bar and tie rod arrangement. The rigidity of this orthosis was greater than the LSU RGO orthosis and the friction of system was less than that of the LSU RGO. Davidson (1994) showed that friction in the IRGO was between 2 and 3 times less than that in LSU RGO orthosis, so it was shown that the performance of the subjects with this orthosis could be better than with the RGO (Davidson, 1994).This orthosis is shown in figure 2.24.

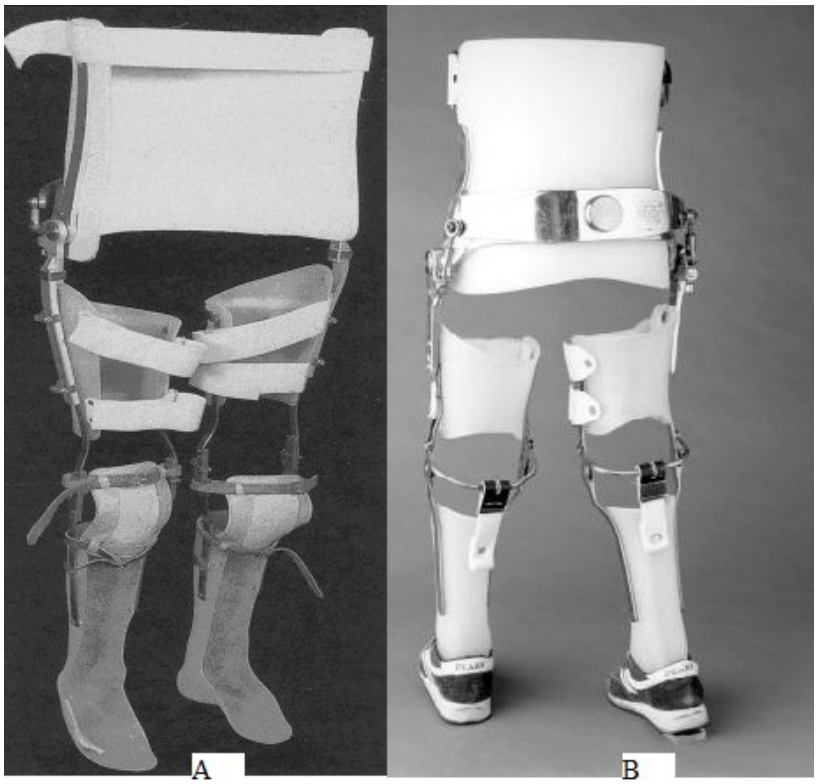


Figure 2.24: The IRGO for SCI subjects, A is anterior view and B is posterior view (Davidson, 1994)

2.9.3. 2. X Four- Bar Gait Control Linkage Orthosis

This orthosis was designed by David and Rolfes (1981) for a patient who had spastic paraplegia with modified Brown–Sequard syndrome at level T_3. The patient was unable to control severe hip adduction in the upright position with bilateral knee ankle foot orthoses. This problem was solved by using a device which was called as the four bar gait control linkage. The scissor deformity during walking was solved and the patient could walk with a reciprocal gait pattern. The linkage was made from two aluminium alloy and two steel bars with three thrust bearing joints. The middle joint was inserted three inches above the knee joint and attached via the stainless steel bars to the medial upper upright of the KAFO orthosis. By using this orthosis, the patients could walk independently and with a reciprocal gait pattern (David and Rolfes, 1981). Figure 2.25 shows this orthosis.

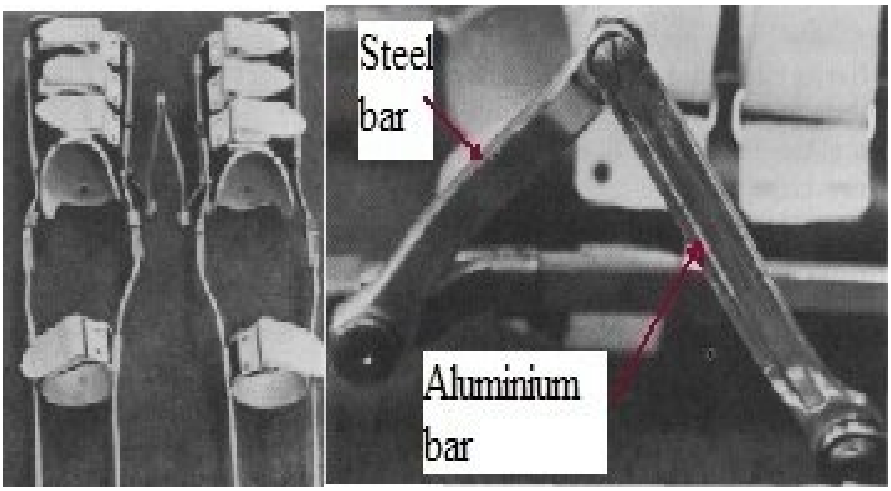


Figure 2.25: Four bar linkage orthosis (David and Rolfes, 1981)

2.9.3. 2. XI Medial linkage orthosis (MLO)

This orthosis was designed by Kirtley and McKay (1992) and was named the 'Walkabout orthosis'. It consisted of bilateral KAFO's with a medial single axis hip joint. Specifically this unit prevented adduction of the swing leg while the body was tilted to clear the swing leg from the ground and also stabilized the supporting leg under body weight. The 'Walkabout Unit', it refers to the hinge, was placed below the perineum and thus was not aligned congruently with the centre of the hip joints. Therefore, there was a discrepancy between the mechanical hip joint axis and anatomical one between 100 mm and 150 mm in this orthosis (Middleton et al, 1998, Kirtley and McKay, 1992). The relative motions between the orthosis and the body of the subject decreased the performance of the orthosis during walking. It seems that the huge discrepancy between the centre of the motion of the mechanical and anatomical hip joints decreased the stride length during walking.

The KAFOs were manufactured individually and were made to be similar to other standard commercially available KAFOs. This orthosis has some advantages, such as being light weight, easy to don and doff and easy to be used with a wheelchair. The short stride length and horizontal rotation of the pelvis in walking were the two

main disadvantages of this orthosis (Genda et al, 2004). This orthosis is shown in figure 2.26.

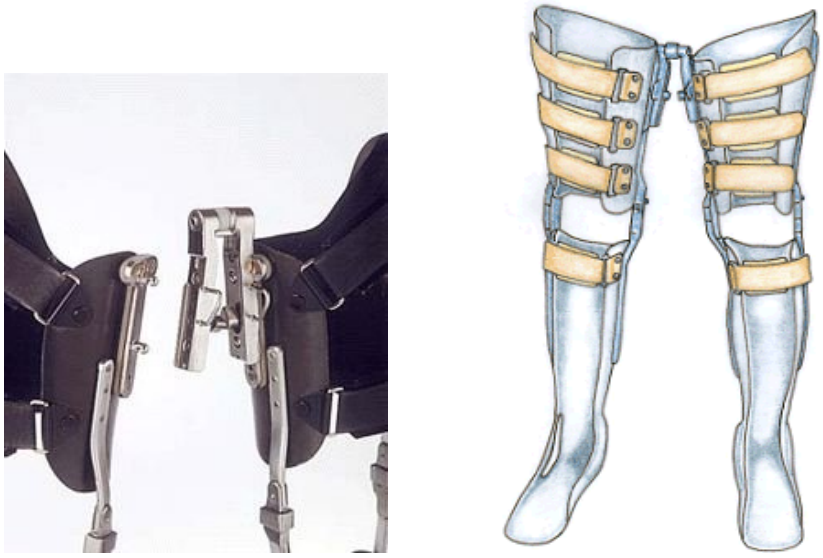


Figure 2.26: The Medial Linkage Orthosis (Kirtley and McKay, 1992)

2.9.3. 2.XII Moorong Medial Linkage Orthosis (MMLO)

This orthosis was designed with the same concept as the MLO. Whilst attempting to reduce the discrepancy between the mechanical hip joint and anatomical one in the MLO orthosis, Kirtley was cited by Middleton et al, that ”due to the length of the limb which is nearly one meter and the range of motion of the hip joint in this system, which is limited, only a small amount of soft tissue distortion is required to accommodate the discrepancy between both mechanical and anatomical hip joints“ (Middleton et al, 1998). However, this amount of discrepancy increases the resistance against leg motion and decreases the hip joint range of motion during walking with this orthosis. In this new orthosis (MMLO) the distance between the hip joint centre and the hinge axis of the MLO was decreased by using a curved sliding link centered on the hip joints. The hip joint axis in this orthosis moves along a circle that coincides better with the anatomical hip joint (Middleton et al, 1998). This orthosis is shown in figure 2.27.

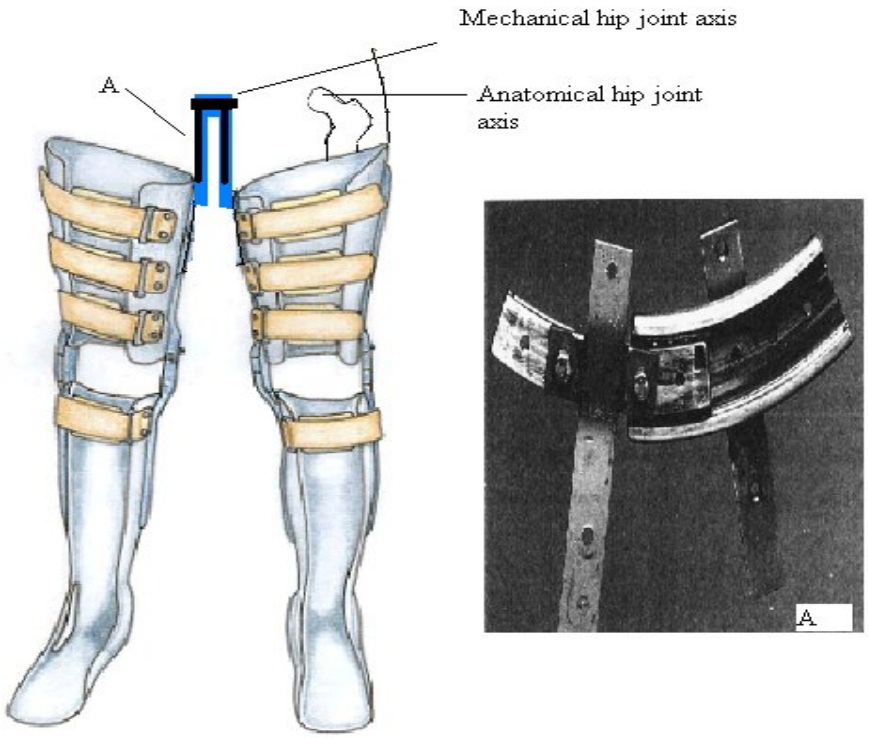


Figure 2.27: Moorong MLO orthosis (left side) and hinge used in this orthosis (A) (Middleton et al, 1998)

2.9.3. 2.XIII Hip and Ankle Linkage Orthosis (HALO)

A further problem of the MLO according to Genda et al (2004) may be related to the lack of a mechanism to assist hip joint flexion and also to the ankle joints which have no motion during walking. These problems increase the instability especially when the step length becomes longer. This problem was solved by using a mechanism that enables the user to keep both feet parallel to the floor and assists the swinging of the leg by dorsiflexion of the ankle on the stance side.

The new orthosis was named the Hip and Ankle Linkage Orthosis (HALO) and consists of a medial single axis hip joint and two KAFOs. The hip joint had two pulleys with the same axis, however they worked independently. The pulley of the

left side was connected to the KAFO of the right side and the pulley of the right side was connected to the KAFO of the left side. In this orthosis the heels of both sides were connected to the hip joints by steel wires. A wire from the left heel was attached to the left hip pulley (right KAFO) and another wire attached the right heel to the right pulley (left KAFO). There was another wire in this system which linked the forefoot sections of both AFOs. As a result plantarflexion of both feet at the same time was impossible. (Genda et al, 2004). Figure 2.28 shows this orthosis.

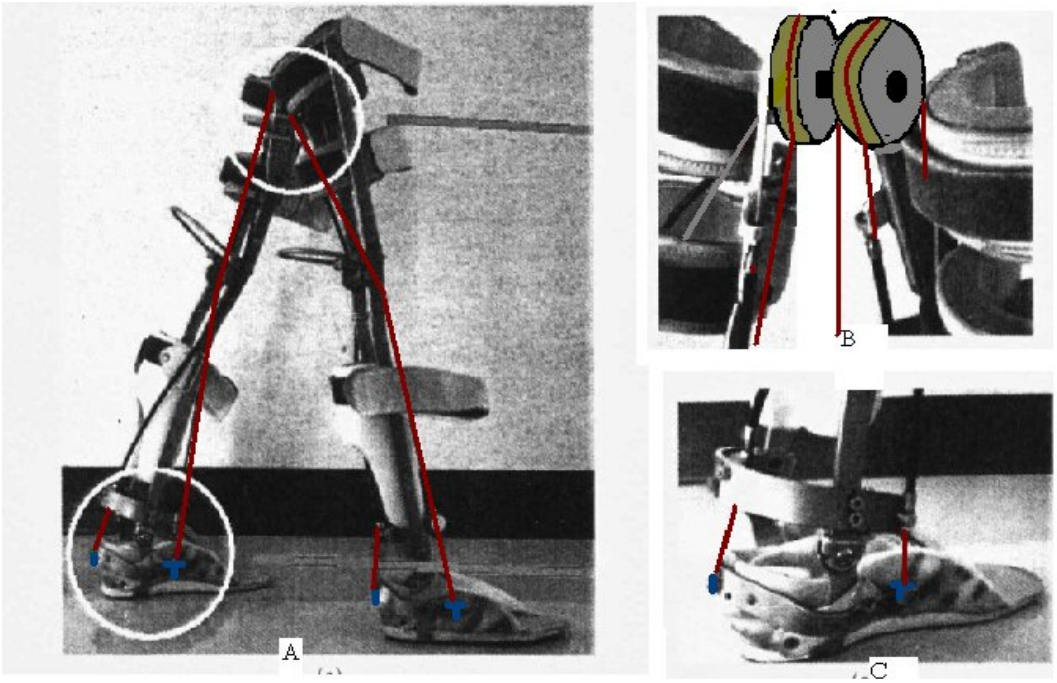


Figure 2.28: HALO orthosis (Genda et al, 2004), A is the orthosis, in B and C the ankle and hip joints are shown in details

2.9.4 Hydraulic, Pneumatic and Electrical Powered Orthosis Designed for SCI Individuals

Different orthoses have been designed for the SCI subjects which used hydraulic or pneumatic control systems or electrical sources of power to help the patients to move their limbs forward during swing phase. Many of these orthoses were only evaluated in the laboratory and have not been produced commercially. Those orthoses include:

a) Hydraulic Reciprocating Gait Hip Knee Ankle Foot Orthosis (HRGO) (Ozyalcin and Ozbasli, 1992)
b) Pneumatic Active Gait Orthosis (PAGO) (Belforte et al, 2001)
c) Powered Gait Orthosis (PGO) (Ryu et al, 2004)
d) Weight Bearing Control Orthosis (WBC) designed by Yano et al (1997)
e) Two degree of freedom motor powered gait orthosis designed by Ohta et al (2007)
f) Driven Gait Orthosis (DGO) designed by Colombo et al, (Colombo et al, 2001)

2.9.5 Functional Electrical Stimulation

Functional Electrical Stimulation (FES) is the application of external stimulation to paralysed muscles to restore their function. Patients with an injured central nervous system often have total or partial paralysis of their extremities however, they have an intact peripheral neuromuscular system. Many attempts have been made to restore the loss of functions by stimulation of the peripheral neuromuscular system artificially. There are three different types of stimulation which include:

a) Electrical stimulation of ventral roots

b) Electrical stimulation of peripheral nerve

c) Electrical stimulation of the muscles themselves

The stimulation electrodes may be applied on the skin, through the skin and also they may be implanted. Transcutaneous stimulation, using electrodes on the skin, is the easiest method to apply. It is used predominantly for stimulation of the common peroneal nerve in patients with drop foot. The main difficulty with stimulation is that the muscle force decreases after several stimulations.

In percutaneous stimulation, thin coiled wires are inserted through the skin into the muscles. This is done via a hypodermic needle. The main advantage of this type of

stimulation is that unique muscles can be selected. However, electrode leads may break and care should be taken to prevent infection of the skin at the site of insertion. The implanted electrodes may be used for direct muscles stimulation or nerve stimulation. The advantage of nerve stimulation is the possibility to stimulate several muscles from one position. However, the main problem with this type of stimulation is that sometimes the balance between different groups of muscles innervated by a nerve fibre is disturbed. Inefficient muscle contraction, fast muscle fatigue and poor control of muscle force are other disadvantages of this method of stimulation (Kralj and Bajd, 1989).

2.9.6 Hybrid Orthosis

The hybrid orthosis is a combination of a mechanical orthosis such as the ARGO, HGO, LSU RGO, or IRGO with a Functional electrical stimulation (FES) system. Researchers have planned to combine mechanical orthoses with FES to provide prolonged standing and ambulation with minimal energy consumption and applied loads on the upper limbs (Stallard and Major, 1993). FES standing and walking are restricted because of inadequate power produced by stimulated muscles. Mechanical orthoses are used with FES systems to control and stabilize frail joints (hip and knee joints) and to reduce the fatigue of the muscles during walking (Goldfarb and Durfee, 1996, Kagaya et al, 1996). Four different applications of FES may be used in these orthoses which include:

a) Reciprocal electrical stimulation of quadriceps and hamstrings muscles

b) Electrical stimulation of the gluteus and hamstring muscles, on the stance side

c) Electrical stimulation of gluteus muscles on the stance side

d) Electrical stimulation of quadriceps femoris, gluteus maximus, gluteus medius, tensor fascia latae, iliopsoas, sartorius and gracilis.

Theses hybrid orthoses are divided into two main groups according to the types of the orthoses which include: available orthoses and new designed orthoses.

2.9.6.1 Hybrid orthosis based on the available orthoses

Patrick and McClelland (1985) were the first researchers who used a FES system with an HGO orthosis. They tried to increase the structural stability of the orthosis during stance phase by stimulation of paralyzed gluteal muscles to provide abducting and extending moments around the hip joints during walking. A simple stimulation mechanism was used, which was operated by patients by using switches attached to the handle of the crutch. The results of this research showed that although the Force Time Integral (FTI) of the crutch force decreased by between 25 and 50 % in contrast to walking with the HGO without stimulation (Patrick and McClelland, 1985, Stallard et al, 1986), it had some problems associated with FES which include (Stallard and Major, 1995):

a) The contraction of abdominal wall muscle associated with gluteus muscles stimulation

b) Difficulty in connecting electrodes accurately

c) Inconvenience of the cable connecting the control switch on the crutch to the stimulators

In the research carried out by Nene and Patrick on five paraplegic subjects who used the HGO with and without stimulation, it was shown that using stimulation yields only a small reduction in energy cost (Nene and Patrick, 1990).

FES system was also used with the RGO, IRGO, and MLO orthoses in order to increase the performance of the paraplegic subjects during walking (Sykes et al, 1996, Hirokawa et al, 1996, Ferguson et al, 1999, Shimada et al, 2006). Ferguson et

al (1999) showed that walking with a hybrid orthosis based on IRGO was perceived to be significantly easier and faster than walking with the orthosis without stimulation. In contrast Sykes et al (1996) mentioned that using FES with the RGO orthosis did not increase RGO use and it did not increase the performance of the subjects in walking with the orthosis.

In summary, the performance of the subjects in walking with hybrid system based on the available orthoses is not significantly improved in contrast to that with the mechanical ones. Moreover, using stimulation has some disadvantages such as difficulty in connecting electrodes accurately, muscle fatigue, and inconvenience of the cable connection.

2.9.6.2 Hybrid orthosis based on the new orthoses

A variety of new orthoses have been designed which specifically focused on producing knee motion during swing phase and locking it during stance phase and, also in controlling the motion of the hip joint during walking. The main difference between the new designed orthoses is related to the system which was used to control the motion in the hip and knee joints. The new designed hybrid orthosis include:

a) Modular hybrid orthosis designed by Andrews (Andrews, 1990)
b) Spring Brake Orthosis (SBO) (Gharooni et al, 2001)
c) Hybrid orthosis with a new knee and ankle joints flexion component (Greene and Granat, 2003)
d) Wrapped Spring Clutch Orthosis (WSO) (Dall, 2004)
e) Hybrid orthosis designed by Baardman et al (2002a, 2002b)

2.10 GAIT ANALYSIS

2.10.1 Introduction

Walking is one of the most important forms of human locomotion. Gait analysis is the term applied to measuring, analysis and assessment of the biomechanical parameters and events which happen during walking. The study of different aspects of gait analysis started from the times of Leonardo da Vinci (1452-1519), Galileo (1564-1642) and Newton (1643-1727). The movement of the Centre of Gravity (COG) and the mechanism of balance during walking were described scientifically by Borelli in 1682. The first clear description of the gait cycle was produced by the Weber brothers in 1836 in Germany. Newton, Galileo and others had good descriptions of the events which happen during walking. Further progress followed by the development of the force platform which has contributed greatly to the scientific study of gait. It measures the direction and magnitude of the ground reaction force beneath the foot (Rose et al, 1994, Whittle, 1996).

Walking requires antigravity muscular support, joint mobility to allow smooth progression, and adequate motor control for the transition of body weight from one limb to the other. Disturbance of normal walking may be caused by disease, trauma, degeneration, fatigue, or pain, which restricts normal activities.

2.10.2 Terminology Used in Gait Analysis

The gait cycle is defined as the time interval between two successive occurrences of one event of walking. The commonly chosen repetitive event in the gait cycle is heel contact of one foot, especially the right foot. The gait cycle is divided into two major parts, which are named as stance, when the foot is in contact with the ground, and swing, when the foot is moving forward through the air. The major subdivisions of the stance phase include:

a) Heel contact (first double limb support period)

b) Mid stance (single limb support period)
c) Terminal stance (second double limb support period)

The swing phase is subdivided into the following parts:

a) Initial swing
b) Mid swing
c) Terminal swing

The stance phase, which is also named the support phase, lasts from heel contact to toe off. Heel contact of the right foot occurs when the left foot is still on the ground. This is actually the first double limb support phase, which is followed by a plantarflexion of the ankle joint to get the entire foot on the ground. The next stage is mid stance in which the body weight is applied completely through the foot in contact with the ground and is a period of the single limb support. In terminal stance the heel leaves the ground and the ankle begins to propel the body forward.

The swing phase, which is between 38 and 40% of the gait cycle, starts with initial swing. In initial swing the lower limb moves forward with a positive acceleration and then followed with mid swing in which the leg is under the body, beside the stance foot (Rose and Gamble, 2006). Finally in terminal swing the acceleration decreases and the foot reaches to a position to start the next heel strike. Figure 2.29 shows the different subdivisions of the gait cycle.

The stance phase lasts 60% to 62% of the gait cycle (Rose and Gamble, 2006, Whittle, 1996). In stance phase each double limb support is considered to be 10% of the total gait cycle and 40% of the cycle is single limb support, which is nearly equal to the swing of the other leg however, when the speed of walking increases the time of double support decreases. The terms used to describe the placement of the foot on the ground include:

Stride length: is the distance between two successive placements of the same foot

Step length: is the distance between two successive placement of right and left foot, for instance the distance between heel contact of the left foot and heel contact of the right foot.

Walking base: is the side to side distance between the lines of the two feet. It is measured usually at the midpoint of the heel however, it can also be measured below the centre of the ankle joint.

Toe out: is the angle between the reference line, which is the line between the second toe and the middle point of the heel, and the line of progression during walking.

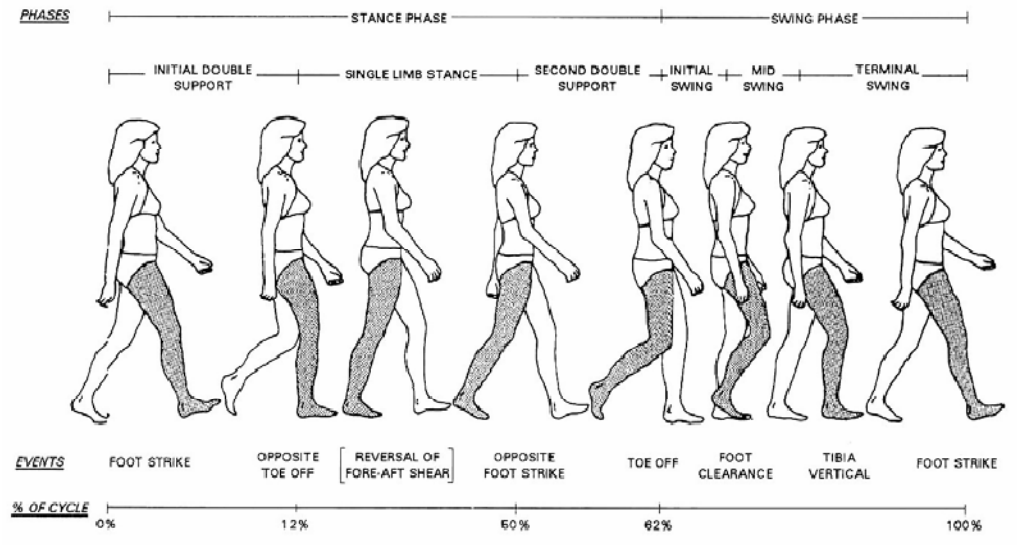


Figure 2.29: Typical normal walking cycle and its subdivisions (Rose et al, 1994)

There are other terms used to describe the linear measurement of the gait cycle, which include:

Cadence: is the number of steps taken in a given time (minute).

Walking speed: is the distance covered by the whole body in a given time. It is measured in metre per second or metre per minute.

Age groups	Numbers of observations	Swing phase %	Stance phase %	Double support %	Stride length (cm)	Cadence (steps/min)	Walking speed (cm/s)
20-25	48	40	60	9	158.8	115	153
30-35	48	39	61	11	156.9	111	145
40-45	48	39	61	11	155.9	122	159
50-55	48	40	60	10	157.9	118	155
60-65	48	39	61	11	153	115	147

Table 2.2: The gait parameters of healthy men who participated in the study by Murray et al, (1964)

parameters	Cadence (steps/min)	Velocity (m/s)	Stride length (m)	Stride time (second)	Stance phase %	Double limb %
Males	112± 9	1.34± 0.22	1.41± 0.14	1.08± 0.08	61± 2.1	10.2 ± 1.5
Females	115± 9	1.27± 0.16	1.3± 0.1	1.05± 0.08	60.7 ± 2.6	10 ± 1.4

Table 2.3: The gait parameters of 40 healthy men and women measured by Kadaba et al, (1990)

An extensive study of gait maturation was carried out by various researchers. The results of those studies showed that gait parameters such as cadence, stride length, walking speed and range of motion of different joints are age dependant. In the work done by Murray and her co-workers (Murray et al, 1964) the gait parameters of 60 subjects with different ages were analysed repeatedly. They found a significant difference between the mean values of the gait parameters between different age groups. Table 2.2 shows some results of this work. In another study by Kadaba et al, (1990) the kinematic parameters of the lower extremity during level walking was measured for 40 female and male participants. The results of this study showed that although the cadence of females was more than that of males, they walked slower than males. The stride length of the women was shorter than that of the men.

The percentage of double limb support was the same between men and women in that research, table 2.3. The stride length of the participants in Murray et al work, 60 subjects, differed between 1.53 and 1.588 metre however, it varied from 1.3 to 1.41 metre in the research of Kadaba et al, 40 subjects. The walking speed of the participants in Murray et al work was more than that in the research carried out by Kadaba et al. The difference between speed of the subjects in the mentioned research studies may be related to the gender of the subjects which differed in these studies (in the research of Kadaba et al two groups of male and female were selected, however the participants of the research carried out by Murray et al were male).

In the research carried out by Murray et al, only male participants were selected however, in the research by Kadaba et al, two groups of male and female were selected. The main reason for the difference between the stride length and other spiro-temporal gait parameters between those stated in their research was related to the participant's sex. As was shown by Kadaba et al the gait parameters of the females differ from males'.

2.10.3 Joint Motion During Level Walking

During gait important movements occur in different joints in all three planes, sagittal, frontal and transverse. Each part of the limb has a specific pattern of motion which it follows repeatedly during walking. For example, the upper body moves forwards throughout the gait cycle. The shoulder girdle has a twisting motion which is in an opposite direction to that of the pelvis during normal walking. The trunk also has a side to side motion, once in each cycle in order to increase the stability of the leg during walking. The pelvic also twists around the vertical axis and also displays forward and backward tipping which is in associated with a change in lumbar lordosis. The motions of the pelvis during walking can be seen in figures 2.30, 2.31 and 2.32.

Maximum hip flexion occurs between the middle and end of swing phase (Whittle, 1996). At the beginning of the stance phase it is in 30 degrees of flexion and then after weight bearing it starts to extend and reach its maximum extension at contralateral foot strike, then starts to flex in order to transfer body weight to the other limb. In the coronal plane it is in a neutral position (not in abducted or adducted position) at foot strike and then it adducts rapidly however, it returns to an abducted position at the end of stance phase. In swing phase, the hip joint starts to adduct and reaches to the neutral position at the end of the gait cycle. The motion of the hip joint in sagittal and coronal planes can be seen in figures 2.30, 2.31, and 2.32.

In swing phase, the hip joint changes its rotational direction from internal rotation into external rotation however, in the stance phase it is in an externally rotated position and reaches its neutral position in terminal stance. Figure 2.32 shows the rotational motion of the hip joint during walking.

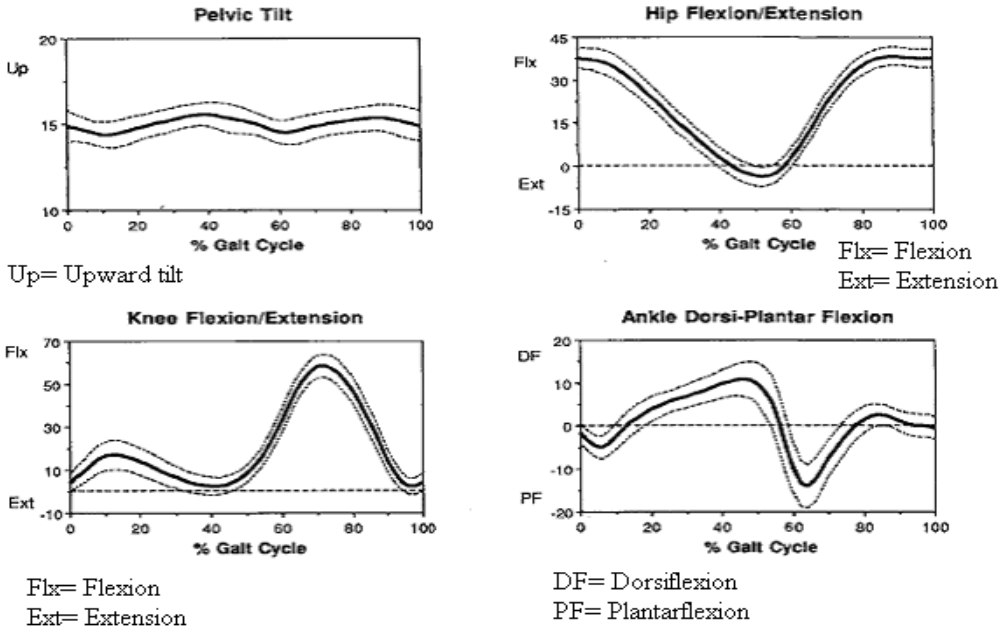


Figure 2.30: The motion of the pelvis, hip, knee and ankle joints in the sagittal plane, men with different age groups, according to the research by Kadaba (Kadaba et al, 1990)

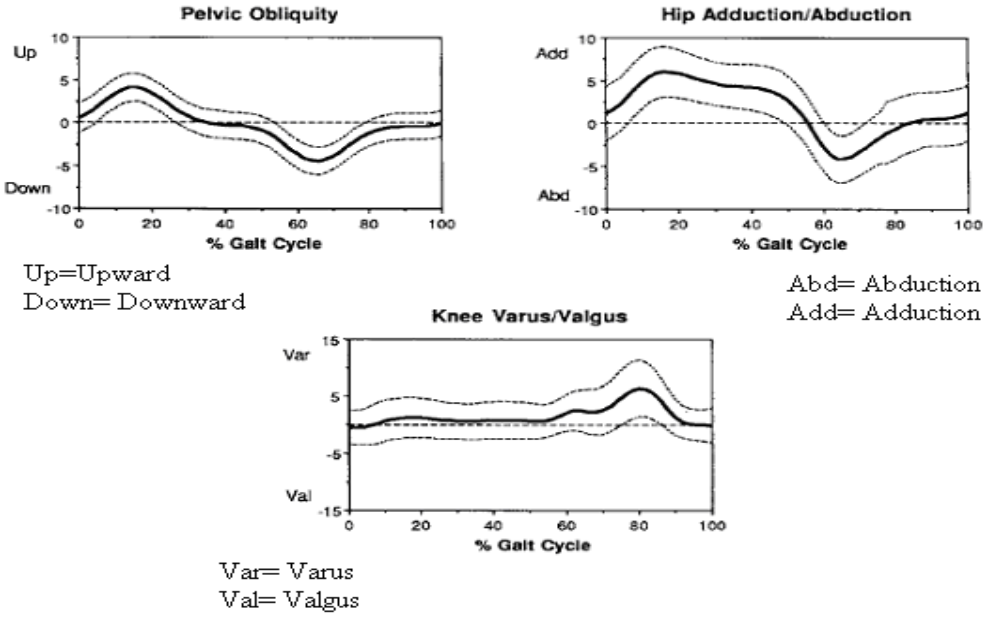


Figure 2.31: The motion of pelvis, hip and knee joints in the coronal plane during level walking, according to the research by Kadaba (Kadaba et al, 1990)

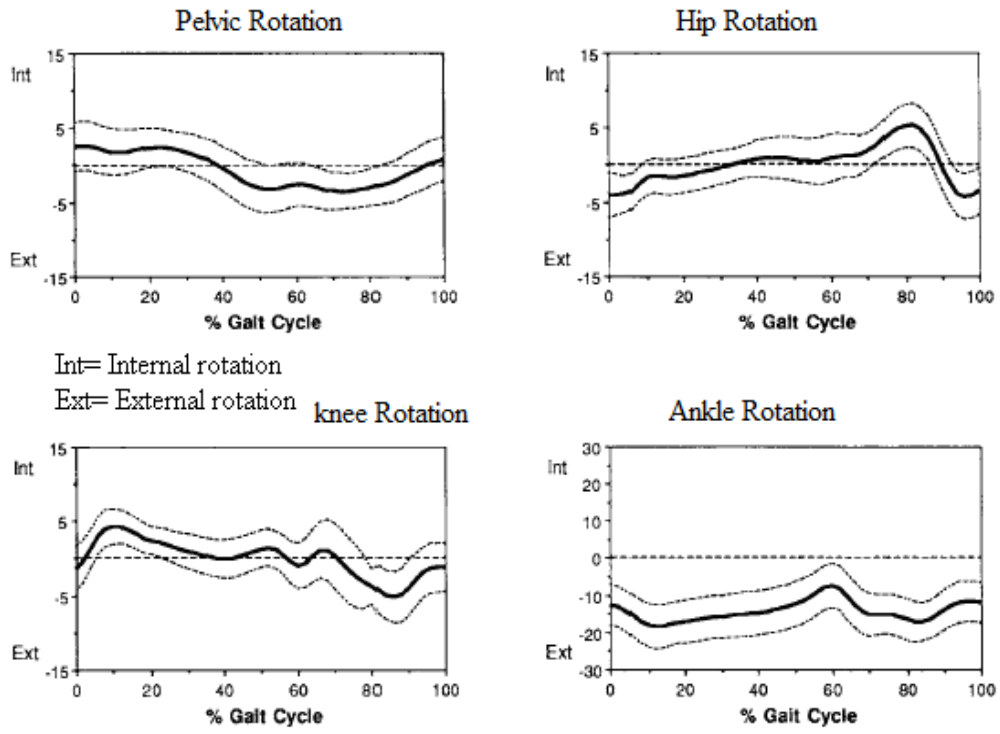


Figure 2.32: The motion pattern of the lower extremity in transverse plane during level walking (Kadaba et al, 1990)

The knee joint has two flexion and two extension patterns in each gait cycle. It is in an extended position before heel contact, it then flexes early in the stance phase, as soon as the body weight is applied on the leg. It goes to extension in mid stance and then flexes at the end of stance phase and reaches its flexion peak during initial swing (Kadaba et al, 1990, Whittle, 1996, Rose et al, 1994). The motion of the knee joint, in the sagittal plane, during normal walking can be seen in figure 2.30.

The knee joint has both abduction and adduction motion within each gait cycle. During stance phase it is in neutral position, not in abduction or adduction position, although it has a little abduction, as soon as body weight is applied on the limb. In swing phase the knee joint starts to adduct however, it reaches a more neutral posture at the end of the swing phase. The pattern of motion of the knee joint in the transverse plane is nearly the same as that for the hip joint. It starts to rotate internally at the beginning of the stance phase and reach to its peak before mid stance. Then it rotates externally up to the terminal stance and rotates internally at the beginning of the swing phase and finally has an external rotation in the swing phase (Rose et al, 1994). The pattern of motion of the knee joint in the coronal and transverse planes during level walking can be seen in figures 2.31 and 2.32.

The ankle joint is almost in the neutral position, when foot strike occurs, it then plantarflexes, as body weight is applied on the limb. In mid stance the ankle is in dorsi flexion, and in the terminal stance it reaches to plantarflexion again to transfer body weight to the contralateral leg. During swing phase, the ankle joint is in a dorsiflexed position to decrease the length of the limb and to prevent contact of the swing foot with the ground (Rose et al, 1994, Kadaba et al, 1990, Whittle, 1996) . Figure 2.30 shows the motion of the ankle joint in sagittal plane during normal walking.

The other motions of the ankle joint complex in the transverse and frontal planes depend on the foot motion. It is in an external rotated position during stance phase however, it rotates slightly inward when the body weight is transferred upon the other leg. During swing phase it remains in an externally rotated position (Kadaba et al, 1990). Figure 2.32 shows the motion of ankle joint during walking in the transverse plane.

2.10.4 Ground Reaction Force During Walking

Ground reaction forces are actually responses to the forces which are produced by muscles and the weight of the body transmitted through the foot. Those forces, which can be measured by using a force plate, are represented as three components, which are:

F_x = Anteroposterior component

F_y = Vertical component

F_z = Mediolateral component

The vertical component of the ground reaction force (GRF) is equal to the force of the body's weight plus the force due to vertical acceleration of the Centre of Gravity (COG). When the COG accelerates downward, the vertical component is less than body weight however, during upward acceleration it is more than that of body weight. The first maximum peak in the vertical GRF in the typical plot of this force occurs during the first double stance phase and it is nearly 120% of body weight. During single limb support the vertical component of GRF decreases to about 80% of body weight. There is another peak in the vertical component which occurs at the second double limb support (Rose et al, 1994, Rose and Gamble, 2006).

The anterior-posterior (AP) force is first a braking force and then a propulsive force. The maximum magnitude of this force is approximately 20% of body weight. The area below this curve is the impulse of the force. The braking impulse and propulsive impulse should be approximately equal for symmetrical gait.

The maximum value of the mediolateral GRF is usually 5% of body weight, which is significantly less than that of the AP force. It should be mentioned that this force is in a medial direction in the first part of stance phase and then in a lateral direction in the second part of this phase (Rose and Gamble, 2006, Winter, 1991). Figure 2.33 show the force applied on the foot during normal walking.

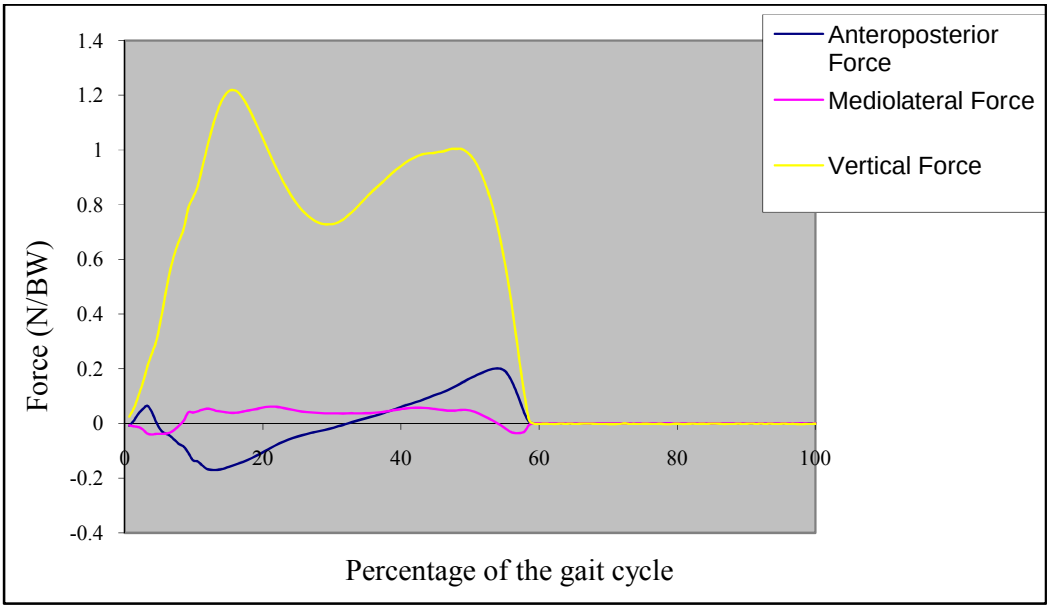


Figure 2.33: The Ground reaction force applied on the foot during normal walking (one of the subject in this project)

2.10.5 Gait Analysis of the Spinal Cord Injury Subject

The gait mechanism selected by spinal cord injury subjects, depends on the level of their lesion, type of lesion and their ability to walk. However, the most common ones are four –points, swing through gait, swing to gait, reciprocal gait and drag-to

patterns. There are three mandatory components for locomotion (Rose, 1986). These include:

a) Stabilization of multi segmental structure, it can be done intrinsically or extrinsically
b) Propulsion power. This can be supplied by muscular contraction or by using external power sources
c) A system to control both a and b

The stability of a multi segmental structure like the human body is achieved by using muscles in the normal and by using orthoses and crutches in handicapped subjects. Depending on the orthosis, different mechanisms are used to increase the stability during standing and walking. They can be done by stabilizing the paralysed joints, such as the knee and ankle joints in Knee Ankle Foot Orthoses (KAFO) or by restricting the range of motion, which is used in the hip joints of the RGO and HGO orthoses. In some orthoses such as the HGO the structural stiffness of the orthosis guaranties the mediolateral stability of the hip joints during standing.

The source of power during normal walking is muscular force which is injected to the hip joint during first part of the stance phase however, in paralysed subjects it is enhanced by using pneumatic, hydraulic or electrical powers. In the other orthosis such as the HGO the force of the upper limb muscles is transmitted to contralateral hip joint to move the hip joint into extension (Major et al, 1981).

In order for stability and propulsion to be maintained, a control system is required to maintain the pattern of energy production and the amount of body stability. Feedback from the sensory or non sensory interface is one of the important control systems which is used during normal walking and walking of a paraplegic subject with an orthosis. Some structural parameters, such as hip joint articulation with a limited range of motion or using a cable are extrinsic control systems selected by the orthosis designer in order to improve the function of the orthosis (Douglas et al,

1983, Butler et al, 1984, Butler and Major, 1987). SCI patients use different patterns during walking with an orthosis (Nixon, 1985, Somers, 1991), which include:

a) Four- points gait pattern
b) Swing through gait pattern
c) Swing to gait pattern
d) Drag –to pattern
e) Reciprocal gait pattern

However, the two most common used methods are swing through and reciprocal gait patterns.

2.10.5.1 Swing through gait

This method of ambulation is selected by the patients who have lesion level at T_9 or lower. This is the quickest form of locomotion, which can be selected by those patients. The arms and crutches move forward and then the body swings forward. For those SCI individuals who have spasticity of the abdominal muscles, this style is not useful. The strength of the elbow extensors is important to lift the body weight during swing phase. Figure 2.34 shows this style of walking (Somers, 1992, Somers, 1991).

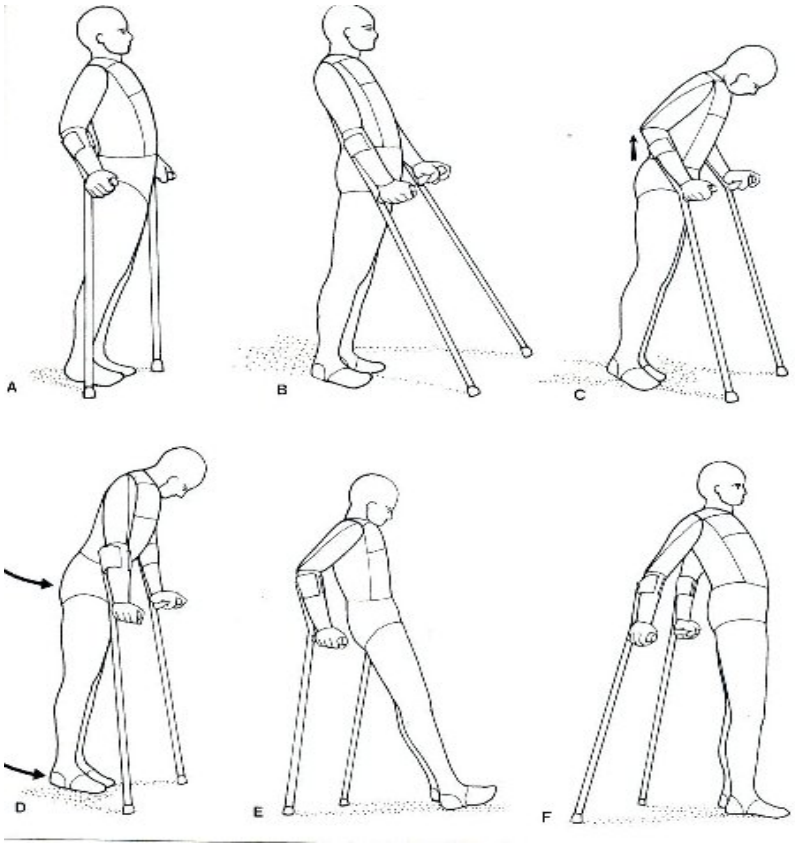


Figure 2.34: Walking with a swing through gait pattern (Somers, 1992)

2.10.5.2 Reciprocal Gait Pattern

Reciprocal gait is defined as a pattern in which the legs move separately and alternatively. In this gait pattern the subject places one foot in front of the other foot in the manner that one leg is always bearing weight (Major et al, 1981, Butler et al, 1984). This form of walking requires three actions, which include:

a) Lifting the swing leg off the ground

b) Moving the swing leg hip joint from extension to flexion

c) Moving the trunk forwards over the stance leg

The paraplegic subjects walk with a reciprocal gait pattern with the new HKAFO orthoses such as with the HGO, LSU RGO and ARGO orthoses. During normal walking, extension of the hip joint is achieved by muscular force however, in paraplegic walking this force must be imported into the system through the arms and crutches. The role of the latissimus dorsi muscle is more important and noticeable than that of other muscles in transmitting the force of the crutch and the upper limb to the pelvis. Other muscles such as pectoralis major, deltoid and trapeziuses are active to stabilize the shoulder joint and to help the latissimus dorsi to transmit the force to the pelvis. As soon as the swing leg clears the ground, it starts to swing forward to the midline by the effect of gravity. The leg swings forward beyond the midline, by inertial effects (Butler and Major, 1987). The gait of the SCI individuals with reciprocal gait pattern with the HGO orthosis is divided into different stages as follows:

Stage 1:

This stage is the same as heel contact during normal walking. The crutch of the stance leg (Right) is positioned forward and the left crutch is behind. This stage is the starting stage of walking (figure 2.35).

Stage 2:

In this stage, the majority of the body weight is applied on the right foot and the left foot is ready to start swing phase. The right crutch is in front of the right foot and the left crutch is positioned slightly ahead of the left foot. It should be mentioned that the force applied on the left crutch is more than that applied on the right crutch. The extensors of the elbow and shoulder joints on the left side stabilize the joints and help the subjects to lift the body weight from the left side and to transmit it to the contralateral side. The amount of flexion of the right hip joint decreases and it starts to move through the uphill phase by the help of the backward directed left crutch force. The function of some muscles such as left and right shoulder joint stabilizers,

left latissimus dorsi, triceps and pectoralis major is significant in this stage of walking with the HGO orthosis (Butler and Major, 1987, Stallard and Major, 1993). Figure 2.35 shows some events that are taking place in this stage during walking with HGO orthosis.

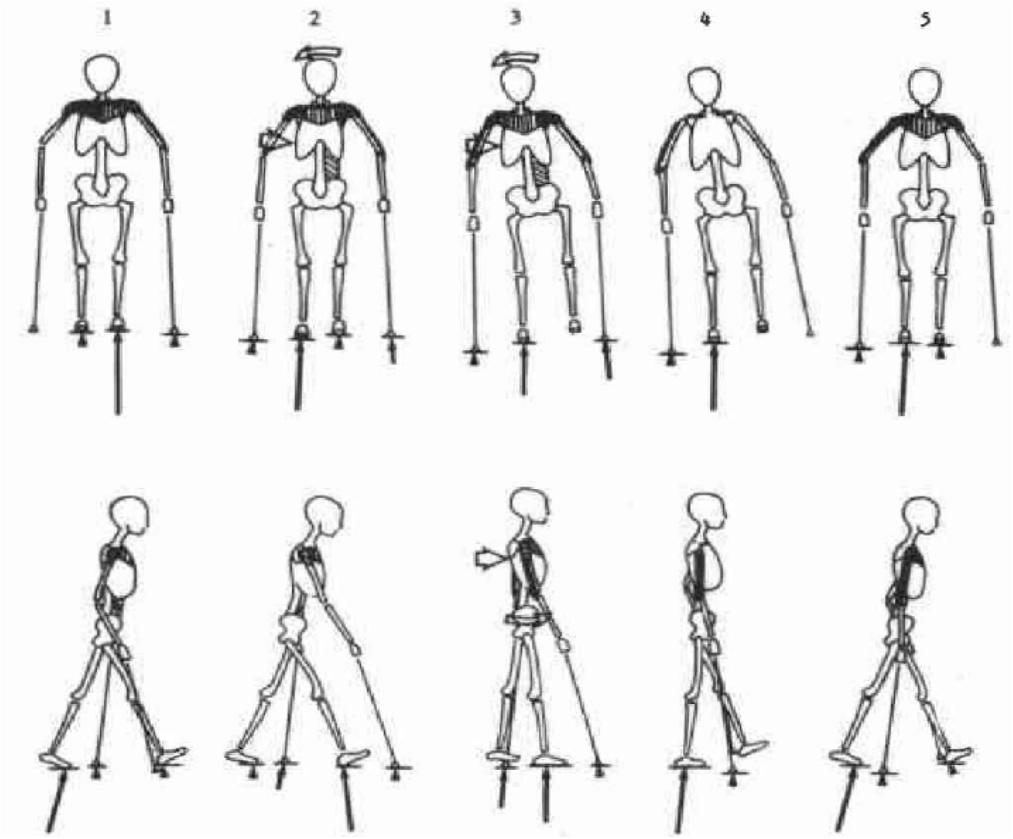


Figure 2.35: The different stages of walking with the HGO orthosis (Bulter et al., 1984)

Stage 3:

This stage is the same as foot flat in the gait of the normal subjects. The vertical force applied on the left crutch is significantly more than that of the right crutch. The left crutch is on the ground and the force of the latissimus dorsi and other shoulder extensors are transmitted to the right side as the main force for pelvic forward

motion. As in the previous stage the role of shoulder joint extensors in the left side is very important. The event which is taking place in this stage is shown in figure 2.35.

Stage 4:

The crutch on the left side is removed from the ground and the force applied on it decreases to zero. In contrast the force applied on the right crutch increases. The right side of the pelvis starts to move to the downhill phase and the right hip joint starts to extend. In this stage the left leg is in swing phase. The activity of some muscles such as, triceps and shoulder girdle muscle is more significant in the right side than in the left side. The structural rigidity of the HGO resists the adducting moments applied on the right leg. This stage is shown in figure 2.35.

Stage 5:

This stage is the same as toe off in the gait of a normal subject. The weight of the body will be transmitted to the left foot at the end of this stage. The forward motion of the right hip joint is significant, due to forward moment gained from the downhill phase. Some muscles such as triceps and shoulder depressors start to contract in order to control the force applied on the right crutch (Stallard and Major, 1993, Butler and Major, 1987). This stage is shown in figure 2.35.

2.10.5.3 Temporal gait parameters

The temporal gait parameters of SCI individuals during walking with an orthosis depend on the pattern of the gait, selected by the patients and also on the type of orthosis used. In research by Melis et al (1999), the temporal gait parameters of 10

Parameters	Walking (speed m/s)	Cadence (Steps/min)	Step length (m)	Stance/swing ratio	Max. Crutch force % of BW
Walker users	0.17 ±0.04	30 ±13	0.3 ±0.11	From 73/27 to 95/5	74% ±3.95
Crutch users	From 0.3 to 0.8	From 42 to 89.3	From 0.43 to 0.67	From 69/31 to 74/26	From 15% to 50%

Table 2.4: Some parameters in walking with swing through gait pattern with crutch and walker (Melis et al, 1999)

Parameters	Normal subjects*		Paraplegic subjects Swing through gait		Paraplegic subjects Swing to gait
	Slow	Fast	Slow	Fast	Combined
Velocity (m/s)	40.4 ±5.7	57.5 ±13.2	41.7 ±5.2	59.9 ±9.8	23.4 ±6.6
Cadence (steps/min)	59 ±6	70 ±10	67 ±7	79 ±7	88 ±3.2
Stride length (m)	1.34 ±0.15	1.6 ± 0.15	1.23 ±0.11	1.5 ±0.17	0.53 ±0.18
Stance phase percentage	78.8 ±4.5	74 ±4.2	70.7 ±5	64.6 ± 5.9	83.9 ±6.4

Table 2.5: Some results of the research done by Noreau et al, (1995)

incomplete SCI patients, with lesion levels between C_5 and T_{12}, were collected during walking with different assistive devices, but without orthosis. The mean walking speed for the walker users varied from 3 to 17.4 m/min however, for the crutch users it was between 18 and 48 m/s.

The walker which was used by the participants was a common one with four rubber tips. Table 2.4 shows the mean values of the temporal gait parameters according to the research by Melis et al (1999).

In research done by Noreau et al (1995) the temporal gait parameters of normal subjects walking with a pair of KAFOs and paraplegic subjects using the same orthosis were measured. The biomechanical parameters of normal subjects, who wore a pair of KAFOs, and the paraplegic subjects, who used the same orthosis differed from each other in walking with swing to gait or swing through gait patterns. The paraplegic subjects walked faster than normal subjects who walked with orthoses however, their walking performance reduced significantly during walking with swing to gait pattern in contrast to swing through gait pattern (Noreau et al, 1995). Table 2.5 shows some results of this research. Although it is not easy to compare the performance of the subjects in walking with the crutches and walker, as the results were shown in different formats, it seems that the subjects had better performance in walking with the crutches than that with the walker.

Slavens et al (2007) examined the temporal distance parameters of SCI patients who walked with reciprocal gait and swing through gait patterns. They found that the cadence, walking speed, stride length and stance phase duration differed in walking with reciprocal gait and swing through gait patterns. The subject population included three girls and two boys with an age between 8 and 12 years and with a myelodysplasia with a level of lesion at L_3 and L_4. They concluded that swing through gait produced a higher walking speed and cadence. Table 2.6 shows the

Temporal Parameters	Walking speed (m/s)	Cadence (Steps/min)	Step length (m)	Stance duration (Sec)
Reciprocal gait	0.39	67.12	0.66	0.66
Swing through gait	0.59	75.43	0.86	0.63

Table 2.6: The result of the research done by Slavens et al, (2007)

Parameters	RGO	A RGO	HGO
Cadence (steps/min)	35	37	37
Stride length (m)	1.02	0.99	0.98
Velocity (m/s)	0.3	0.31	0.3
Stance phase %	67	67	67

Table 2.7: Gait parameters of a paraplegic subject in walking with three different orthoses (Jefferson and Whittle, 1990)

Parameters	LSU RGO	ARGO	HGO
Hip joint flexion	15	12	16
Hip joint extension	33	35	21
Hip joint abduction	3	0	9
Hip joint adduction	8	10	7

Table 2.8: Hip joint range of motion during walking with different orthoses (Jefferson and Whittle, 1990)

results of the research done by Slavens et al. The gait parameters in walking with a reciprocal gait pattern also depend on the orthosis. The walking speed in walking with the RGO and the HGO orthoses is nearly 0.3 m/s (Jefferson and Whittle, 1990, Moore and Stallard, 1991).

Table 2.7 shows some gait parameters during walking with the RGO, HGO and A RGO orthoses. Although the speed of walking was nearly the same in three orthoses however, the legs in stance and swing phases remained nearly parallel to each other in the HGO than that in the other orthoses.

2.10.5.4 Kinematic parameters during paraplegic walking

A paraplegic individual walking with a swing through gait, with KAFO's has almost the same hip joint flexion as that in normal subject (35 degrees). The excursion of the shoulder joint in the sagittal plane, which is approximately 40 degrees doesnot vary significantly between normal subjects and paraplegic subjects during walking with a swing through gait pattern. Since the stance phase of the crutch is longer in paraplegic subjects in contrast to that in normal subjects, flexion of the shoulder occurs with a delay in patients (Noreau et al, 1995). In their research 8 paraplegic subjects and 9 normal subjects were selected and were trained to walk with a pair of KAFOs.

SCI individuals who walked with a walker have a forward flexion of the trunk during the entire the gait cycle. According to the results of the research done by Melis et al (1999), trunk flexion varied between 10 and 40 degrees during walking with crutches (Melis et al, 1999). In this research, in which 10 subjects with incomplete SCI participated, the mean value of hip joint flexion/extension excursion during walking with a walker was a little more than that during walking with crutches. In contrast those who walked with crutches had more extension in the trunk and were able to extend their hip joint during stance phase (Melis et al, 1999).

During walking with an HGO orthosis, a paraplegic's hip joint flexes more than that

Parameters	RGO	Steeper RGO	HGO
Motion in sagittal plane	16	17	11
Motion in coronal plane	16	17	12
Motion in transverse plane	23	26	33

Table 2.9: Pelvic range of motion in the different planes during walking with different orthoses (Jefferson and Whittle, 1990)

Patients	Maximum vertical force applied on the foot (% of BW)	Maximum vertical force applied on the crutch (% of BW)	Foot vertical force impulse (% of total)	Crutch vertical force impulse (% of total)
Skilled	78.4%	29.6%	71.2%	28.8%
Unskilled	104.2%	28.85	79.4%	20.6%

Table 2.10: The kinetic parameters of paraplegic walking with HGO (Ferrarin et al, 1993)

during walking with the RGO and ARGO orthoses. In contrast, the hip joint extends less in an HGO orthosis compared with the other two orthoses. The motion of the pelvis with HGO differs from that in the other two orthoses, it has less motion in the coronal and sagittal planes in contrast to other orthoses (Jefferson and Whittle, 1990).

Tables 2.8 and 2.9 show the hip and pelvic angles for a paraplegic individual walking with the HGO, RGO and ARGO orthoses. The main factor which restricts the motion of the hip joint in extension is the shape of the hip joint and the stiffness of the structure surrounds it. It is unlikely that the hip joint has a range of extension as mentioned in this research.

2.10.5.5 Maximum forces applied on the crutch and foot during walking with orthoses with various walking styles

The magnitude of the forces applied on the crutch and foot during walking of paraplegic subjects depends not only on the pattern of walking, but also on the type of orthosis used. The magnitude of the anteroposterior shear and the vertical forces applied on the crutch during walking with swing through gait is slightly greater than that in walking with swing to gait. However, there is no difference between the mediolateral force applied on the crutch in walking with the two styles (Crosbie and Nicol, 1990).

In the research conducted by Slavens et al, the peak force applied on the crutches was between 44.7 and 45.1 % of BW with a reciprocal gait pattern and between 55.62 and 57.2 % of BW during walking with a swing through gait pattern (Slavens et al, 2007).

Major et al (1981) carried out research to show the magnitude of the forces applied on the foot and crutch in walking of a paraplegic subject with the HGO orthosis,

with reciprocal gait pattern. According to the results of this study, the magnitude of the vertical ground reaction force applied on the right foot and left crutch were 90% and 22% of BW, respectively at initial contact. At foot flat 65% of the BW was applied on the right leg, compared to 35% of the left crutch. The maximum magnitude of the vertical force was applied on the foot just prior to toe off (110% of BW). The peak of the mediolateral force applied on the crutches during walking with the HGO was 5 % of BW.

However, in the research done by Nene and Major (1987) with nine paraplegic subjects with lesion between levels T_4 and T_9 the maximum values of the vertical force applied on the foot varied between 29% and 98% of BW, compared to 40% of BW applied on the crutch. In further research done in Milan University by Ferrarin et al, and his co-workers (Ferrarin et al, 1993) the biomechanical parameters of five HGO users with lesion levels between T_1 and T_{10} and also a matched control group were assessed during walking. The results of this research showed that there was a significant difference between the duration of stance and swing phases between normal subjects and paraplegics and also between skilled and unskilled Parawalker users. The results of this research are shown in table 2.10.

According to the research by Tashman et al (1995), the maximum values of the ground reaction force (vertical component) applied on the limb and crutch was 83% and 33% of BW during walking with the RGO orthosis. The hip joint range of motion (flexion/extension) in this research was nearly 25 degrees. The magnitude of the mediolateral shear forces applied on the foot was minimal. In another research project carried out by Ijzerman et al (1997b) the peak of the crutch force of five paraplegic subjects (with lesion between levels T_4 and T_{12}) during walking with the ARGO orthosis with various degrees of abduction was measured. According to the results of this research the maximum values of the crutch force varied between 0.33 to 0.43% of BW. This research also is presented in table 2.13.

It can be concluded from the above mentioned research that the force applied on the crutch during walking with a reciprocal gait pattern is significantly less than that with swing through gait and swing to gait patterns. Moreover, the amount of the force differed between skilled and unskilled subjects.

2.11 ASSESSMENT OF THE AVAILABLE ORTHOSES USED FOR STANDING AND WALKING OF PARAPLEGIC SUBJECTS

A variety of orthoses have been designed to enable SCI to stand and walk again however, none of them are without any problems. The important point is that the appropriate orthosis must be selected according to the level of lesion and also of the ability of the subjects to walk. There are several methods that can be used to assess the performance of SCI individuals during standing and walking with different orthoses. According to Stallard and Major (1998), the main factors for assessment of the orthosis include:

a) Independency of patients in using the orthosis

b) Energy cost of walking with the orthosis

c) Cosmesis

d) Mechanical reliability

e) System cost

Concerning the cosmesis, other parameters such as the style of walking and degree to which the orthosis can be seen under the clothing were considered in the above paper. The other parameters that can be used for evaluation of the orthosis are as follow (Major et al, 1997):

a) Efficiency of the orthosis during walking

b) Ease of application

c) Assistive devices required for walking

d) Cosmesis of walking and of the orthosis

The efficiency of an orthosis was defined as the amount of energy consumption during walking with the orthosis. However, Whittle et al, (1991) selected other parameters to compare the performance of 22 paraplegic subjects who walked with the HGO and RGO orthoses. They considered factors such as the facilities and time required to fabricate the orthosis, the time required to train the subject, gait parameters, the cosmesis of the orthosis itself and the cost of the final orthosis and training cost. The cosmesis was evaluated according to the style of walking and the extent by which the orthosis could be disguised under clothing. The gait parameters which were selected by different investigators to compare the performance of the orthoses include (Whittle et al, 1991, Jefferson and Whittle, 1990):

a) Cadence, stride length, walking velocity, percentage of the stance phase in contrast to the total gait time

b) Pattern of movement

c) Hip joint range of motion in the sagittal and coronal planes

d) Pelvic angular motion and translations

The stability of the subject during quiet standing and while conducting hand tasks was another parameter which was selected by different investigators (Baardman et al, 1997, Middleton et al, 1999, Kaoru, 2006). Other parameters such as the weight of the orthosis are not important factors for ambulation of the patients with orthosis because it is not required to lift the orthosis completely from the ground by patients during reciprocal walking (Stallard and Major, 1998). Further research to support

the concept that the weight of the orthosis does not affect the performance of the subject during walking was published by Corcoran et al (Corcoran et al, 1970).

Therefore, in order to evaluate a newly designed orthosis, parameters such as standing stability during quiet standing and while undertaking different hand functions, energy consumption during walking and gait parameters should be measured. Other parameters such as the cosmesis of the orthosis and the style of walking, and mechanical reliability of the orthosis also influence the willingness of the subjects to use an orthosis.

2.11.1 Standing Stability

Stability during standing is achieved by a complex process which involves the coordination of activities of multiple sensory, motor and biomechanical components. In normal subjects stability is maintained by coordinated motions occurring at the hip, knee and ankle joints. The role of the muscles which surround these joints is very important and effective in maintaining the stability during standing. It should be mentioned that most of the control is achieved by the hip and ankle joints mechanisms whereas the influence of the knee joint is slight. In order to have good balance the COG of the body must be within the base of support. During normal standing, some strategies such as head and trunk movement strategies, and hip and ankle strategies can be used in order to maintain stability (Jacobson et al, 1993). However, in SCI individuals these strategies cannot be used and the amount of stability depends on the external support, which is achieved by using the orthosis. The structural stiffness of the orthosis is an important factor which increases the amount of stability during paraplegic standing (Stallard and Major, 1993).

There are two different assessment methods which are used to check the amount of standing stability. The first method which was developed by Romberg at the beginning of nineteen century was based on the amount of body sway under open

and closed eyes conditions. The difference between body sway during standing with eyes open and closed represents the functional performance of the somatosensory system which controls the stability. By using force platform technology the researchers are more able to measure the postural sway to analyse the stability in different positions. The second approach was to check the stability when an unexpected force was applied on the body.

2.11.1.1 Assessment methods to evaluate the standing stability during quiet standing based on force plate data

To assess the amount of stability, the location of the Centre Of Pressure (COP) is measured during a period of time. Many of the parameters mentioned in the literature for stability analysis are based on COP location change with respect to time. The following parameters were used by different investigators to measure the standing stability.

a) The COP path length (Middleton et al, 1999)
b) The COP sway excursion in the mediolateral and anteroposterior directions (Baardman et al, 1997, O'Connell et al, 1998)
c) The average speed of the COP change (Raymakers et al, 2005)
d) The location of the COP in relation to the base of support (Baardman et al, 1997)
e) Mean amplitude of the COP sway in the mediolateral and anteroposterior planes (Lafond et al, 2004)
f) Measuring the force applied on the force plate (Goldie et al, 1989)
g) Hip joint motion in the standing position (Kagawa et al, 2006)
h) The amount of the force applied on the crutches during walking (Baardman et al, 1997)

Amongst the various parameters which can be used for measuring the stability during quiet standing, using the excursions of the COP in the mediolateral and anteroposterior planes has been used by many researchers. These excursions are easy to obtain and have good validity and repeatability in showing the standing

stability (O'Connell et al, 1998, Raymakers et al, 2005). Moreover, the use of the force applied on the crutches in order to analyse the standing stability of the paraplegic subjects, has been recommended (Baardman et al, 1997).

2.11.1.2 Standing stability during hand function

The stability test of paraplegics and normal subjects during standing with an orthosis was carried out during quiet standing in many research projects. However, the functional stability test is another important factor which was considered only in a few studies. The Jebson test of the hand function is one of the standard tests used for analysis of the stability during hand function. This test was extended to include tasks which required vertical reaching and crossing the midline while standing and represents both fine and gross motor skills. Triolo et al (1993) evaluated the functional stability of 69 able-bodied and 2 paraplegic subjects. Subjects undertook the following tasks during standing:

a) Move small objects on a countertop
b) Lift objects from a high to a low shelf
c) Lift objects from a low to a high shelf
d) Push objects from dominate side

The time required to do these tasks was the main factor selected for final analysis. The results of the SCI patients showed that this test is very patient dependant, because one of the participants did the test in the normal limit but, the second performed poorly. The results of this research showed that more work must be done to check reliability and repeatability for both normal and paraplegic subjects.

The functional stability of paraplegic subjects while undertaking different hand tasks was measured by other investigators. They measured some parameters such as, the excursions of the COP in the mediolateral and anteroposterior planes, the time

required to undertake various hand tasks and the force applied on the crutch (Baardman et al, 1997, Middleton et al, 1999).

2.11.2 Evaluation of Walking Performance by Measuring the Amount of Energy Consumption During Ambulation

The amount of energy consumed during walking is one of the important parameters which are selected routinely for evaluation of the performance of different assistive devices. Measuring the energy consumption during various activities based on indirect calorimetry, which is based on the assumption that all energy releasing reactions in the human body ultimately depends on the utilization of the oxygen. For measuring the amount of oxygen during walking the following methods were used by various investigators, which include:

a) Douglas bag (Waters et al, 1978)
b) Mobile Automatic Metabolic Analyser (MAMA) (Huang et al, 1979)
c) Cosmed K2 b2 gas analyser (Massucci et al, 1998)
d) Cosmed K4 b2 gas analyser (Yano et al, 1997, Ulkar et al, 2003)

From the above procedures, the use of Cosmed K4 gas analyser is more reliable and easier to use than others (Hood et al, 2002). Measuring the rate of oxygen consumption is a good way to assess the energy used during walking however, the instruments are cumbersome to wear and also may not be available in all clinics. Using these systems also restricts the abilities of the participants and indirectly influences their performances. This involves using a nose clip by subjects and breathing through a snugly fixed mask. However, in clinical situations involving different persons with physical handicap, using these methods is not very practical and it is better that other methods be used instead (Rose et al, 1994, Rose and Gamble, 2006).

Heart rate is an accurate estimation of the oxygen consumption and is a simple and easy to use parameter in any conditions (Rose and Gamble, 2006). It has been stated by several authors that apparently there does not seem to be a close relationship between energy expenditure and heart rate. But it is clear that the main part of the energy in our body is supplied by aerobic oxidation reaction, in which oxygen is the main part of the process. The oxygen is carried by the blood and the blood is pumped into muscles by the heart. The harder our muscles work the more oxygen is used and more blood is required, so the heart must work harder and the rate of breathing would be increased. Therefore, it is clear that there is a noticeable relationship between heart rate and energy and oxygen consumption (Astrand and Rodahl, 1986).

The relationship between heart rate and oxygen consumption was evaluated in the different research studies. In research carried out by Rose et al (1990), the mean value of the correlation coefficient was 0.98±0.2 and 0.99±0.1 for normal and CP participants (18 normal and 13 CP patients), respectively. Moreover, in research done by Goosery and Tolfrey (Goosey and Tolfrey, 2004), which was done on trained female wheelchair athletes, the correlation coefficient between heart rate and oxygen consumption was 0.973. Bar-On and Nene (1990) were other investigators that measured the correlation between the heart rate and oxygen consumption in paraplegic subjects with various lesions between levels T_3 and T_{10}. Their heart rate and their oxygen consumption were monitored during various activities. The results of this study showed a high correlation coefficient between heart rate and oxygen consumption during activities. For patients with lesion level between T_3 and T_6 the co-efficient of correlation was 0.7824 and for those with lesion level from T_7 to T_{10} it was 0.8592. The patients with high spinal cord injury level miss the control of the para-sympatic centre which is supposed to be around T_4 (Bar-On and Nene, 1990).

2.11.2.1 Heart Rate per Distance Walked

Heart rate expressed per distance walked indicates the energy economy (Rose et al, 1994). The following equation was used to check the Energy Expenditure Index (EEI, beats per metre) (McGregor, 1979):

$$\text{EEI (beats/metre)} = \frac{\text{heart rate during exercise - heart rate during resting (beats/min)}}{\text{Walking speed (metre/min)}}$$

Eq. 2.1

This equation has been mostly used in various research projects to evaluate the efficiency of different orthoses, which is also named the Physiological Cost Index (PCI). In the research carried out by Rose et al (1990) the amount of oxygen consumed during walking and the heart rate per metre were compared in 12 children with cerebral palsy and 18 normal subjects. They found that the curve of the heart rate per metre and oxygen consumed per metre was similar for both groups. It was also shown that the mean value of EEI in a disabled group was significantly more than that in the normal group (Rose et al, 1990).

The results of the different researches carried out on normal and paraplegic subjects showed that the PCI has high test retest reliability (0.843-0.944). Moreover, it was shown that PCI is an easy to use, a valid and reliable measure of energy expenditure and it is a good factor to check the efficiency of any orthoses and to evaluate any locomotion disabilities. However, some researchers such as Ijzerman et al (1999) recommended that since the number of patients participating in research related to SCI subjects is limited, it is recommended that use of other variables be made to give strong statistical results (Ijzerman et al, 1999).

2.12 EVALUATION OF THE AVAILABLE ORTHOSES WHICH ARE USED FOR WALKING AND STANDING OF SCI SUBJECTS

Different types of orthoses, mechanical, hybrid and externally powered have been designed for paraplegic subjects however, many of them have not been produced commercially. The performance of the well known orthoses is discussed in the following section.

2.12.1 Evaluation of the Performance of Paraplegics During Walking with AFO and KAFO Orthoses

There is no doubt that many paraplegic subjects cannot use AFO orthoses, since many of them have knee extensor paralysis and the AFO cannot provide enough support for this joint. The Vannini_Rizzolo stabilizing orthosis is one of the specifically designed AFO orthoses for paraplegic subjects. However, a number of contraindications were considered in selecting the patients to use this orthosis. The contraindication parameters which were considered in that research were: contractions of the lower limbs joints, instability of the knee joint due to laxity of the ligaments, overweight by more than 20% of ideal weight, instability of the spinal column and any problems in the cardiovascular system (Kent, 1992).

From the 58 patients with lesion levels between T_2 and L_5 who participated in this study, 29 patients were selected for final analysis according to those above contraindication factors. They were asked to walk with a comfortable speed. The distance ambulated with the boot differed from 1.524 to 152.4 metre, and averaged 26.03 metre. The energy consumption of a group of paraplegic subjects (22 patients) was measured by Waters and Lunsford (1985). The results of this research showed that the mean values of walking speed and heart rate during ambulation with bilateral ankle foot orthoses were 26±16 m/min, 131±24 beats/min, respectively. Some results of this research are shown in table 2.11.

The performance of paraplegic subjects during walking with KAFO orthoses was evaluated by many investigators. In the research carried out by Huang et al (1979), the amount of energy consumption during walking with a Craig-Scott orthosis was measured on 8 paraplegic subjects with lesion level between T_4 and T_{12}. In the resting state, the average O_2 consumption was 0.061 ml/s/kg, giving a mean energy cost of 17.12 cal/min/kg however, they were 0.1867 ml/s/kg and 52.95 cal/min/kg respectively during ambulation. The results of this research showed that the oxygen consumption during walking with this orthosis was three times more than that during resting position (Huang et al, 1979).

Other research work was carried out by Merkel et al, (1984) to evaluate the efficiency of two KAFO orthoses in standing and walking of paraplegic patients. Eight paraplegics with lesion levels between C_7 and T_{12} participated in this study. They walked with a Scott- Craig KAFO and single-stopped long-leg KAFO with walker and crutches. The speed of walking with the Scott- Craig and walker was 8.8±5.8 m/min in contrast to 6.3± 2.45 m/min for single-stopped KAFO orthosis (plantar flexion fixed). However, the energy did not differ when the subjects used crutches as their assistive device. The results of this study showed that the Scott-Craig was a more energy efficient orthosis than the single-stopped long-leg KAFO in walking, by 25% to 34% depending on the type of the selected assistive device (Merkel et al, 1984). The results of other research done by Lehman et al, (1969) showed that the performance of subjects using KAFO orthoses with anterior and posterior ankle stops, no motions in the ankle joint, was significantly better than those who walked with KAFO orthoses with free dorsiflexion motion (Lehmann et al, 1969).

In conclusion, many paraplegic subjects cannot use AFO orthoses for walking. This orthosis is suitable for SCI subjects with a lower lesion of the spinal cord and those who have some knee extensor power.

Parameters	Heart rate (beats/min)	Speed (m/min)	Oxygen rate (ml/kg/min)	Oxygen cost (ml/kg/m)
Mean value	131± 24	26± 16	13.8 ±4.8	0.73 ±0.49

Table 2.11: Some results based on the research carried out by Waters and Lunsford (1985)

However, many paraplegic subjects can use KAFO orthoses for standing and walking. The performance of SCI subjects with Scott-Craig KAFOs with fixed ankle joints is better than other available KAFO orthoses.

2.12.2.2 Evaluation of the functional performance of SCI individuals walking with the RGO orthosis

The first research on the performance of the SCI subjects while walking with the RGO was done by Douglas et al (1983). They mentioned in this research that the brace was successfully fitted on 138 patients having disorders such as spina bifida, paraplegia, cerebral palsy, multiple sclerosis, muscular dystrophy, and sacral agenesis. It was found that adults, paralyzed from spinal cord injury accepted this orthosis because it was more energy efficient than the conventional orthoses. They were able to walk on average 304.8 metre with no more than two 30 seconds rest periods.

2.12.2 Evaluation of the Performance of Paraplegics Walking with HKAFO Orthoses

Amongst various HKAFO orthoses designed for paraplegic subjects, the HGO, RGO and ARGO orthoses are the orthoses which have been produced commercially and used by these patients. The results of the research to evaluate the performance of the SCI individuals in using the HKAFO orthoses are as follows.

2.12.2.1 Evaluation of the functional performance of SCI individuals walking with HGO orthosis

The energy cost of ten paraplegic subjects, with complete spinal cord lesion between T_4 and T_9, in walking with the HGO orthosis was measured by Nene and Patrick (1989). They walked with crutches and with a self selected comfortable speed. The average walking speed varied from 0.133 to 0.349 m/s, the mean value was 0.214

m/s. The mean values of the energy cost and energy consumption in walking with the HGO were 16 J/kg/m and 3.1 J/kg/s, respectively.

In other research work carried out by Moore and Stallard (1991), the performance of the HGO orthosis was evaluated on 50 paraplegic subjects with lesions ranging from level L_1 to T_3 by using direct interview. The main criterion in selecting the patients was using the orthosis for at least 6 months. The results of this study showed that 64% of the HGO users were still using their devices. It should be mentioned that the mean time of review follow up after orthosis supply was 34.4 months. Nearly 78% of them used their orthoses, independently. Approximately 20% of users reported that their orthosis had some functional use for them. According to the results of this research, using the orthosis in driving or using public transportation systems were the main problems associated with the users.

In further research carried out by Stallard and Major (1993) the effect of increasing the lateral stiffness of the HGO orthosis on the gait performance of SCI individuals, was evaluated by the introduction of the "Parawalker 89". The amount of energy consumption of three participants with lesion levels between T_8 and L_1 was analyzed by using PCI. The results of this study showed that the PCI was reduced when subjects walked with the "Parawalker 89" from 1.4 to 0.98 (30% reduction). Moreover, in other research work, they showed that increasing the lateral stiffness of the orthosis increased the walking speed between 13 and 83% and decreased energy cost between 12 and 42% (Stallard and Major, 1993).

The performance of the paraplegic subjects in walking with the "Parawalker 89" is significantly better than that of older versions of this orthosis, because its lateral stiffness is more than the previous orthoses. Nearly two third of the paraplegic subjects used this orthosis only inside their homes and for therapeutic purposes. They had some problems when they used their orthosis in the community. The problems

Orthosis	Energy consumption ($V O_2$ /kg/min)	Energy cost ($V O_2$ /kg/meter)	Walking velocity (m/s)
RGO	11.44 (±1.85)	0.81 (±0.34)	0.27 (±0.11)
Traditional HKAFO	21.1 (±3.08)	0.54 (±0.12)	0.68 (±0.20)

Table 2.12: The results of the research done by Cudderford et al (1997)

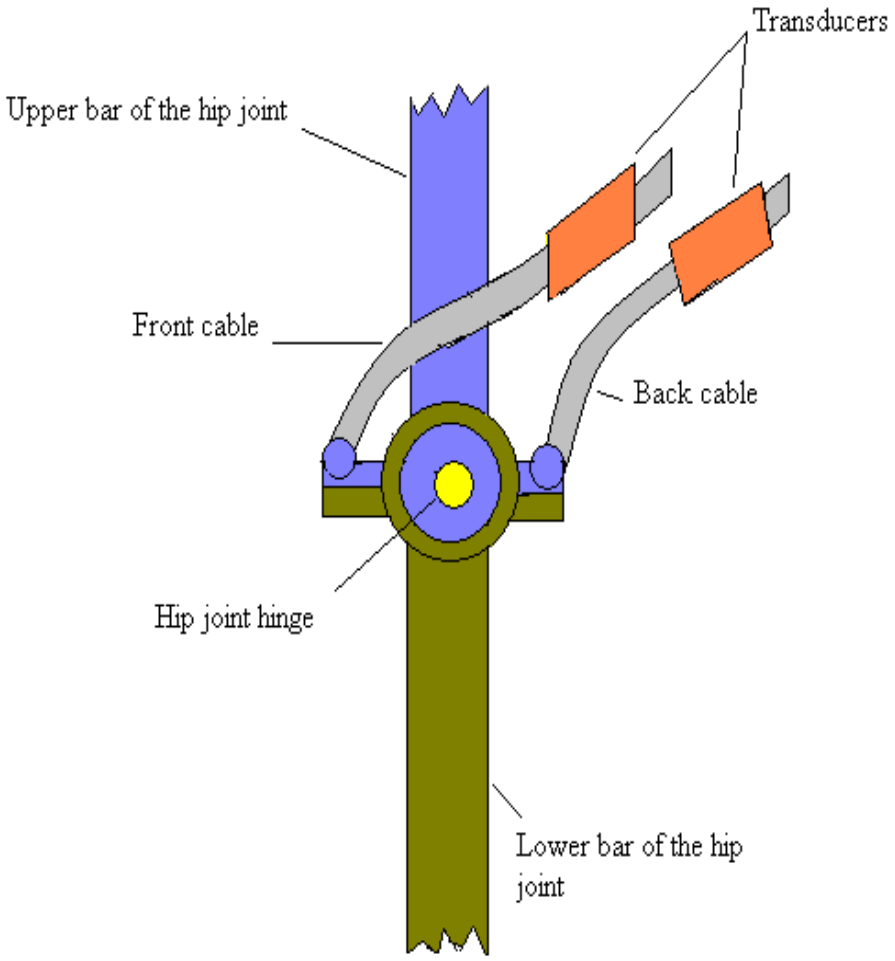


Figure 2.36: The sketch of the hip joint of the RGO orthosis with transducers used in the research carried out by Dall (2004)

with driving and using public transportation systems were the two most common issues mentioned by the users.

2.12.2.2 Evaluation of the functional performance of SCI individuals walking with the RGO orthosis

The first research on the performance of the SCI subjects while walking with the RGO was done by Douglas et al (1983). They mentioned in this research that the brace was successfully fitted on 138 patients having disorders such as spina bifida, paraplegia, cerebral palsy, multiple sclerosis, muscular dystrophy, and sacral agenesis. It was found that adults, paralyzed from spinal cord injury accepted this orthosis because it was more energy efficient than the conventional orthoses. They were able to walk on average 304.8 metre with no more than two 30 seconds rest periods.

Energy consumption in children with myelomeningocele during walking with the traditional HKAFO and the RGO was evaluated by Cuddeford et al (1997). This research was done on 26 children with myelomeningocele, 15 of them were selected to wear RGO and 11 used a traditional HKAFO orthosis. The average velocity of the RGO users was 0.27 m/s compared to 0.68 m/s for those who used the HKAFO orthosis. There was a significant difference between the energy costs during walking with two orthoses. Some results of this research are shown in table 2.12. There was no information regarding the gait parameters used in this research however, since the subjects walked with a swing through gait pattern with the HKAFO orthosis, more force was applied on their upper limbs in contrast to that in walking with the RGO orthosis.

Dall (2004) carried out research to check the magnitude of the forces applied at the front and back cables of the LSU RGO orthosis during paraplegic walking and then calculated the moments applied on the hip joint. To measure the cable tension, special transducers were embedded between the cables and the hip joint attachments,

figure 2.36. Six paraplegic subjects with lesion levels between C_5/C_6 and T_{11}/T_{12} participated in this study. The magnitude of the forces and moments of both cables was evaluated during swing and stance phases. The result of this study showed that the role of the back cable is more important than that of the front cable during walking especially during the double limb support period.

In four of six subjects the front cable was not used (the force recorded was zero). In the other two subjects the moments produced by this cable varied between 0 and 5 Nm. In double limb support phase, the back cable was in tension between 97% and 100% of the stance phase; but it was in tension from 40% to 90% of the swing phase for all subjects. The maximum moment generated by this cable, according to the result of this research was in the double limb support and it varied from 12 to 35 Nm. In contrast, it was between 8 and 14 Nm in the swing phase of gait. The flexing moment around the hip joint in normal subjects as cited by Dall from Winter (1991) is around 40 Nm, so the moment applied on the front cable during swing phase is very low to produce any motion (Dall et al, 1999, Dall, 2004).

It was expected that the reciprocal cables in the RGO orthosis transmit the motion from one side to other side. This means that the extension of one side produces flexion in the contralateral side (Douglas et al, 1983, Yongue et al, 1984). However, the results of the research done by Dall et al (1999) showed that the tension developed in the front cable is significantly small. However, the back cable is in the tension for the most parts of the stance and swing phases. Moreover, the tension developed in the back cable is not sufficiently high to force the legs to move.

Orthosis	CTFI (N.s)	CPF (N/BW) in stance phase	CPF (N/BW) in swing phase	Walking speed (m/s)
ARGO (6 degrees adduction)	0.59± 0.12	0.39 ±0.05	0.43± 0.02	0.29± 0.09
ARGO with 0 degrees abduction	0.57± 0.12	0.36± 0.04	0.4 ±0.02	0.28± 0.09
ARGO with 3 degrees abduction	0.56± 0.13	0.36± 0.04	0.41 ±0.03	0.28± 0.11
ARGO with 6 degrees abduction	0.59± 0.21	0.33± 0.07	0.40± 0.07	0.26± 0.11

Table 2.13: The results of the research done by Ijzerman et al (Ijzerman et al, 1997b)
CTFI = Crutch Time Force Integral, CPF= Crutch Peak Force

2.12.2.2 Evaluation of the functional performance of SCI individuals walking with the ARGO orthosis

The first research which focused on the performance of a paraplegic subject during walking with the ARGO orthosis was carried out by Jefferson and Whittle (1990). The results of this research showed that the performance of the ARGO was not as good as the HGO orthosis. The results of this study have already been shown in tables 2.7 and 2.8 and discussed.

In other research carried out by Ijzerman et al (1997b) the effects of frontal alignment in the ARGO was evaluated on the gait performance of paraplegic subjects. Five paraplegic subjects with lesion from levels T_4 to T_{12} were selected for this study. The results of this study showed that incorporating an abduction angle in the alignment of the ARGO increases the functional performance of the orthosis. Table 2.13 shows some results which were derived from this study.

The effect of the Bowden cable of the ARGO on the walking performances of paraplegic subjects was analyzed by Ijzerman et al (1997a). Six paraplegic subjects were selected for this study with lesion levels between T_4 and T_{12}. The average walking speed with the ARGO and NRGO (ARGO without the cable) were 0.24 and 0.23 m/s, respectively. The mean difference in oxygen cost in walking with the NRGO varied from 25% higher to 17% lower than that of the ARGO. There was no significant difference between the performances of the two orthoses during walking of the participants. For participants with higher lesion level, the oxygen consumption in the NRGO was nearly 40% higher than the ARGO. The walking speed of the participants with the NRGO was slower than that of the ARGO.

However, for those with lower lesion levels, their performance was better during walking with the NRGO orthosis. According to the results of this research, paraplegics with higher lesion levels could benefit less from the NRGO orthosis than those with lower lesion level. For higher lesion levels the motion of the hip joint must be more limited in order to increase the stability of the participants during walking. The results of this research showed that the effect of using reciprocal cables in the ARGO orthosis on the walking performance is not as important as expected (Ijzerman et al, 1997a).

In other research carried out by Baardman et al (1997) the influence of using Bowden cable in the ARGO on standing of paraplegic subjects was evaluated**.** Six paraplegic subjects participated in this study. The standing performances of the participants with two types of the ARGO, with removed Bowden cable (A_GO) and the ARGO, was analyzed after 4 weeks training programme. There was no difference between the functional performances of the two orthoses in standing of the subjects. The mean COP anteroposterior ranges were 37.94 and 35.22 millimetres for the A_GO and the ARGO orthoses, respectively. In the mediolateral direction the ranges were 34.53 mm for the A_GO and 41.72 mm for the ARGO orthosis. According to the results of this research, using the back cable in the ARGO does not have a significant influence on standing stability (Baardman et al, 1997).

The effect of the lesion level on the gait performance of the SCI subjects was examined by Kawashima et al (2003). Ten paraplegic subjects with a complete injury at thoracic levels (T_5 to T_{12}) were selected for this study. All participants underwent 10 weeks of training using the ARGO. The mean walking speed of the participants during walking with the ARGO, according to the results of this research was 19.88 m/min. The results of this research showed that the slower gait speed and higher energy cost of the patients with a high lesion level can be attributed to the limited range of motion of the hip joint. The mean values of the hip joint range of motion was 45 degrees (Kawashima et al, 2003).

In summary, the review of the above three papers indicated that the performance of paraplegic subjects in walking with the ARGO orthosis, aligned in a slight abduction, was significantly better than that with the orthosis without abduction. The effect of the reciprocal cable on the standing stability and gait performance is not as supposed to be. There was no difference between the energy consumption of the subjects in walking with the ARGO orthosis with and without cable. However, it can be concluded that SCI subjects with a higher level of lesion should use the orthosis with the cable.

2.12.3 Evaluation of the Functional Performance of the SCI Individuals During Walking with the Other Types of Orthoses

The HGO, RGO, and ARGO orthoses are three commonly used orthoses for paraplegic subjects. Some researchers have tried to design some orthoses to improve the function however, the final results was not successful. The design of some mechanical orthosis such as the WO (Walkabout Orthosis) and MLO (Medial Linkage Orthosis) orthoses improved the donning and doffing of the orthoses by the subjects however, it decreased the function of the subjects during walking (Harvey et al, 1997). Using some mechanisms, such as the sliding mechanism to decrease the height discrepancy between the hip joints (mechanical and anatomical ones) may improve the performance of the subjects during walking on the level surface however, it decreases the performance of the paraplegics in walking on uneven surface (Middleton et al, 1998). Moreover, it decreased the cosmesis of the orthosis and the willingness of the subjects to use the orthosis. Using other types of mechanisms such as, attaching the hip and ankle joints to each other, had no effects on improving the function of the orthosis however, it obviously decreased the cosmesis of the orthosis (Genda et al, 2004).

The performance of the externally powered orthoses is not as good as the commonly used mechanical orthoses. Moreover, the patients have to use the orthosis which is heavy and more difficult to donn and doff independently (Yano et al, 1997,

Kawashima et al, 2003, Ragnarsson et al, 1975). Sometimes they have to charge the batteries regularly which take a lot of time and need special facilities (Ohta et al, 2007).

In the hybrid orthosis (combination of the mechanical orthosis with functional electrical stimulation as discussed before) the main emphasis of the designers was to improve the function of the orthosis by using knee flexion, ankle and knee motions and by increasing the stiffness of the orthosis. The results of different research showed that in some of them the performance of the subjects did not improve significantly, however the style of walking improved as the patients had knee flexion during swing phase (Baardman et al, 2002a, Baardman et al, 2002b, Greene and Granat, 2003). Although using FES with the HGO orthosis improved the performance of the subjects in using the orthosis however, they had some problems which include (Stallard and Major, 1993):

a) They had problems with using the electrodes in suitable locations
b) They achieved inconsistent stimulation
c) Donning and doffing the orthosis with stimulation electrodes was very time consuming
d) Cross stimulation of abdominal muscles occurred

In conclusion, the performance of paraplegic subjects in using commonly used orthoses such as the HGO, RGO and ARGO orthoses is better than the hybrid and externally powered orthoses.

2.13 COMPARISON BETWEEN THE DIFFERENT LOCOMOTION MECHANISMS SELECTED BY THE SCI INDIVIDUALS

The main locomotion methods which are selected by SCI individuals are using orthoses and wheelchairs. Both of them have some advantages and disadvantages.

Although these subjects have to use orthoses in order to maintain their health and to improve the functions of various organs, they may prefer to use wheelchairs as a main mode of the locomotion.

2.13.1 Comparison Between the Various Orthoses Used by the SCI Individuals

As was mentioned in the previous part of this thesis, a variety of orthoses have been designed for SCI subjects in order to stand and walk. However, their walking performance significantly differs during walking with various orthoses. In order to improve the performance of these subjects, we need to compare various orthoses according to gait, stability and energy consumption parameters.

Many of the SCI subjects cannot use AFO orthoses. For the specific 'boot' orthosis designed for paraplegic subjects by Kent (1992) a lot of contraindications were considered in selecting the patients who could use the orthosis. The performance of AFO orthoses for paraplegic subjects is significantly lower than that with other available orthoses (Merkel et al, 1984, Huang et al, 1979, Waters and Lunsford, 1985).

The stability of SCI subjects in standing with traditional HKAFO orthoses is better than with the KAFO orthoses however, the walking speed and stride length of the subjects in walking with the KAFO is greater than those with traditional HKAFO orthoses. Most paraplegic subjects walk with the traditional HKAFO orthosis with swing through gait mechanism however, they can walk with the new designed HKAFOs by a reciprocal gait pattern. Although, the walking speed, stride length and energy cost are higher with swing through gait mechanism than with reciprocal gait (Cuddeford et al, 1997), the force which is applied on the upper limb through the crutch is higher in swing through gait than with reciprocal gait (Tashman et al, 1995, Requejo et al, 2005, Slavens et al, 2007).

Amongst a variety of the new orthoses designed for paraplegic subjects, the HGO orthosis has the best performance. In comparison with the RGO paraplegic subjects walk with the HGO faster and more comfortably (Banta et al, 1991). In the HGO orthosis the limbs remains parallel during walking. Moreover, the maximum peak value of the vertical displacement of the pelvis during walking with the HGO is half of that with the RGO and ARGO orthoses (Jefferson and Whittle, 1990). The main reason for better performance of the HGO in contrast to other orthoses is its highest lateral rigidity (Stallard and Major, 1993).

2.13.2 Comparison Between the Performance of SCI Individuals During Ambulation with Orthoses and Wheelchairs

There is no doubt that ambulation with wheelchair has less energy consuming than walking with orthosis. In research carried out by Cerny et al (1980) eleven SCI subjects were selected to walk with KAFO orthoses, with swing through gait pattern, and ambulate with wheelchair. The amount of energy consumption of the subjects, who used orthosis as the main type of locomotion system, differed from those who chose wheelchair. Those who walked with orthoses could use wheelchairs and orthoses better than those who used only wheelchair. The mean values of the speed in using orthoses and wheelchairs were 32.4 and 84.9 m/min, respectively. The oxygen uptake in using orthosis was 0.99 ml/kg/m compared to 0.205 ml/kg/m for using wheelchairs. The results of this research showed that walking with orthoses was so demanding because it required a lot of energy and oxygen.

In another research project by Water and Lunsford (1985) the performance of paraplegic subjects with orthoses and wheelchairs was compared. A group of normal subjects who walked with a comfortable speed was also included in this study for comparison purpose. The handicapped subjects in this research used different types of orthoses such as, AFO and KAFO orthoses. The results of this research showed that in contrast to ambulation with wheelchair, walking with orthoses is high demanding in terms of energy consumption. There was no significant difference

Parameters	Paraplegics using wheelchair	Paraplegics walking	Normal subjects
Heart rate (beats/min)	123 ±25	138 ±27	100± 14
Speed (m/min)	72 ±17	27 ±17	80 ±11
Oxygen rate (ml/kg/min)	11.5± 3.1	14.5± 4.3	11.9 ±2.3
Oxygen cost (ml/kg/m)	0.16± 0.03	0.74± 0.5	0.15 ±0.02

Table 2.14: Some results of the research done by Waters and Lunsford (1985)

between energy consumption of paraplegic subjects in using wheelchair and normal subjects (walking). So using a wheelchair is highly efficient means of locomotion with average speed, rate of oxygen uptake which is nearly the same as that in normal subjects (Waters and Lunsford, 1985). Table 2.14 shows some results of this research.

2.14 PROBLEMS ASSOCIATED WITH USING DIFFERENT AMBULATION METHODS

Patients who suffer from SCI have some problems during walking with orthoses or during ambulation with wheelchairs. The main reason for using orthoses is only for therapeutic exercises. However, many of SCI individuals do not use their orthoses regularly. According to the results of various research studies, SCI individuals use their orthoses especially for standing, but not for performing more purposeful tasks.

The main problem which was stated by paraplegic patients is that walking with an orthoses is a demanding task in terms of energy expenditure and the mechanical work required. It is the main reason for avoiding the use of orthoses. Actually the energy consumption in utilization of the orthoses is not high when it used only for standing however, for walking energy expenditure is high and patients have unsustainable fatigue after walking for a short distance.

Another problem mentioned by SCI individuals was related to the cosmesis of the orthosis. The results of the research carried out by Whittle et al (1991) showed that although the HGO orthosis seems to have a better functional performance than the RGO, it was not selected by many patients since it is not as cosmetic as the RGO orthosis.

Donning and doffing of the orthosis is another important problem associated with orthosis usage. Hawran and Biering (1996) did research by following up 45 SCI patients for 10 years. He found that only 3 out of 45 patients continued using their orthoses. The reason that they mentioned for withdrawing from the use of the orthoses was a considerable of time that they needed to spend in putting on and taking off the orthosis (Hawran and Biering, 1996).

The high percentage of the force applied on the upper limb musculature is another issue that affects the use of orthoses. Depending on the style of walking between 30 % and 55% of BW is applied on the crutch during walking (Requejo et al, 2005, Major et al, 1981, Crosbie and Nicol, 1990, Melis et al, 1999). This high value of force, which is transmitted to the upper limb joints, increases the incidence of some diseases and also shoulder pain.

Another problem which is mentioned regarding unsuitability of the orthoses is related to the fear of falling, especially during performing hand functions. The stability of the subjects during standing with orthoses must be high enough to allow them to do different hand functions without the need to apply a lot of force on the crutches.

Although, the energy expenditure of wheelchair users is nearly the same as that of normal subjects, there are a lot of problems associated with wheelchair use. Bone osteoporosis, joint deformities, problems of musculoskeletal systems are some problems which were mentioned in the literature (Goemaere et al, 1994, Sabo et al, 2001, Rosenstein et al, 1987, Eng et al, 2001, Dunn et al, 1998, Mazur et al, 1989, Rowley and Edwards, 1987, Douglas et al, 1983). Moreover, they have a lot of problems with architectural features from landscapes and buildings. Another problem associated with wheelchair use is shoulder pain and decreasing the range of motion of the upper limb joints (Dalyan et al, 1999). More than 30% of the

wheelchair users have shoulder pain and a decrease of shoulder range of motion (Subbarao et al, 1995). Carpal tunnel syndrome is another condition which commonly happens in these patients as a result of repeated movement with their wrist (Dalyan et al, 1999).

2.15 SUMMARY

The incidence of the SCI varies between 12.7 and 59 new cases per million each year in the different countries. It is estimated that in the USA between 183,000 and 230,000 are living with SCI, compared to 40,000 in UK. These individuals lose the abilities to stand and walk normally and have to use different transportation methods. The two main types of ambulation methods selected by the SCI subjects are orthoses and wheelchairs.

Although, they can mobilize with wheelchairs using the same energy consumption and speed as normal subjects, they have some problems in using wheelchairs, such as restriction to mobility from architectural features from the landscape and buildings. Some health issues such as bone osteoporosis, joint deformities, decubitus ulcers, shoulder pain, and wrist pain are the main condition associated with wheelchair use.

In contrast to mobilization with wheelchairs, walking with orthoses has some benefits for the SCI individuals. Prevention of bone fractures and osteoporosis, improving the functions of the cardiovascular and digestive systems, prevention of joint deformities, and improving the psychological health are some of the benefits of walking with orthoses.

A variety of orthoses have been designed to enable SCI individuals to stand and walk again, which use different mechanisms to stabilize the paralyzed joints and to

move the limbs forward during walking. Different sources of power such as pneumatic and hydraulic pumps, muscular force resulting from electrical stimulation, and electrical motors have been attempted for walking. However, the results of different research have shown that the performance of the SCI individuals during walking with the mechanical orthosis is better than other types of orthoses.

Different types of mechanical orthoses are available to help these subjects to stand and walk again however, the two most common ones are the HGO and RGO. The performance of paraplegic subjects while using orthoses was evaluated by gait analysis, energy consumption tests and stability analysis during quiet standing and during performing hand functions. According to the results of different research the performance of SCI individuals during walking with the HGO is better than that of other available orthoses. The main reason is the greatest lateral rigidity of this orthosis in contrast to other available mechanical orthoses.

Although walking with orthoses brings a lot of benefits to these subjects, they prefer to use wheelchairs as a main type of the ambulation method. Many of the SCI individuals withdraw from using their orthoses after they obtain it. The patients reported some problems such as, walking with orthoses is a demanding task in terms of energy expenditure and the mechanical work required, poor cosmesis of the orthoses, especially the HGO, donning and doffing the orthosis that takes considerable time and sometimes they need assistance, and experience problems related to the fear of falling.

In order to improve the performance of SCI subjects during walking and to increase their willingness to use orthoses, the aforementioned problems need to be solved. The design of a new orthosis must allow easy donning and doffing of the orthosis by the users, have enough stability during walking and standing, ability of changing the alignment of the orthosis to suit the patient's need, have modular structure, have

maximum lateral rigidity, be cosmetic, decrease the energy consumption during walking, and apply the smallest possible force on the upper limb musculature during walking.

It was planned to test the new design of the orthosis on normal subjects. The description of this test is given in chapter 4.

CHAPTER 3: DESIGN OF A NEW RECIPROCAL GAIT ORTHOSIS

The previous chapters highlighted the problems associated with paraplegic subjects during walking and standing with different orthoses. The design of any new orthosis must be directed towards solving the problems associated with available orthoses which include:

a) Independent donning and doffing is difficult
b) Energy consumption during walking is high
c) Walking speed is slow compared to normal walking
d) Transporting the orthosis from place to place is difficult due to its weight and size
e) Changing the alignment of the orthosis components according to patients' need is difficult
f) Cosmesis is poor
g) The force applied on the upper limbs is high

3.1 THE AIMS OF THIS PROJECT

The main aim of this project was to design an orthosis to overcome some of the problems associated with the previous designs. Further aims were to evaluate the performance of this orthosis during walking of normal subjects wearing the orthosis and to develop a benchmark which represents the best performance that can be achieved by SCI subjects in walking with the orthosis. It was also an aim to compare the performance of normal subjects walking with this orthosis with that achieved with the HGO, which is the best available orthosis for function during walking (Winchester et al, 1993, Stallard and Major, 1998), and also to measure the loads applied on the lateral bar of the orthosis during walking.

3.2 DESIGN SPECIFICATION

The new orthosis was designed based on the same concept as that of the HGO orthosis. No connecting cable between the hip joints on the left and right sides, so they could move independently, were to be used. The new orthosis was designed with a safety factor of 3 on the yield strength or 0.2% of proof strength of the material which was also selected for designing the RGO orthosis by Douglas et al (1983). Introducing some degree of abduction in the orthosis, depends on the patient's need, and use of special components to change the alignment of the orthosis, when worn by the subject, were the main features of this orthosis.

The modularity of the orthosis should allow changes of the alignment of the components in three planes to be made. The hip joint of this orthosis was to have two hinges, the first one (distal one) is used for walking and the second one (proximal one) is used for sitting. A secure locking system would prevent the hip joint motion around the second hinge during walking. The range of motion of the hip joint during walking should be capable of being changed according to the patient's need.

The rigidity of the orthosis should be high in order to resist the adducting moment applied to the orthosis during walking. The knee joint should be capable of adjustment so that it can be fitted to patients with up to 15 degrees of flexion contracture. The orthosis should have an open structure above the knee joints, the same as that in the ARGO which has no medial thigh bars, in order to facilitate donning and doffing and to improve the cosmesis of the orthosis. The AFO components of the orthosis were to be custom moulded and intimately fitted on the leg. This would improve the cosmesis of the orthosis and allow the patients to use any suitable shoes they desire.

The orthosis is to be made of three main parts: the AFO's, the Torso section, and the lateral bars with the hip and knee joints. Special attachment components are to be inserted above the hip and below the knee joints for changing the alignment of the orthosis in different planes. The main parts of the orthosis are to be connected to each other by using special locking pin mechanisms. This is to be done by the subjects after receiving training. It should also possible to don and doff the orthosis with the same manoeuvre as used for the ARGO.

3.3 ESTIMATION OF THE JOINT MOMENTS AND FORCES

Before proceeding with the detailed design of the mechanism, an estimate of the forces and moments that could be applied to the mechanism during walking was made. They would give an indication of the conditions under which the mechanism would have to operate which will influence the type of selected material and the size of the components.

The magnitude of the force applied on the leg during walking with the orthosis depends on the type of the orthosis (Ferrarin et al, 1993, Nene and Major, 1987, Tashman et al, 1995). The maximum value of the vertical component of the ground reaction force during walking of an adult subject with an HGO orthosis was reported to be 104% of BW with an orthosis (Ferrarin et al, 1993). In research done by Greene, the mean value of the vertical ground reaction force was reported to be 800 N. However, no information was given on the weight of the subject tested (Greene, 2002). Regarding the horizontal ground reaction forces which could be applied in the frontal and coronal planes during paraplegic walking, there was no information in the literature. However, during normal walking the mean values of the ground reaction force are 20% of BW for the anteroposterior force and 5% for the mediolateral force (Rose et al, 1994).

In various studies done on the evaluation of the walking performance of paraplegic subjects during walking with an HGO orthosis, the main emphasis of the researchers was to measure the magnitude of the adducting moment applied on the hip joint (combined anatomical and mechanical hip joint system) during walking. According to the results of the research done by Stallard et al (2003) the mean value of the adducting moment applied on the hip and knee joints in the HGO orthosis were 123.3 and 42.9 Nm, respectively. In another paper they have shown that the maximum value of the adducting moment for the heaviest subject attending the clinic that walked with the HGO orthosis was 128 Nm (Stallard et al, 2001).

The magnitude of the flexing moments applied on the hip and knee joints were other important parameters which were used to design the orthosis. The mean value of flexing moment of the hip and knee joints was 23.9 Nm and 36 Nm, respectively (Stallard et al, 2003). In the research carried out by Greene (2002), some Parawalker data obtained from ORLAU were used for a simulation of a model. The mean value of the flexing moments applied on the hip and knee joints according to the ORLAU data, as was shown in Greene's thesis, were 0.7 and 0.1 Nm/kg mass of subject, respectively (Greene, 2002).

In other research done by Johnson (Johnson et al, 2004) the hip, knee and ankle moments were collected during walking of paraplegic subjects. Thirteen subjects with different lesion levels participated in this study. There is no information about the types of orthoses used neither by the participants nor of the type of walking studied in this investigation. The results of this research, which was normalized according to the body weight and leg length, showed that the hip, knee and ankle moments varied from 0.031 to 0.09, from 0.031 to 0.06 and from 0.091 to 0.12 Nm/N body weight/m leg length, respectively. The mean value of velocity in walking with the HKAFO was 0.19 m/s (Johnson et al, 2004).

Parameter	Derivation	Value
Height	H	1.75 m
Weight	W	784 N
Length of the trunk	0.288H	0.506 m
Length of the thigh	0.245H	0.43 m
Length of the shank	0.285H	0.5 m
Length of the foot	0.152H	0.267 m
Weight of the user and total orthosis	W+ 124.5 N	914.1 N
Weight of one thigh and orthosis	0.1 W +13 N	91.4 N
Weight of one shank and orthosis	0.061W+14 N	61.8 N
Weight of total leg and orthosis	0.161 W+27 N	165 N
Distance of COM of thigh from the hip joint	0.106H	0.186 m
Distance of COM of shank from the knee	0.173H	0.304 m
Radius of gyration of thigh about the hip	0.132H	0.232 m
Radius of gyration of shank about the knee	0.209H	0.367 m
Moment of inertia of orthotic knee joint	0.017H	0.052 kgm²

Table 3.1: The parameters used in the research by Dall (adapted from Dall 2004), where, H and W stand for height and weight, respectively

Dall (2004), in her research calculated the applied moment around the hip joint for a base model. According to the results of her research the applied moment around the hip and knee joints during walking of a paraplegic subject were:

a) 70 Nm at the hip joint resisting flexion or resisting extension

b) 165 Nm at the knee resisting flexion

c) 270 Nm at the knee resisting extension

It should be mentioned that these values were modified by Dall by a number of intermediate factors which could increase or decrease the magnitude of the applied moments. The parameters used in this model were selected from various research papers. The parameters for the length of the segments and centre of body mass were selected from research done by Tilley (Tilley, 1993) and Winter (1991). This model was done for a subject with 1.75 m height and 784 N weight (Dall, 2004). The parameters of this model are shown in table 3.1. The result of the model was in reasonable agreement with another model described in the literature by Tashman et al (1995). The maximum difference between the results of these two models was 20 Nm.

Thus, the maximum values of the vertical and anteroposterior components of ground reaction force used for designing the new orthosis were 104% and 15% of BW, respectively. The adducting moment applied on the hip and knee joints were 128 and 42.9 N.m, respectively. The flexing moment applied on the knee joint was 278 N.m. However, the flexing moment of the hip joint for 25 degrees of flexion had to be determined.

Parameter	Derivation	Value
Height	H	1.8 m
Weight	W	856.5 N
Length of the trunk	0.288H	0.518 m
Length of the thigh	0.245H	0.441 m
Length of the shank	0.285H	0.513 m
Length of total leg	0.53H	0.954 m
Length of the foot	0.152H	0.274 m
Weight of the user and orthosis	W+ 124.5 N	981.0 N
Weight of one thigh and orthosis	0.1 W +13 N	99.0 N
Weight of one shank and orthosis	0.061W+14 N	66.36 N
Weight of one leg and orthosis	0.161 W+27 N	165.36 N
Distance of COM of thigh from the hip joint	0.106 H	0.19 m
Distance of COM of shank from the knee	0.173 H	0.311 m
Distance of COM of the leg from the hip joint	0.237 H	0.426 m

Table 3.2: Parameters used to calculate the applied flexing moment during walking

3.3.1 Determination of the Flexing Moment of the Hip Joint to Produce 25 Degrees of Flexion

The range of flexion and extension of the hip joint during walking of a paraplegic subject with the HGO orthosis with reciprocal gait pattern was reported to be 15 and 21 degrees, respectively (Jefferson and Whittle, 1990). In order to design an orthosis that will be suitable for a large number of SCI individuals resulting in adequate functional capabilities, it was required that the range of motion of the hip joint be between that of normal subjects and paraplegic subjects. It was planned that the hip joint in the new design would allow 25 degrees of flexion and 10 degrees of extension. It was clear that the flexion/extension moments around the hip joint depend on the range of motion of the hip in the sagittal plane. It was thus necessary to calculate the moments which would be applied on the mechanical hip joint with 25 degrees of flexion. The hip joint range of motion in the sagittal plane cannot influence the adducting moment applied on this joint during walking. So the maximum value of the adducting moment mentioned in the literature could be used for designing the new orthosis without any limitation.

It was assumed that the maximum weight (with orthosis) and height of subjects in this project were to be 981 N and 1.8 m, respectively. Some parameters such as the lengths of the segments, mass and the position of centre of gravity, relative to the height and weight of the body were derived from Winter (1991). Table 3.2 shows the parameters used in this project to calculate the moment applied to the orthotic joints during walking with the orthosis. In this stage it was assumed that the location of the COG of the thigh and shank with the orthosis would be at the same level as those in the human body without the orthosis. It was planned that the motion of the knee joint was to be completely restricted during walking and it was to be locked in an extended position.

Figure 3.1 shows the free body diagram of the leg when the hip joint flexes 25 degrees. It was clear in the literature that during double limb support, with both feet on the ground, the moment applied on the hip joint was a maximum (Dall, 2004). So in that stage the flexion moment around the hip joint according to the data collected from the literature could be determined as follows.

$$\sum M = 0$$

$$(F_{x1}L_l\cos\theta) - (F_{y1}L_l\sin\theta) + (W_lD_l\sin\theta) + M_{zh1} = I \cdot \alpha \qquad \text{Eq. 3.1}$$

Where L_l, W_l and D_l, I and α are the length of the leg, the weight of the leg , the distance of leg COG from the hip joint centre, mass moment of inertia and angular acceleration of the leg, respectively . Since the speed of walking is not high, especially in the stance phase, the angular acceleration was assumed to be zero.

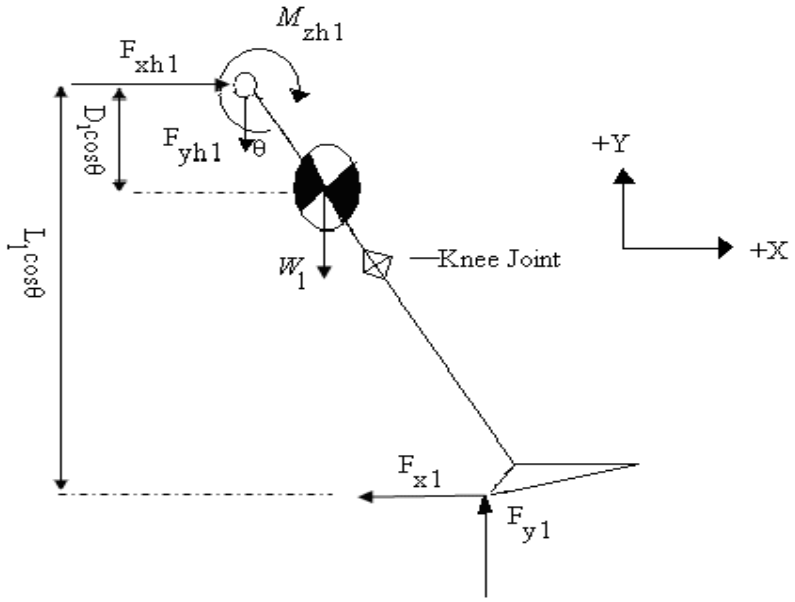


Figure 3.1: Free body diagram of subject/orthosis up to the first hip joint centre

D_l is the distance of leg COM from the hip joint centre, L_l is the length of the leg

W_l is the weight of leg with orthosis

$$M_{zh1} = (F_{y1}L_l\sin\theta) - (W_lD_l\sin\theta) - (F_{x1}L_l\cos\theta) \quad \text{Eq. 3.2}$$

By inserting the values of L_1, W_1 and D_1, from table 3.2, the above equation could be reduced as follows:

$$M_{zh1} = (0.954F_{y1} - 70.44)\sin\theta - (0.954F_{x1})\cos\theta \quad \text{Eq. 3.3}$$

The maximum values of F_{x1} and F_{y1} are taken as 15% and 104% of BW, respectively (Rose et al, 1994, Ferrarin et al, 1993). So the flexion moment applied on the hip joint could be found as:

$$M_{zh1} = 902.95\sin\theta - 140.38\cos\theta \quad \text{Eq. 3.4}$$

Depending on the angle of flexion of the hip joint, the moments would vary. These are 50.42, 98.1, and 254.38 Nm if the angle of flexion at initial contact is 12, 15, and 25 degrees, respectively. In comparison with the data in the literature, which were related to the moment of the hip joint during paraplegic walking, with the hip joint flexion angle between 12 and 15 degrees, the results were in close agreement with them. According to Dall (2004) the flexing moment of the hip joint was 70 Nm, which is between the calculated values for 12 and 15 degrees. Johnson et al (2004) showed that the flexing moment of the hip joint varied between 0.031 and 0.09 Nm, which was normalized by body weight and leg length. For a body weight and leg length of 981.0 N and 0.954 m, respectively the applied moment was between 29.01 and 84.23 Nm. However, the hip joint of the new orthosis was designed to have 25 degrees of flexion. The flexing and adducting moments applied on the hip joint during walking were considered to be 254.38 and 128.0 Nm, respectively.

3.3.2 Determination of the Moments Applied on the Knee Joint During Walking

According to Dall (2004) the maximum values of the flexing moment at the knee joint is 270.0 Nm. However, Johnson et al (2004) suggested that it is between 0.031 and 0.06 Nm, which was normalized by body weight and leg length. For a body weight and leg length as 981.0 N and 0.954 m, respectively the maximum value of the flexing moment would be between 29.01 and 56.15 Nm. In another project undertaken by Stallard et al (2003) the main value of the knee flexing moment was 36.0 Nm. In order to design an orthosis according to the maximum values of the moments and forces, the highest value of the knee joint flexing moment was taken to be 270.0 Nm. It should be mentioned that the main reason that the flexing moment applied on the knee joint was more than that of the hip joint, was that the moment of the knee joint was calculated in terminal stance in contrast to that of the hip joint which was determined during heel strike.

The maximum value of the adducting moment applied on the knee joint according to the results of the research done by Stallard et al (2003) was taken to be 42.9 Nm.

3.3.3 Determination of the Magnitude of the Forces Applied on the Hip Joint Centres

The maximum values of the moments applied on the hip joint during walking were taken as 128.0 and 254.38 Nm for adducting and flexing moments, respectively. The structural stability of the orthosis was the main factor which resists the adducting moment during walking. However, the flexing moment is restricted by using a special screw (F_{x2}) which is located below the first hip joint and by a locking system which is located above the second hip joint centre. The flexion restriction screw was located 50 mm below the first hip joint centre, figure 3.2 and 3.3.

The force applied on the flexion restriction screw can be determined as follows:

$M_{zh1} = 254.38$ Nm

$M_{zh1} = F_{x2} 0.05$

$254.38 = F_{x2} 0.05$

$F_{x2} = 5087.6$ N

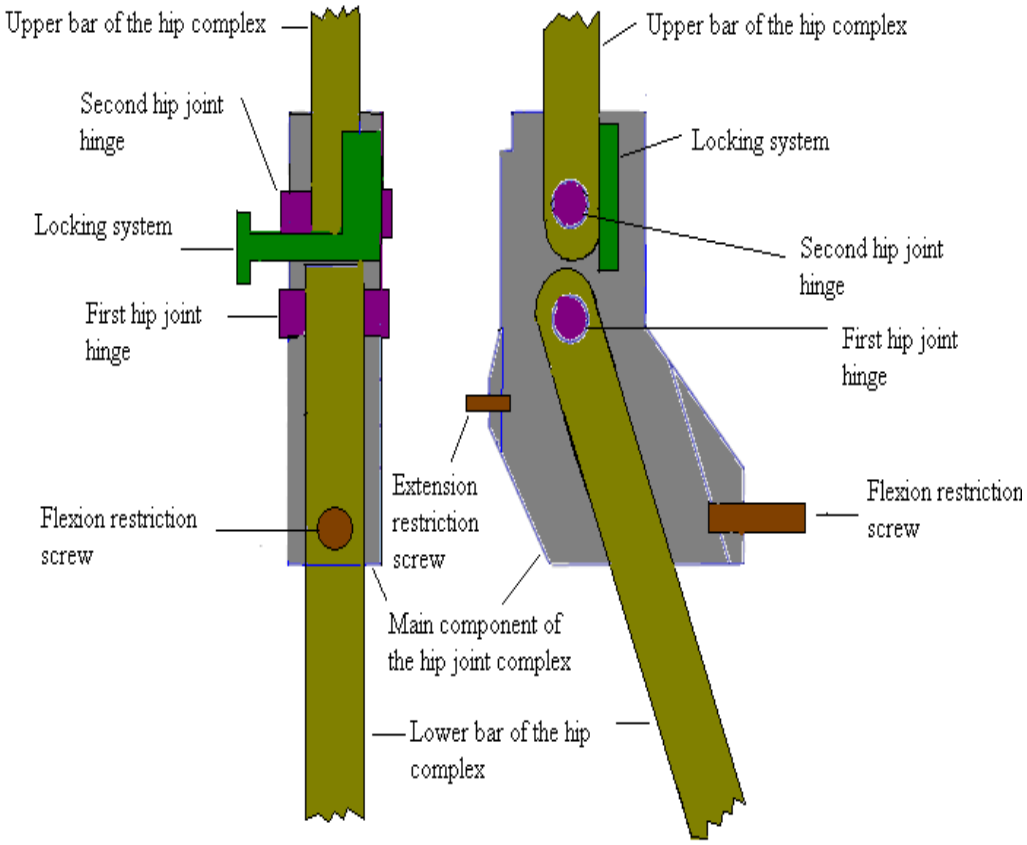


Figure 3.2: A simplified sketch of the hip joint complex

The flexing moment applied on the second hip joint axis is controlled by a locking system mechanism which worked by using a force couple (F_{x3}) with 40 mm lever arm. The force of the locking system was determined as follows:

$M_{zh2} = M_{zh_1} = 254.38$ Nm

$M_{zh2} = F_{x3} 0.04$

$254.36 = F_{x3} 0.04$

$F_{x3} = 6359.5$ N

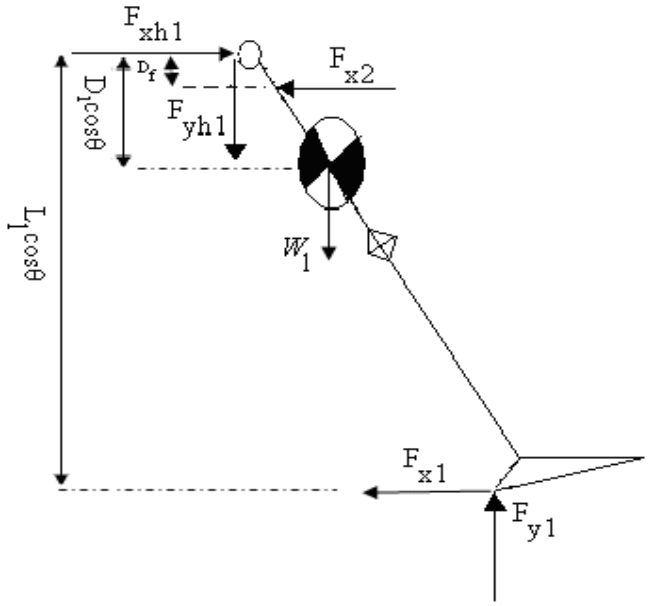


Figure 3.3: Free body diagram of the first hip joint centre

In which: F_{x1} and F_{y1} are the ground reaction forces applied on the anteroposterior and vertical directions, respectively

F_{xh1}, F_{yh1} are the force components applied on the first hip joint hinge in the anteroposterior and vertical directions, respectively

W_1 is the weight of the leg

D_1 and L_1 are the distance of leg COM from the hip joint centre and the length of the leg, respectively

F_{x2} is the force on flexion restriction screw

D_f is the distance between the flexion restriction screw and the first hip joint hinge

The force applied on the first hip joint hinge, figure 3.3, could be calculated as follows.

$$\sum Fx = 0$$
$$F_{xh1} - F_{x1} - F_{x2} = 0$$
$$F_{xh1} = F_{x1} + F_{x2}$$
$$F_{xh1} = 147.15 + 5087.6$$
$$F_{xh1} = 5234.75 \text{ N}$$

$$\sum Fy = 0$$
$$- F_{yh1} - W_l + F_{y1} = 0$$
$$F_{yh1} = F_{y1} - W_l$$
$$F_{yh1} = 1020.24 - 165.36$$
$$F_{yh1} = 854.88 \text{ N}$$

There is another force applied on the hip joint hinge in a mediolateral direction which results from the adducting moment. The stage which was selected for calculating the forces and moments applied on the hip joint in this project was the first period of the double limb support, which was shown in the paper of Butler et al (1984) as the second stage of walking cycle. Figure 3.4 shows the forces applied on the body during this stage.

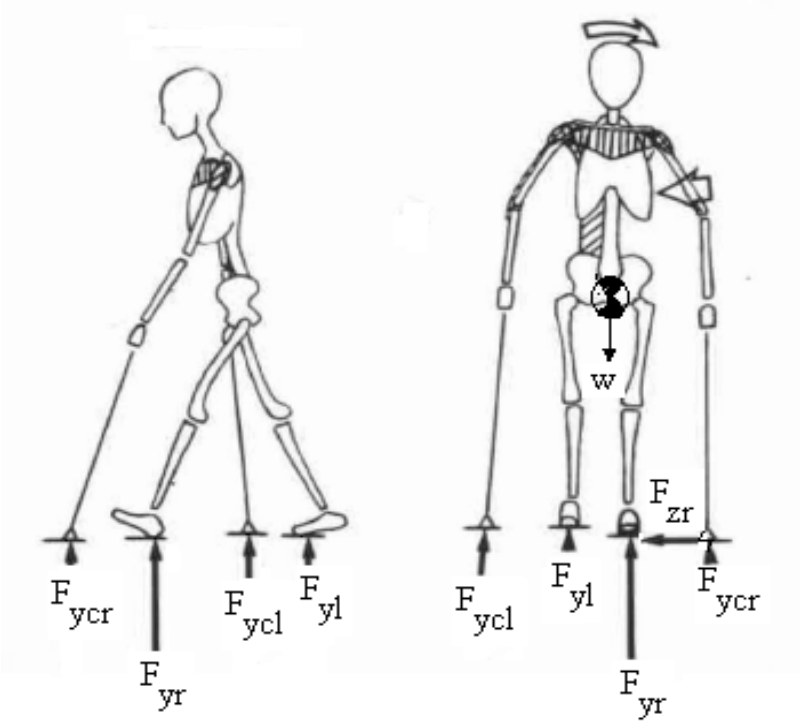


Figure 3.4: The force applied on the body during walking with the orthosis and crutches, second stage of the gait cycle, adapted from Butler et al (1984)

F_{yr}, F_{yl}, F_{ycr}, F_{ycl}, F_{zr}, W are the vertical forces applied on right foot, left foot, right crutch, left crutch, the mediolateral force applied on right foot, and the body weight, respectively.

The pattern of the forces applied on the feet and crutches during walking of a paraplegic subjects, taken from Nene and Major (1987), is shown in figure 3.5.

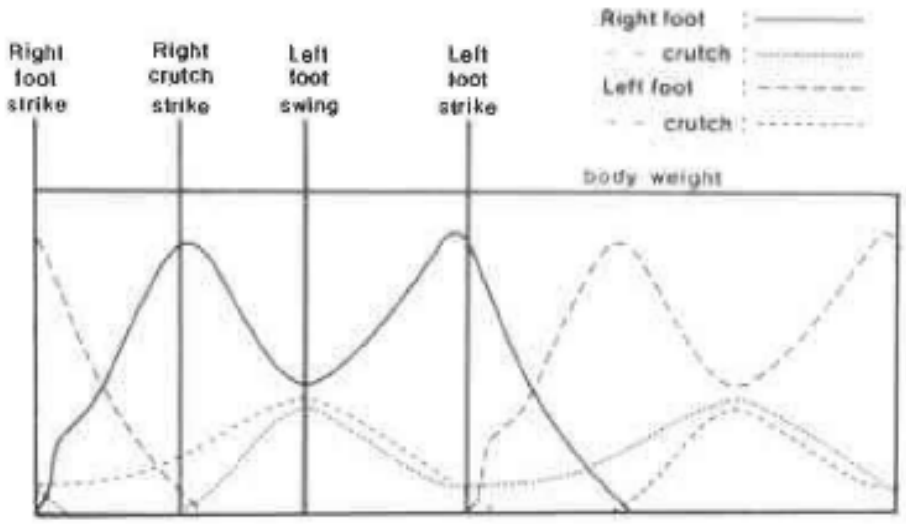


Figure 3.5: The pattern of the forces applied on the foot and crutches (adopted from Nene and Major (1987)

It was assumed that the forces applied on the right crutch and left leg were negligible. The distance between the left crutch and right hip joint centre was assumed to be 1.5 times the pelvic width (PW). The force applied on the left crutch was nearly 1/3 of BW (Butler et al, 1984). The body weight is applied through the midpoint of the pelvic width and produces an adducting moment. However, the left crutch force produces an abducting moment. The magnitude of the adducting and abducting moments produced by the body weight and left crutch force are equal. So the final free body diagram of the right leg which is separated at the hip joint can be shown as figure 3.6.

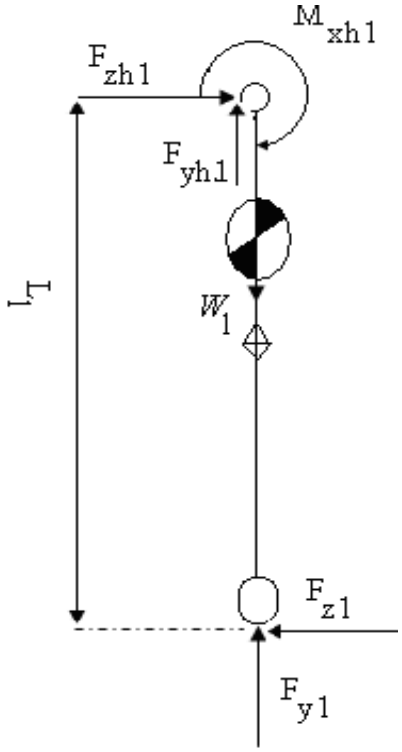


Figure 3.6: The free body diagram of the first hip joint in the coronal plane

where: F_{zh1}, F_{z1} and M_{xh1} are the first hip joint force in the mediolateral direction, mediolateral component of the ground reaction force and the moment applied on the hip joint around sagittal axis, respectively

$M_{xh1} = 128$ Nm

$M_{xh1} = F_{z1} 0.954$

$F_{z1} = 134.17$ N

$\sum F_z = 0$

$F_{zh1} - F_{z1} = 0$

$F_{zh1} = F_{z1}$

$F_{zh1} = 134.17$ N

The force applied on the second hip joint hinge, figure 3.7, can be calculated as follows.

$$\sum Fx = 0$$
$$F_{xh2} - F_{x1} - F_{x3} = 0$$
$$F_{xh2} = F_{x1} + F_{x3}$$
$$F_{xh2} = 147.15 + 6359.5$$
$$F_{xh2} = 6506.65 \ N$$

$$\sum Fy = 0$$
$$-F_{yh2} - W_l + F_{y1} = 0$$
$$F_{yh2} = F_{y1} - W_l$$
$$F_{yh2} = 1020.24 - 165.36$$
$$F_{yh2} = 854.88 \ N$$

The free body diagram of the second hip joint hinge in the coronal plane is the same as that of the first hip joint, so the mediolateral force applied on the second hip joint hinge would be the same as the first one (134.17 N).

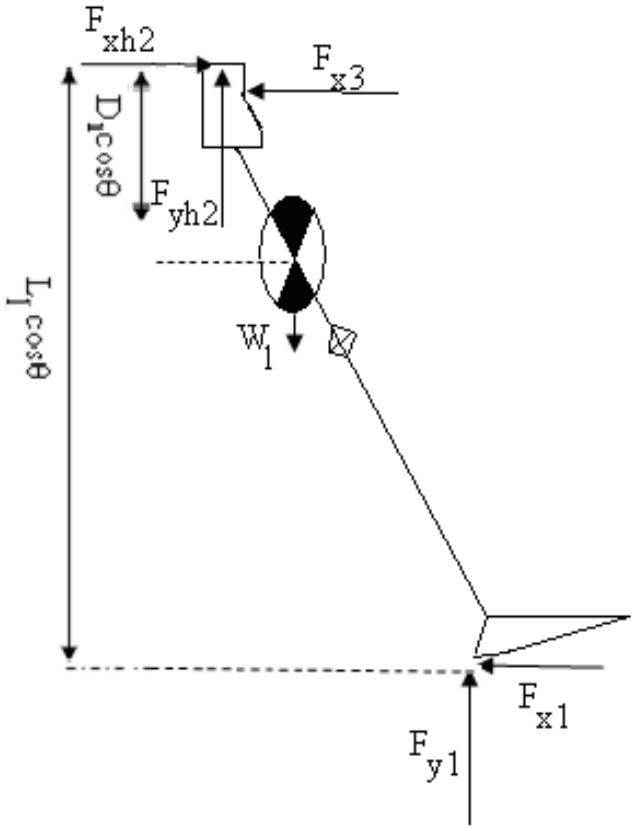


Figure 3.7: The free body diagram of the leg up to second hip joint centre

Where: F_{xh2}, F_{yh2} are the force applied on the second hip joint hinge on the anteroposterior and vertical directions, respectively. F_{x3} is the force of the locking system

3.3.4 Determination of the Magnitude of the Forces Applied on the Knee Joint Hinge

The maximum value of the flexing moment applied on the knee joint during walking was 270 Nm as was shown by Dall (2004). To secure the knee joint in an extended position during walking a special locking system was used which was located 2 cm above the knee joint hinge, figure 3.8.

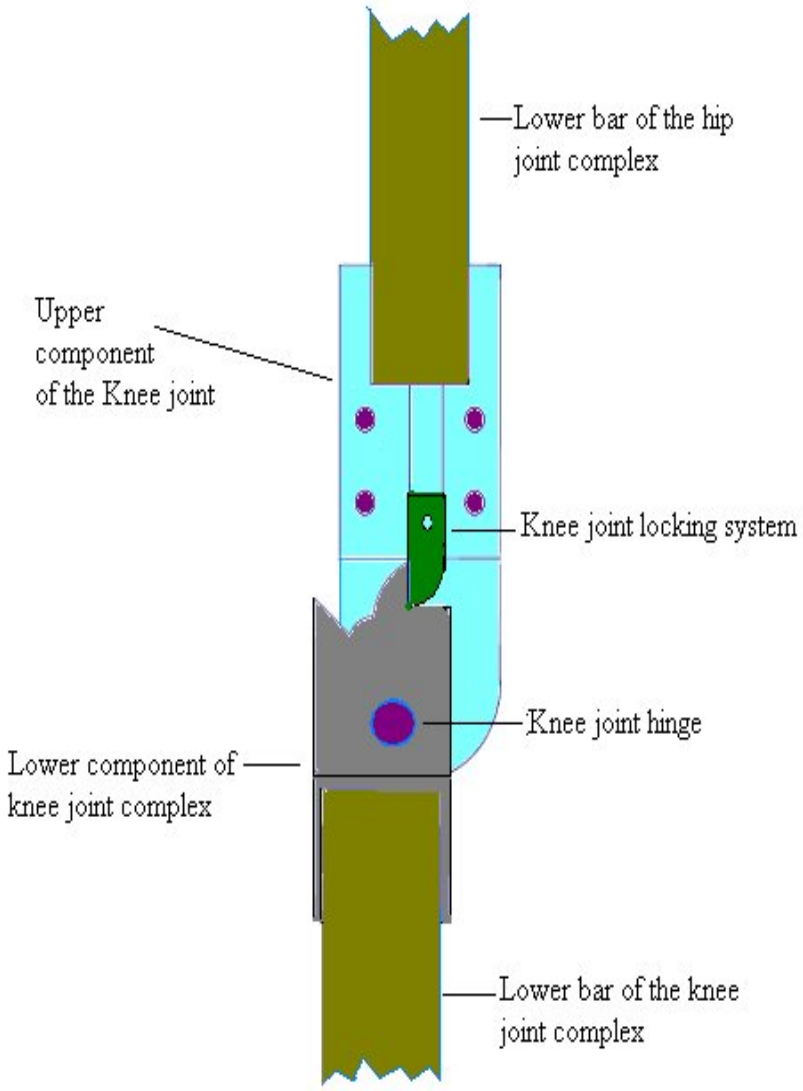


Figure 3.8: The simplified sketch of the knee joint complex

The locking system force can be determined as follows, figure 3.9.

$M_{zk} = 270$ Nm

$M_{zk} = F_{x4} 0.02$

$270 = F_{x4} 0.02$

$F_{x4} = 13500$ N

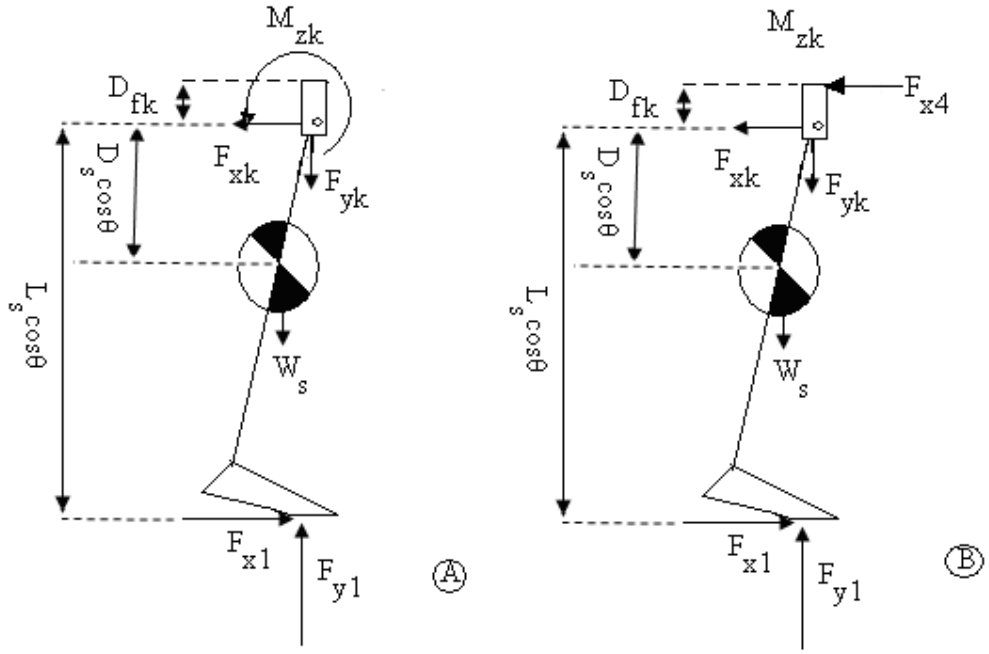


Figure 3.9: The free body diagram of the knee joint centre (A)

The extending moment needed to stabilize the knee joint was replaced by an extensor force (B), where: F_{xk}, F_{yk} and M_{zk} are the forces applied on the knee joint centre in the anteroposterior and vertical directions and the extending moment, respectively

W_s is the weight of the shin

D_s and L_s are the distance of leg COG from the knee joint centre and the length of the shin, respectively

F_{x4} is the force of locking system

D_{fk} is the distance between the locking system and the knee joint centre

The force applied on the knee joint hinge during walking can be determined as follows.

$\sum F_x = 0$

$-F_{xk} + F_{x1} - F_{x4} = 0$

$F_{xk} = F_{x1} - F_{x4}$

$F_{xk} = 13352.85$ N

$\sum Fy = 0$

$-F_{yk} - W_s + F_{y1} = 0$

$F_{yk} = F_{y1} - Ws$

$F_{yk} = 1020.24 - 66.36$

$F_{yk} = 953.88$ N

$\sum F_{zk} = 0$

$-134.17 + F_{zk} = 0$

$F_{zk} = 134.17$ N

3.4 IDENTIFICATION OF THE VARIOUS FUNCTIONS OF THE SYSTEM

The hip joint mechanism in the new orthosis is required to perform the following functions:

a) Allow 25 degrees of flexion and 10 degrees of extension during walking

b) Allow some degree of adjustment to abduction and adduction which is to suit the patients needs

c) Allow the full range of hip flexion and extension, which is necessary for sitting

d) Structural integrity. The design must have sufficient strength to stabilize the paralyzed joints during walking

e) The weight of the orthosis components was an issue; they have to be as light as possible

f) Cosmesis of the final orthosis must be better than the HGO orthosis

g) Attachments. Special types of rivets and screws must be used to attach various segments in this design

h) Adjustability of the orthosis was necessary to suit the different subjects

For the knee joint the following function was identified:

a) Allow full range of the motion necessary for sitting down and standing up

b) Have high security during walking

c) Allow the patients to stand in two stages, i.e. it should lock the knee joint at 45 degrees of flexion and in full extension

3.5 DETERMINATION OF THE REQUIRED DIMENSIONS OF THE SEGMENTS

The dimensions of this orthosis depended on the range of motion of the various components and also the magnitude of the loads applied on them. It was decided that the hip joint of the orthosis to have 25 degrees of flexion and 10 degrees of extension during walking. The flexion restriction screw was located 50 mm below the first hip joint centre, so according to figure 3.10 the wide of the main component of the hip joint near the flexion restriction screw could be determined as follows.

$$50\tan\theta + 50\tan\beta + \text{The width of the middle component} \qquad \text{Eq. 3.5}$$

In which, β and θ are the angles of the flexion and extension during walking with orthosis, respectively.

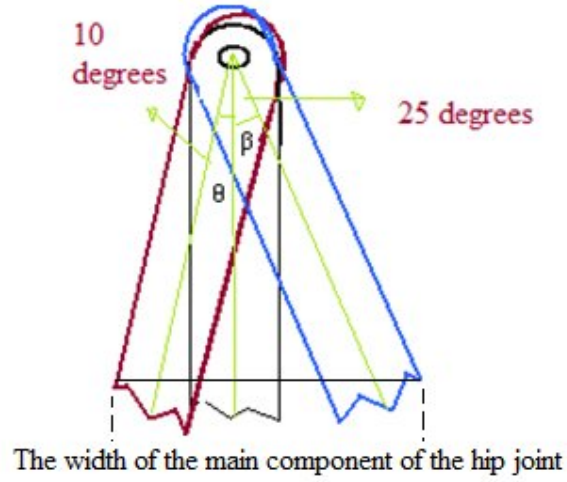


Figure 3.10: The dimension of the hip joint depends on the range of motion of the system. β and θ are the angles of the flexion and extension during walking with orthosis, respectively

The best option to change abduction, adduction and rotation in the orthosis was using components such as a pyramid and clamp, the same as what used routinely in lower limb prostheses. The size of these components differs from those used for prostheses, it was therefore necessary to be designed according to the applied loads and moments as shown above. It was assumed that the range of adjustment of adduction and abduction of the hip joint should be capable of changing by 10 degrees.

The knee joint was designed specifically to suit the dimensions and location of the locking system. Since the applied flexing moment around the knee joint was considered to be 270.0 Nm, so the smallest cross sectional dimension for the locking system was 10× 10 $(mm)^2$. In order to decrease the applied forces on the knee joint pivot during walking, it was assumed that the locking system applied its force at least 20 mm above the knee joint centre. It was decided that the knee joint of the

orthosis could be aligned also for a patient with up to 20 degrees of a flexion contracture. The designs of the different components of the new RGO orthosis are shown in figures 3.11 to 3.22.

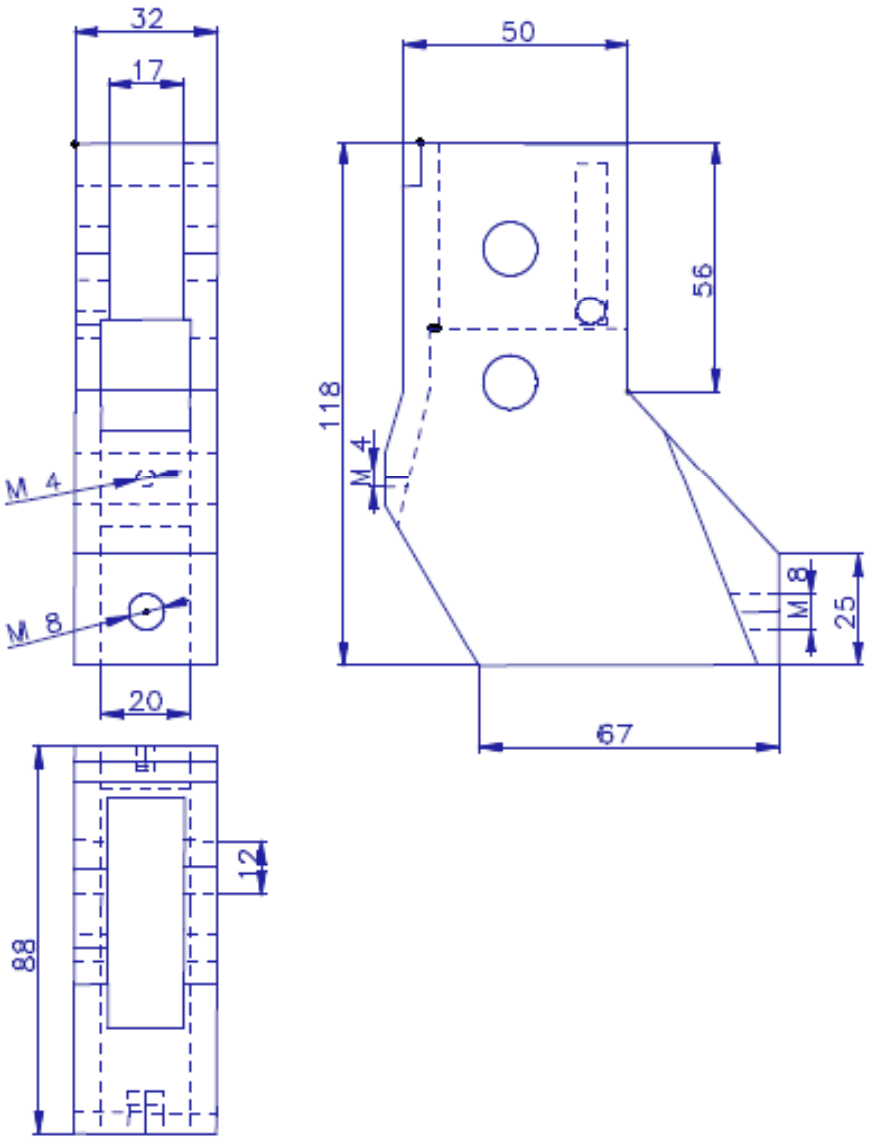


Figure 3.11: The main component of the hip joint, showing the main dimensions in mm

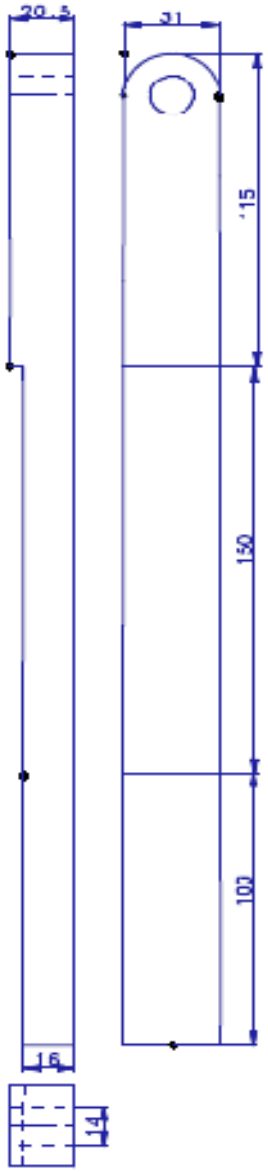


Figure 3.12: The lower bar of the hip joint

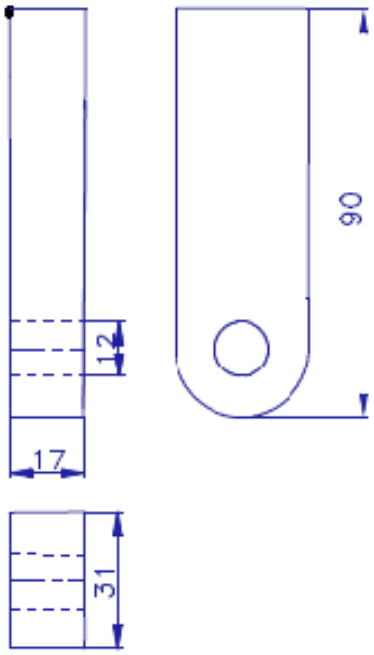


Figure 3.13: The upper bar of the hip joint

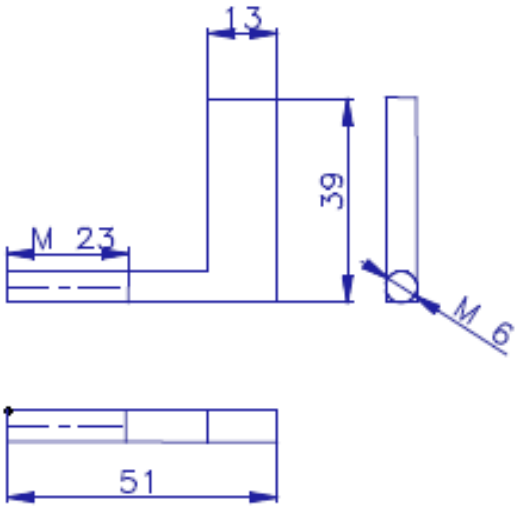


Figure 3.14: The locking system of the hip joint

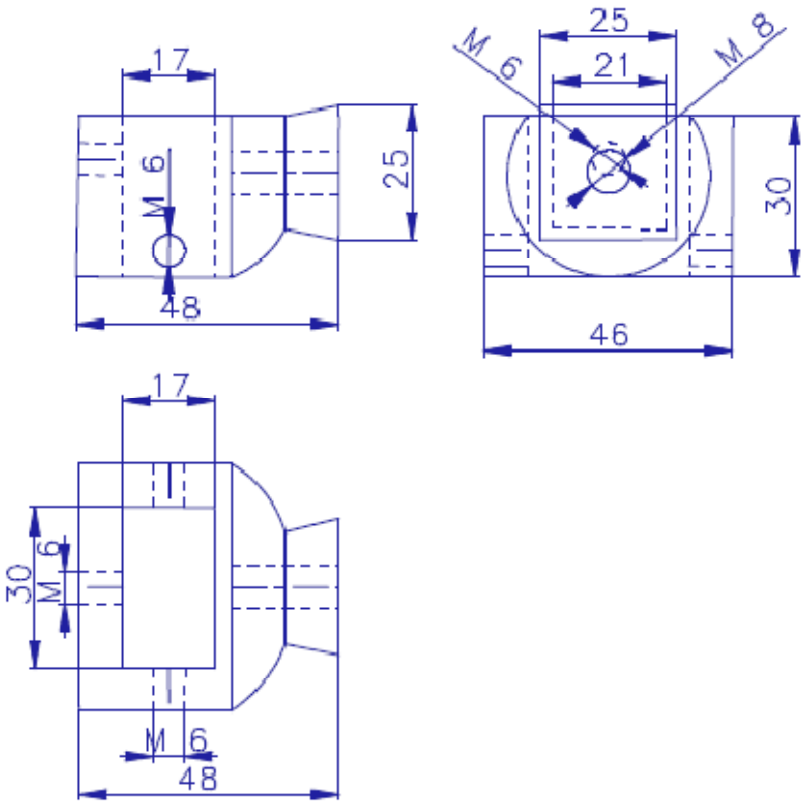


Figure 3.15: The first component of the hip joint attachment

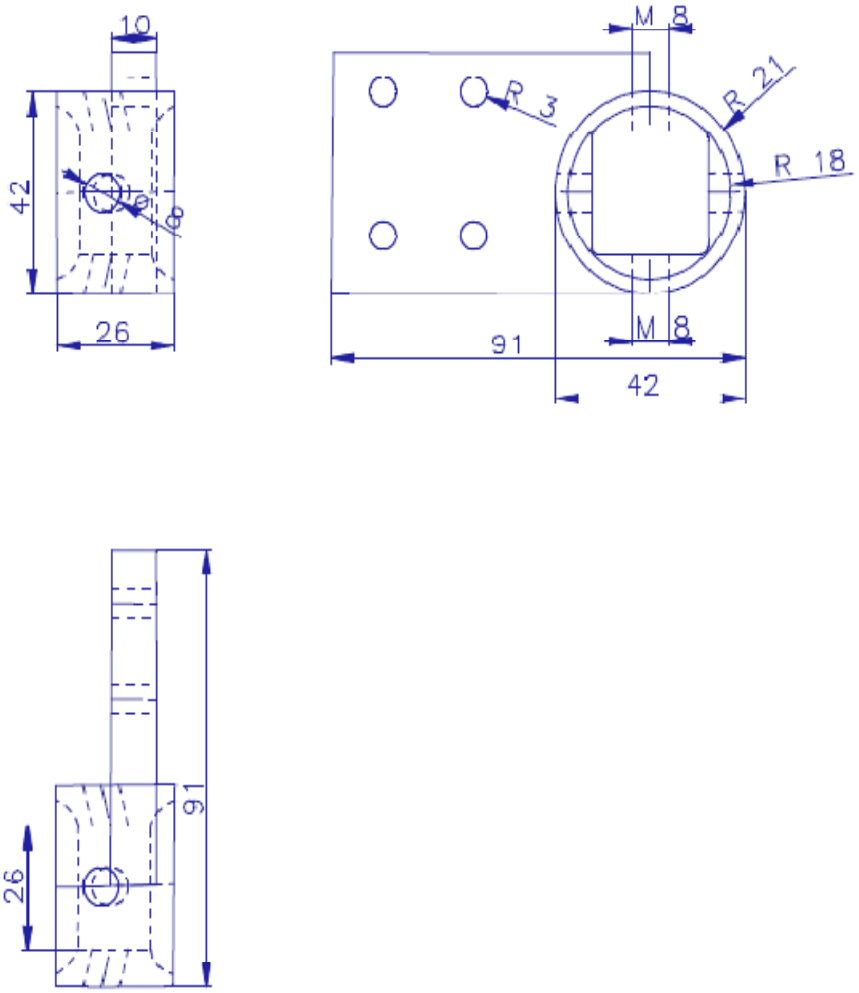


Figure 3.16: The second component of the hip joint attachment

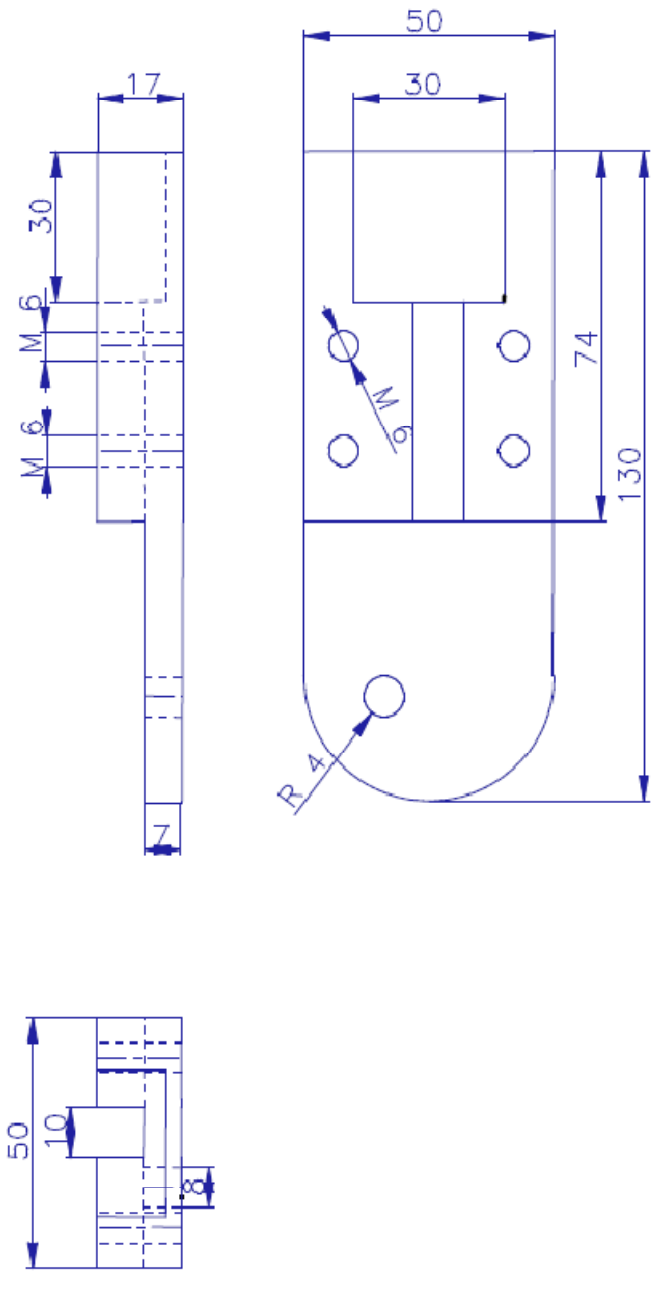


Figure 3.17: The first part of the knee joint

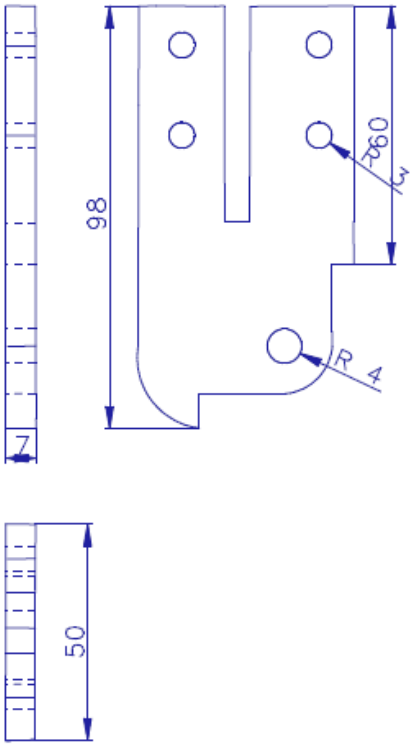


Figure 3.18: The second part of the knee joint

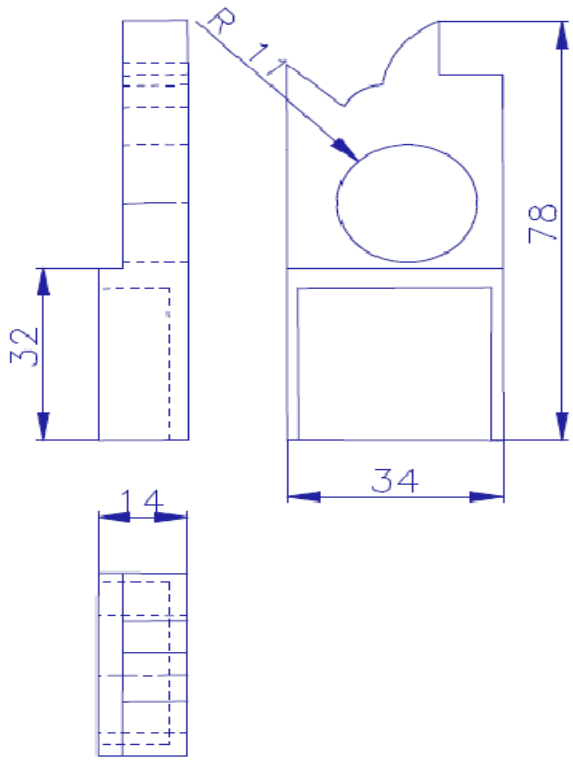


Figure 3.19: The lower bar of the knee joint

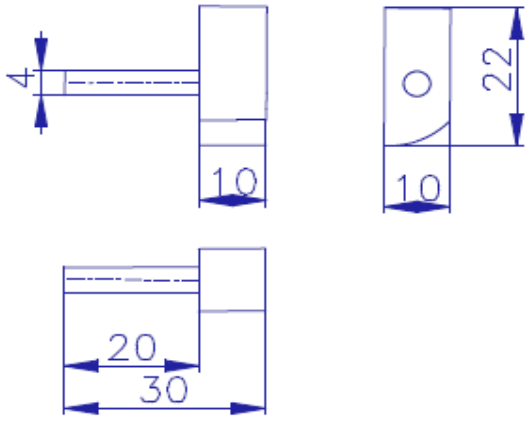


Figure 3.20: The knee joint locking system

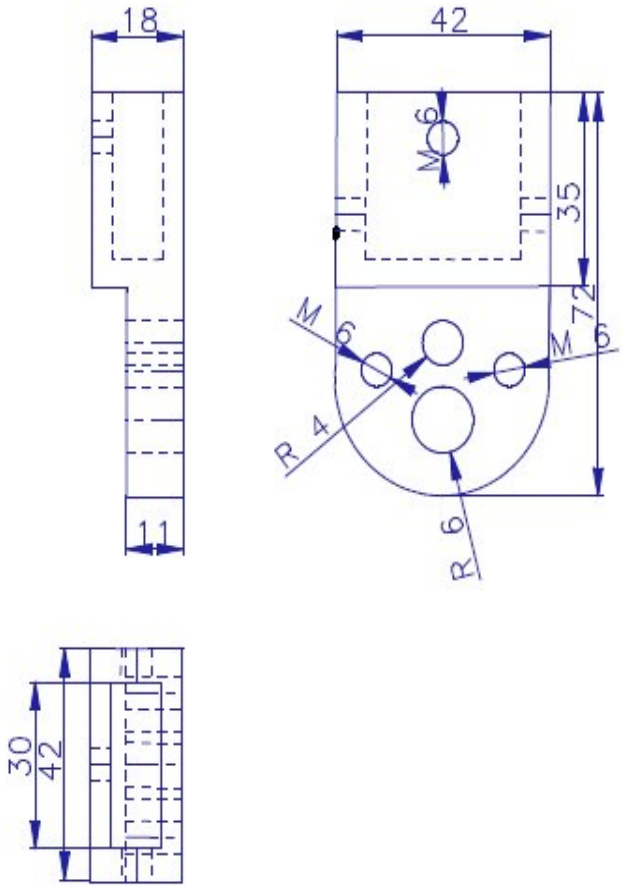


Figure 3.21: The first component of the knee joint attachment

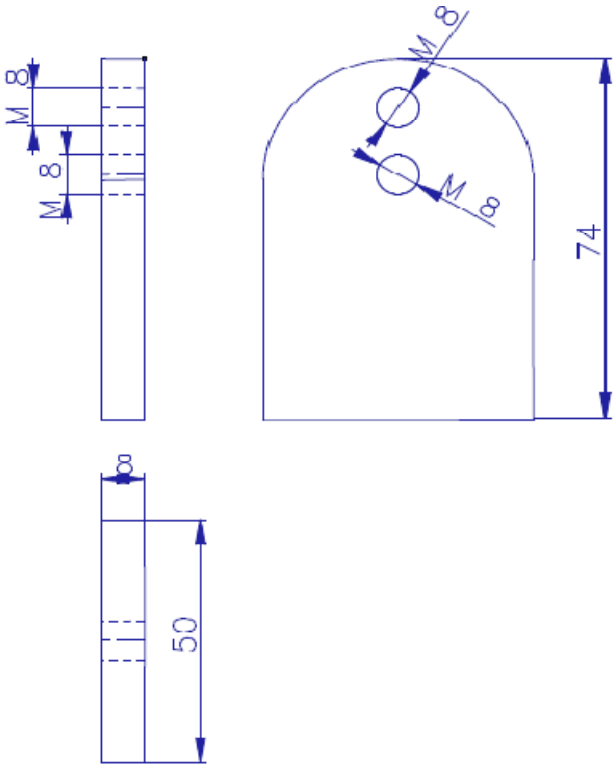


Figure 3.22: The second part of the knee attachment

3.6 FORCE ANALYSIS

In order to analyze the stresses developed in the various components, several cross sections of the components were selected which were considered to be the main areas transmitting the loads.

3.6.1 Force Analysis of the Hip Joint Complex

The hip joint complex of the new orthosis consisted of the lower and upper bars, the main component of the hip joint and the attachment components.

3.6.1.1 Force analysis of the lower bar of the hip joint

The free body diagrams of the leg are shown in figure 3.1 and 3.3. It was assumed that the adducting moment applied on the hip joint from its centre down to 50 mm below the hip joint centre, was resisted by the main component. So the main moment applied on the proximal part of this component (from centre down to 50 mm below the centre) was flexing moment. However, from 50 mm below the centre both adducting and flexing moments applied on the bar.

3.6.1.1. I Force analysis of the lower bar at the centre of the hip joint

The cross section of this component at the centre of the hip joint is shown in figure 3.23. The forces and moments applied on this component are as follows:

F_{xh1} = 5234.75 N
F_{yh1} = 854.88 N
M_{zh1} = 254.38 Nm
M_{xh1} = 0 Nm

According to the cross section area of this component, which is shown in figure 3.23, the second moment of area and the area are:

$$Izz = 46.21\times10^{-9}\ m^4$$
$$A = 348.5\times10^{-6}\ m^2$$

The maximum stress developed in this cross section area could be determined by using the following equation (Shigley and Mischke, 2001):

$$\sigma = \frac{M_z \times y_1}{I_{zz}} + \frac{M_x \times y_2}{I_{xx}} + \frac{F_y}{A} \qquad \text{Eqi. 3.6}$$

Where y_1 and y_2 are the distance between the central axes and the location of the highest stress concentration. So according to the above equation the maximum stress developed in this section could be determined as follows:

$$\sigma = \frac{254.36 \times 0.0155}{46.2 \times 10^{-9}} + \frac{854.88}{348.5 \times 10^{-6}} = 87.78\ \text{MPa}$$

With safety factor as 3 it was 263.34 MPa.

The shear stress in this cross section could be determined by using the following equation (Shigley and Mischke, 2001):

$$\tau = \frac{V \times Q}{I \times b} + \frac{V}{A} \qquad \text{Eqi. 3.7}$$

Where τ is shear stress, V is the shear force, Q is the first moment of area and b is the width of the section. So the maximum shear stress was determined as follows:

$$Q = y \times dA$$

$$Q = 0.01125 \times 0.02 \times 0.0085 = 1.9125 \times 10^{-6}\ m^3$$

$$\tau = \frac{5234.15 \times 1.9125 \times 10^{-6}}{0.02 \times 46.2 \times 10^{-9}} + \frac{5234.15}{348.5 \times 10^{-6}} = 25.85\ MPa$$

With safety factor as 3 it was 77.65 MPa.

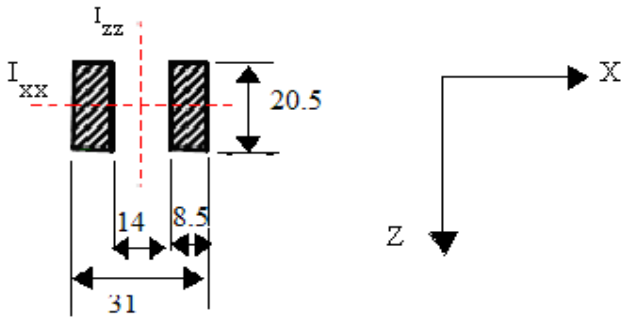


Figure 3.23: The cross section area of the lower bar at the first hip joint centre, all dimensions are in mm

3.6.1.1. II Force analysis of the lower bar 30 cm below the first centre of the hip joint

The free body diagrams of this cross section are shown in figures 3.24 and 3.25. The force and moments applied on this cross section could be determined as follows.

$$\sum Fx = 0$$

$$F_{xh1} - F_{x2} - F_{x5} = 0$$

$$F_{x5} = F_{xh1} - F_{x2}$$

$$F_{x5} = 5234.75 - 5087.6 = 147.15\ N$$

$\sum Fy = 0$

$F_{y5} - F_{yh1} = 0$

$F_{y5} = F_{yh1}$

$F_{y5} = 854.88$ N

$\sum M_z = 0$

$F_{xh1}0.03\cos\theta - F_{yh1}0.03\sin\theta - F_{x2}0.025\cos\theta - M_{z5} = 0$

$M_{z5} = 142.312 - 10.84 - 115.25 = 0$

$M_{z5} = 16.22$ Nm

$\sum M_x = 0$

$128 - F_{zh1}0.3 - M_{x5} = 0$

$M_{x5} = 87.76$ Nm

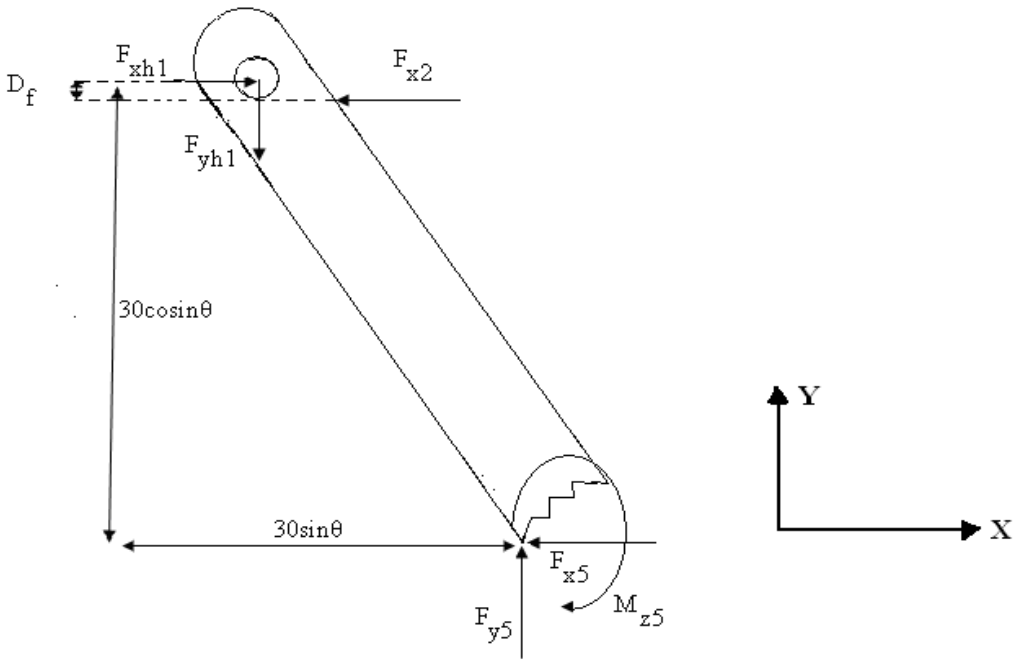


Figure 3.24: The free body diagram of the lower bar of the hip joint complex, anteroposterior plane

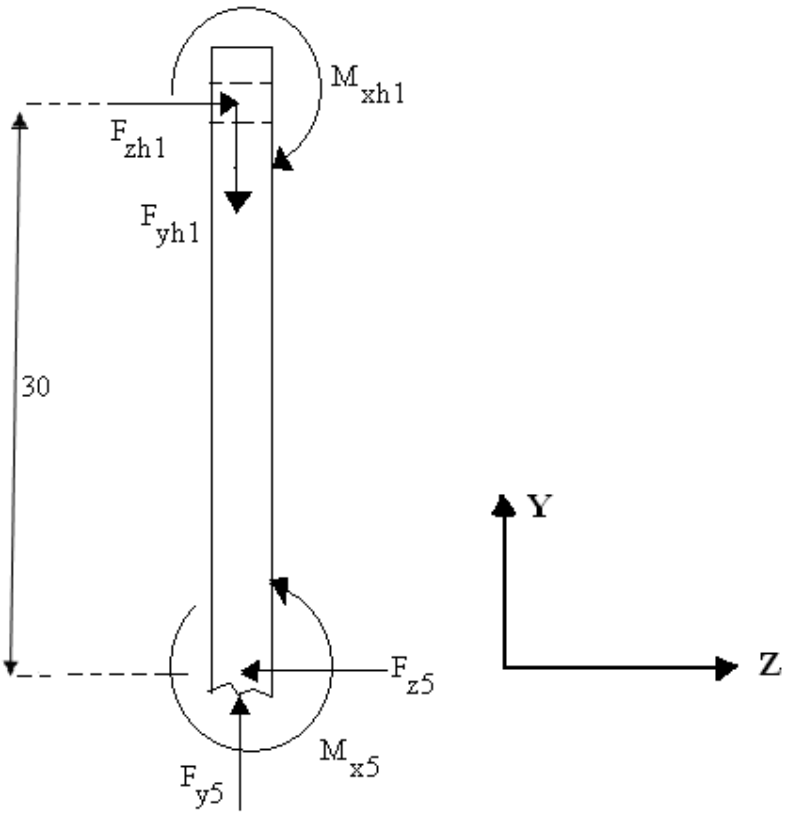


Figure 3.25: The free body diagram of the lower bar of the hip joint complex, mediolateral plane

The actual values of the compression and shear forces after axial conversion were determined as follows:

$F_y = 713.44$ N

$F_x = 227.92$ N

The second moments of area and the area of this section, figure 3.26, are:

$I_{xx} = 10.581 \times 10^{-9}$ m^4

$I_{zz} = 39.72 \times 10^{-9}$ m^4

$A = 496 \times 10^{-6}$ m^2

The bending stress in this cross section could be determined as follows:

$$\sigma = \frac{0.0155 \times 16.22}{39.721 \times 10^{-9}} + \frac{0.008 \times 87.76}{10.581 \times 10^{-9}} + \frac{713.44}{496 \times 10^{-6}} = 74.11 \text{ MPa}$$

With a safety factor of 3 it was 222.33 MPa. The shear stress in this cross section could be determined as follows:

$$Q = 0.00775 \times 0.0155 \times 0.016$$

$$Q = 1.922 \times 10^{-6} \text{ (m)}^3$$

$$\tau = \frac{1.922 \times 10^{-6} \times 298.84}{0.016 \times 39.72 \times 10^{-9}} + \frac{227.92}{496 \times 10^{-6}} = 1.36 \text{ MPa}$$

With a safety factor of 3 it was 4.08 MPa. The stress analyses of the other components of the new orthosis are shown in appendix 1.

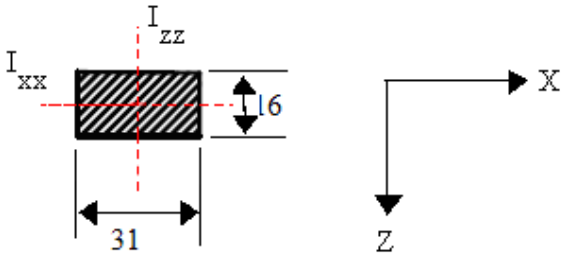


Figure 3.26: The second cross section area of the lower bar of the hip, all dimensions are in mm

3.7 MATERIAL SELECTION

Various materials were selected to manufacture the components of this orthosis. The materials were selected according to the results of the stress analysis which was shown in the previous section.

3.7.1 Material Selection for the Hip Joint Complex

The main hip joint component was manufactured from a special aluminum alloy which is named as HE 30WP and also called 6082 condition T6. The proof strength of this type of aluminum is between 250 and 260 MPa (Aluminum Association., 1982, Aluminum Association., 2000). The mechanical properties of this alloy are shown in table 3.3. The pins of the hip joint were made from steel (structural steel grade 65). The minimum proof strength of the steel selected for this orthosis was 450 MPa as provided by supplier; Bethlehem Steel Corporation, Table 3.4 shows the mechanical properties of the steel used for this orthosis. As can be seen from the appendix 1, the flexion and extension restriction screws were subjected to stresses of 416.96 and 318.1 MPa, respectively. The selected screws were Spline Socket–Head Cup Screws and were made from steel with medium carbon, with the mechanical properties as shown in table 3.5 (Bickford and Nassar, 1998, Parmley, 1997, Parmley, 1989, Shigley and Mischke, 2001). The locking system and the hip joint attachment components were manufactured from the same steel which was used for the pivots. The screws used for attachment between the pyramid and adaptor had the same mechanical properties as the flexion restriction screw. The screws selected for the pyramid and adaptor were Socket-Head Cap and Spline socket Set Screws (Parmley, 1997), respectively.

3.7.2 Material Selection for the Torso Section of the Orthosis

The Torso section of the orthosis was manufactured from the same aluminum alloy selected for the hip joint. The screws and nuts used to attach the hip joint complex to the Torso were made from the same material as the flexion restriction screw.

3.7.3 Material Selection for the Knee Joint Complex

The main component of the knee joint was manufactured from the same aluminum alloy which was used for the hip joint. The lower bar of the knee joint and the locking system were made from steel.

Parameters	Density	Hardness Vickers	Ultimate tensile strength (MPa)	Yield Tensile strength (MPa)	Elongation at break %
Value	2.7 g/cc	95	290-310	250-260	10

Table 3.3: The mechanical properties of aluminum alloy (6082 condition T6) selected for manufacturing some components of the orthosis (Aluminum Association., 2000, Aluminum Association., 1982)

Parameters	USA Standard	Ultimate Strength (MPa)	Yield Strength (MPa)	Shear modulus (GPa)	Elongation at break %
Value	ASTM A510	550	450	80	17

Table 3.4: Mechanical properties of the steel selected for manufacturing of some components of the orthosis as is shown by suppler, Bethlehem Steel Corporation

Parameters	Property Class	Minimum Proof Strength (MPa)	Minimum Tensile Strength (MPa)	Minimum Yield Strength (MPa)	Material
Value	9.8	650	900	720	Medium Carbon, Q&T

Table 3.5: The mechanical properties of the flexion and extension restriction screws of the hip joint (Shigley and Mischke, 2001)

Parameters	Density (kg/m^3)	Tensile modulus (GN/m^2)	Shear modulus (GN/m^2)	Tensile Strength (MPa)
Value	0.901	1.13	0.4	30.8

Table 3.6: The properties of the copolymer Polypropylene used to manufacture AFO (Crawford, 1998)

The mechanical properties of the knee joint bolt and the screws of the attachment components were the same as that of the restriction screw of the hip joint.

3.7.4 Material Selection for the AFO

The AFO section of the orthosis was made from copolymer polypropylene with 6 mm thickness. It is used specifically for manufacturing of AFO of other orthoses such as the ARGO, RGO, and IRGO. The mechanical property of this material is shown in table 3.6.

3.8 CONSTRUCTION OF THE FINAL DESIGN

The orthosis was made of three main parts, the AFO, Torso and lateral bars with hip and knee joints.

3.8.1 Construction of the AFO

A Plaster cast was taken of the participant's leg from the toe to 5cm above the knee joint when the subject was in the sitting position. The ankle joint was maintained in a right angle and any inversion or eversion of the ankle joint was manually corrected. The limb was covered with stocking and a simple surgical tube was used on the anterior surface of the limb to permit safe use of a cutter in order to remove the cast at the appropriate time. The model of the limb was made by filling the cast with plaster. Any deformities or misalignment which happened during casting were corrected in this stage.

An aluminum plate, 30 cm long, 6 cm wide and 0.5 cm thickness, was cut and inserted on the lateral surface of the positive cast to secure the connection between knee joint attachment component and AFO. To reinforce the ankle areas to have

more rigidity a precut carbon composite was used. It was heated and formed behind the ankle joint.

The positive models of the legs were set up for hand draping and vacuum forming a sheet of thermoplastic in the usual fashion. Two layers of nylon stocking were pulled over the plaster model. A 6mm polypropylene sheet, white colour was cut according to the size taken from the positive cast. It was heated at 180 C° for 25 minutes in an oven. It was then draped over the plaster model and the edges were stuck together along the anterior side. It was tightened around the suction cone by means of a rope and finally the suction valve was opened.

A trim line was drawn on the polypropylene and then it was cut with an oscillating saw. The trim line of the orthosis was smoothed. Velcro straps were inserted above the ankle and across the patellar tendon to secure the attachment between orthosis and the participant's body.

The shoes selected for walking with this orthosis were sport shoes. The sole of each shoe was removed and then replaced with polyethylene foam. The aim of this replacement was to make a heel similar to a SACH (Solid Ankle Cushion Heel) heel. The thickness of the SACH heel was approximately 3 cm and it was covered by a rubber sheet with 3 mm thickness. It was easy to fit the AFOs in the shoes because the shoe was one size longer than the participant foot. Figure 3.27 shows the AFO parts of the new RGO orthosis.

3.8.2 Construction of the Torso section

The TLSO (Thoraco Lumbo Sacral orthosis) of this orthosis was made from sacral and thoracic bands and lateral bars which were made from aluminum alloy. The sacral and thoracic bands were manufactured from 15 mm thickness aluminum bar

and were shaped on the participant's body. The lateral bars and sacral band were connected to the adaptor of the hip joint attachment by using 4 bolts and nuts which secure the attachment. Chest and abdominal Velcro straps were used to guaranty a secure and adjustable connection between the human body and the orthosis. Figure 3.27 shows the TLSO part of the new RGO orthosis.

3.8.3 Construction of the Lateral Bar of the Orthosis

The lateral bar of the orthosis consisted of the hip and knee joints and the bars of the knee and hip joints. The lower bar of the hip joint was attached to the knee joint by 2 bolts and nuts which secured the attachment. The lateral bar was attached to the hip and knee joints attachment components by using some pins. Figures 3.27 and 3.28 show the manufactured components of the orthosis and the final orthosis.

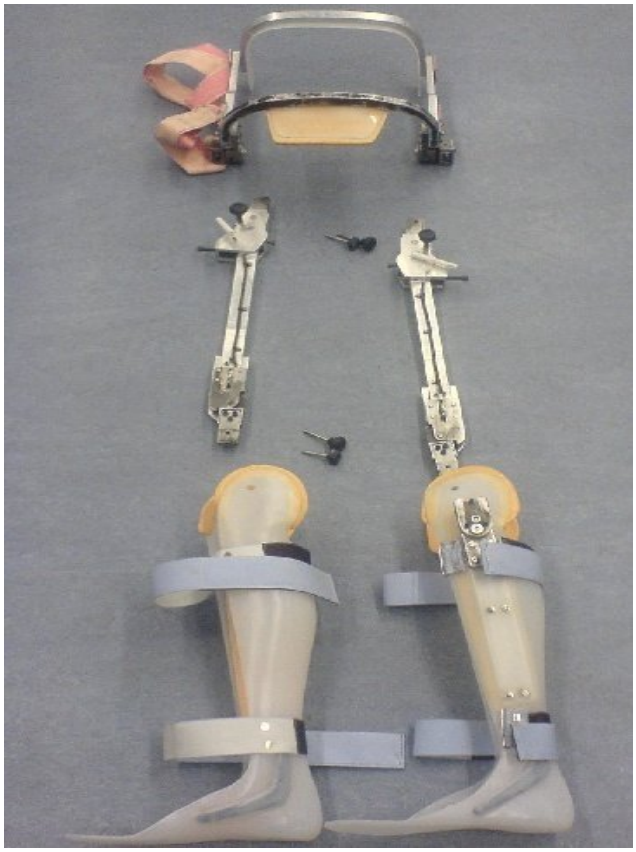


Figure 3.27: The components of the orthosis (AFO, lateral bar with the hip and knee joints, and Torso part of the orthosis)

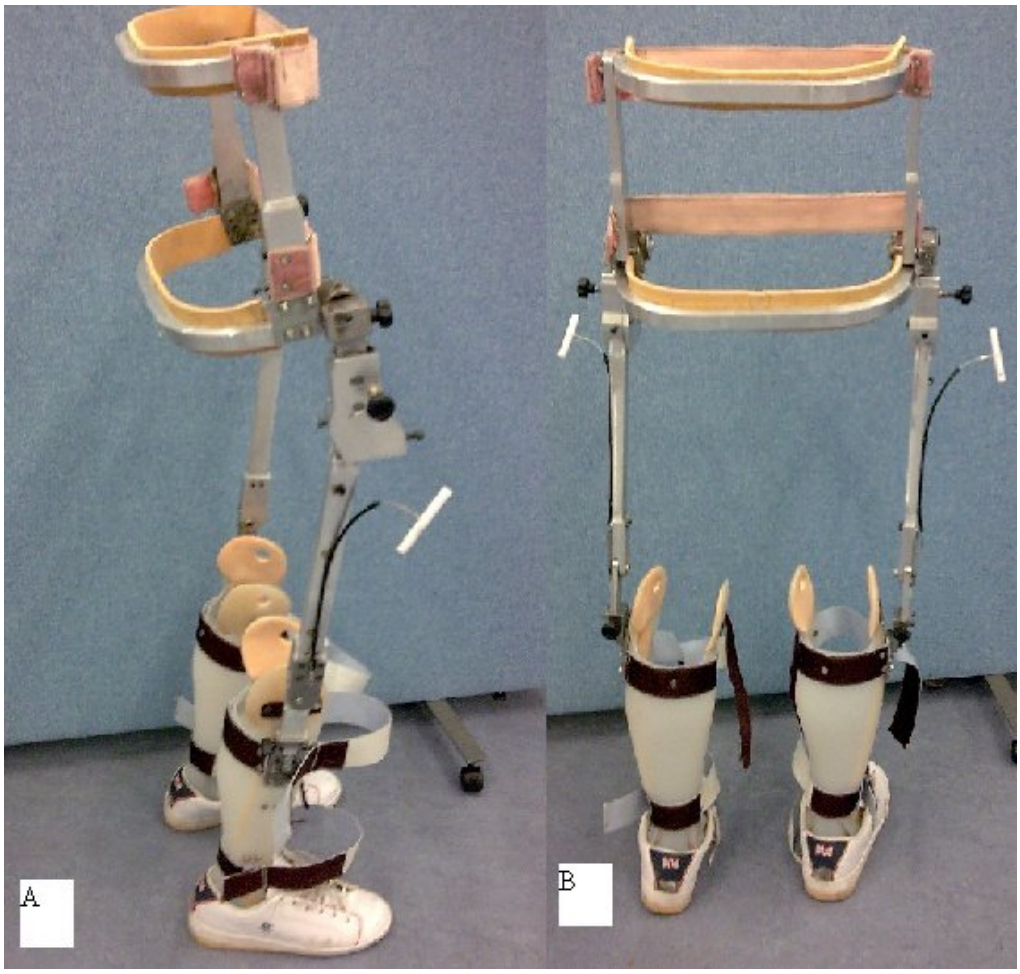


Figure 3.28: The lateral view (A) and posterior view (B) of the new RGO orthosis

CHAPTER 4: TESTING OF THE NEW RECIPROCAL GAIT ORTHOSIS ON NORMAL SUBJECTS

Prior to the main programme of comparing the new reciprocal gait orthosis with the HGO orthosis, a testing procedure was carried out with three normal subjects. Testing the RGO orthosis with different hip, knee and ankle joints configurations on normal subjects was also done by Yang et al, (1996). This was done for the following reasons:

a) To allow an investigation of the functional performance of the normal subjects during walking with the orthosis, which would be the best performance that paraplegic subjects would hope to achieve during walking with the orthosis
b) To establish a procedure which would allow testing of the various components of the orthosis in order to evaluate the effects of changes to their alignment configuration
c) To determine the best testing procedure which would highlight any design faults
d) To determine the best configurations of the hip joint during walking with the orthosis

4.1 MATERIALS AND METHOD

A group of healthy volunteer subjects was recruited. They were required to stand and walk over a level walkway with the new orthosis with various hip joint configurations and also without the orthosis. The crutches were adjusted to suit the subjects according to standard criteria stated in the literature (Cicenia and Hoberman, 1957). The subjects were asked to stand and walk with the following hip joint configurations:

a) Hip joint with free flexion/extension (between 25 and 10 degree flexion and extension , respectively) and with abduction angle set at zero (configuration 1)
b) Hip joint with free flexion/extension and with some abduction (configuration 2)
c) Hip joint with flexion/extension restricted (between 12 and 5 degree flexion and extension , respectively) without abduction (configuration 3)
d) Hip joint with flexion/extension restricted with abduction (configuration 4)

As stated above, the orthosis in configurations 2 and 4 was aligned in 5 degrees of abduction. Rose (1979) stated that the best abduction angle for an orthosis was 5 degrees. The results of the research by Ijzerman et al, (1997b) also showed that building up the orthosis in some degrees of abduction decreases the magnitude of the loads applied on the crutch during paraplegic gait. Last but not least, setting the orthosis in 5 degrees of abduction was for cosmetic reasons. Increasing the abduction angle by more than 5 degrees at the hip joint increases the base of support more than the value which could be accommodated in a commonly used wheelchair.

The range of motion of the orthosis in configurations 3 and 4 was decreased to 12 degrees of flexion and 5 degrees of extension. The performance of the participants with and without the orthosis was analyzed by assessing standing stability, gait analysis and by energy consumption tests.

4.1.1 Subjects

Three normal males participated in this preliminary investigation. According to the literature review the number of the participants in research related to new orthoses for paraplegic subjects varied between 1 and 5. In order to achieve a statistical power and P-value as 0.8 and 0.05, respectively, the number of participants varies between 3 and 5, depending on the parameters under investigation (for instance, the mean value and standard deviation of the flexing moment of the hip joint were 0.8 and 0.2 Nm/BW, respectively). Moreover, it was too difficult to increase the number of the participants for this part of the research, as it would have taken a considerable

amount of time and funding. They had no deformities and contraindications for standing and walking or complicated medical histories. Their mean age was 20 and their height and mass were 1.77 m and 78 kg, respectively. Table 4.1 summarizes the features of the subjects that participated in this study. For this part of the research ethical approval was obtained from Strathclyde University's Ethics committee, appendix 2.

There was a slight difference in the size of the AFO and Torso components required for the orthosis amongst the participants. Thus, the AFO was moulded for every subject and the TORSO section was made specifically to suit the size of the participants.

4.1.2 Test Parameters

The new orthosis was tested on the normal subjects by conducting standing stability analysis, gait analysis and energy consumption tests. The participants were asked to stand and walk with the orthosis with the various hip joint configurations and without the orthosis.

4.1.2.1 Standing stability parameters

There are many different parameters which can be used for evaluation of standing stability however, the two most common ones which are also used for paraplegic subjects are the excursion of the centre of pressure (COP) in the mediolateral and anteroposterior directions. A Kistler force platform instrumented with piezoelectric force transducers was used to measure the COP which is considered to be a good approximation to sway. Sway during quiet standing is defined by movements of the centre of gravity (COG) in a horizontal plane. These movements are due to small deviations of the COG line from the vertical ground reaction vector. Many researchers have studied sway by measuring the COP on the force platform (Cybulski and Jaeger, 1986, Murray et al, 1975).

Number of the participant	Age (year)	Height (meter)	Mass (kg)
Subject 1	24	1.76	84.5
Subject 2	18	1.78	89
Subject 3	18	1.77	60.5

Table 4.1: Subject information

It was chosen as a good method to quantify standing stability because it is a valid measure of postural stability (Maki et al, 1987) and also measuring the COP with a force platform is a quick and convenient method for stability analysis.

The force platform and the amplifiers associated with it produce six voltage outputs which represent the following mechanical inputs:

$$F_x, F_y, F_z, M_x, M_y, M_z$$

Which are the forces and moments exerted on the force platform in the different directions as is shown in figure 4.1.These outputs which are in volts were sampled and stored and then transformed into the units of Newton (force) and Newton-meter (moment) by using the force plate calibration factors. Calibration of the force plate involves the use of a 6×6 matrix which transforms the electrical inputs to a computer into mechanical outputs. Since the transducers of the force plate may not be perfectly aligned with force plate system and if the piezoelectric crystals are affected by loads other than these designed, cross effects could appear in the system. However, the magnitude of the cross talks is very small and negligible (Kistler manual).

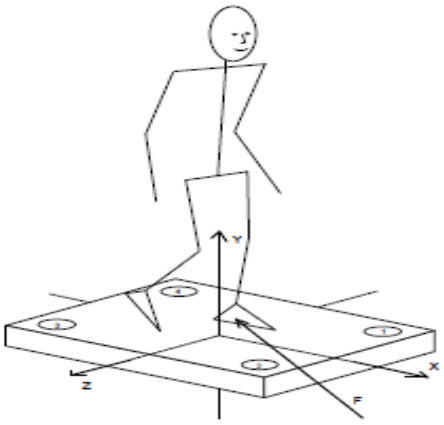


Figure 4.1: The force plate reference axis system (adapted from Kistler manual)

The instantaneous position of a vertical force applied on the force platform, figure 4.2, in x, z planes can be determined as follows (Barnett, 1990).

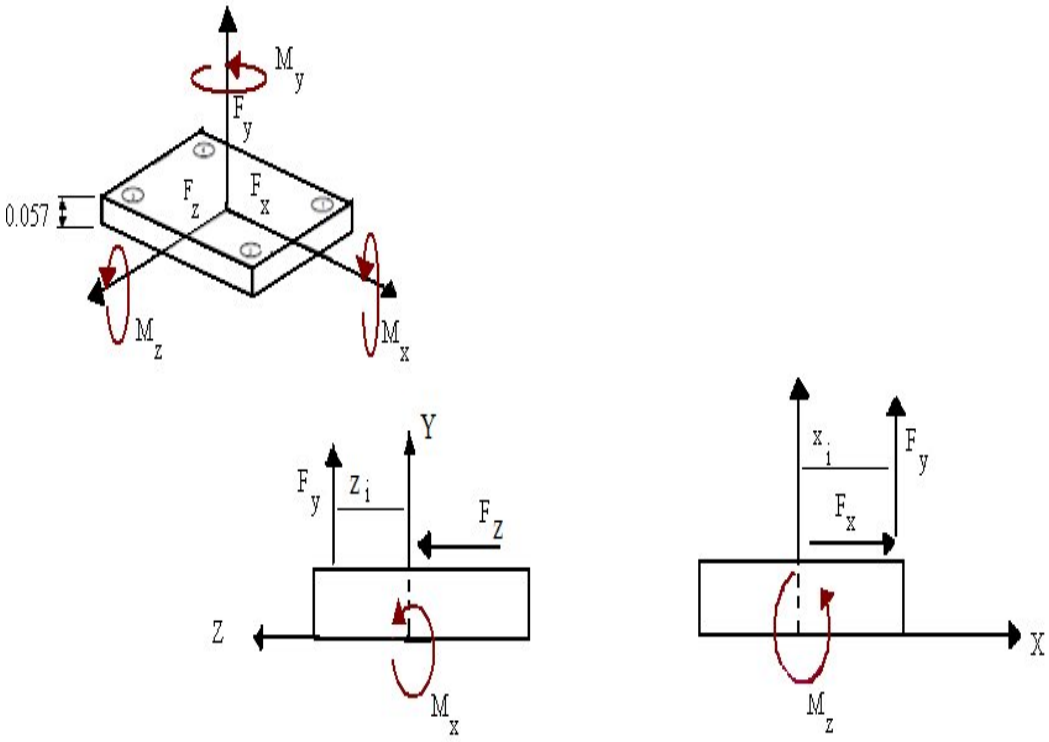


Figure 4.2: The Force platform axes and the force applied on it (adapted from Barnett, 1990)

$$M_z = F_y x_i \text{ and } M_x = -F_y z_i \qquad \text{Eq. 4.1}$$

$$\text{Thus } x_i = \frac{M_z}{F_y}, \text{ and } z_i = \frac{-M_x}{F_y} \qquad \text{Eq. 4.2}$$

Where, F_y, M_x, M_z are the calibrated data pointed at sample number i.

However, in quiet standing the net force is seldom applied vertically. As a result there are two small frictional force components applied on the upper surface of the platform, which are represented as F_x and F_z in figure 4.2. According to the

geometry of the force platform shown in figure 4.2 the moments applied on the force platform could be determined as follows.

$$M_z = F_y x_i - 0.057 F_x \qquad \text{Eq. 4.3}$$
$$M_x = -F_y z_i + 0.057 F_z$$

$$x_i = \frac{(0.057F_x + M_z)}{F_y} \qquad \text{Eq. 4.4}$$

$$z_i = \frac{(0.057F_z - M_x)}{F_y} \qquad \text{Eq. 4.5}$$

These equations define the coordinates of the base position of the Ground reaction Vector (GRV) relative to the centre of the force platform upper surface (Barnett, 1990, Geurts et al, 1993). The COP excursions could be determined as follows.

$$\text{COP range in AP} = x_{max} - x_{min} \qquad \text{Eq. 4.6}$$
$$\text{COP range in ML} = z_{max} - z_{min}$$

4.1.2.1.I Reliability of the COP excursions in the mediolateral and anteroposterior planes to evaluate the standing stability

The reliability of the force plate based on the excursions of the mediolateral and anteroposterior COP sway was measured by many investigators, however the test, retest conditions varied from one researcher to another. Murray et al (1975) emphasized that the high standard deviations for total excursion indicated mainly the variability from one subject to another subject. The repeated tests of the individuals represented high correlation coefficients (Pearson's correlation) of reliability which was more than 0.77. According to the results of the research carried out by Doyle et al (Doyle et al, 2005) the range of COP AP sway was the best traditional variable that can be used to evaluate the amount of stability. The Intraclass correlation coefficient (ICC) of this parameter varied between 0.28 and 0.72. In another study

(Swanenburg et al, 2008) the stability of 37 participants (29 women and 8 men) was found to be repeatable with 7 days time interval. For the mediolateral COP range the mean value of ICC was 0.77, compared to 0.55 for the anteroposterior COP range.

Lafond et al (2004) assessed the reliability of the COP measurements in the mediolateral and anteroposterior planes on a group of 7 normal participants. The results of this study showed that the ICC of the COP ranged between 0.52 and 0.62 if the test was done one time and for 120 seconds, however if the tests were repeated for 3 trials and for 120 seconds the ICC would be over 0.8. In another study carried out by Santos et al (2008) the reliability of the force plate data for evaluating of standing stability was measured on a group of healthy subjects. According to the results of this study the reliability of the anteroposterior and mediolateral COP sways (ICC) were 0.38 and 0.57, respectively, if the test was done only for one time and for 60 seconds. However, if the tests were repeated several times, the reliability of these parameters would be acceptable (more than 0.75). According to the results of this study the reliability of the anteroposterior COP sway was 0.77 for 4 trials (60 seconds) and 0.75 for the mediolateral COP sway, if the test was repeated for 5 times.

The results of the above mentioned studies show that the reliability of the COP sway in both sagittal and coronal planes is more than 0.75 and it can be used to represent the stability during standing, if the tests were repeated 5 times and the data were collected for 60 seconds.

4.1.2.1. II Calibration of the force plate

The accuracy of the force platform according to the manufacturers manual is very high and the error of this system is less than 1% (Hall et al, 1996). However, to maintain a guarantee of the output quality, some tests must be done to check the accuracy of the data for shear loads both in the mediolateral and anteroposterior

directions and also for vertical loads. Some investigators used various procedures to calibrate the force plate. In order to calibrate the force plate three calibration procedures were performed in total for each force platform. The arrangement of the force plates in the gait laboratory of Bioengineering Unit of Strathclyde University is shown in figure 4.3. In the first procedure the vertical forces were applied using calibrated weights however, the horizontal forces were applied using a purpose built rig. The weights used for calibration of the force plates were standard weights.

The output corresponding to the vertical force was calibrated by applying dead weights up to 1000 N. For applying the vertical load an especially designed jig was employed which was the same as the one used by Hall et al (1996). Figure 4.4 shows the jig used to calibrate the force plate for vertical force. The force plates were also calibrated for shear forces applied in the mediolateral and anteroposterior directions. In order to calibrate the force plates for shear forces, a special pulley system was used, which is shown in figure 4.5. The reliability of the force plate's outputs was evaluated by repeating the tests after 7 days with the same procedures. The result of force platform calibration shows that the error of the system is not high however, it was more than suppose to be. The results of the force plate calibration and reliability test are shown in table 4.2 to 4.5.

4.1.2.1. III Procedure used for carrying out the stability tests

Subjects were instructed about the testing procedures and instruments and then their weight and height were measured and recorded. They were asked to stand on the force plate (force plate 1) for one minute. Data were acquired with subjects in double leg stance with feet at pelvic width during normal standing. The position of the foot while standing with the orthosis was dependant on the alignment of the orthosis. They were instructed to look straight ahead, with their head erect and their arms at their sides in a comfortable position. Five successful trials with subjects eyes

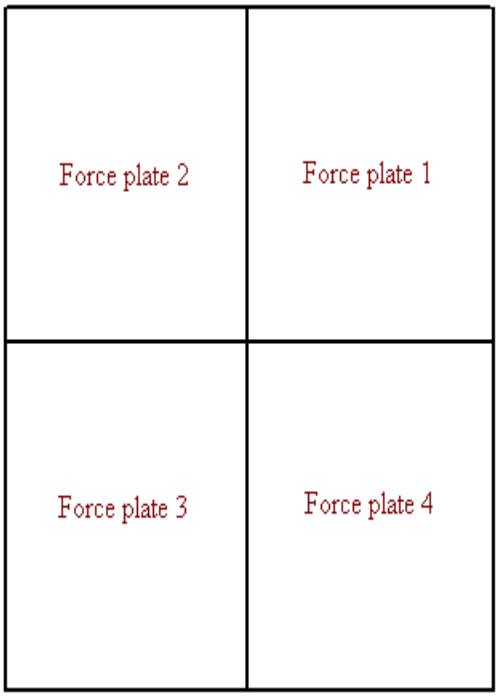


Figure 4.3: The arrangement of the force plates in the gait laboratory of Strathclyde University

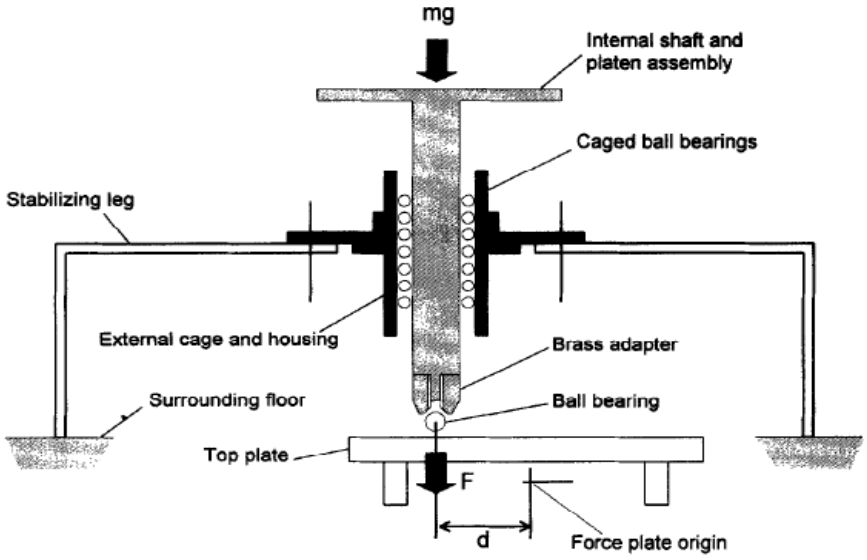


Figure 4.4: The calibration jig which was used for applying the vertical force (Hall et al, 1996)

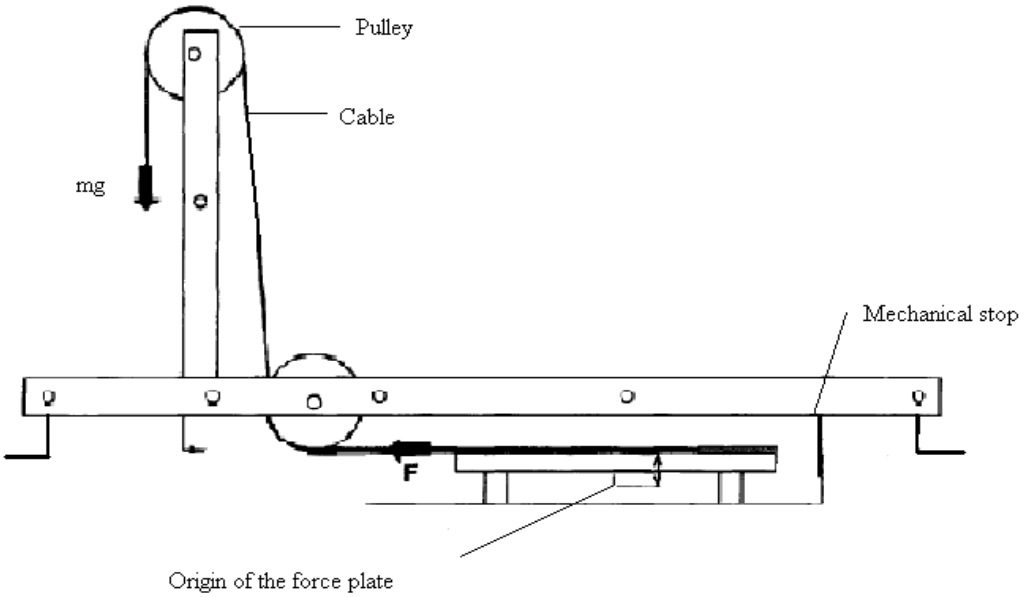


Figure 4.5: The calibration jig which was used for applying the horizontal force (Hall et al, 1996)

The mean value of error (%)	5.7 kg	10.7 kg	20 kg	25.7 kg	30 kg	40 kg	99.5 kg
Mediolateral direction	-2%	-1.8%	--------	-------	---------	--------	--------
Anteroposterior direction	--------	- 0.1%	-------	1%	--------	---------	--------
Vertical direction	--------	--------	1.2 %	---------	0.27%	1.1%	1.1%

Table 4.2: Errors of force plate 1 in different directions. The negative sign indicates that the force plate showed a mean value less than the actual weight

The mean value of error (%)	5.7 kg	10.7 kg	20 kg	25.7 kg	30 kg	40 kg	99.5 kg
Mediolateral direction	-1.97%	-1.43 %	-------	-------	---------	--------	--------
Anteroposterior direction	--------	-1.26%	-------	- 0.34%	--------	--------	--------
Vertical direction	--------	--------	1.49 %	---------	1.36 %	1.27%	1 %

Table 4.3: Errors of force plate 2 in different directions

Crosstalk	Force applied in ML direction	Force applied in AP direction	Force applied in vertical direction
F_x (N)	0.228%	----------	- 0.1718%
F_y (N)	----------	-0.032%	-0.056231%
F_z (N)	-1.247%	-1.3975%	----------

Table 4.4: The crosstalk of the force plate 1

Crosstalk	Force applied in ML direction	Force applied in AP direction	Force applied in vertical direction
F_x (N)	0.813%	----------	0.005343%
F_y (N)	----------	-0.0883%	0.38%
F_z (N)	1. 47%	1.678 %	----------

Table 4.5: The crosstalk of the force plate 2

open for 60 seconds were recorded in this research. Analogue signals were sampled at a frequency of 120 Hz with an analogue to digital converter and were stored on a computer. The collected data (in volts) were thereafter transferred into Newton and Newton metre by multiplying the data by the full calibration matrix which was specific for each force plate and was provided by manufacturer. The signal of the force plate was filtered with a Woltring filter with cut off frequency of 10 Hz (the frequency of filtering in the Vicon system was set at 10 Hz) (Santos et al, 2008, Lafond et al, 2004).

4.1.2.2 Gait analysis parameters

Various gait parameters were selected to be analyzed during walking of the normal subjects with and without orthosis, which included:

a) Excursion of the hip joint flexion/extension
b) Excursion of the hip joint abduction/adduction
c) Hip joint flexing/extending moment
d) Hip joint abducting/adducting moment
e) The magnitude of the vertical force applied on the foot
f) The magnitude of the vertical force applied on the crutch
g) The Force time integral (FTI) of the crutch force
h) Spatio-temporal parameters

Hip joint flexion/extension angles during walking were defined as the angle of rotation of the thigh segment relative to the pelvic segment (created by attaching the four markers on the pelvis), figure 4.6. So the flexion/extension excursion was defined according to the following equation.

Hip flexion/extension excursion = The peak of flexion + the peak of extension Eq. 4.7

Hip joint abduction/adduction angles during walking were defined as the angle of

rotation of the thigh segment relative to the pelvis segment, figure 4.7. The abduction/adduction excursion was defined according to the following equation.

Abduction/adduction excursion = The peak of abduction + the peak of adduction Eq. 4.8

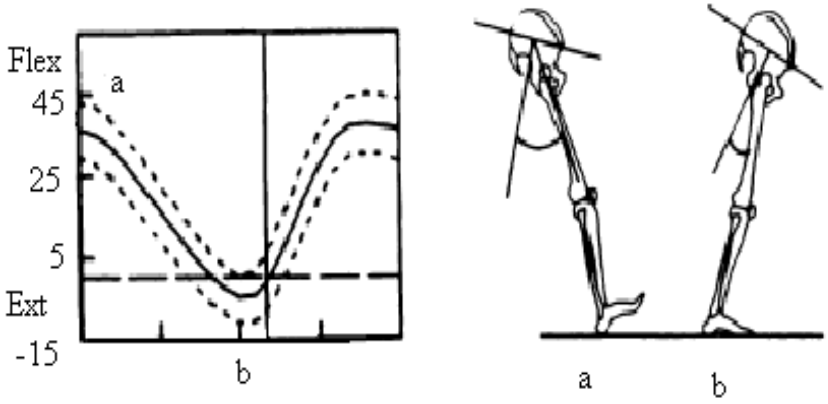


Figure 4.6: The flexion/extension angle of the hip joint is measured according to the angle between the thigh segment and pelvic segment (Gage et al, 1995)

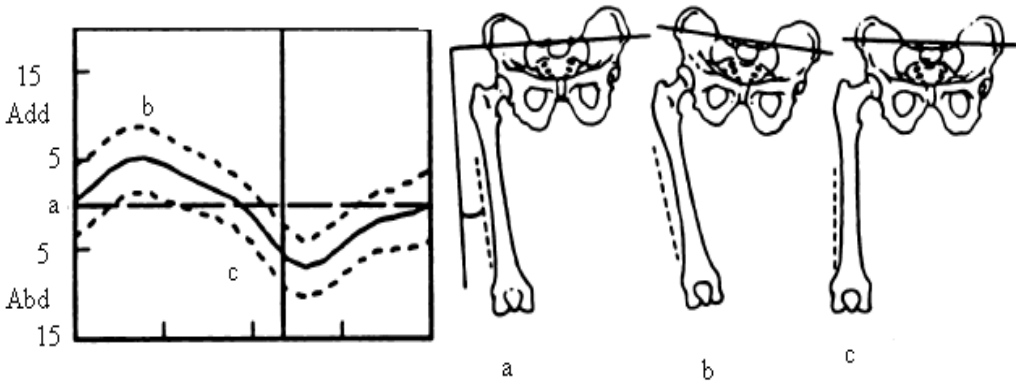


Figure 4.7: The abduction/adduction angle of the hip joint is measured according to the angle between the thigh segment and pelvic segment (Gage et al, 1995)

Stride length was calculated by measuring the horizontal distance travelled by the centre of gravity from a point of one gait cycle to a correspondence point in the next

gait cycle. In practice it was calculated by measuring the horizontal distance travelled by the heel marker during a gait cycle (heel contact to heel contact). Walking speed was calculated as measuring the distance travelled by COG and the corresponding time from a point of one gait cycle to the same point in the next gait cycle (in practice by measuring the walking speed of the marker attached on the sacrum). In this study it was represented as metre/minute (metre/min). Cadence was calculated by dividing 120 by the time taken for each gait cycle. The detection of the heel strike was done from the data collected from the force plate and from TV data.

To obtain the magnitude of the hip joint moments, a mathematical equation based on the second law of Newton was used. This approach is named as inverse dynamics and is used noticeably in biomechanics. In this approach the lower limb segments are disconnected from each others and each is considered separately. The human body is divided into a foot, shank, thigh and trunk with their mass which is concentrated in a point called Centre of Mass (COM). The COM of each part of the human body was calculated by different researchers of which a suitable one was done by Winter (1991). The applied moments around the hip joint were collected using a model which was developed using "the Bodybuilder for Biomechanics" (Vicon Motion Systems Ltd, Oxford). This software allowed calculation of the external joint forces and moments from the collected data. The location of the COM of each part of the body was defined using the same study carried out by Winter (1991). The calculated moments were normalized by body mass.

There were some limitations in using inverse dynamics for a multi segmental and combined structure like orthosis and human body. The first limitation was the interface motion between the orthosis and the participant's body. By proper design of the orthosis components, the interface motions could be minimal and negligible. The second limitation was related to the estimation of the hip joint centre which is deep in the body and difficult to determine. The third limitation was regarding the

centre of rotation of the joints, such as the knee joint centre, which is changing during walking. Motion of the markers was another problem which influenced the accuracy of the calculated moments, especially those which were attached on the clusters. The location of the COM of the limb segments were estimated using the procedure suggested by Winter (1991), however there may be some small differences between the location of the COM amongst the subjects.

The validation of the model used, appendix 3, written with Bodybuilder software, was evaluated in the different gait analysis works carried out in the Bioengineering Unit of Strathclyde University (Agustsson, 2002). This model was developed by Victoria Hood and Alexander Nicol (unfinished PhD project). The accuracy of the outputs of this model was also evaluated by Malizos during walking of able body subjects (Malizos, 2006).

It was assumed that the combination of the body and the orthosis acts as a single rigid body. Although there may be some relative motions between the orthosis and the body during walking, by appropriately fitting of the orthosis, these motion are small and negligible (Johnson et al, 2004). For calculation of the moment it was assumed that the orthosis and the limb act as a single rigid structure so the location of the COM was supposed to be in the same place as that in the body, although there was some discrepancy between the location of the COM of the normal body and the orthosis. In order to check the accuracy of the calculated moments using this assumption, the applied moments around the hip joint were calculated manually, for one subject only by considering the combination as a rigid body and in the second method by calculating the moments according to the new location of the COM. The position of the COM of the orthosis components was estimated by balancing the segments on a knife edge and measuring the distance between the edge and the joint. The overall mass properties of the subject and orthosis were obtained by using the parallel axis theorem. The following equation was used to determine the new location of the COM of the orthosis and body.

$$COM = \frac{y_1 m_1 + y_2 m_2}{m_1 + m_2} \qquad \text{Eq. 4.9}$$

Where m_1 and m_2 were the mass of the orthosis and the body segments, respectively, and y_1 and y_2 were the locations of the COG of the orthosis and the body segments relative to a specific joint. The parameters which were used in order to determine the difference between the two moments are listed in the table 3.2. The graph of the moment applied at the hip joint is represented by choosing the combination of the orthosis and body segments as a single structure and then separately, figures 4.8.

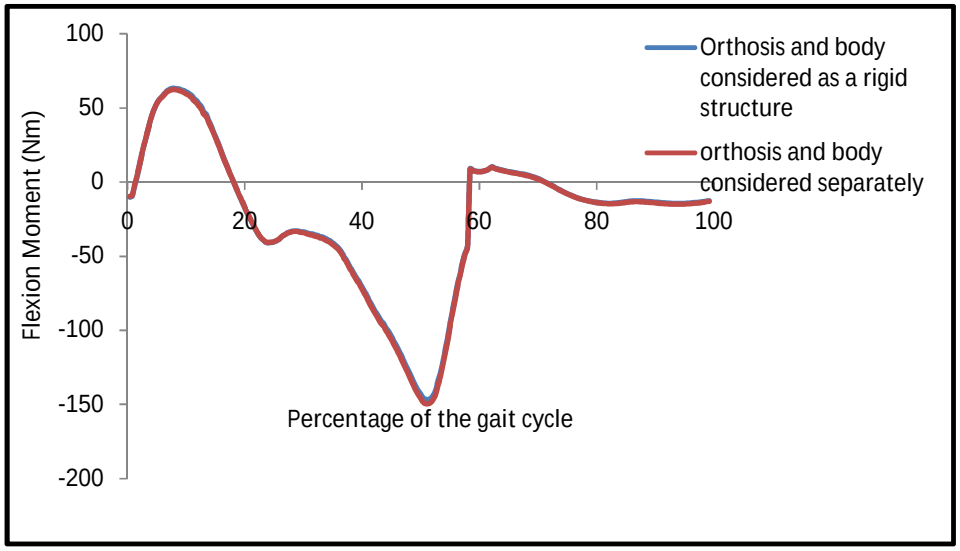


Figure 4.8: The difference between two methods of the moment calculations, i.e. (1) Orthosis and body segments considered as a rigid structure, and (2) orthosis and body segments considered separately. As can be seen there is no difference between the pattern and the peak values of flexion and extending moments between the methods

The magnitude of the vertical force applied on the foot and crutch was determined using the force plate. It was normalized by body weight. The vertical force applied on the crutch was another parameter selected in this study, which was normalised by

body weight. The reliability of the crutch force was evaluated by Ijzermen et al (1999). They mentioned in their research that the reliability of the crutch force is high enough to be used as a good parameter to represent the performance of any orthoses used for SCI subjects. The crutch force impulse was another parameter used to check the force applied on the crutch with respect to time. It is the integral of the crutch force in respect with the time. It was determined according to the following equation.

$$I = \sum Fdt \qquad \text{Eq. 4.10}$$

Where, I is the impulse, F is the crutch force and dt is an infinitesimal amount of time.

4.1.2.2. I Global reference frame used in this study

The global reference frame which was used in this study was a right handed orthogonal three axes system which is used as a standard coordinate system for research related to the biomechanics field (Cole et al, 1995). The reference frame can be illustrated as follows, figure 4.9.

a) The positive X axis is described as an axis projected on the plane of the ground during level walking and pointing toward the direction of the progression
b) The positive Y axis is described as an axis pointing superiorly parallel to a line describing the direction of the gravitational force
c) The positive Z axis is described as an axis perpendicular to the defined X and Y. The positive Z axis of the right limb points laterally, however it points medially for the left limb

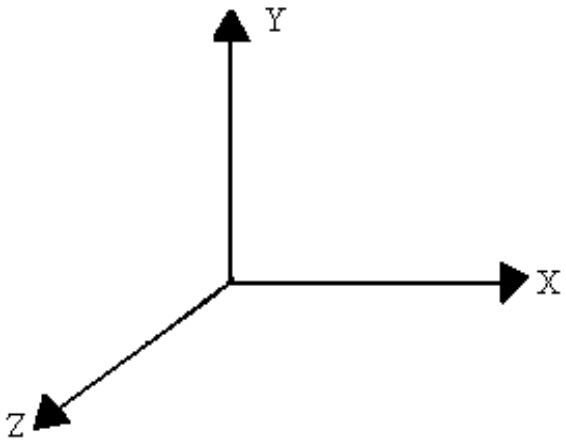


Figure 4.9: The reference frame used in this study

4.1.2.2. II The centres of the hip, knee and ankle joints

The hip joint centre was determined according to the method mentioned by Bell et al, 1990. The following equations were used to determine the hip joint centre (Bell et al, 1990).

$$X = -0.19\ PW \qquad \text{Eq. 4.11}$$
$$Y = -0.3\ PW$$
$$Z = 0.36\ PW$$

Where, PW (Pelvic Width) equals to inter ASIS (Anterior Superior Iliac Spine) distance and X, Y and Z are the coordinate system of the right hip joint centre in the pelvic anatomical coordinate system, figure 4.10. The knee joint was calculated as the midpoint between the medial and lateral epicondyles and the ankle joint centre was determined as the midpoint between lateral and medial malleoli.

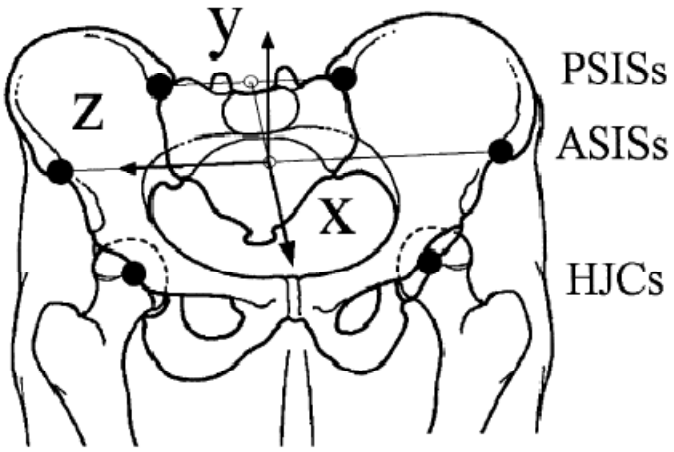


Figure 4.10: The anatomical landmark of the pelvis used for determining the coordinate system of pelvic segment (Cappozzo et al, 1995)

4.1.2.2. III Marker placement

The markers consist of a 14 millimeters sphere covered with a reflective sheet that is recognized by the cameras. The subjects wear special clothing to decrease the reflection from other parts of the body. The marker placement protocol described here depicts the preferred method of marker adhesion to the body and subsequent identification within the Bioengineering Unit of Strathclyde University. Table 4.6 shows the locations of the markers used in this study. Moreover, four marker clusters comprising four markers attached on rhomboid plates were attached to the anterior surfaces of the shins and thighs by using extensible Velcro straps. There was no problem in using the markers during walking with the orthosis, because they were attached on the relevant sections of the orthosis. In order to increase the visibility of the camera the clusters were placed equally between the anterior and lateral planes of the subject legs. The marker attachment process begun from the most distal segment of the lower extremity, i.e. the foot. Markers were placed on the foot when the subject was in a sitting position. The location of the epicondyles of the knee joint in the medial and lateral sides was determined using a Pointer (Erdemir and Piazza, 1999), on the fully marked-up subject standing on the force plate area during static calibration, figure 4.11.

Marker	Location
RASIS	Right anterior superior Iliac spine
LASIS	Left anterior superior Iliac spine
RPSIS	Right posterior superior Iliac spine
LPSIS	Left posterior superior Iliac spine
RT1	Anterior surface of right thigh (right thigh cluster)
RT2	
RT3	
RT4	
LT1	Anterior surface of left thigh (left thigh cluster)
LT2	
LT3	
LT4	
RMM	Right medial malleoli
RLM	Right lateral malleoli
LMM	Left medial malleoli
LLM	Left lateral malleoli
RMT1	Right first metarsal
RMT5	Right fifth metatarsal
LMT1	Left first metarsal
LMT5	Left fifth metarsal
RH	Right heel
LH	Left heel
RS1	Anterior surface of right shin (right shin cluster)
RS2	
RS3	
RS4	
LS1	Anterior surface of left shin (right shin cluster)
LS2	
LS3	
LS4	

Table 4.6: The location of the markers used for the gait analysis test

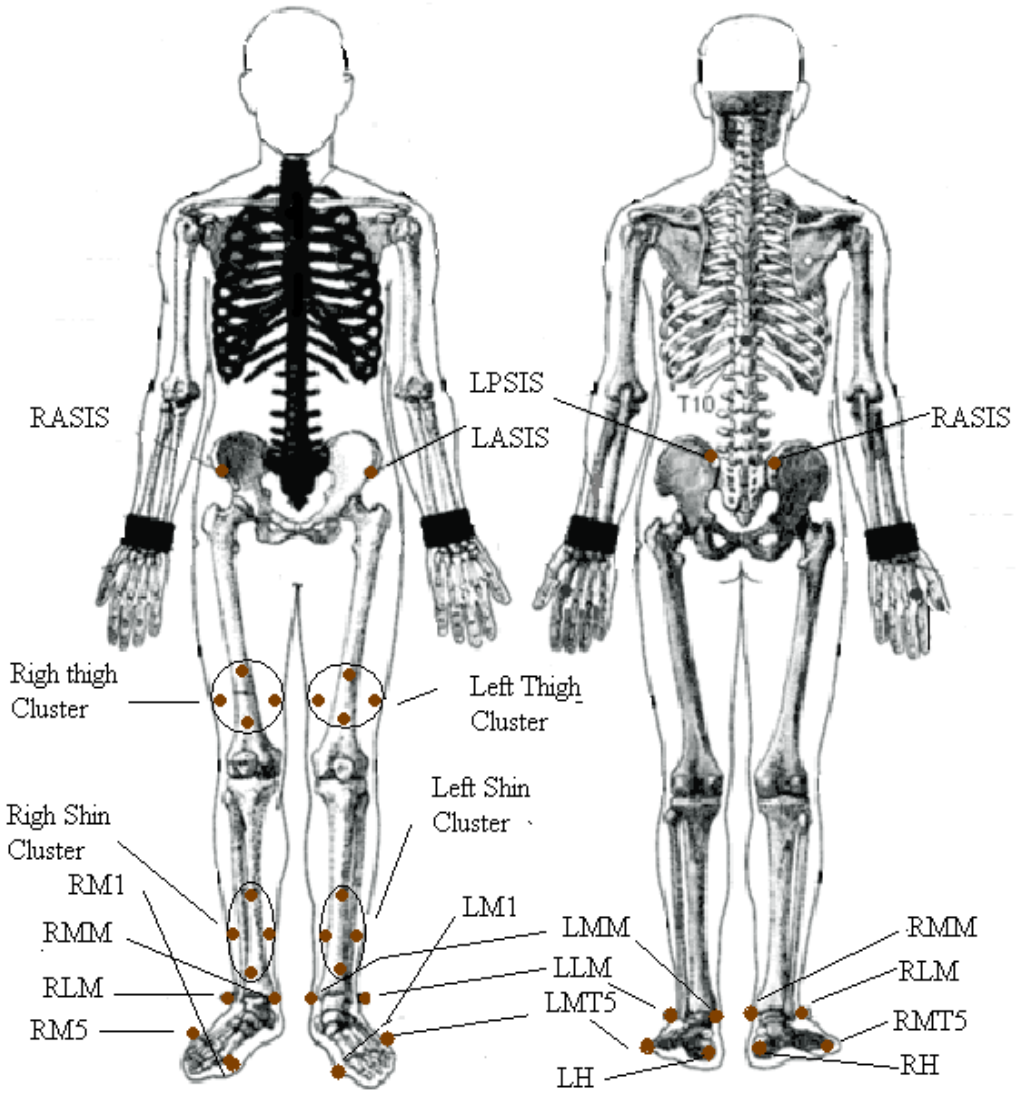


Figure 4.11: The locations of the markers used in this research study

Parameters	Mean value
Mean Residual (SD)	0.792 mm (±0.217)
Residual Range	0.637 (0.403-1.04)
Wand visibility	48.25%
Static Reproducibility	0.65%

Table 4.7: The calibration data of the Vicon system. The mean residual must be less than one mm. It is the mathematical mean of the individual values

4.1.2.2. IV Calibration of the Vicon gait analysis system

According to the results of a study carried out by Ehara (Ehara, 2002), the accuracy of the Vicon system to estimate the distance between two markers is better than other available systems.

According to the results of this research the maximum value of the error with the Vicon system is less than 1%. Before starting data collection with the Vicon system, the system was calibrated. The calibrations were repeated for static and dynamic trials simultaneously. Table 4.7 shows the calibration results of the Vicon system which was done in this research.

4.1.2.2. V Gait analysis procedure

The subjects were trained how to wear the orthosis independently. First the AFO of the orthosis which was fitted into the shoes was worn by the subjects. In the second stage the Torso part of the orthosis was donned and secured by two straps. Finally the lateral bar of the orthosis was attached to the Torso and AFO sections and secured by using the appropriate pins. It took only half an hour to train the subjects how to wear the orthosis independently. Figure 4.12 shows a subject standing with the new RGO orthosis. The subjects received the necessary training to walk, in two sessions, with the orthosis using two sticks. The subjects were asked to stand near the middle of the calibration volume and static tests data were collected and repeated 5 times. Then, the subjects were asked to walk with a comfortable speed along the gait lab. In order to increase the accuracy of the collected data, the trials were repeated 5 times. In the next stage, the tests were repeated to collect the magnitude of the force applied on the crutch during walking (5 times).

4.1.2.3 Energy consumption test

In order to check the amount of energy consumption during walking with the orthosis with different hip joint configurations and in normal walking, heart rate

monitoring was selected. The heart rate during resting and walking and the walking speed were the parameters used for energy consumption based on PCI. PCI was used to represent the energy consumption of the participants during normal walking and walking with the orthosis. It is determined according to the following equation (McGregor, 1979).

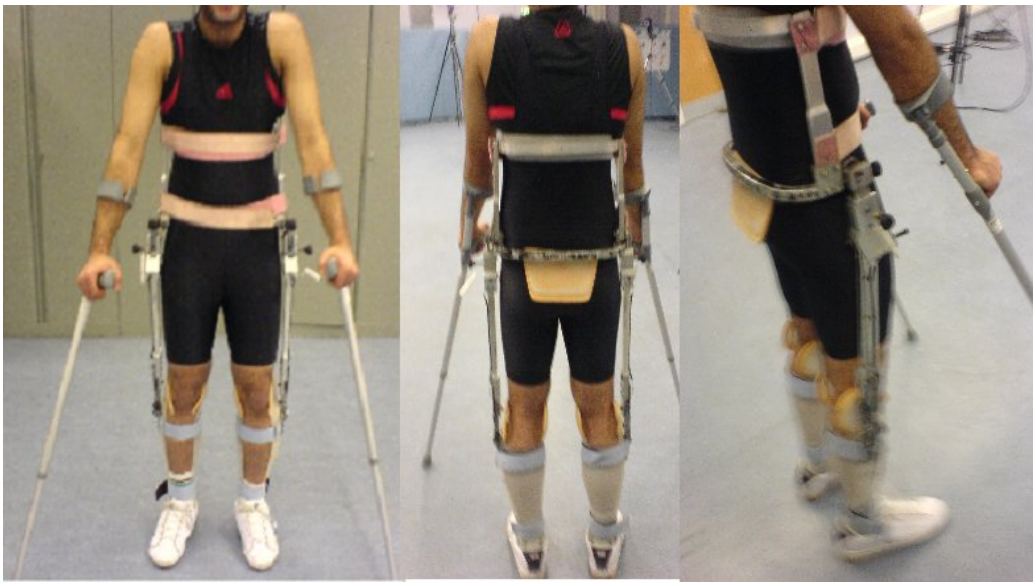


Figure 4.12: The new RGO orthosis, configuration 1, donned by a participant

$$\text{PCI (beats/metre)} = \frac{\text{heart rate during exercise - heart rate during resting (beats/min)}}{\text{Walking speed (metre/min)}} \quad \text{Eq. 4.12}$$

For the energy consumption test, a Polar Accurex Plus heart rate monitor was used, which was manufactured by Polar Company, Finland. This system is also named as Polar electro, Finland and consists of a transmitter embedded in an electrode belt. The receiver and recorder are located in an especially designed wrist watch. The belt has two electrodes that are covered by a special rubber and is worn around the chest below the nipple line. The collected heart rate was transmitted to the wrist watch by the help of electromagnetic waves. The data was collected by a receiver in a wrist watch with 5 seconds intervals. The Polar interface Plus was used to transmit the collected data from the wrist watch to a personal computer. The accuracy of this system in collecting the heart rate is claimed to be ±1 beats per minute. According to the results of the various studies carried out, PCI is an easy to use, valid and reliable

measure of energy expenditure and it can be used to analyze the efficiency of any orthoses and assistive devices (Bailey and Ratcliffe, 1995). The reliability of PCI according to the result of the work carried out by Jaigesimi and Fashakin (Jaiyesimi and Fashakin, 2007), was acceptable, as was discussed in chapter 2 in details.

A 30.4 meter tract with an 8 shape figure was measured out in the lab as is shown in figure 4.13. The figure of eight is common in the literature for evaluation of energy consumption during walking. Walking along this figure enabled the subjects to have a steady walking speed during walking and the effects of the dominate limb would be diminished. In the literature a 25 metre eight shape track was used however, with the size of space available in the lab of Bioengineering Unit it was possible to have an eight shape tract with 30.4 m length.

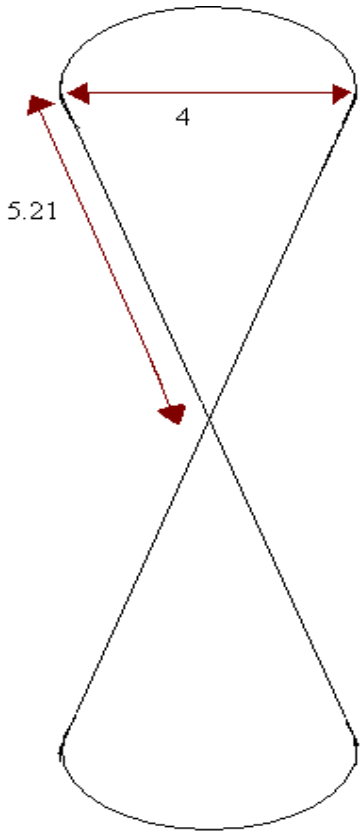


Figure 4.13: The figure of the tract used for the energy consumption test in this project

4.1.2.3. I Test procedures used to measure energy consumption

Subjects were asked to attend the laboratory with the same clothes as they wear every day however, they walked with the same shoes during all the tests. They were asked not to eat, drink coffee or tea at least two hours before the test. None of the participants were smokers. In the first session of the test, the subjects were given information about the Polar system and how the data could be collected. The electrodes of polar heart rate monitor were moistened with water and its straps were adjusted according to the participant's size to obtain a snug fit. In the next stage subjects had worn the watch on their wrist. There was an upper limit of heart rate on the watch that could be changed according to subject's criteria. The upper limit on the watch was set to activate the alarm at 80 % of the subjects maximum predicted heart rate. This was calculated according to the following equation that was mentioned by Mc Ardle et al (McArdle et al, 1996).

$$\text{Upper limit} = (220\text{-age}) \times 0.8 \qquad \text{Eq. 4.13}$$

The lower limit was set at 40 beats per minutes and the data were collected at 5 seconds intervals. It should be mentioned that during the tests the environment temperature and humidity of the space remained constant. The test was done according to the following procedure:

a) Heart rate monitor worn by subject
b) Five minutes resting heart rate collected
c) Standing up and then remaining in this position for two minutes
d) Ten minutes of walking with a self selected walking speed around a 30.4 meter figure of eight path, during which data collection was continued
e) Five minutes of resting during which data was collected

After finishing the test the chest strap and wrist watch were removed and the data was send to a personal computer by using Polar interface Plus. Five minutes of recording the heart rate during the resting period was felt to be sufficient to achieve

a steady state before and after walking. The 10 minutes data collection during walking was reported by different investigators to be sufficient to achieve a steady state of heart rate. The mean values of the heart rate from the first to 4th minute and from 18th to 21st were used for measuring the resting heart rate. The mean value of heart rate during walking was obtained by averaging the heart rate between the 4th and 7th minute of walking.

4.1.3 Data Analysis

The data of the gait and stability analysis were sampled with a frequency of 120 Hz. The data were filtered with a Woltring filter and with a cut off frequency of 10 Hz (Santos et al, 2008, Granat et al, 1990). The data of the hip joint moments and the force applied on the crutch and foot were normalized by body mass and body weight, respectively. The mean values of five successful trials were obtained for every subject. As the number of the subjects who participated in this study was 3, the normal distributions of all mentioned parameters were tested by utilizing the Shapiro-Wilk test. As the parameters had normal distributions, a parametric statistical test could be used for analysing the difference between the mean values. The difference between the mean values of all mentioned parameters namely: stability, gait analysis and energy consumption, during normal walking and walking with the orthosis with different hip joint configurations were compared by using the Paired T test. The significant point (α point) was 0.05 for all parameters.

4.2 RESULTS

The final results of the gait analysis, stability analysis and energy consumption are shown in tables 4.8 and 4.9. The result of the statistical test is shown in tables 4.10 and 4.11. The details of the results from all parameters are shown in appendix 4.

	Parameters	Normal walking	Walking with orthosis with configuration 1	Walking with orthosis with configuration 2	Walking with orthosis with configuration 3	Walking with orthosis with configuration 4
Stability parameters	COP sway in AP (mm)	30.77 ±12.62	21.96 ±5.07	21.68 ±10	16.6 ±7.55	13.93 ±4.52
	COP sway in ML (mm)	17.72 ±9	11.37 ±0.92	10.31 ±1.48	11.49 ±4.66	8.96 ±3.47
Gait parameters	Flexion extension excursion (degree)	43.03 ±2.5	31.92 ±2	29.2 ±2.25	27.16 ±1.06	25.75 ±5.5
	Abduction adduction excursion (degree)	12.34 ±1.64	7 ±1.675	6.1 ±1.61	6.28 ±1.56	6.48 ±2.1
	Extending moment (Nm/kg)	0.88 ±0.225	0.447 ±0.167	0.477 ±0.04	0.646 ±0.267	0.455 ±0.047
	Flexing moment (Nm/kg)	0.853 ±0.119	0.615 ±0.153	0.618 ±0.343	0.617 ±0.47	0.68 ±0.292
	Adducting moment (Nm/kg)	1.13 ±0.074	1.012 ±0.135	1.025 ±0.176	0.84 ±0.267	0.819 ±0.061

Table 4.8: The mean values of the different parameters during standing and walking with and without the orthosis

Parameters	Normal walking	Walking with orthosis with configuration 1	Walking with orthosis with configuration 2	Walking with orthosis with configuration 3	Walking with orthosis with configuration 4
Stride length (m)	1.66 ±0.235	1.2 ±0.258	1.275 ±0.188	1.075 ±0.176	1.093 ±0.054
Cadence (steps/min)	105.2 ±5.87	52.95 ±3	58.6 ±1.6	59.63 ±1.45	58.36 ±3.34
Foot force (N/BW)	1.188 ±0.021	0.993 ±0.076	1.005 ±0.07	1.02 ±0.058	1.0167 ±0.066
Crutch force (N/BW)	--------	0.223 ±0.11	0.185 ±0.05	0.2 ±0.063	0.19 ±0.066
FTI (Ns)	--------	167.6 ±115	96 ±36.2	106.7 ±57.4	116 ±36.9
Stance phase %	60.8 ±2.46	62.62 ±4.4	61.6 ±2.22	62.36 ±3.73	63.28 ±0.97
Walking speed (m/min)	88.8 ±19.2	35.8 ±7.5	40.94 ±3.82	35.39 ±2.9	35.34 ±1.28
PCI (beats/min)	0.311 ±0.185	0.85 ±0.168	0.74 ±0.381	1.087 ±0.31	0.83 ±0.24

Table 4.9: The mean values of the different parametres, spatio-temporal and energy consumption, during walking with and without the orthosis

Parameters	Normal walking and configuration 1	Configurations 1 and 2	Configurations 1 and 3	Configurations 2 and 4
COP sway in AP	0.203	0.941	0.17	0.45
COP sway in ML	0.324	0.503	0.973	0.61
Flexion extension excursion	0.040.040.0.00000	0.022	0.02	0.485
Abduction adduction excursion	0.011	0.006	0.314	0.483
Flexing moment	0.078	0.75	0.126	0.709
Extending moment	0.244	0.979	0.994	0.165
Adducting moment	0.423	0.102	0.064	0.091

Table 4.10: The P-values of the difference between the mean values of the parameters in standing and walking with and without the orthosis

Parameters	Normal walking and configuration 1	Configurations 1 and 2	Configurations 1 and 3	Configurations 2 and 4
Stride length	0.021	0.642	0.101	0.271
Cadence	0.006	0.024	0.094	0.935
Foot force	0.071	0.857	0.497	0.64
Crutch force	----------	0.41	0.703	0.524
FTI	----------	0.41	0.526	0.005
Stance phase	0.535	0.659	0.89	0.429
Walking speed	0.024	0.141	0.903	0.163
PCI	0.007	0.538	0.187	0.584

Table 4.11: The P-values of the difference between the mean values of the parameters in walking with and without the orthosis

4.2.1 Stability Parameters

The stability of the participants in the **anteroposterior direction** improved when they stood with the orthosis however, the difference between the mean values was not significant (p-value=0.2). Aligning the orthosis in abduction did not influence the stability in the anteroposterior plane, as was expected. However, restriction of the hip joint range of motion increased the stability of the subjects. The stability of the subjects during standing with the orthosis using configuration 4 was better than that with configuration 3.

The amount of stability of the participant in the **mediolateral direction** improved when the range of the motion of the hip joint was restricted and also by increasing the amount of abduction in the hip joint of the orthosis. The stability of the subject in the coronal plane increased when using the orthosis in contrast to that in normal standing. The mean values of the stability parameters in standing with the orthosis using different hip joint configurations and those of normal standing are shown in table 4.8.

4.2.2 Gait Analysis Parameters

The mean values of the gait parameters during normal walking and walking with the orthosis are shown in table 4.9.

4.2.2.1 Spatio-temporal gait parameters

The values of stride length, walking speed, and cadence were calculated for each gait cycle during normal walking and walking with the orthosis with different hip joint configurations, table 4.9. The paired sample t test was used to evaluate the difference between the means of the mentioned parameters during walking with and without the orthosis.

The mean value of the stride length during walking was 1.66 m, compared with 1.2 m during walking with the orthosis. There was a significant difference between the mean values of the stride length during normal walking and walking with the orthosis (p-value= 0.02). Building up the orthosis in abduction increased the stride length partially (the p-value of the difference between the means of the stride length was (0.64). Although restriction of the hip joint range of motion (configuration 3) decreased the stride length, the difference was not significant (p-value = 0.1).

The mean value of the velocity during walking with the orthosis using configuration 1 was less than half of that in normal walking. The p-value of the difference between the velocity of walking in normal walking and in walking with the orthosis was 0.0214. Incorporating some degrees of abduction in the orthosis (configuration 2) increased the velocity of walking, as it was 35.8 m/min for configuration 1 and 40.94 m/min for configuration 2 however, the difference was not significant (p-value = 0.141). The mean value of the walking speed in the orthosis with configuration 1 was 35.8 compared to 35.4 m/min in configuration 3.

The mean value of the cadence during normal walking was two times more than that with the orthosis using configuration 1. Building up the orthosis in abduction increased the cadence significantly; the p-value was 0.024. Restricting the range of motion of the hip joint in the orthosis with configuration 3 increased the cadence however, the difference was not significant.

The percentage of the stance phase during normal walking and walking with the orthosis varied between 60.8 (normal walking) and 63.28 % (walking with the orthosis utilizing configuration 4). There was no significant difference between the percentages of the stance phase during walking with the orthosis using different hip joint configurations and normal walking.

4.2.2.2 Hip joint excursions in the frontal and coronal planes

The range of motion of the hip joint in the sagittal plane significantly decreased during walking with the orthosis in contrast to that in normal walking (p-value = 0.04). Incorporating 5 degrees of abduction decreased the hip joint range of motion during walking with the orthosis; it was 31.9 and 29.2 degrees with configuration 1 and 2, respectively (p-value = 0.022). The hip joint range of motion in configuration 3 was almost 5 degrees less than in configuration1. The flexion extension patterns of motions of the hip joint during walking with and without the orthosis are shown in figures 4.14 to 4.18.

The abduction-adduction excursion of the hip joint during walking with the orthosis using configuration 1 was significantly less than that during normal walking (p-value = 0.011). The hip joint range of motion in the orthosis with configuration 2 was significantly less than that with configuration 1; it was 7 degrees for configuration 1 compared to 6.1 degrees for configuration 2. The p-value of the difference between the mean values was 0.006. Decreasing the range of motion reduced the excursion of the hip joint in the coronal plane however, this difference was not significant (p-value = 0.314). The excursion of the hip joint in the coronal plane decreased during walking with the orthosis using configuration 4 in contrast to that in configuration 2 (p-value = 0.091). The abduction-adduction patterns of motions of the hip joint are shown in figures 4.19 to 4.23.

4.2.2.3 Hip joint flexing/extending and abducting/ adducting moments

The hip joint flexing/extending moments during normal walking and walking with the orthosis using different configurations are shown in figure 4.24 to 4.28 (subject 1). The mean value of the flexing moment applied at the hip joint during walking with the orthosis with configuration 1 was less than that in normal walking however, the difference between the mean values was not significant. There was no significant difference between the mean values of the flexing moments applied at the hip joint using different hip joint configurations.

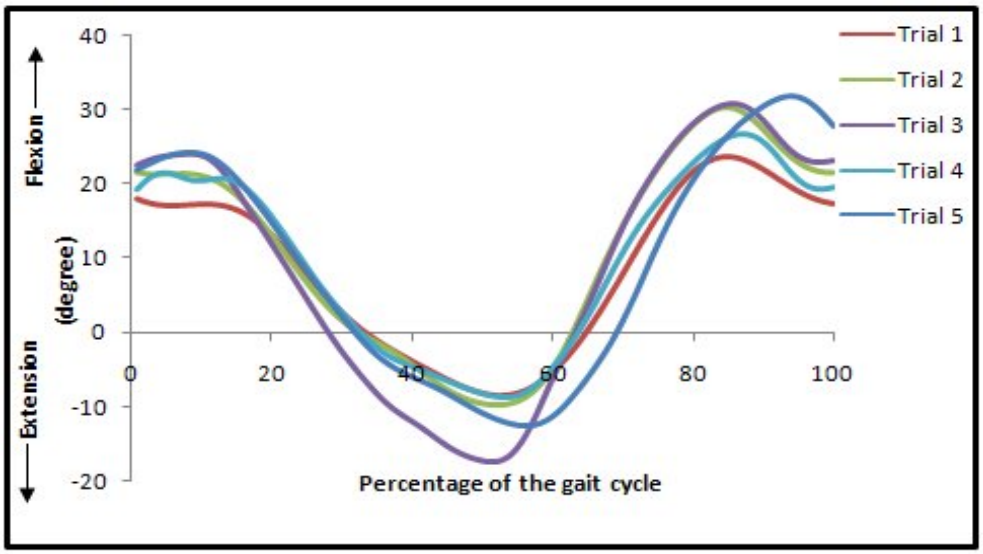


Figure 4.14: Flexion/extension angle of the hip joint during normal walking, subject 1

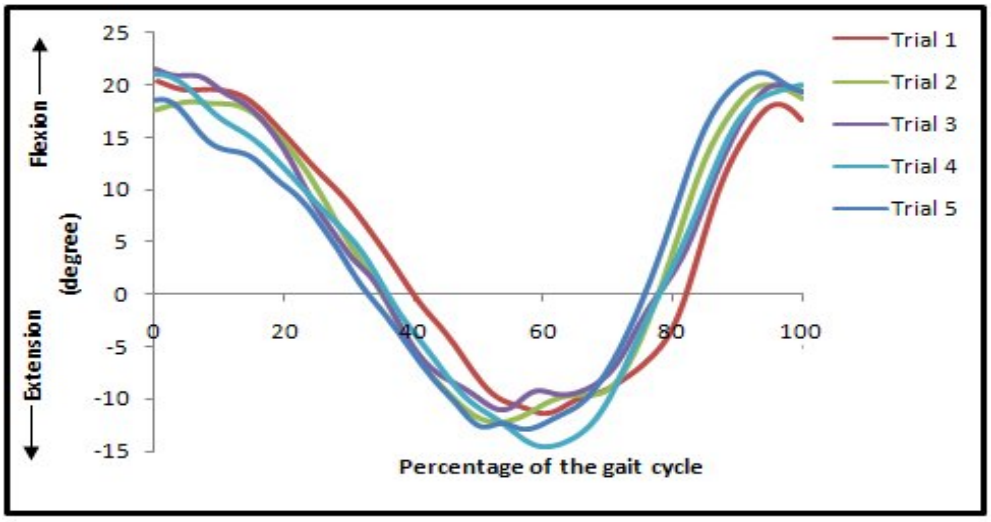


Figure 4.15: Flexion/extension angle of the hip joint during walking with the orthosis, configuration 1, subject 1

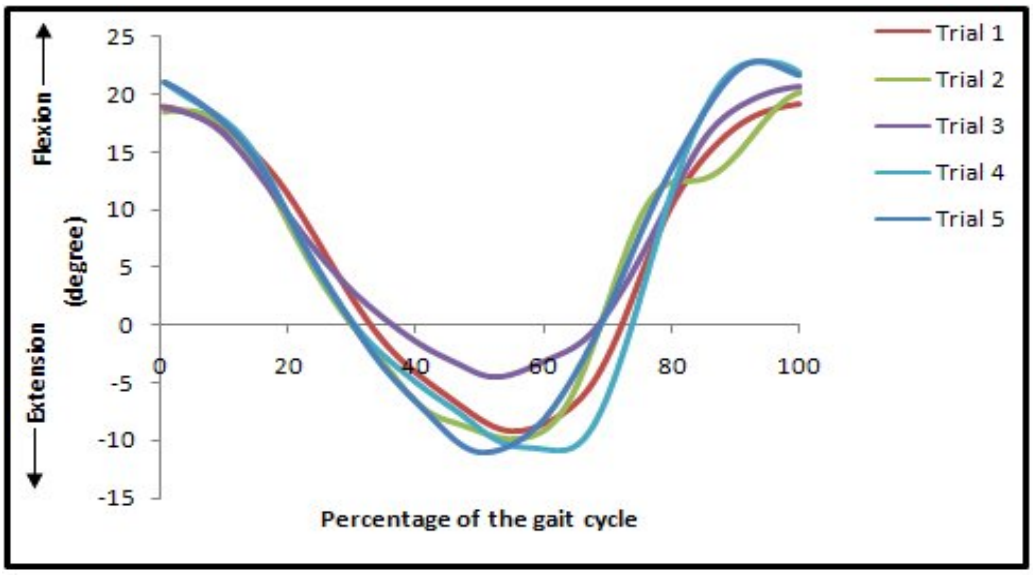


Figure 4.16: Flexion/extension angle of the hip joint during walking with the orthosis, configuration 2, subject 1

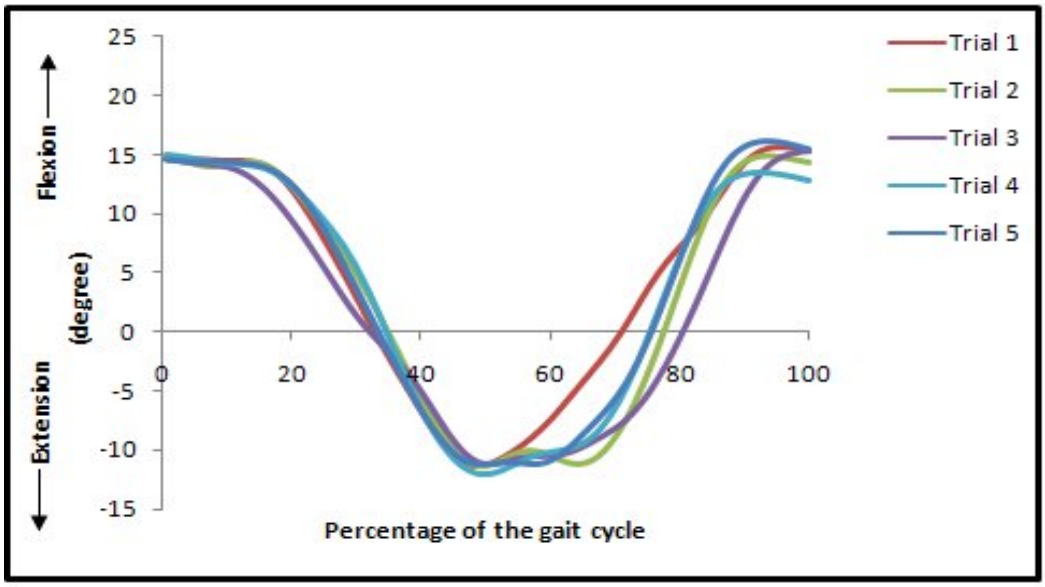


Figure 4.17: Flexion/extension angle of the hip joint during walking with the orthosis, configuration

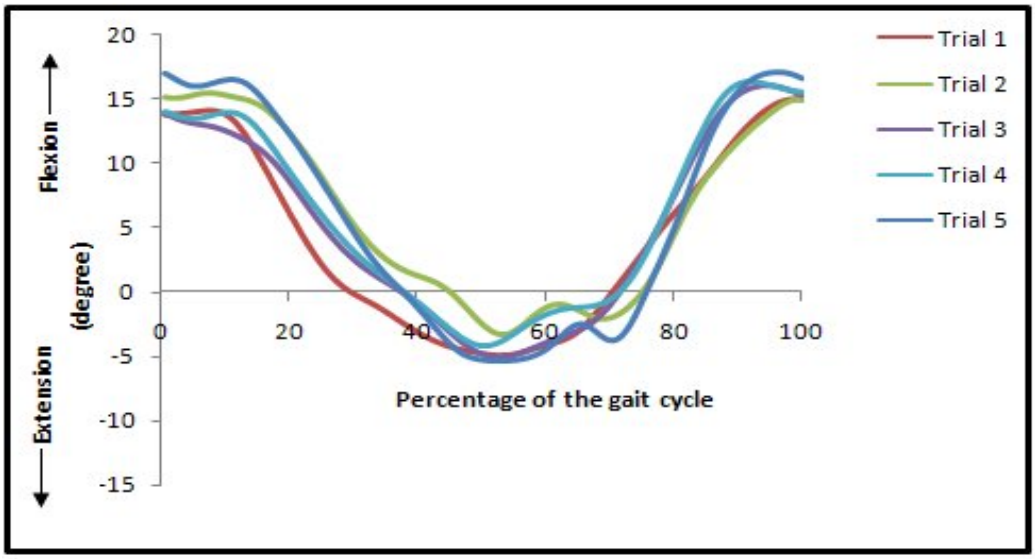


Figure 4.18: Flexion/extension angle of the hip joint during walking with the orthosis, configuration 4

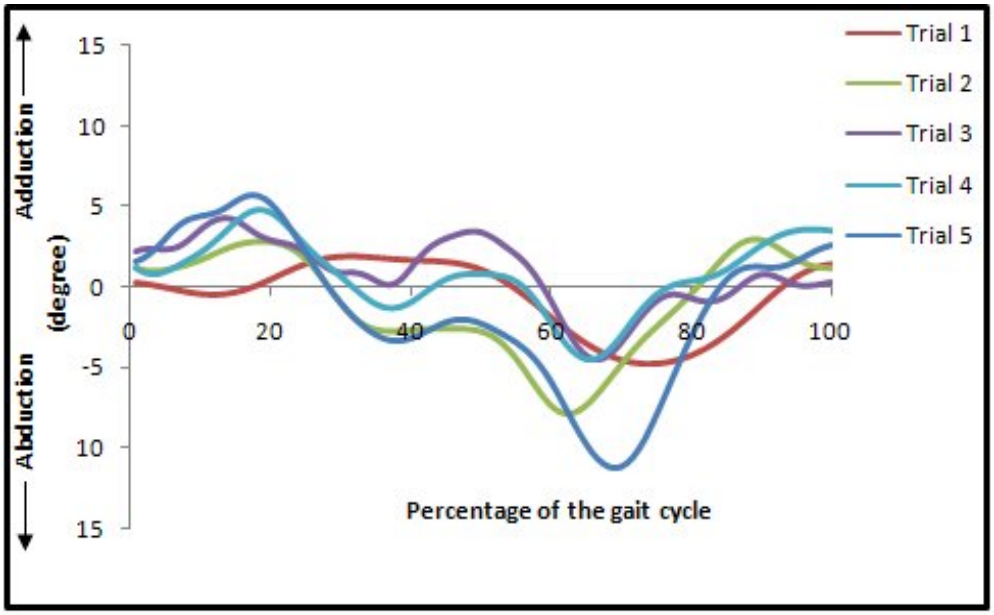


Figure 4.19: Abduction/adduction angle of the hip joint during normal walking, subject 1

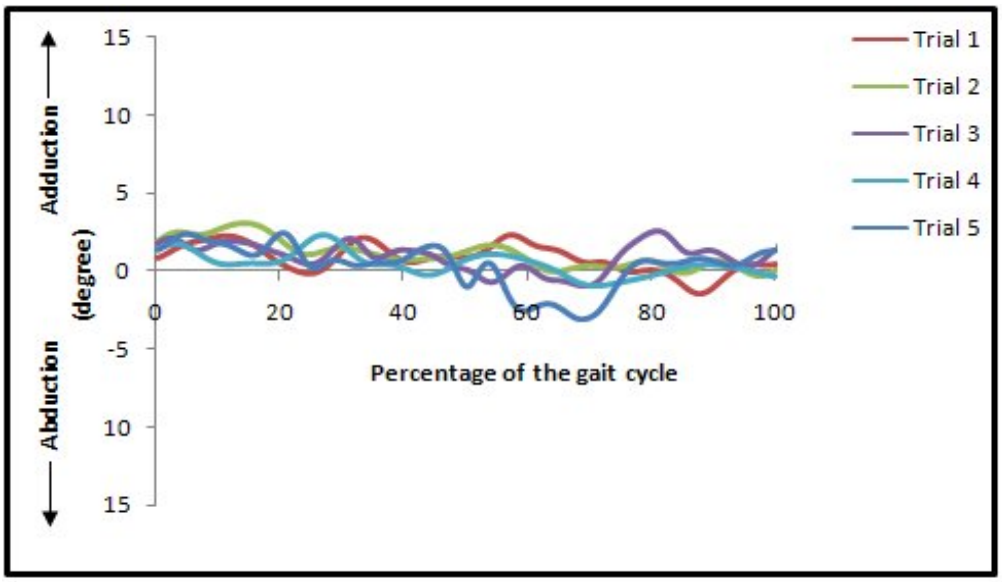


Figure 4.20: Abduction/adduction angle of the hip joint during walking with the orthosis with configuration 1

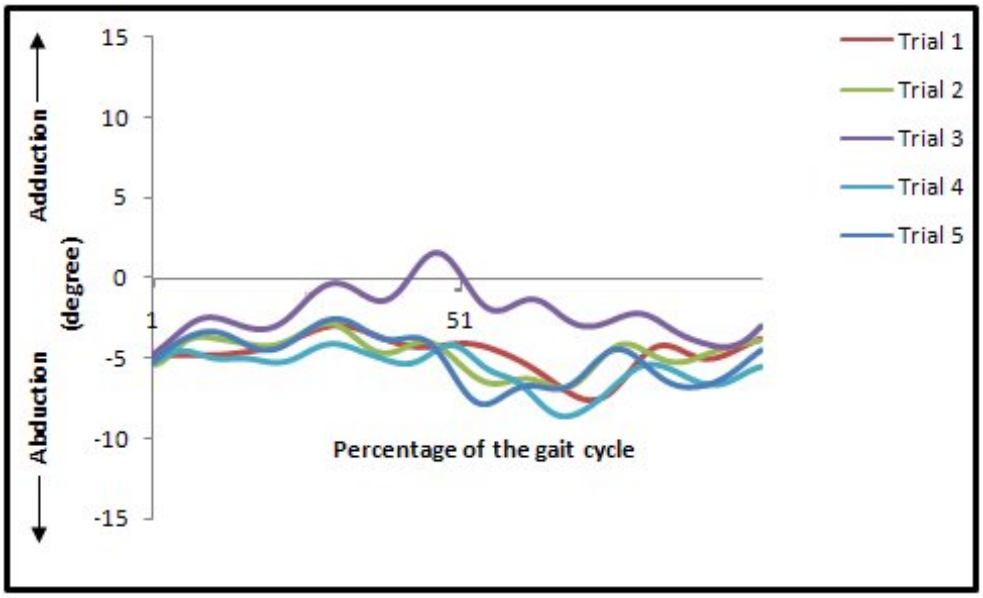


Figure 4.21: Abduction/adduction angle of the hip joint during walking with the orthosis with configuration 2

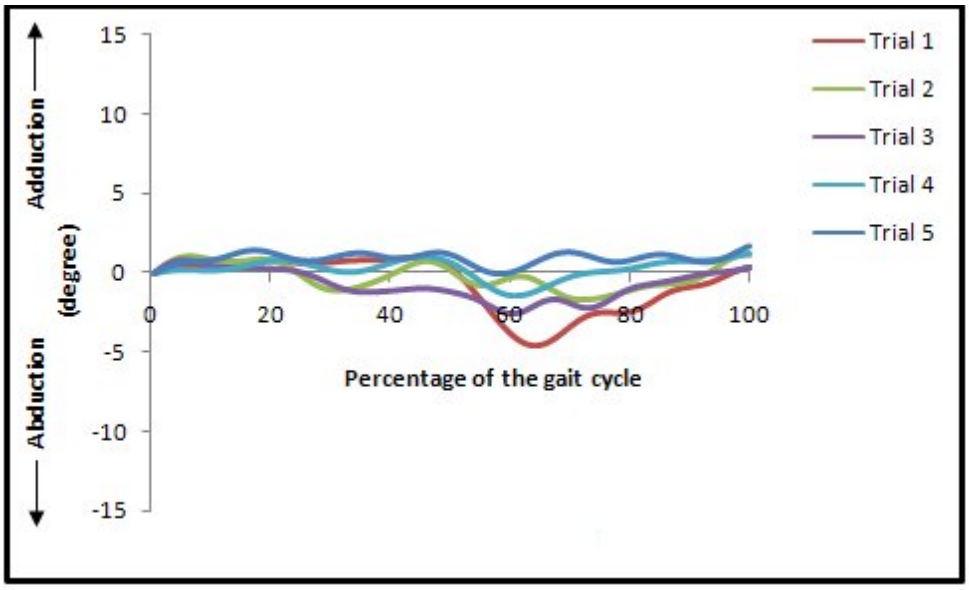


Figure 4.22: Abduction/adduction angle of the hip joint during walking with the orthosis with configuration 3

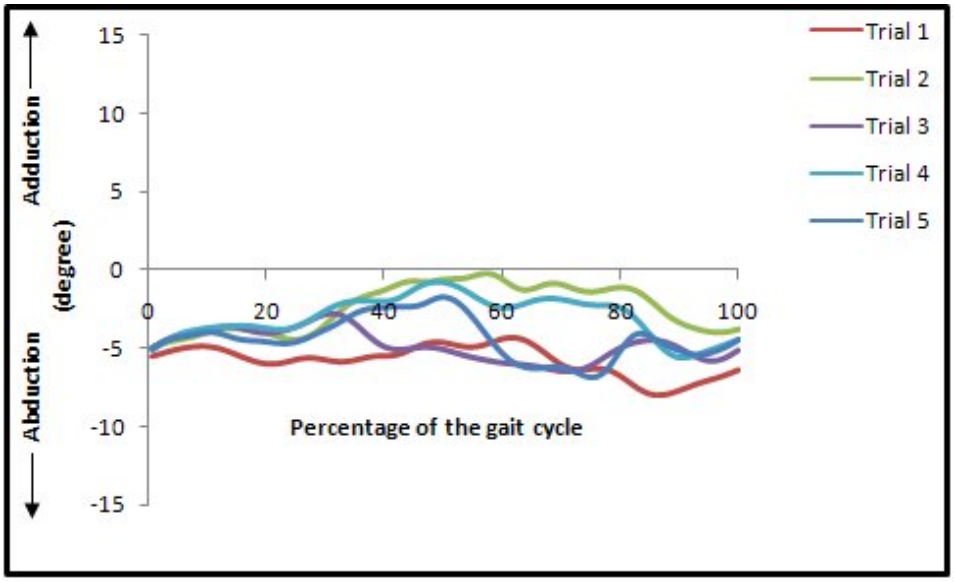


Figure 4.23: Abduction/adduction of the hip joint during walking with the orthosis with configuration 4

The maximum extending moment of the hip joint during normal walking was twice than that during walking with the orthosis utilizing configuration 1. Building up the orthosis in abduction increased the extending moment of the hip joint in configuration 2. Restricting of the hip joint motion in the sagittal plane increased the extending moment however, the difference between the mean values was not significant.

The adducting moments applied at the hip joint in walking with and without the orthosis are shown in figures 4.29 to 4.33 (subject 1). The mean values of the adducting moments of the hip joint in walking with the orthosis decreased in contrast to those in normal walking, table 4.8. Restricting the hip joint range of motion lowered the adducting moment applied on the orthosis in configuration 3. The mean values of the adducting moments applied at the hip joint were 1.025 and 0.819 Nm/kg in configurations 2 and 4, respectively.

4.2.2.4 Force applied on the foot and crutch

The forces applied on the foot during walking with and without the orthosis are shown in figures 4.34 to 4.38 (subject 1). The mean values of the force applied on the foot were 1.188 and 0.993 N/BW in normal walking and walking with the orthosis with configuration 1, respectively.

Restriction of the hip joint range of motion and incorporating 5 degrees of abduction improved the amount of force applied on the foot however, the difference between the mean values in configurations 1, 2, 3 and 4 was not significant.

The vertical component of the crutch force during walking with the orthosis with various configurations is shown in figure 4.39 to 4.42, subject 1. The mean value of the crutch force in configuration 1 was 0.223 N/BW compared with 0.185 using

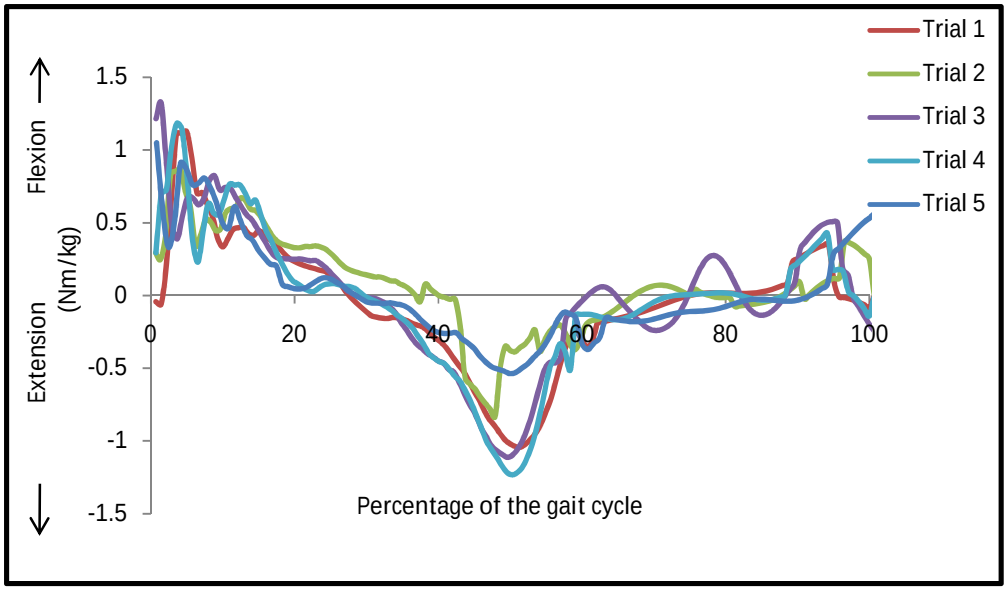


Figure 4.24: The flexing/extending moment of the hip joint during normal walking, subject 1

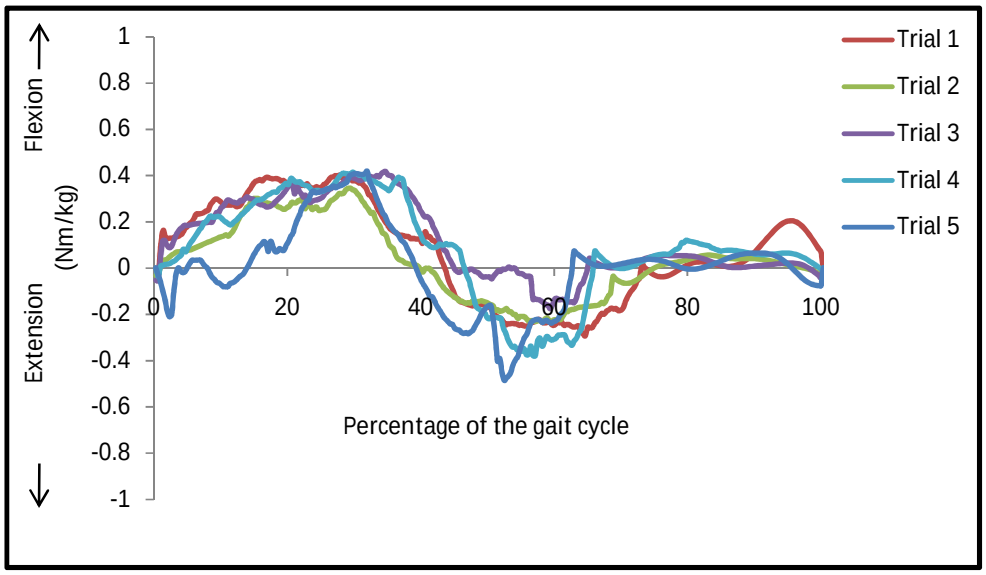


Figure 4.25: The flexing/extending moment of the hip joint during walking with the orthosis with configuration 1

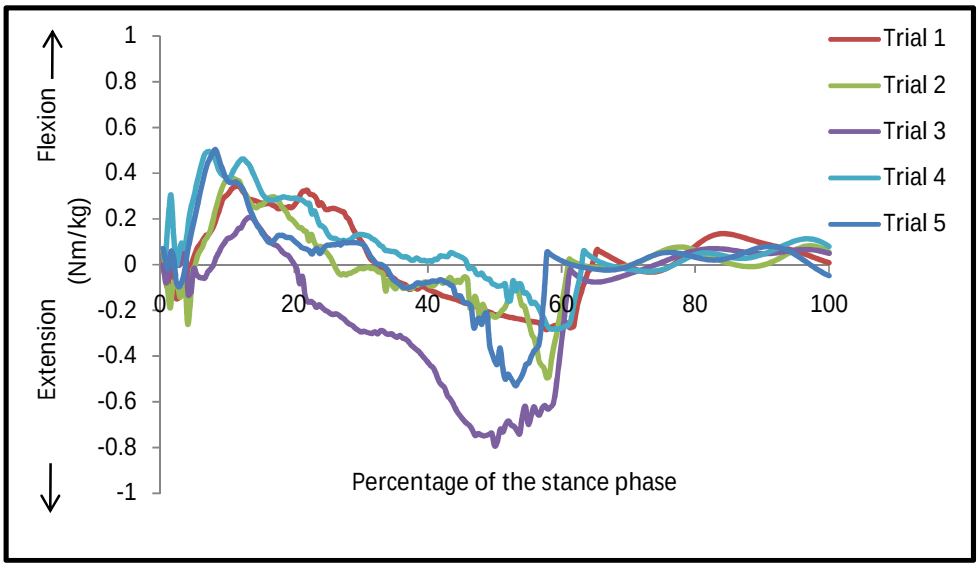


Figure 4.26: The flexing/extending moment of the hip joint during walking with the orthosis with configuration 2

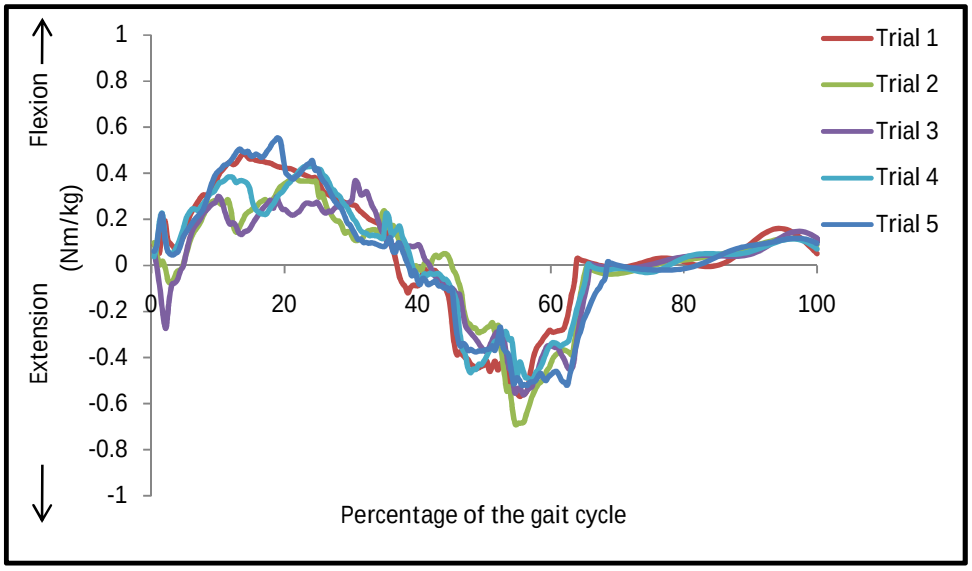


Figure 4.27: The flexing/extending moment of the hip joint during walking with the orthosis with configuration 3

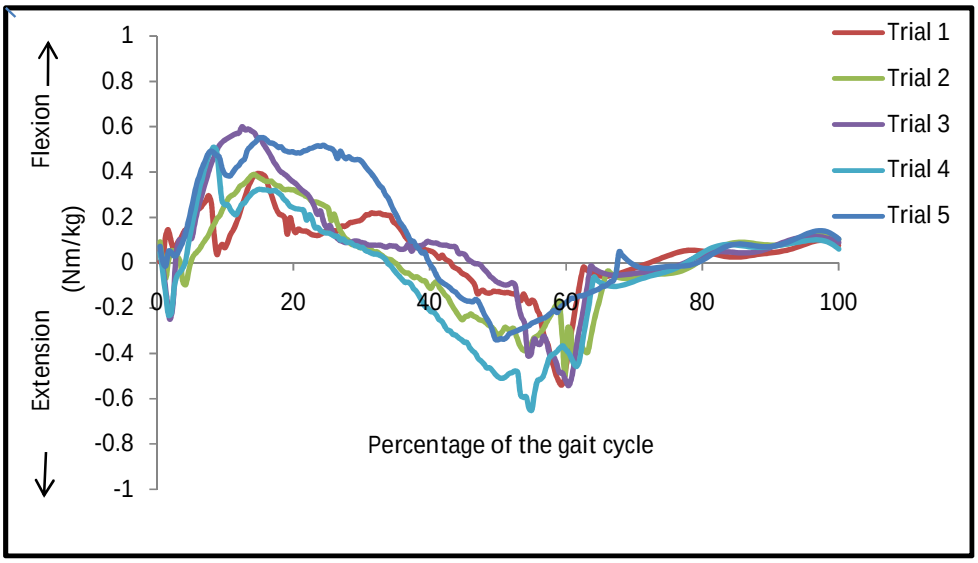


Figure 4.28: The flexing/extending moment of the hip joint during walking with the orthosis with configuration 4

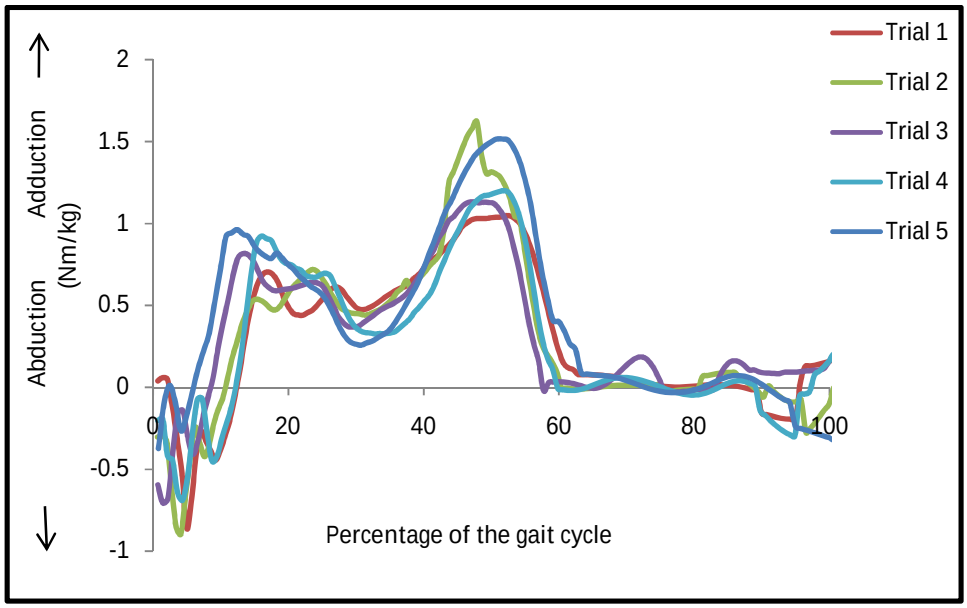


Figure 4.29: The adducting moment of the hip joint during normal walking, subject 1

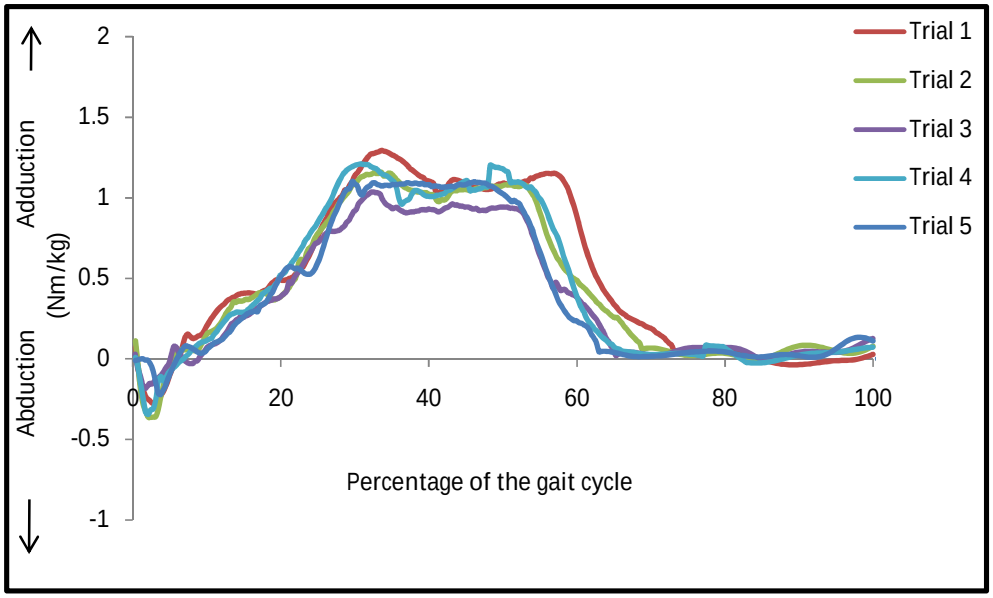


Figure 4.30: The adducting moment applied at the hip joint during walking with the orthosis with configuration 1

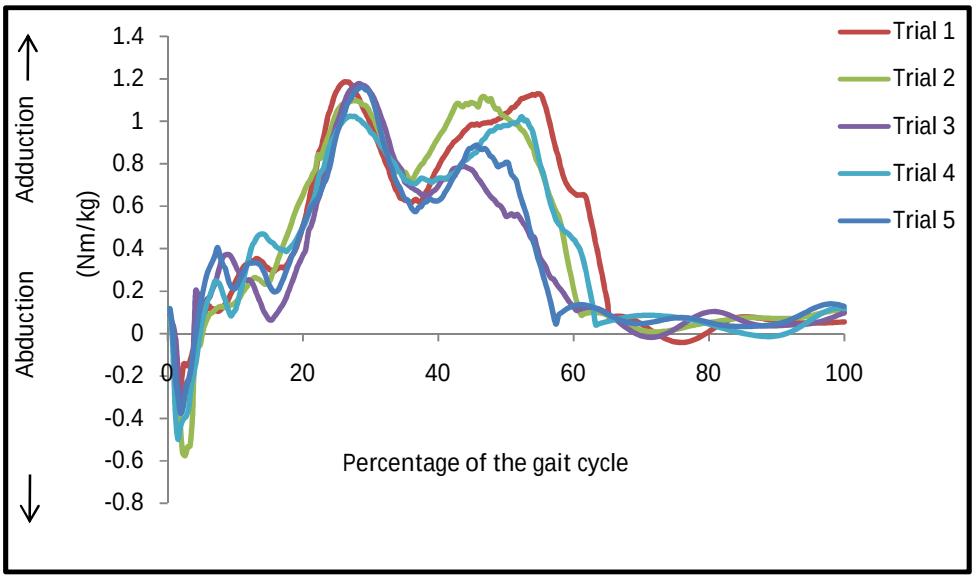


Figure 4.31: The adducting moment applied at the hip joint during walking with the orthosis with configuration 2

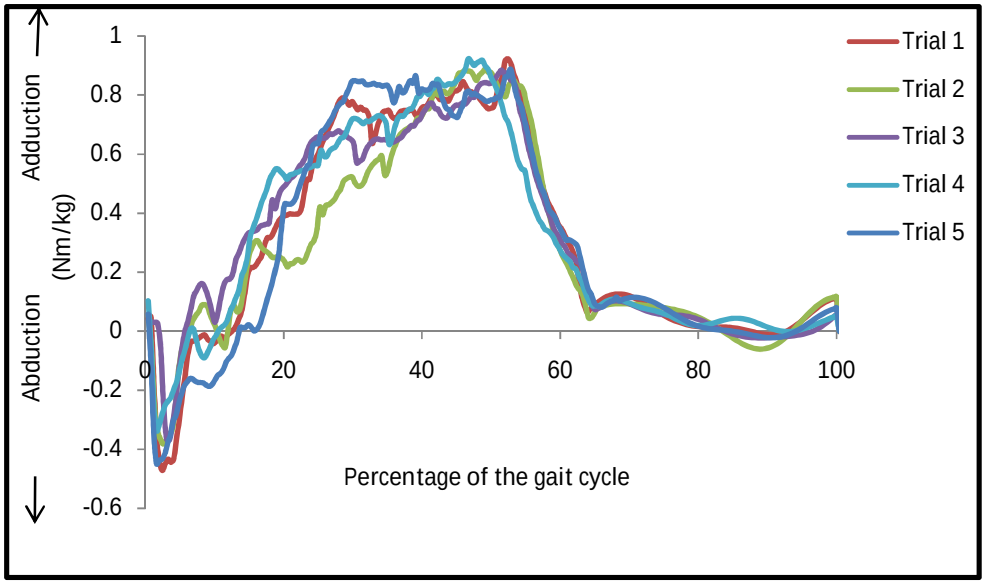


Figure 4.32: The adducting moment applied at the hip joint during walking with the orthosis with configuration 3

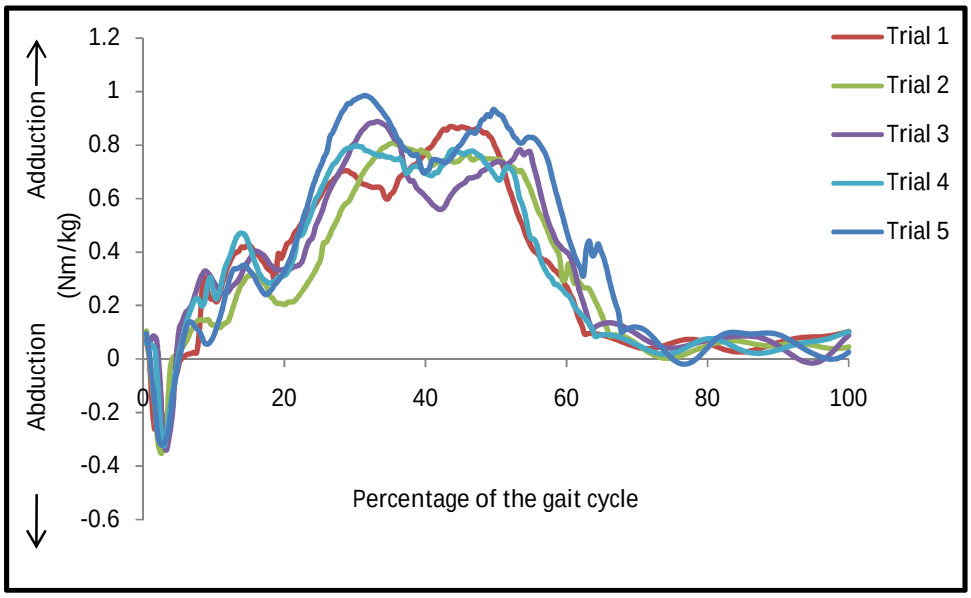


Figure 4.33: The adducting moment applied at the hip joint during walking with the orthosis with configuration 4

configuration 2. Building up the orthosis in abduction decreased the loads applied on the crutch. The mean value of the crutch force in configuration 3 was less than that in configuration 1 however, the difference was not significant.

The mean values of force time integral of the crutch force during walking with the orthosis utilizing configurations 1, 2 and 3 were 167.6, 96, and 106.7 N.s, respectively. Incorporating some degrees of abduction in the orthosis and restricting the hip joint motion in the sagittal plane decreased the force time integral however, the difference was not significant. The mean values of the force time integral of the crutch force is shown in figure 4.43.

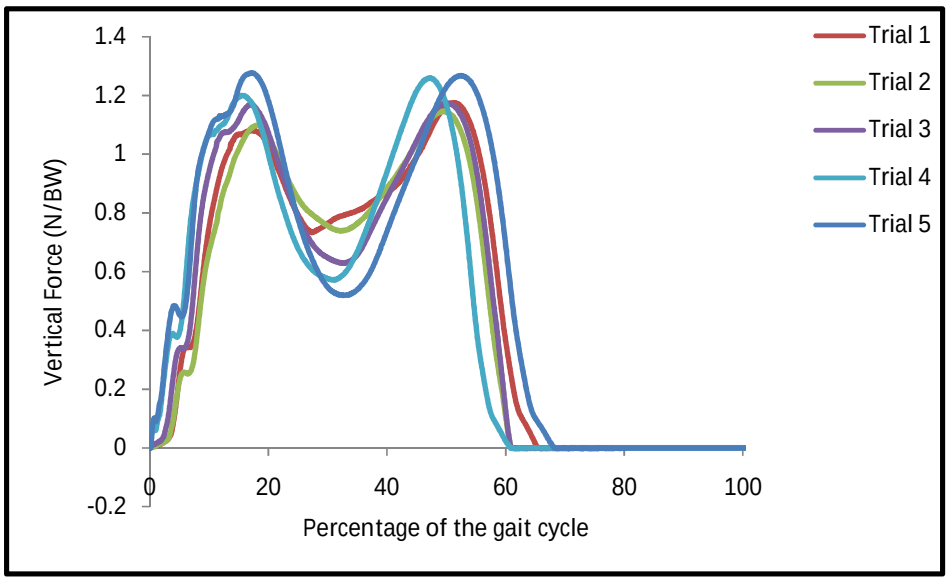


Figure 4.34: The vertical force applied on the foot during normal walking, subject 1

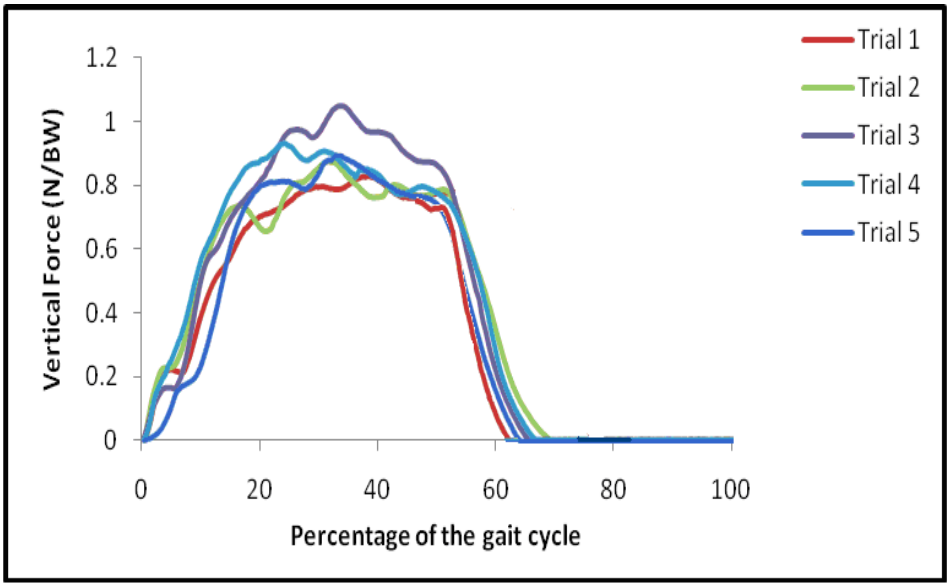


Figure 4.35: The force applied on the foot during walking with the orthosis with configuration 1

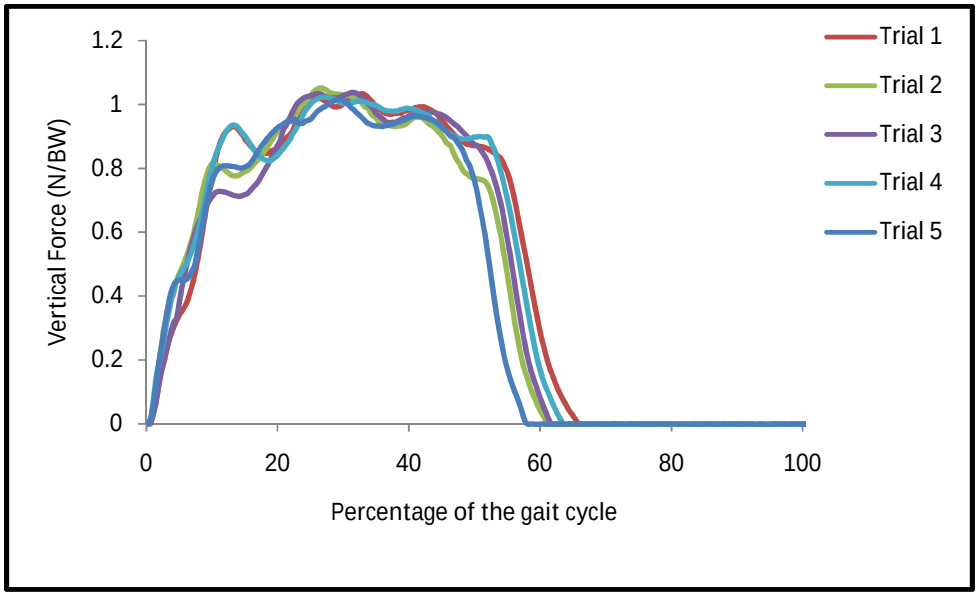


Figure 4.36: The force applied on the foot during walking with the orthosis with configuration 2

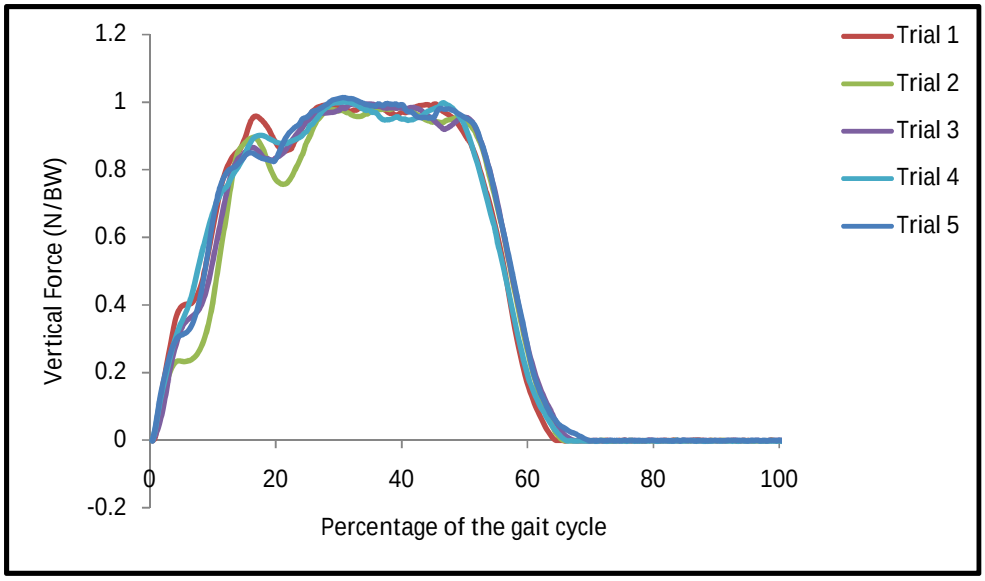


Figure 4.37: The force applied on the foot during walking with the orthosis with configuration 3

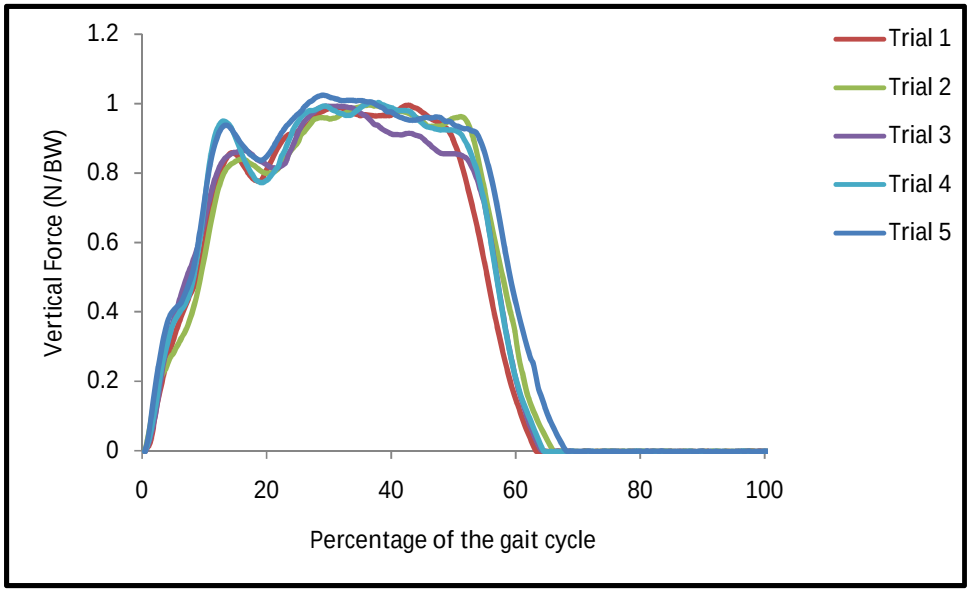


Figure 4.38: The force applied on the foot during walking with the orthosis with configuration 4

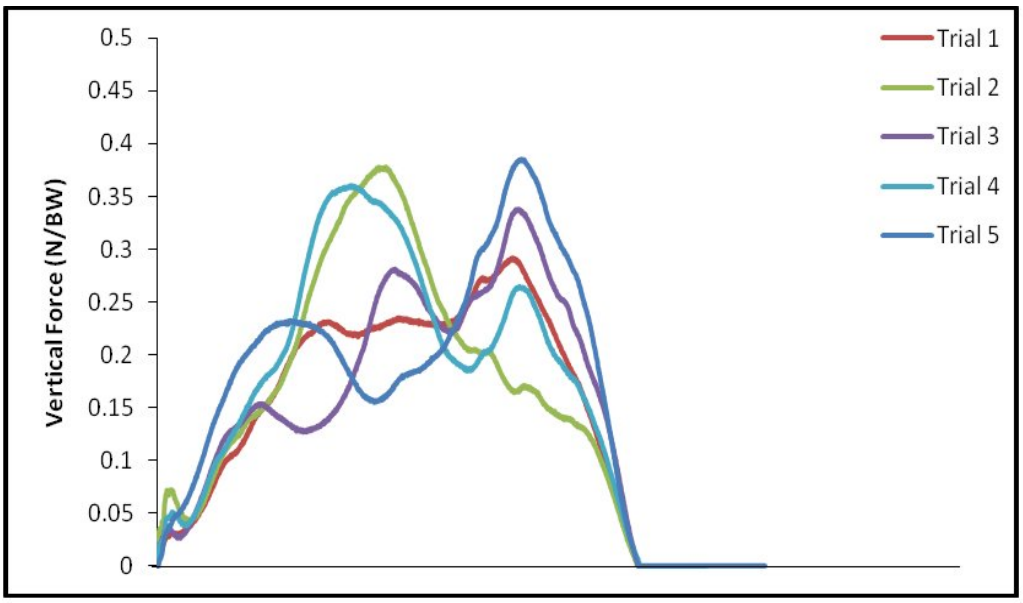


Figure 4.39: The vertical force applied on the crutch during walking with the orthosis with configuration 1

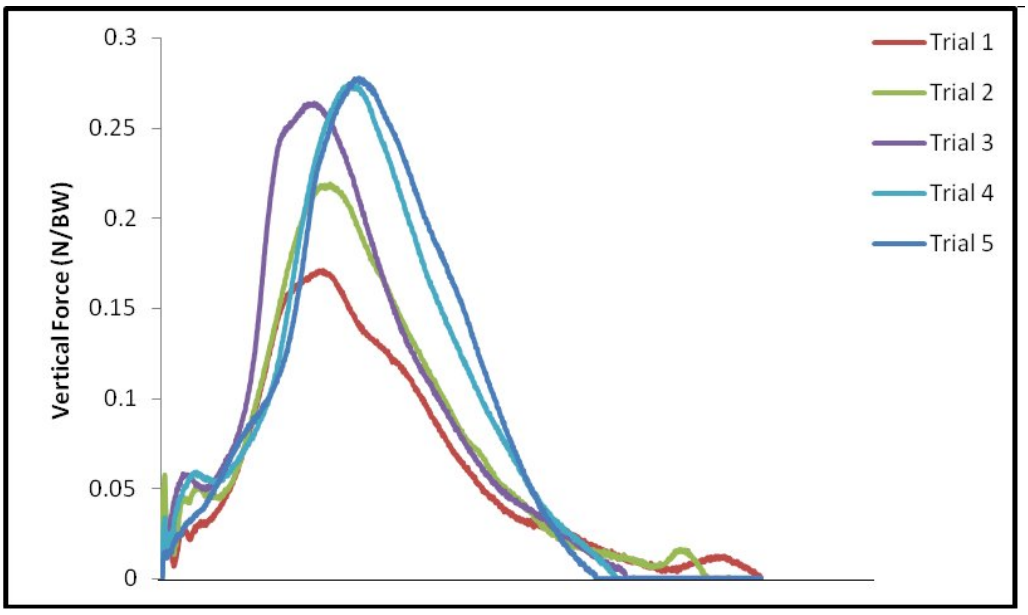


Figure 4.40: The vertical force applied on the crutch during walking with the orthosis with configuration 2

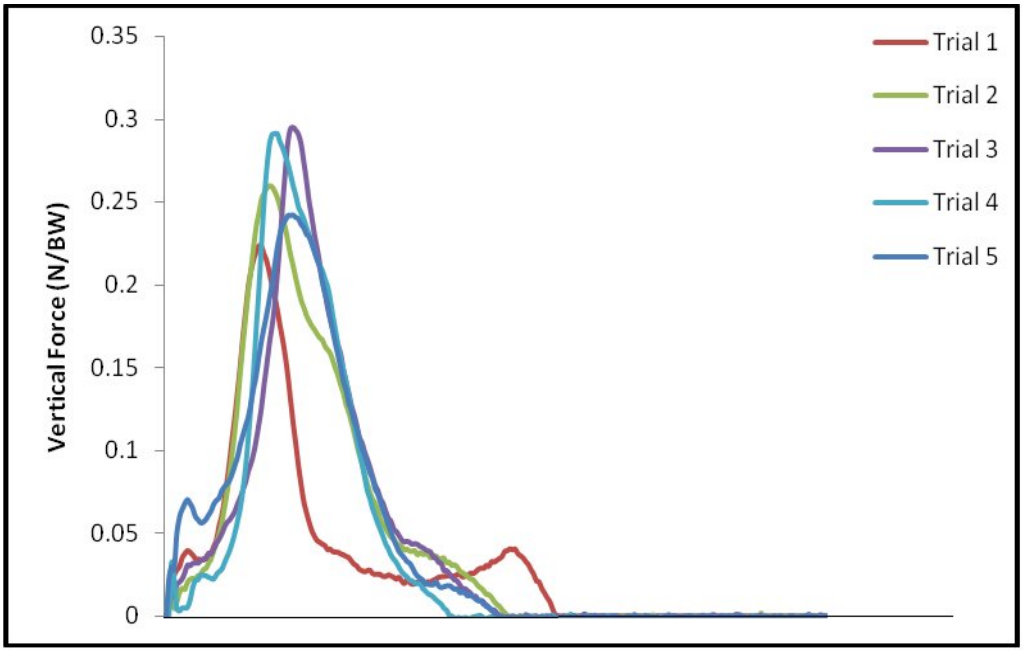


Figure 4.41: The vertical force applied on the crutch during walking with the orthosis with configuration 3

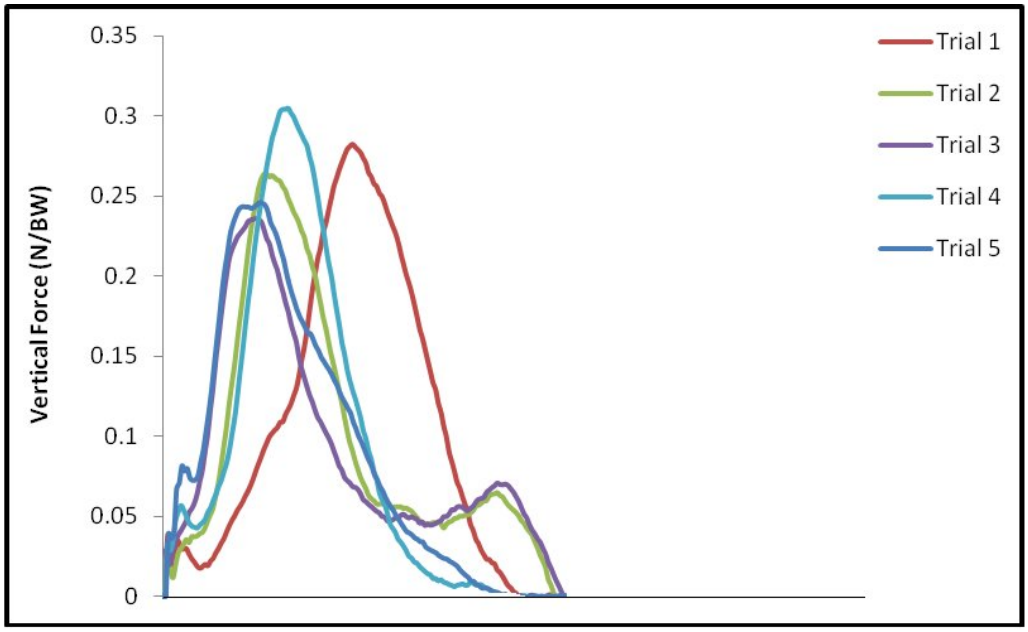


Figure 4.42: The vertical force applied on the crutch during walking with the orthosis with configuration 4

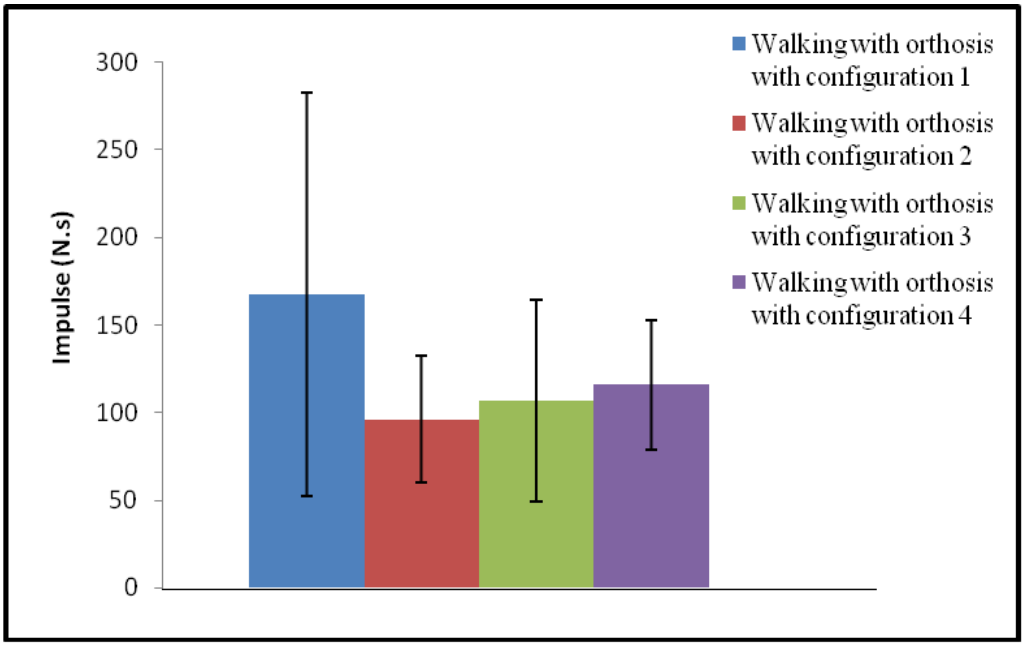


Figure 4.43: The mean values of the force time integral of the crutch force during walking with the orthosis with different configurations. As can be seen inserting some degrees of abduction and decreasing the range of motion of the hip joint decreased the crutch force impulse

4.2.3 Energy Consumption Analysis

The heart rate during normal walking and in walking with the orthosis using different hip joint configurations is shown in figures 4.44 (subject 1). The mean value of PCI during normal walking was 0.311 compared to 0.85 beats/metre for walking with the orthosis with configuration 1, which represented a significant difference between the mean values (0.007). Inserting 5 degrees of abduction in the hip joint of the orthosis decreased the amount of energy consumption during walking with the orthosis. Restricting the hip joint range of motion in the sagittal plane increased the energy required for walking. Figure 4.45 shows the mean values of the PCI during walking with and without the orthosis.

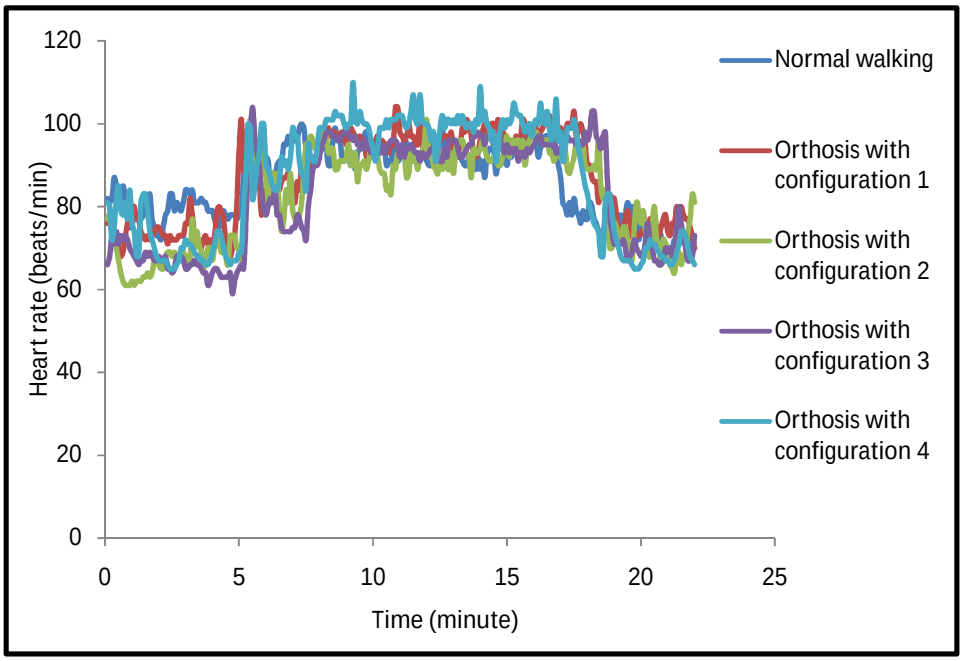


Figure 4.44: The heart rate graph during normal walking and walking with the orthosis with different hip joint configurations, subject 1

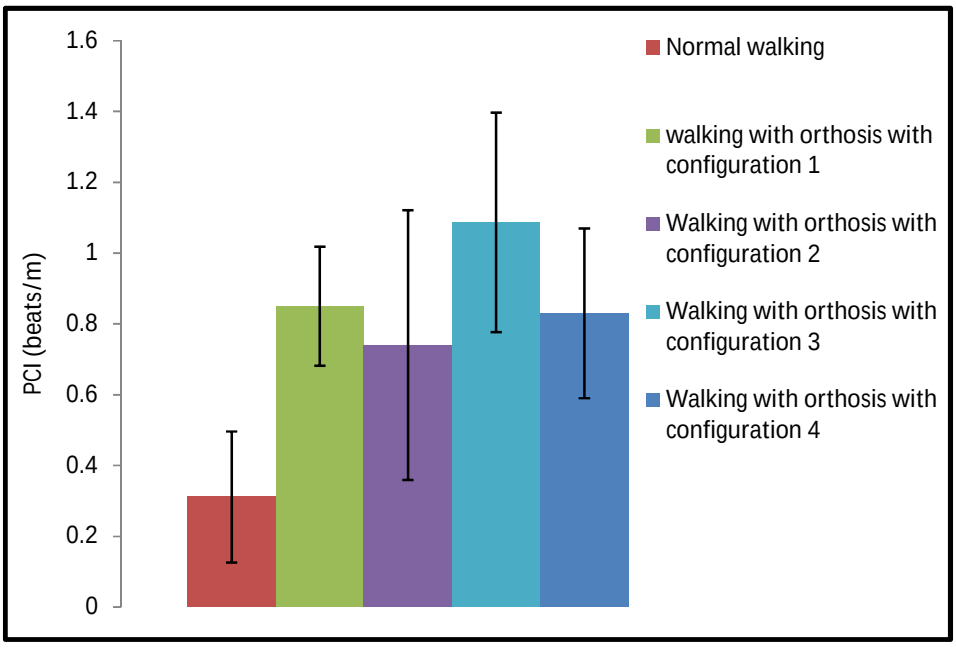


Figure 4.45: The mean values of the PCI during walking with and without the orthosis

4.3 DISCUSSION

4.3.1 Standing Stability

The mean value of the COP sway in the anteroposterior direction was 30.77±12.62 mm during normal standing. It was nearly the same as the values stated by Murray et al (1975) and O'Connell et al (1998) in their research, as shown in table 4.12. The stability of the participants during standing with the orthosis was better than normal standing however, the difference between the mean values was not significant. The main reason is that the hip joint motions were restricted by the orthosis. Incorporating 5 degrees of abduction in the orthosis did not influence the stability in the anteroposterior plane, since it did not influence the base of support in the anteroposterior direction. As it was expected the restriction of the hip joint motion improved the standing stability.

There is no information in the literature regarding the stability of the paraplegic subjects based on the HGO orthosis however, Baardman et al (1997) carried out research to check the effects of using a reciprocal cable in the ARGO orthosis on the standing stability of SCI individuals. The mean value of the COP excursion in the anteroposterior when using crutches was between 35.22 and 37.94 mm. In contrast, the mean values of the anteroposterior COP excursion in the current research varied between 13.93 and 21.96 mm. It suggested that although the structural stability of the orthosis is important, the normal mechanisms which are used by the human body involuntary, such as the ankle and hip joints mechanisms are also important (Jacobson et al, 1993).

The mean value of the COP sway in the mediolateral direction in the current research of the subjects without the orthosis was 17.72±9 mm. It was 14±4 in the research carried out by O'Connell et al (1998) and 29±7.6 in the research study by Murray et al (1975).

Parameters	Participants	AP COP sway (mm)	ML COP sway (mm)
Current study (with orthosis)	Normal subjects	13.93-21.96	8.96-11.49
Current study (without orthosis)	Normal subjects	30.77±12.62	17.72±9
O'Connell et al (1998)	Normal subjects	29± 4	14± 4
Murray et al (1975)	Normal subjects	29 ±7.9	29 ±7.6
Baardman et al (1997)	Paraplegic subjects	35.22 -37.94	35.53 -41.72

Table 4.12: The mean values of the COP excursions of the normal subjects collected in the current project and compared with other research work

The stability of the participants in this project was greater than those who participated in the research carried out by Murray and was slightly poorer than those in the research of O'Connell. As it was expected the stability of the participants improved during standing with the orthosis, because the stiffness of the orthosis restricted the mediolateral motion of the hip joint during standing. Incorporating a few degrees of abduction increased the stability during quiet standing, as the base of support of the subjects was increased, by using a few degrees of abduction in the hip joint of the orthosis.

According to the results of the research carried out by Baardman et al (1997) the mean values of the excursion of the COP in the mediolateral varied from 35.53 to 41.72 mm. However, it differed from 8.96 to 11.49 mm in the current research for the subjects wearing the orthosis, which represents the effects of the functions of musculoskeletal and neurological systems on the stability of the normal subjects during quiet standing.

As can be seen the excursions of the COP during standing with orthosis decreased in contrast to those in normal standing. It means that the subjects had more stability in standing with the orthosis especially with configurations 2 and 4.

4.3.2 Gait Analysis

The mean value of walking speed during normal walking varies between 76.2 and 91.8 m/min (Kadaba et al, 1990) which is nearly the same as that in the current research. The mean value of the velocity during walking with orthosis was nearly one third of that during normal walking. The reason was decreased cadence which was reduced by 50 % during walking with orthosis in contrast to that in normal walking and also was related to stride length. Using a few degrees of abduction in the orthosis improved the velocity of walking however, the difference between the mean values was not significant. It was easier for the participants to lift the swing

leg off the ground when the orthosis was being aligned in an abducted position. Restricting the hip joint range of motion did not decrease the velocity of walking as much as expected. The subjects tried to increase the velocity by increasing the cadence during walking with orthosis with configuration 3. In the research carried out by Yang et al (Yang et al, 1996) the performance of three normal subjects was evaluated during walking with the RGO orthosis with various hip, knee and ankle joints configurations. The mean value of walking speed was between 21.72 and 33.78 m /min, which was less than that in the current study.

The velocity of the paraplegic subjects that walked with the HGO orthosis was between 8 and 18 m/min (Jefferson and Whittle, 1990, Yano et al, 1997). In contrast to paraplegics, from the work carried out by author of this thesis, the normal subjects walked with orthosis with a speed which was 2.5 times more than that of the paraplegic subjects. This represents the gap which can be decreased by designing a new generation of the orthosis. The difference between the walking speed of the normal and paraplegic subjects relates to the role of the muscles and control systems in the normal body which produce and control the motions.

According to the literature, the mean value of cadence during normal walking is 115±9 steps/min (Kadaba et al, 1990) which is nearly the same as that found in current research (105.2±5.87 steps/min). The cadence during walking with the orthosis reduced significantly however, configuring the alignment to have more abduction in the orthosis improved it. It was easier for the participants to take the orthosis off the ground when it was aligned in abduction (Ijzerman et al, 1997b). The cadence of the normal subjects that participated in the work done by Yang et al (1996) was between 50 and 52 steps/min, which was less than that of the participants in this research. It means that the subjects could walk with the orthosis being investigated in this project better than with the RGO orthosis. The cadence of a paraplegic subject with the HGO orthosis, according to the result of the research

done by Jefferson and Whittle (1990), was 37 steps/min, which was noticeably less than that of the normal subjects on this project (59.63 in configurations 3).

The stride length of the normal subjects varies between 1.3 to 1.58 m (Kadaba et al, 1990). However, it was 1.66 m in the current research, which was a little more than those of these authors. The stride length during walking with the orthosis decreased significantly in contrast to the normal walking. The main reason for that was the decrease of the hip joint range of motion during walking with the orthosis. The stride length of the paraplegic subject during walking with the orthosis was 0.98 m compared to 1.27 m for the normal subjects.

The percentage of the stance phase duration during normal walking varies between 60 and 61 % of the walking cycle which was the same as that in the current research. Walking with orthosis with various hip joint configurations did not have any significant effects on the stance phase duration. The percentage of the stance phase in walking of the paraplegic subjects with the HGO orthosis was reported by Jefferson and Whittle to be between 72 to 79.6 % of the total gait cycle, which is more than that of the normal subjects. It can be related to lack of sufficient stability as a result of the paraplegic subjects attempting to increase the stance duration to have more stability during walking.

The mean value of the hip joint flexion/extension excursion during normal walking was 43 degrees which was the same as that in other research (Kadaba et al, 1990). The mean value of the excursion of the hip joint during walking with the orthosis was less than the value which was expected, according to design specifications (35 degrees). The range of motion of the hip joint during walking with the orthosis with configuration 3 was expected to be less than 22 degrees however, it was 27 degrees. The main reason for this difference was the performance of the TLSO part of the orthosis which acted as a reciprocal linkage between the right and left sides. The TLSO transmitted the motion from one side to other side, so extension of left side

added to flexion of right side. It means that extension of the hip joint in the contralateral side moved the TLSO segment in to extension. As the TLSO segment was also attached to the ipsilateral hip joint, it produced a twisting motion which increased the range of motion of the hip joint. As a result the hip joint can flex more than the designed value. The data of the hip joint excursion during walking could be used to design a new generation of the orthosis. As the range of motion of the hip joint was more than the designed value it was possible to decrease the size of the hip joint component, according to what was shown in equation 3.5 and figure 3.10.

According to the result of the research carried out by Jefferson and Whittle (1990), the hip joint excursion during walking of a paraplegic subject with the HGO orthosis was 37 degrees; the range of the hip joint flexion and extension was 16 and 21 degrees, respectively. In contrast to normal walking, paraplegic subjects have more extension and less flexion. The main reason may be the lack of sufficient stability during walking. The paraplegic subjects try to compensate the lack of stability by using more extension in the hip joint which is accomplished with lumbar lordosis. However, the maximum value of hip joint extension cannot be 21 degrees (it cannot exceed 15 degrees of extension), as the anatomical structures around the hip joint, like bony structures and soft tissues restrict the hip joint extension. There may be some errors in the result of the research done by Jefferson and Whittle (1990) as a result of using the pelvic markers in inappropriate positions.

The hip joint abduction/adduction excursion was 12.4 degrees however, it decreased during walking with orthosis. Building up the orthosis in abduction decreased the excursion of the hip joint in the frontal plane. In contrast to walking of the normal subjects with the orthosis, paraplegic subjects had 16 degrees of excursion in walking with the HGO orthosis. The difference may be related to lack of abductor muscles power which is absent in paraplegic subjects.

The mean value of the extending moment applied at the hip joint during normal walking is between 0.65 and 1 Nm/kg (Eng and Winter, 1995, Moisio et al, 2003). In the current research it was 0.88 ±0.225 Nm/kg which is between the values shown in the literature. The extending moment during walking with the orthosis varied between 0.44 ±0.16 and 0.646 ± 0.27 Nm/kg. Decreasing the amount of loads applied on the foot in walking with the orthosis and the force of the crutch may be two important reasons for this difference. The extending moment of the hip joint during walking of a paraplegic subject was 0.5 Nm/kg, which is between the values of the normal subjects during walking with the orthosis (Greene, 2002).

The mean value of the flexing moment applied at the hip joint during normal walking, according to the results of the current research, was 0.853±0.119 Nm/kg. It was 0.93 ±0.26 Nm/kg according to the works carried out by Moisio et al (2003). In contrast Eng and Winter (1995) showed that the maximum value of the hip joint flexing moment was 1.3 ±0.3 Nm/kg. The flexing moment applied at the hip joint during walking with the orthosis in the current study varied between 0.615 ± 0.153 and 0.681 ±0.29 Nm/kg, which was less than that during normal walking. For paraplegic subjects walking with the HGO orthosis it was 0.7 Nm/kg (Greene, 2002), which was a little more than that of the normal subjects.

In this study, the flexing and extending moments applied at the hip joint decreased during walking with the orthosis in contrast to normal walking. The main reasons for that may be related to the force applied on the foot which decreased during walking with the orthosis. The crutch force is another factor which influenced the moment around the hip joint. As can be seen from figures 4.24 to 4.28 extending moment of the hip joint reaches to zero at nearly 40% of the gait cycle however, it reaches to zero during normal walking at 30% of the gait cycle. The force of the crutch from the contralateral side is transmitted to the hip joint (Butler et al, 1984) however, there was some time delay between the peak of the crutch force and foot force. As

the result, it increased the duration of the flexing moment applied on the hip joint and deceased the amount of the extending moment.

The pattern of movement of the hip joint moments when walking with the orthosis was the same as that in normal walking. There was a flexing moment occurring in the beginning of the stance phase and it was followed by an extending moment at the end of stance phase. During the swing phase, the hip joint had a flexing moment. The pattern of the hip joint moments during walking of normal subjects with the orthosis was the same as that of the paraplegic subjects who walked with the HGO orthosis. It would expected that the pattern of the hip joint moments in walking of paraplegic subjects with the new orthosis be the same as that of the normal subjects.

The maximum value of the adducting moment of the hip joint in normal walking was 1.13 ± 0.074 Nm/kg which is nearly the same as the results of the research carried out by Eng and Winter (1.15 ±0.2). The adducting moment of the hip joint during walking of the normal subjects with an orthosis varied from 0.819 to 1.025 Nm/kg, which was a little less than that in the normal walking. Building up the orthosis in abduction decreased the adducting moment applied on the orthosis. The main reason for this reduction was the decreased lever arm of the lateral force during walking with orthosis with configuration 2.

The adducting moment of the SCI subjects during walking with the HGO orthosis was 128 Nm which was more than that of the normal subject (Stallard et al, 2003, Stallard et al, 2001). The increased abduction/adduction excursion of the hip joint in paraplegic gait in contrast to that of the normal subjects who walked with the orthosis was one of the reasons which can be considered for increasing the adducting moment in paraplegic subjects. Moreover, paraplegic subjects have to apply more force on the crutch in the contralateral side to take the swing leg off the

ground. As a result they have more side to side motion in contrast to the normal subjects.

The force applied on the foot decreased during walking with the orthosis, with various hip joint configurations, in contrast to that in the normal walking however, the difference between the mean values was not significant. In paraplegic walking the force applied on the foot varied between 78.4 and 110% of BW (Major et al, 1981, Ferrarin et al, 1993) which is less than that of the normal subjects. During walking the SCI subjects with the orthosis some parts of the body weight supports by the crutch. As a result the percentage of the body weight transmitted through the foot decreased in contrast to that in the normal subjects.

The mean value of the force applied on the crutch during walking of the normal subjects with orthosis was between 0.185 and 0.223 N/BW. The maximum value of the crutch force for the paraplegic subjects who walked with the HGO orthosis varied from 0.24 to 0.4 N/BW which was more than that of the normal subjects with the orthosis (Ferrarin et al, 1993, Major et al, 1981). According to the work carried out by Butler et al (1984) the crutch force is transmitted to the other side to produce a progressive force in the uphill part of the stance phase. Since the muscular force of the paraplegic subjects is absent their need for crutch force must be more than that of the normal subjects.

The main reason for selecting only the vertical component of the crutch force in this research project was that the magnitude of the force applied on the crutch in other planes is significantly less than that of the vertical component. Moreover, all investigators have selected only the vertical component of the crutch force. It was mentioned that the vertical force which was transmitted to the upper limb through the crutches can result in some diseases in the wrist and shoulder joints.

Building up the orthosis in abduction decreased the force applied on the crutch (but the p-value of the difference between the mean values was not significant). It was expected that aligning the orthosis in a slight abduction decreased the amount of force required to stabilize the stance leg and also yielded the better utilization of swing crutch force for propulsion (Stallard and Major, 1993). The force time integral of the crutch could be decreased by inserting a few degrees of abduction in the hip joint of the orthosis.

4.3.3 Energy Consumption Analysis

The energy consumption during normal walking based on PCI was 0.3 beats/m in the current research. It was 0.4 beats/m for children aged 3-12 and 0.47 for those aged between 6 and 18 (Rose et al, 1994). The mean value of PCI in the current research was the same as that found by Nene (0.31±0.07) (Nene, 1993). The energy consumption of the normal subjects during walking with orthosis, configuration 1, was nearly three times more than that of normal walking. The main reason for that was the velocity of walking, which decreased significantly in walking with the orthosis. Building up the orthosis in abduction decreased the PCI, because the velocity of walking increased in the new configuration.

The other reason which can be considered for the decrease of the PCI during walking with the orthosis aligned in slight abduction was the function of the lattismus dorsi muscle. It is an adductor and extensor of the shoulder joint and plays a significant role in transmitting the moment from shoulder joint to the contralateral sacroiliac joint. The moment which was produced by this muscle has a maximum value when the shoulder joint is in an abducted and flexed posture. When the orthosis was aligned in a slight abduction the subject had to move the crutch outward by employing some abduction in the shoulder joint. So the force produced by the latissimus dorsi decreased and energy cost improved.

Although the new design of the orthosis has some features such as it allows the alignment of the components to be changed and had a modular structure, it had some problems which need to be resolved. The knee joint of the orthosis was bulky and heavy. The attachment components of the knee joint were difficult to be used by subjects. Moreover, the security of the attachment components needs to be improved. It was difficult to unlock the hip joint as the subjects had to push and hold the locking pins medially during sitting down. The TLSO part of the orthosis was not completely fitted on the body of the participants and was less cosmetic.

4.4 CONCLUSION

The results of this research highlighted that the performance of the normal subjects during walking with the orthosis was significantly less than that of normal walking. However, in contrast to the performance of the paraplegic subjects, there is a huge gap between the normal and paraplegic individuals in walking with orthosis. The results of the current research showed that the best performance that paraplegic subjects can hope to achieve during walking with the orthosis is the performance of the normal subjects with the orthosis. Inserting 5 degrees of abduction in the orthosis decreased the energy consumptions and increased the performance of the normal subjects in walking with orthosis.

The range of motion of the hip joint in walking with the orthosis with configuration 1 was less than was supposed to be however, it was more than the predicted value in the configuration 3. Having special screws in the hip joint to change flexion/extension during walking provided this capacity to select various ranges of motion according to the patients' abilities.

4.5 SUGGESTION FOR FUTURE WORK

The new generation of the orthosis could be designed to have the following features.

a) Have the hip joint range of motion the same as hip joint flexion/extension excursion collected from this research
b) The locking system of the hip joint be less bulky and easier to use
c) The cosmesis of the orthosis to be improved
d) The rigidity of the knee joint attachment components to be increased
e) The size of the knee joint to be decreased by redesigning the knee joint
f) The weight of the orthosis to be decreased

CHAPTER 5: DESIGN AND EVALUTION THE SECOND GENERATION OF THE NEW RGO ORTHOSIS

The first generation of the new RGO orthosis was designed and evaluated on normal subjects with various hip joint configurations. The results of the first part of this research showed the positive effects of using abduction in the hip joint of the orthosis which increased the functional performance of the subjects in using the orthosis. The range of motion of the hip joint was less than the range provided in the design. So it was possible to decrease the size of the hip joint component according to the range of motion which was recorded from the previous research (see chapter 4). Moreover, unlocking the hip joint for sitting was difficult for the participants and the cosmesis of the orthosis needed to be improved. The main aims of this part of the research were:

a) To redesign the new generation of the orthosis to be less bulky , easier to use and more cosmetic
b) To evaluate the performance of the new generation of the orthosis during walking of the normal subjects

5.1 METHOD

The new generation of the orthosis was designed to overcome the aforementioned problems of the first generation. So the specifications were as follows:

a) The size of the main component of hip joint was to be decreased
b) The knee joint was redesigned to be less bulky and lighter in contrast to the first generation
c) The locking system of the hip joint was redesigned to be easier to use and less bulky
d) The rigidity of the knee joint attachment components was to be increased during walking with the orthosis

e) The weight of the final design was to be decreased in contrast to the first generation
f) The cosmesis of the orthosis was to be improved by selecting appropriate materials for the TLSO part of the orthosis

5.1.1 Design of the New Generation of the Orthosis

The moments and the forces which were used to design the new generation of the orthosis were the same as those used for designing the first generation.

5.1.1.1 Design of the hip joint

The range of motion achieved by the subjects during walking with the first design of the hip joint was less than the predicted value in configuration 1. It was found that during walking with the orthosis in configuration 3, the range of motion was more than the range provided in the design. It was concluded that the TLSO part of the orthosis acts as a reciprocal linkage which transmits the motion from one side to another side. The range of motion of the hip joint in the new generation is 25 degrees. The other problem of the first design, which was seen during walking, was an increase of the excursion of the hip joint in mediolateral plane, when the hip joint was in extension. These problems were solved by redesigning the hip joint.

5.1.1.2 Designing the locking system of the hip joint

The locking system of the hip joint in the first generation of the orthosis was bulky and more difficult to use. The participants had to push and hold the locking pins medially during sitting down. In the new design, the locking system restricts the motion of the second hip joint pivot in contrast to the first design which restricted the motion of the upper bar. The new locking system, figure 5.1, is operated by applying a pulling force. It is not necessary to apply the unlocking force continuously during sitting down.

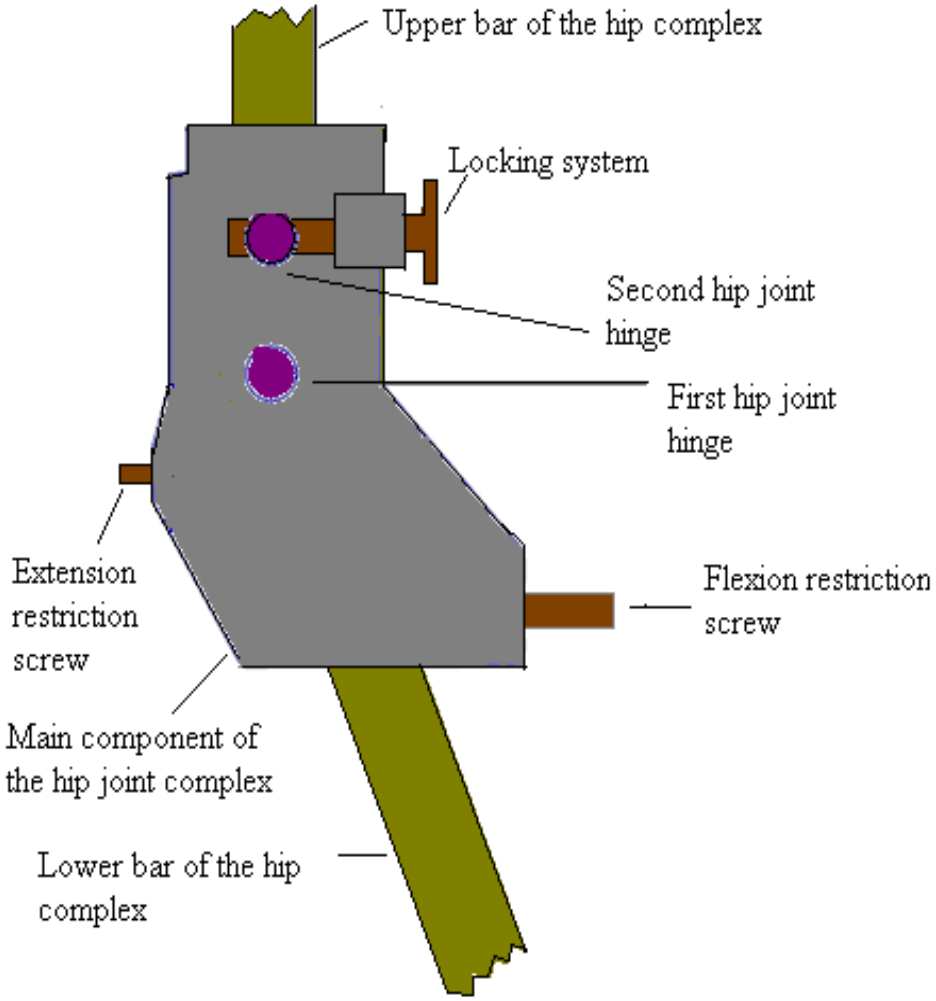


Figure 5.1: Sketch of the locking system of the hip joint

5.1.1.3 Design of the knee joint

The knee joint of the orthosis in the first generation was bulky and heavy. In the second generation, a new knee joint was designed and manufactured which has a smaller size and is lighter in contrast to the first generation. The lower bar of the new knee joint is made from the aluminum alloy and is attached directly to the knee joint attachment components, figure 5.2.

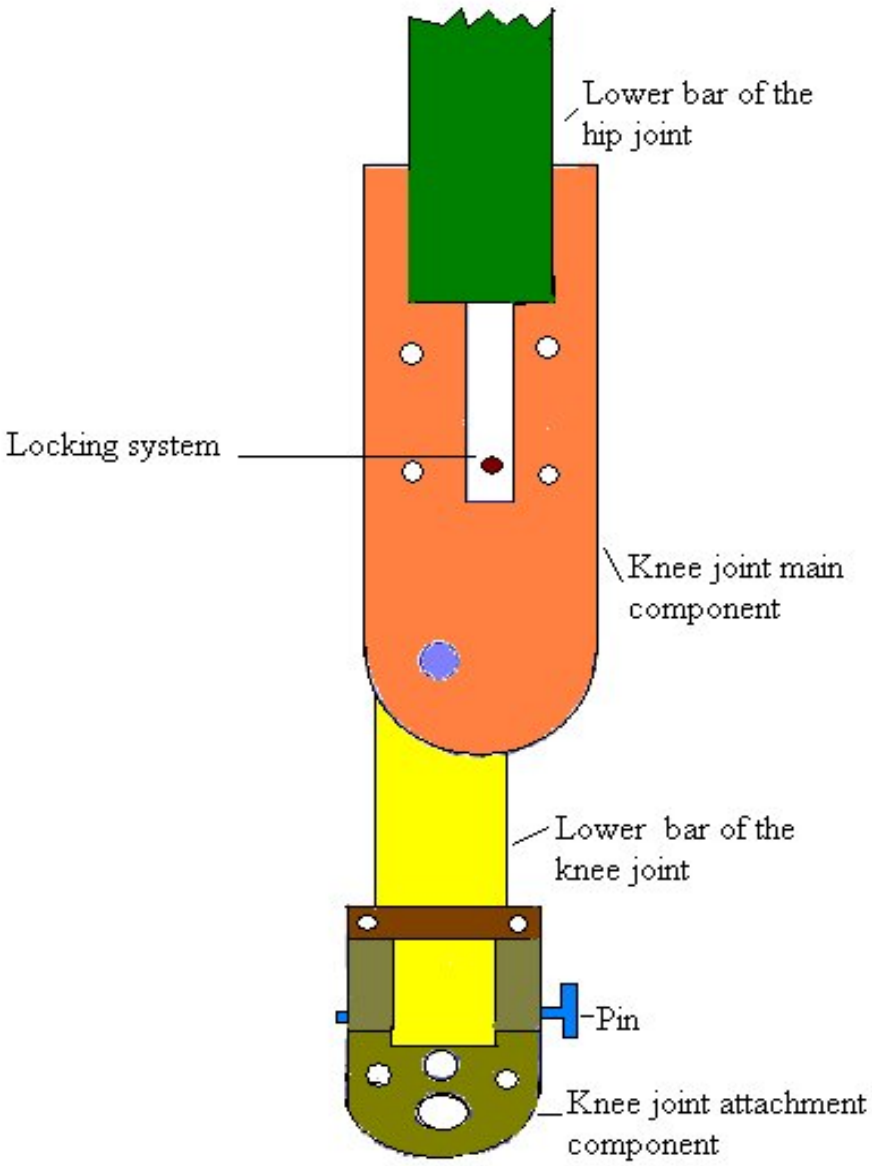


Figure 5.2: Sketch of the second generation orthosis knee joint

5.1.1.4 Design of the knee joint attachment components

The attachment components of the knee joint were redesigned to provide more security during walking. The alignment capability of this component was the same as that in the first design. It was made from the same material as was used for the first design.

Parameters	Density (kg/m^3)	Tensile modulus (GN/m^2)	Shear modulus (GN/m^2)	Tensile Strength (MPa)
Value	0.91	1.51	0.55	31-32

Table 5.1: Mechanical properties of homopolymer Polypropylene (Crawford, 1998)

5.1.1.5 Construction of the AFO of the new generation of the orthosis

The AFO of the new generation is made to be the same as that of the first generation however, the first part of the knee joint attachment component was inserted inside the AFO in contrast to that in the first generation which was inserted outside the AFO. The first part of the attachment component was secured to the positive cast and then the polypropylene sheet was vacuum formed on it.

5.1.1.6 Construction of TLSO part of the orthosis

The TLSO part of the first generation of the orthosis was made from aluminum alloy which was heavy and less cosmetic than a custom fitted body orthosis. In the new generation it is made from homopolymer polypropylene. The mechanical properties of this material are shown in table 5.1.

For the manufacture of the TLSO, it was necessary to take a cast from the Torso of the participants. The best position for taking the cast was in prone position with the hip and knee joints in a straight position. A piece of cotton stockinet was cut and was draped over the Torso and tucked under the participant anteriorly. The locations of the greater trochanter, anterior superior iliac spine in both sides were marked. A measuring tape was used to measure the distance between the two greater trochanters and ASIS to ASIS in both sides. A plaster of Paris bandage, 15 cm wide and 5 layers thick was used to take the cast from the back of the participant. It was soaked in water and draped over the participant body and was smoothed into place. It extended from 5 cm below the greater trochanter to below the inferior angle of scapula. When the cast was set it was removed from the participant's body and checked.

The cast was prepared and was filled with plaster of Paris. Then it was formed according to the measurements taken. An aluminum bar, 10 millimeters thick and 55 millimeters wide which had a length equal to ASIS to ASIS minus 6 cm (the

distance between ASIS and hip joint centre was 3 cm in each side) was used. It was formed according to the shape of the positive cast above the iliac crest. It was secured in its place by using some plaster. A sheet of copolymer was cut according to the size of the positive cast and prepared for vacuum forming. The positive model of the TLSO was set up for hand draping. Two layers of nylon stockinet were pulled over the plaster. The polypropylene sheet was heated at 180 Cº for 25 minutes in an oven. Then it was draped over the plaster model. In the next stage the trim lines were drawn on the polypropylene and it was cut with an oscillating saw. Then the trim line of the orthosis was ground and smoothed. Velcro straps were attached to the upper and lower parts of the TLSO and the aluminum bar was secured using 6, 8 millimeters diameter, screws. Figure 5.3 shows the second generation of the new orthosis.

5.1.2 Subjects

The subjects who participated in the first study were asked to take part in this research as well. Their age, weight and height are shown in table 4.1. It was decided to ask the same subjects to participate in the second part of this research project. The main reason was that they were trained how to walk with the orthosis with the crutches, so it was not necessary to spend more time for their training. Moreover, it was possible to compare the performance of the subjects in walking with the second generation of the orthosis with that of the first generation, as was collected in the first part of this research project.

5.1.3 Parameters

The parameters selected in this part of the study were the same as those used before. The performance of the subjects with the orthosis was evaluated by gait analysis, standing stability analysis and by the energy consumption test. Since the best configuration for walking with the orthosis according to the result of the previous part of this research was configuration 2, the orthosis was aligned in 5 degrees of abduction.

The same protocols were used for data collection for stability and energy consumption tests. However, using all four force plates provided the opportunity to collect the force applied on the crutch in the same trials. The difference between the mean values of the selected parameters during walking with the orthosis, generation 1 and 2, was evaluated by using the paired t test. The significant point was 0.05 for all parameters. The normality of the parameters was checked by using the Shapiro-Wilk test.

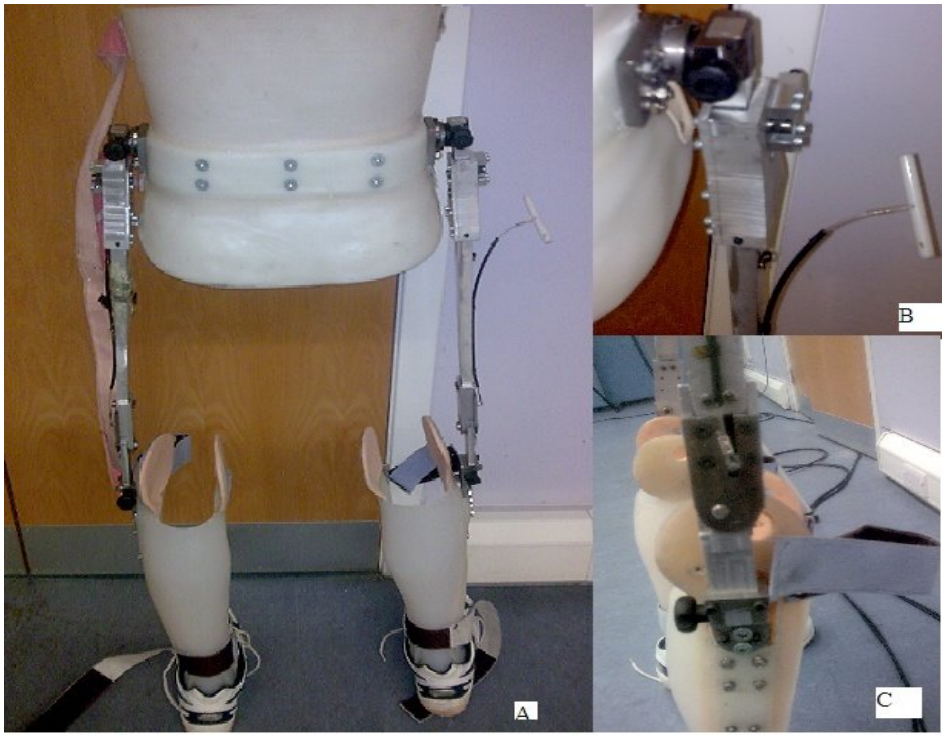


Figure 5.3: The second generation of the new RGO orthosis (A), the hip joint and its locking system (B), Knee joint and its attachment components (C)

5.2 RESULTS

The final results of the gait analysis, stability analysis and energy consumption and the p- values of the difference between the mean values of the parameters of the first and second generations are shown in tables 5.2 and 5.3.

Parameters	First generation	Second generation	P-value of the difference
COP sway, ML (mm)	10.31± 1.48	10.34± 0.739	0.945
COP sway, AP (mm)	21.68±10.02	13.2±0.64	0.267
Flexion extension excursion (degree)	29.18.18±2.24	30.44±2.51	0.687
Abduction adduction excursion (degree)	6.1±1.6	8.1±1.96	0.143
Walking speed (m/min)	40.9 ±1.2	39.3 ±1.2	0.611
Cadence (steps/min)	58.61± 1.69	57.74 ±4.91	0.838
Stride length (m)	1.27± 0.187	1.21± 0.006	0.616

Table 5.2: The mean values of the selected parameters during walking with the first and second generations of the orthosis

Parameters	First generation	Second generation	P-value of the difference
Percentage of the stance phase	61.6 ±2.22	57.27± 2.5	0.244
Flexing Moment (Nm/kg)	0.6183± 0.343	0.745± 0.2132	0.1185
Extending Moment (Nm/kg)	0.476± 0.041	0.5173± 0.188	0.357
Adducting Moment (Nm/kg)	1.0247 ±0.176	0.903± 0.134	0.2375
Crutch Force (N/BW)	0.1855 ±0.053	0.137± 0.0414	0.05
Foot Force (N/BW)	1± 0.0724	0.991± 0.0085	0.365
FTI (impulse) (Ns)	95.96 ±36.2	60.72 ±9.11	0.114
PCI (beats/min)	0.74±0.381	0.561±0.148	0.323

Table 5.3: The mean values of the selected parameters during walking with the first and second generations of the orthosis

5.2.1 Standing Stability

The mean values of the COP sway during standing with the second generation of the orthosis are shown in table 5.2. There was no difference between the stability of the participants in the mediolateral direction during standing with the first and second generations. The stability of the participants in the anteroposterior plane improved during standing with the second generation in contrast to that in the first generation however, the difference was not significant.

5.2.2 Spatio-Temporal Gait Parameters

The mean value of the stride length during walking with generations 1 and 2 of the new orthosis was 1.27±0.187 and 1.21±0.006 m, respectively. The small difference between the mean values was not significant (p-value = 0.616). The difference between the mean value of the walking speed with generations 1 and 2 of the orthosis was not significant; it was 40.9 and 39.3 m/min for the first and second generations, respectively. The mean value of the cadence during walking with the first generation was 58.61, compared with 57.74 steps/min for the second generation.

5.2.3 Hip Joint Excursions in the Frontal and Coronal Planes

The excursion of the hip joint in the sagittal plane during walking with the second generation, figure 5.4, was 30.44±2.51 degrees, which was nearly the same as that in generation 1 (29.18±2.24). The amount of abduction/adduction excursion of the hip joint in generation 1 and 2 was 6.1±1.6 and 8.1±1.96 degrees, respectively. Figure 5.5 shows the motion of the hip joint in the coronal plane during walking with the second generation orthosis. Although there was a difference between the mean values of the hip joint excursion in the frontal plane, the difference was not significant (p-value = 0.143).

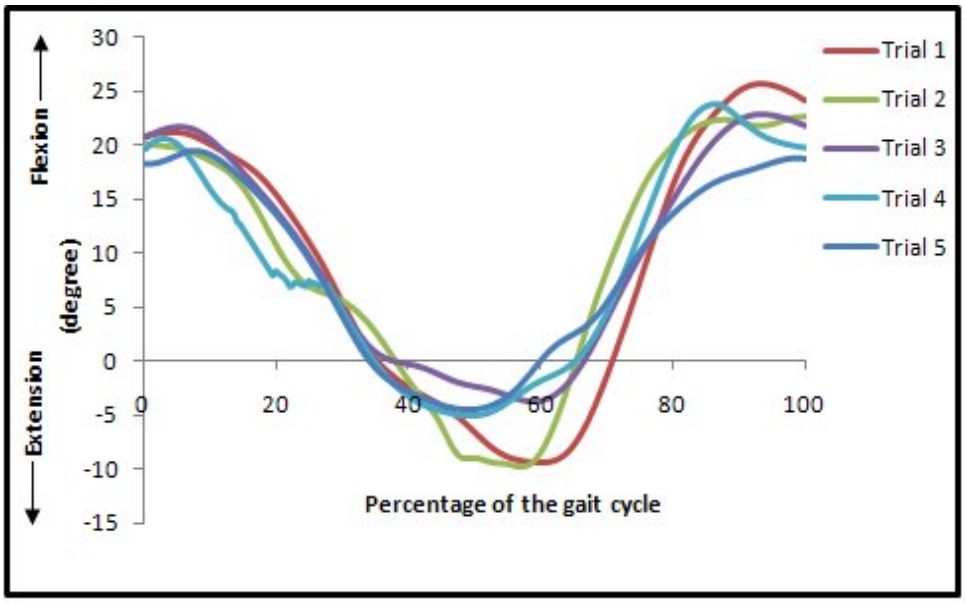


Figure 5.4: Flexion/extension angle of the hip joint during walking with the second generation of the orthosis

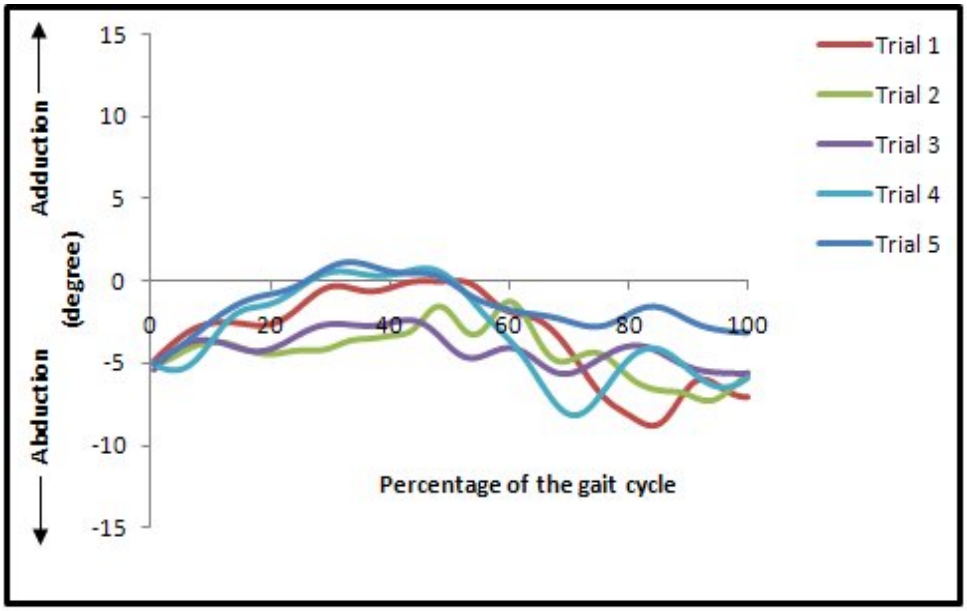


Figure 5.5: Abduction/adduction angle of the hip joint during walking with the second generation of the orthosis

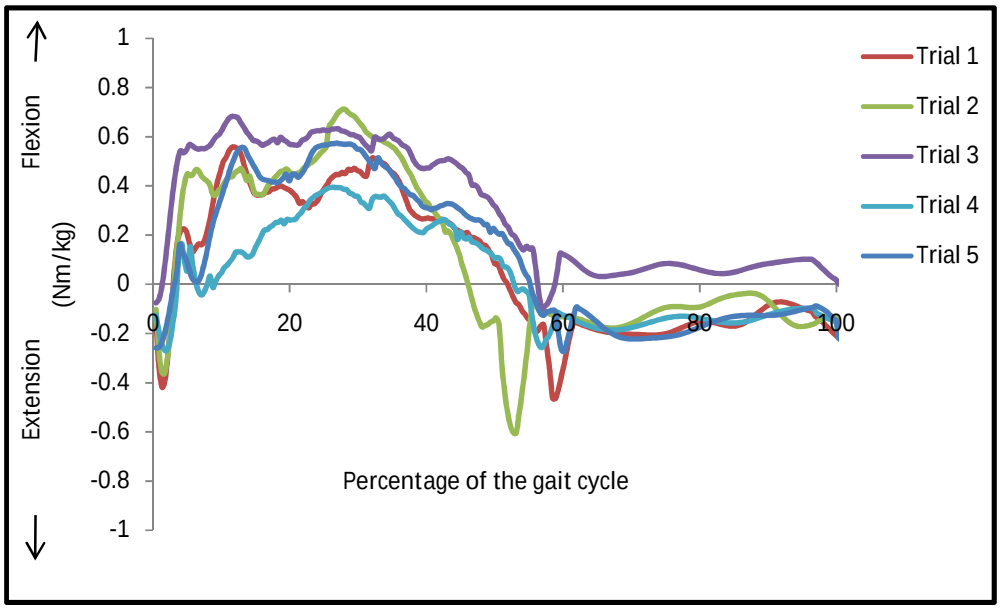


Figure 5.6: The flexing/extending moment of the hip joint during walking with the second orthosis

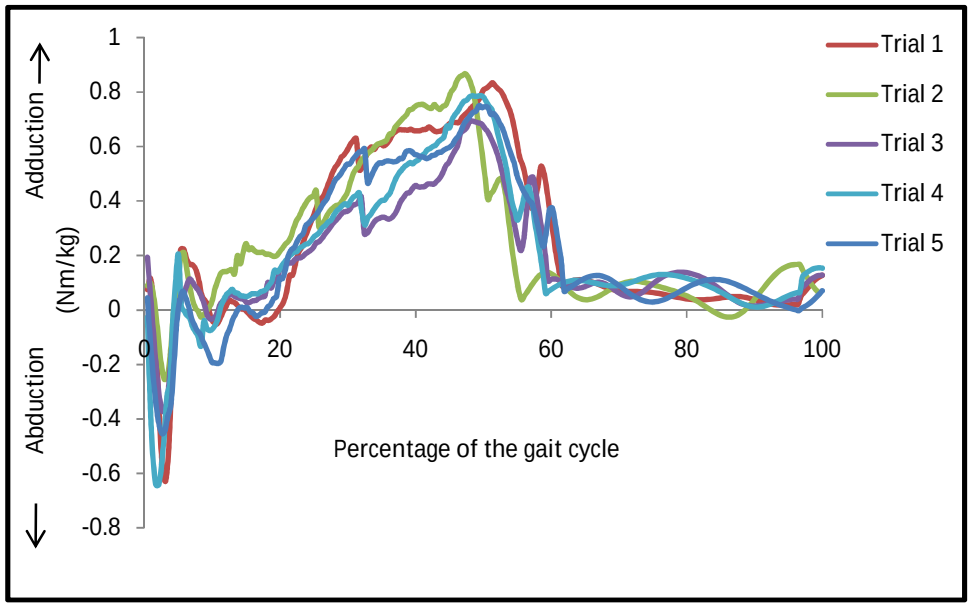


Figure 5.7: The abducting/adducting moment of the hip joint during walking with the second orthosis

5.2.4 Hip Joint Flexing Extending and Adducting Moments

The flexing extending moments of the hip joint in walking with the second generation orthosis is shown in figure 5.6. The flexing moment applied on the hip joint increased during walking with the second generation of the orthosis. It was 0.745±0.213 Nm/kg compared with 0.618±0.343 Nm/kg in walking with the first generation. Although the amount of the flexing moment of the hip joint was more in the second generation compared with the first one, the difference between the mean values was not significant.

The mean value of the extending moment of the hip joint was 0.475±0.04 Nm/kg in the first generation compared with 0.517±0.188 in the second generation. As it is shown in table 5.1, the adducting moment of the hip joint decreased slightly during walking with the second generation in contrast to the first one. Figure 5.7 shows the adducting moment applied on the hip joint in the second design of the orthosis.

5.2.5 Force Applied on the Foot and Crutch

The difference between the mean values of the force applied on the foot during walking with orthosis with the first and second generations was small and it was not statistically significant (p-value = 0.365). Figure 5.8 shows the force applied on the foot during walking with the second generation of the orthosis. The force applied on the crutch in walking with the second generation, figure 5.9, was 0.137± 0.0414 N/BW, which was significantly less than that in the first generation (0.1855 ±0.053). The force time integral (FTI) of the crutch force was 95.96 and 60.72 N.s for the first and second orthosis, respectively. The difference between FTI in walking with both generations was not significant (p-value = 0.114).

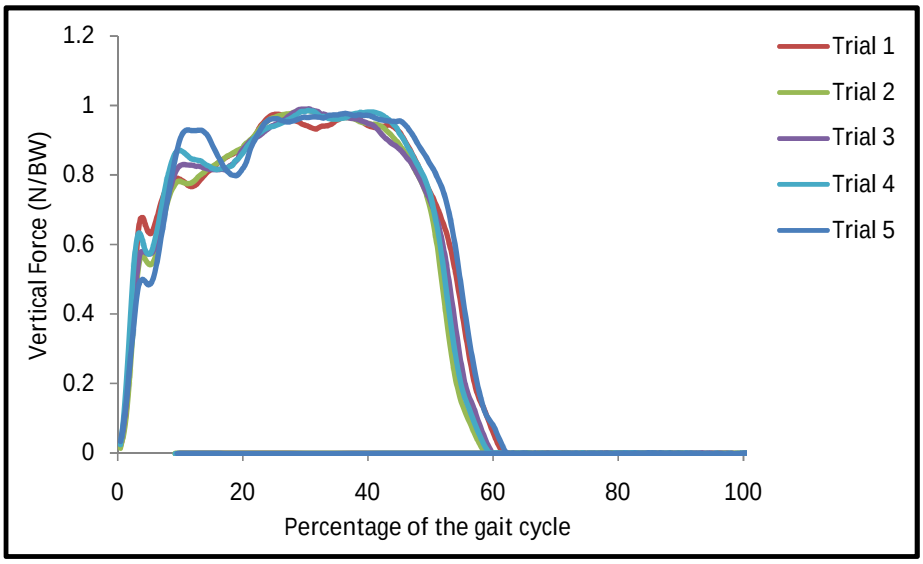


Figure 5.8: The force applied on the foot during walking with the second generation of the orthosis

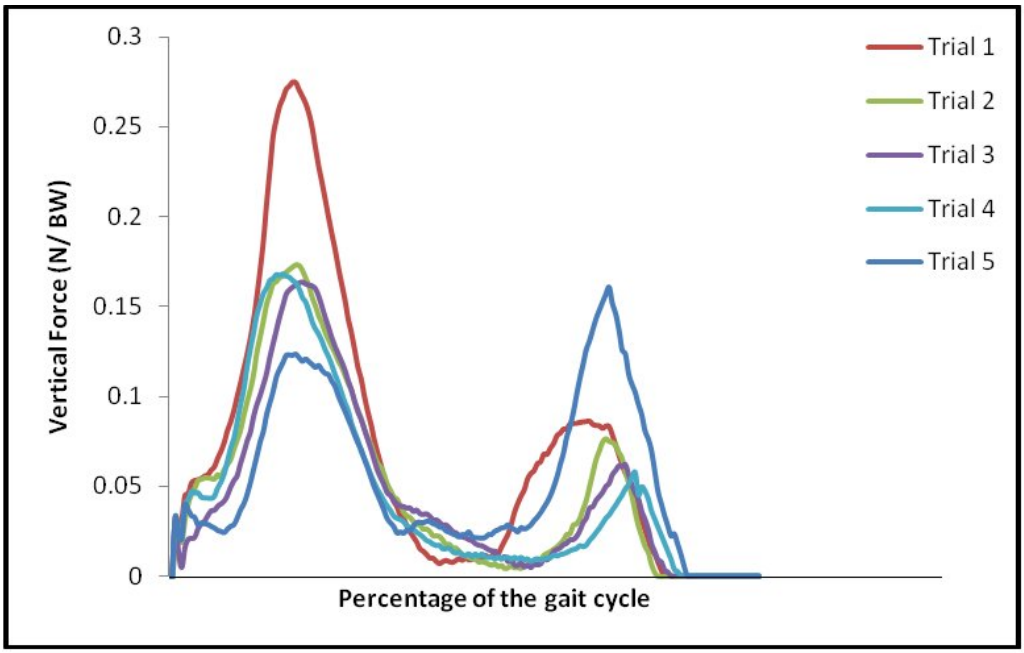


Figure 5.9: The force applied on the crutch during walking with the second generation of the orthosis

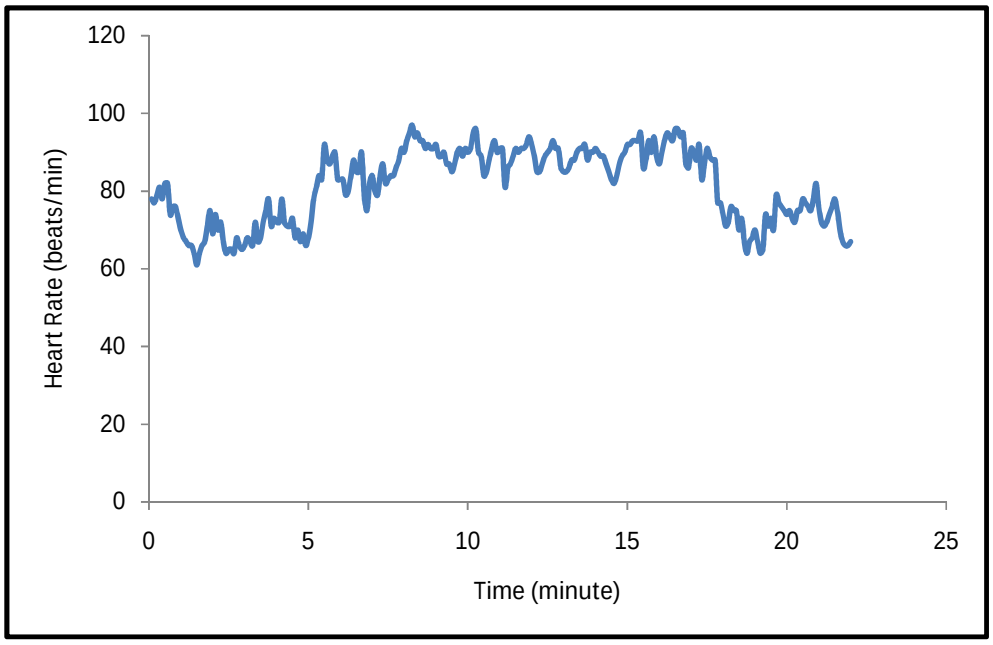


Figure 5.10: The heart rate of the first subject during walking with the second generation of the orthosis

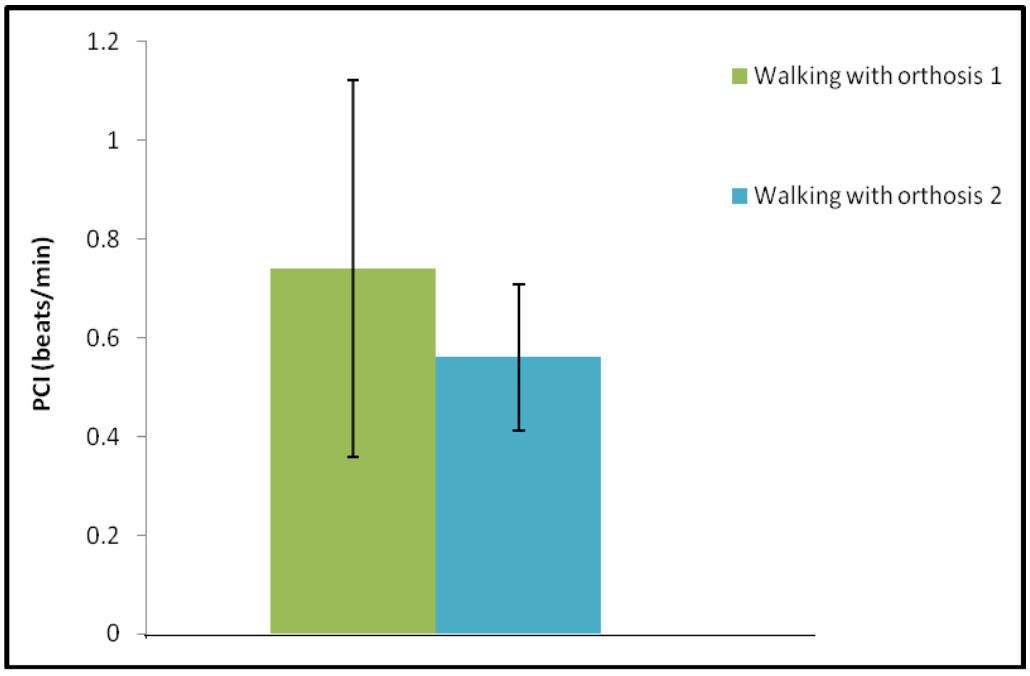


Figure 5.11: The mean values of PCI during walking with the first and second generations

5.2.6 Energy Consumption

The mean values of the PCI during walking with the first and second generations of the orthosis were 0.745±0.381 and 0.561±0.148 beats/min, respectively. Figure 5.10 shows the heart rate during walking with the second orthosis. The difference between the mean values of the PCI in the generations 1 and 2 was not significant (p-value = 0.178). Figure 5.11 shows the mean values of PCI during walking with the first and second generations of the orthosis.

5.3 DISCUSSION

There was no difference between the stability of the participants in the mediolateral plane during standing with the first and second generations of the orthosis. It was expected that manufacture of the TLSO part of the orthosis from polypropylene sheet would decrease the structural stiffness of the orthosis and decrease the stability in the coronal plane. However, the result of the stability analysis showed that stability during quiet standing was the same for both orthoses, as the stiffness of the orthosis was the same in both orthoses. The excursion of the COP in the anteroposterior plane decreased in the second generation in contrast to the first one. The flexibility of the TLSO section made of polypropylene is more than that, which was made of aluminum alloy however, in the new design an aluminum bar was put inside the TLSO to increase the stiffness. As the result the structural stiffness of the new TLSO is the same as the old designed one.

It should be mentioned that the stiffness of the orthosis was not directly measured in this research study. However, using some parameters such as the excursion of the hip joint in the frontal plane during walking and the peak of the vertical force applied on the crutch were some parameters which indirectly represent the structural stiffness of the orthosis. As there was no significant difference between the hip joint excursion in frontal plane between the two generations of the new orthosis and

because of the crutch force which was less in the second generation of the orthosis in contrast to that in the first generation it can be concluded that the stiffness of the new generation was not less than that of the first one.

The difference between the Spatial-temporal gait parameters between the two orthoses was very small. However, the amount of the force applied on the crutch during walking with the second generation of the orthosis decreased significantly in contrast to the first one. This may be related to better fitting of the orthosis in the second generation. The fitting of the orthosis in the second generation was improved as a result of using custom moulded technique for the TLSO part of the orthosis.

The amount of energy consumption during walking decreased in the second generation, but the difference between the PCI of the two orthoses was not significant. The mean value of the walking speed during the energy consumption test in the first and second generations of the orthosis was 39.4 and 37.2 m/min, respectively. So the main reason for decreasing the PCI was the difference between heart rate during walking and resting which was less in the second generation in contrast to the first one. It means that the subjects were more comfortable in walking with the second orthosis than with the first one. It appeared that decreasing the PCI during walking with the second generation of the orthosis may be related to the effects of training. However, if that was the cause, the walking speed of the subjects in walking with the second generation of the orthosis would have been more than that of the first generation. As the walking speed of the second generation was less than that of the first generation, the effects of the training could not be considered to be the final conclusion. So according to the PCI equation, the heart rate of the subjects in walking with the second generation of the orthosis was less than that of the first one. It means that the subjects were more comfortable in using the second orthosis than using the first one.

As it was mentioned in chapter 2, the cosmesis of the orthosis can be defined according to the style of walking and the degree to which the orthosis can be disguised under clothes. In the second generation of the orthosis the TLSO part of the orthosis was custom molded so it was completely fitted on the body. Moreover, the sizes of the hip and knee joints were decreased. As a result the cosmesis of the orthosis in the second generation was better than that of the first generation.

The weight of the orthosis in the first generation was 10.2 kg however; it was 8.75 kg in the second generation. The main reason for the decrease of the weight of the orthosis in the second generation was the TLSO part of the orthosis which was made from metal in the first generation however; it was made from plastic in the second generation.

The subjects were asked to give their comments regarding both generation of the orthosis. They agreed that using the second generation of the orthosis was easier to be used especially during sitting down. The participants had to push and hold the locking pins medially during sitting down in the first design. However, the locking system in the new design was operated by applying a pulling force. It was not necessary to apply the unlocking force continuously during sitting down.

5.4 CONCLUSION

The performance of the subjects in using an orthosis can be determined according to walking speed, energy consumption, the force applied on the crutch during walking and excursion of the COP during standing. The performance of the subjects with the second generation orthosis was better than with the first one. The cosmesis of the second generation was improved and it was lighter in contrast to the first one. The close fitting of the orthosis not only improved its cosmesis, but also improved its

function. It was much easier for the subjects to lock and unlock the hip joint of the second generation in contrast to that in the first one.

5.5 FURTHER WORK

The performance and the cosmesis of the orthosis were acceptable to be used for SCI subjects. However, before testing the orthosis on paraplegic subjects it was decided to compare the new generation orthosis with the best available orthosis, for spinal cord injury orthosis it is the HGO orthosis, in the same body of normal subjects. The main reason for comparing the orthosis with the HGO on the normal subjects was the limitation to have paraplegic patients at this stage. Evaluation of the loads applied on the orthosis may be done using strain gauges to show the absolute values of the loads applied on the orthosis. These values can be used for redesigning the orthosis.

CHAPTER 6: COMPARISON OF THE FUNCTIONAL PERFORMANCE OF NORMAL SUBJECTS DURING WALKING AND STANDING WITH THE NEW RGO AND HGO ORTHOSES

The functional performance of the normal subjects was evaluated during walking with the new RGO and HGO orthoses. According to the literature, the HGO orthosis is the best available orthosis for the SCI subjects (Jefferson and Whittle, 1990, Stallard and Major, 1998). The main reason is its greatest lateral rigidity. The magnitude of the loads applied on the orthosis was another important parameter which was selected in this part of the research. There were no data about absolute values of the loads applied on the orthosis during walking with the HKAFO orthosis in the literature. The magnitude of the loads applied on the orthosis during walking of the normal subjects was measured using suitable strain gauges which were attached on the lateral bar of the orthosis. The main aims of this part of this research were:

a) To compare the stability of the normal subjects with the new RGO and HGO orthoses during quiet standing and while performing various hand tasks
b) To compare the gait performance of the normal subjects during walking with each orthosis
c) To compare the energy consumption during walking with each orthosis
d) To compare the magnitude of the forces applied on the crutch during walking with each orthosis
e) To measure the magnitude of the loads applied on the lateral bar of the orthosis during walking the normal subjects with the new orthosis

6.1 METHOD

Number of the participant	Age (year)	Height (meter)	Weight (kg)
Subject 1	24	1.76	80.5
Subject 2	18	1.78	89
Subject 3	18	1.77	60.5
Subject 4	31	1.72	70
Subject 5	29	1.77	76.73

Table 6.1: Subject information

A group of healthy subjects were recruited to stand and walk over a flat walkway with the new RGO and HGO orthoses. The first 3 subjects were the same in this part and the second part of the research project. However they also received sufficient training in walking with the HGO orthosis. It should be mentioned that for the first 3 subjects the tests of walking with the new orthosis were repeated again. The crutches were adjusted to the subjects according to the standard criteria suggested by Cicenia and Hoberman (1957). The subjects were asked to stand and walk with each orthosis according to a special procedure.

6.1.1 Subjects

Five normal volunteers participated in this study. They had neither deformity nor contraindications for standing and walking or due to complicated medical history. The mean values of their age, height and their mass were 24 ±6.04, 1.76 ±0.023 m and 75.35 ±10.75 kg, respectively. Table 6.1 shows the characteristics of the subjects that participated in this part of the study. For this part of the research ethical approval was obtained from Strathclyde University's Ethics committee to test the HGO and new RGO orthoses on 5 normal subjects.

6.1.2 Orthoses

The orthoses which were used in this research were the second generation of the new RGO and HGO orthoses.

6.1.2.1 New RGO orthosis

The second generation of the orthosis was selected to be compared with the HGO orthosis during walking of normal subjects. The AFO and TLSO parts of the orthosis were custom moulded and were manufactured according to the size of the participants individually. Figure 5.1 shows the second generation of the new orthosis.

6.1.2.2 HGO orthosis

The HGO orthosis was assembled from the standard kit of the parts in such a manner so as to provide the best fit for the participants. Several of the components were cut and shaped according to the size and measurements collected from the subjects in order to ensure a close fit of the orthosis. The HGO orthosis consists of body brace, hip joint, the callipers and shoe plates. The hip joint of this orthosis was the third generation of the hip joint designed for adults. Figure 6.1 shows the HGO orthosis which was used in this research. The structure of the HGO orthosis was described in the literature review.

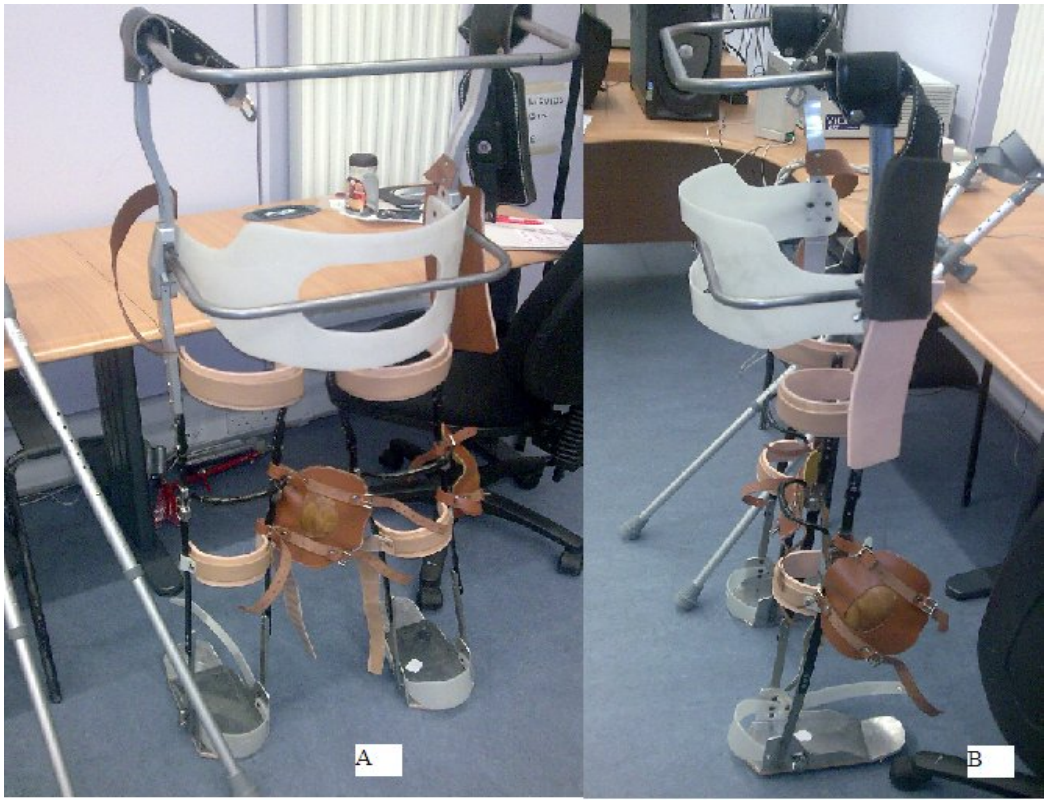


Figure 6.1: The HGO orthosis, A posterior view, B lateral view

6.1.3 Training Procedure

The subjects were trained to stand and walk with the orthoses before starting the data collection. They were trained to walk and stand with the HGO for two hours

(two sessions) and then in the next session, they were asked to use the orthosis to undertake the stability, gait and energy consumption tests. In the fourth and fifth sessions they were trained to walk and stand with the new RGO orthosis and finally the data were collected with the new RGO orthosis.

6.1.4 Testing Parameters

The performance of the orthoses during walking and standing were analysed by standing stability, gait analysis and by energy consumption tests. To analyse the magnitude of the loads applied on the lateral bar of the orthosis, strain gauges were attached on the lateral bar to check the axial force and the anteroposterior and mediolateral moments applied on the orthosis.

6.1.4.1 Standing stability parameters

The stability of the participants during standing with each orthosis was evaluated during quiet standing and while undertaking different hand functions. For testing the stability during quiet standing and while performing various hand functions, a force plate was used to check the location and the trajectory of the COP excursion in the mediolateral and anteroposterior planes. Moreover, the time required to undertake various hand functions was also measured.

6.1.4.1. I Stability analysis during quiet standing

The stability of the participants during quiet standing was evaluated by measuring the excursion of the COP in both mediolateral and anteroposterior planes. It was achieved by a Kistler force platform instrumented with piezoelectric force transducers. The reliability of the COP sways in the mediolateral and anteroposterior planes were tested by different researchers as was discussed in the chapter 4 (section 4.1.2.1.I). The same procedure was used to measure the COP sway during standing with the orthosis as was stated in chapter 4. The stability of the subjects during quiet

standing was represented by measuring the excursion of the COP in the mediolateral and anteroposterior planes.

6.1.4.1. II Stability analysis while performing hand tasks

The stability test of the paraplegics and normal subjects during standing with orthosis was done during quiet standing in many research studies however, the functional stability test was another important parameter which was used only in a few studies. The "Jebson test "of hand function is one of the standard tests used for analysing the functional stability test. This test was extended to include tasks which required vertical reaching and crossing the midline of the body while standing (Triolo et al, 1993). The subjects lift light and heavy objects during this test. The functional standing test consisted of 18 tasks which were divided into three main groups according to the difficulties of the tasks such as mild challenge, moderate challenge and difficult challenge. In the research carried out by Triolo et al (1993) 69 normal subjects and 2 paraplegic subjects participated and were asked to do the following tasks:

a) Move small objects on countertop
b) Lift objects up to lower shelf
c) Lift objects from lower to a higher shelf
d) Push objects using the dominate side

The time required to do these hand functions were selected for final analysis. Case studies in the SCI population indicated that the test may be very patient dependent. According to the results of this research further work was necessary to establish the sensitivity, accuracy and reliability of the test. It was concluded that the data of able bodies and disabled individuals need to be reanalysed to find the most stressful and sensitive tasks to represent the functional standing ability.

Some investigators used other parameters such as the excursions of the COP sway in the mediolateral and anteroposterior planes and the COP path length (Baardman et

al, 1997, Middleton et al, 1999). The procedure which was used by them differed from each others. Moreover, none of the above mentioned researchers checked the reliability of the parameters which they used to analyse the functional stability. So as a first step, the reliability and repeatability of the parameters used was evaluated on 10 normal subjects.

6.1.4.1. III Evaluation of the reliability of the functional stability parameters

The reliability and repeatability of different parameters, which were used by the above mentioned researchers for functional stability test was evaluated in this part of the research project. The stability parameters were analysed on 10 normal subjects, who had no medical history of the stability disorders or contraindications for standing. Table 6.2 shows the characteristics of the subjects that participated in this part of the study. The number of trials was 5 times and the test was repeated with one day interval.

The subjects were asked to stand in front of a table (wide 80 cm, depth 60 cm) with the height equals to 5 to 10 cm below the iliac crest. They were requested to move five cylindrical weights painted with five different colors, with mass, height, and diameter equal to 0.25 kg, 5 cm and 5 cm, respectively. They were positioned approximately 15 cm apart from left to right on the five different colored circles. Behind the cylinders a row of colored circles was inserted at the same spacing between them but in a reverse orders. For the second part of the test, a small table was used with a 20 cm height for analysing the stability during vertical reaching. This small table was located 25 cm behind the edge of the main table.

The subjects were instructed to stand on the force plate and then after gaining stability were asked to move the weights from left to right to the corresponding colors on the rear row as quickly as possible and back again from right to left. In this way the anteroposterior and mediolateral COP sways and the time necessary to do

Parameters	Age (year)	Mass (kg)	Height (m)
Mean value	26 ±2.4	74 ±10	1.75 ±0.04

Table 6.2: The information of the subjects who participated in the functional stability test

Parameters	Pearson correlation	P-value for Pearson correlation	ICC correlation	P- value for ICC correlation
Time for transverse motion (second)	0.947	0.00	0.899	0.00
COP excursion in the AP plane (transverse motion) (mm)	0.355	0.175	0.53	0.156
COP excursion in the ML plane (transverse motion) (mm)	0.922	0.00	0.96	0.00
Time for vertical motion (second)	0.895	0.00	0.917	0.00
COP excursion in the AP plane (vertical motion) (mm)	0.694	0.013	0.799	0.016
COP excursion in the ML plane (vertical motion) (mm)	0.759	0.005	0.66	0.072

Table 6.3: The result of the reliability test of the parameters used to evaluate the functional stability

the tasks were measured. The test was repeated to collect 5 successful trials. In the second part of the test the small table was located on top and 25 cm behind the edge of the main table and the subjects were asked to move the cylindrical weights and put them on the top of the small table, without considering the colures and the location, and then return them to the first positions. The same parameters were collected and the tests were repeated 5 times. The results of this part of the research showed that the reliability and repeatability of the time necessary to do these functions was more than COP sway, especially for anteroposterior plane. The result of the reliability test of the functional stability parameters is shown in table 6.3.

6.1.4.1. IV Procedure used for performing stability test

The procedure used to perform the stability test was the same as that used in the previous research described in chapter 4. The subjects were instructed about the procedures and instruments and then their mass and height were recorded. For stability analysis during quiet standing, the subjects were asked to stand on the force plate for 60 seconds. The test was repeated 5 times and the data were sampled with a frequency of 120 Hz. The collected data were transformed into Newton and Newton meter by multiplying them by the full calibration matrix which was produced by manufacturer of the force plate, specifically for each force plate. The signal of the force plate was filtered with a Woltring filter with cut off frequency of 10 Hz (the frequency of filtering in the Vicon system was set at 10 Hz). The excursion of the COP in the mediolateral and anteroposterior planes was used to represent the stability during quiet standing.

The functional stability test was done with the same procedure as previously stated. Before starting data collection, the subjects were trained how to perform the test. A reliable digital stop clock was used to record the time necessary to perform these tests. The tests were repeated five times for transverse and vertical motion separately. The time necessary to undertake these functional tasks and the excursion

of the COP in the mediolateral and anteroposterior planes were used for the final analysis.

6.1.4.2 Gait analysis parameters

The gait analysis was done during walking with the HGO and the new RGO orthoses after the subjects received sufficient training. The selected parameters included:

a) Excursion of the hip joint flexion/extension
b) Excursion of the hip joint abduction/adduction
c) Hip joint flexing/extending moment
d) Hip joint abducting/adducting moment
e) The magnitude of the vertical force applied on the left foot
f) The magnitude of the vertical force applied on the left crutch
g) The Force time integral (FTI) of the crutch force
h) Spatio-temporal parameters

The procedure which was used for gathering the gait analysis data was the same as that used in chapter 4. However, in this research the data were collected from the left side. The data corresponding to the force applied on the crutch were collected simultaneously, as with the data of the force applied on the foot were being collected.

6.1.4.3 Energy consumption analysis

The energy consumption test during walking with both the HGO and new orthoses was based on PCI. The procedure which was used for this part of the research project was exactly the same as that used in chapter 4. The heart rate was monitored for two resting periods, each one for 5 minutes, and during walking for 10 minutes. The subjects were asked to walk along a figure of 8 track, as was done before.

6.1.4.4 Analysis of the force applied on the lateral bar of the orthosis

The measurement of the loads applied on the orthosis during walking could be done by using strain gauges or by using appropriate transducers. A strain gauge is an electronical device (resistance) which converts the mechanical energy into electrical signals. The change in resistance is proportional to the strain developed in the strain gauge. The strain sensitivity is a function of the dimensional changes taking place when a conductor is deformed elastically, plus any change in the basic resistance of the material within strain. The electrical resistance of a conductor can be determined as follows.

$$R = \frac{\rho l}{A} \qquad \text{Eq. 6.1}$$

Where ρ is resistivity, A is cross section area, l is length and R is resistance. When strain is introduced, the strain sensitivity, which is also called "Gauge Factor (GF)", can be determined as follows (Window, 1992).

$$GF = \frac{(\Delta R/R)}{(\Delta l/l)} = \frac{(\Delta R/R)}{\text{Strain}} \qquad \text{Eq. 6.2}$$

Where GF is gauge factor or strain sensitivity, R is initial resistance, ΔR is the change in the resistance, l is initial length and Δl is change in the length. In order to measure strain with a strain gauge it must be connected to an electronic circuit which be capable of measuring the changes in the resistance corresponding to strain. To reach to this goal, four strain gauge elements are connected to each others to form a Wheatstone bridge circuit. In figure 6.2, if $R_1/R_4 = R_2/R_3$, the output potential difference will be zero. However, if R_1 is changed, the output potential voltage will be changed as well. By knowing the primary resistance of R_1 it is possible to check the total resistance of the network. The bridge output voltage is given by the following equation (Window, 1992):

$$V_{out} = \frac{K\varepsilon N V_{in}}{4} \qquad \text{Eq. 6.3}$$

Where K is the gauge factor (GF), V_{in} is the bridge voltage supply, ε is strain and N is the number of active arms of the bridge.

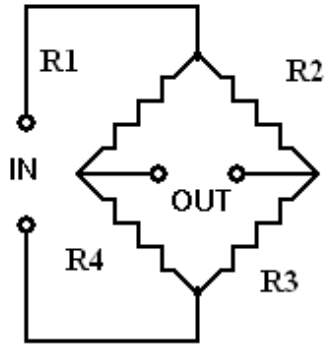


Figure 6.2: Wheatstone bridge which is used for circuit of strain gauge

However, an important point is that the output of the Wheatstone bridge varies linearly with the applied load. Since the strain gauges must be attached on the orthosis and during walking they will be at some distance from the recording equipment, it was recommended that a full bridge should be used. In the full Wheatstone bridge all four arms were active. For measuring the bending moment the value of the N is 4 and for compression and tension it is 2.6. The other advantage of the full bridge is that all the lead wires from the measuring point to the instrumentation, including plugs, connectors are outside the measuring circuit and contribute minimal errors to the system (Window, 1992).

Using transducers designed in the Bioengineering Unit of Strathclyde University was another way to measure the magnitude of the loads applied on the orthosis during walking. The design of the transducer is based on the strain gauge technology however, it could be used only in special circumstance where the

moments and the loads are below certain values, i.e. the design values. The design values were determined by the designers, table 6.4. Since there was no information about the loads and moment transmitted by an orthosis during walking of a paraplegic or normal subject with the HKAFO orthosis in the literature it was necessary to determine the loads before selecting transducers or using strain gauges for the main research project.

6.1.4.4.I A pilot study to determine the magnitude of the loads applied on the orthosis during walking

In order to determine the loads applied on the orthosis during walking of a normal subject, strain gauges were attached on the left lateral bar of the orthosis. The main aims of this were to check the possibility of using the transducers listed in table 6.4 and also to determine the maximum force and moments which would be used in order to calibrate the transducer or the strain gauge arrangement to be used in the main research study.

Appropriate foil strain gauges purchased from Showa Measuring Instruments Company (Tokyo, Japan) were used, which were attached on the lateral bar of the orthosis using special glue, M-Bond AE-10 Adhesive which was recommended by Vishay Measuring Group (USA). References lines were drawn on the surfaces of the lateral bar using a hard pen. The adhesive was used according to the procedure recommended by the supplier. The strain gauges were covered with silicon rubber to protect them during sitting of the participants with the orthosis.

Parameters	Axial force (N)	Anteroposterior bending moment (Nm)	Mediolateral bending moment (Nm)
Gozal	1600	30	30
Maqsood	800	35	25

Table 6.4: The maximum service loads allowed by the Bioengineering Unit transducers

Channel	Parameter Measured	Voltage across	Amplifier gain
1	AP moment	3	2,000
2	ML moment	3	2,000
3	Compression force	6	10,000

Table 6.5: Bridge voltages and amplifier's gain used for the different channels

Three full strain gauge bridges on the orthosis were connected by a special 4-wire ribbon cable to a 25 way terminal plug. A length of 25 way cable connected the gauges to a set of amplifiers, which were developed specifically in the Bioengineering Unit of Strathclyde University. The output of the amplifiers was connected to a DAQ card inserted in a laptop. The output data were collected by lab view software and at the same time by the Vicon system through the force plate amplifiers. The force plate amplifiers were synchronized with the strain gauge amplifiers to collect the data at the same time and with the same sampling frequency. This was achieved using a switch which supplied a signal to both the laptop and Vicon system.

The three channels were attached to a power supplier as channel 1 to channel 3. Table 6.5 shows the name of the channels, the bridge voltages and the amplifier gain settings which were used for the different channels. A normal subject with a body mass around 84 kg participated in this study. Both lab view and the amplifiers of the Vicon system were set to collect data with a frequency of 120 Hz. The amplifier output was adjusted to zero volts measured on a Digital Voltmeter (DVM). The outputs of the bridges were zeroed when the orthosis was in the sitting position without the subject. The subject was asked to walk with a comfortable speed after donning the orthosis. The tests were repeated to collect five successful trials.

In order to change the outputs into force and moments, the following equations were employed (Window, 1992).

$$V_{out} = \frac{K\varepsilon N V_{in}}{4} \qquad \text{Eq. 6.3}$$

$$\sigma = E\varepsilon = \frac{Mc}{I} = \frac{F_y}{A} \qquad \text{Eq. 6.4}$$

Where, σ is stress, ε is strain, M is the applied moment, c is the distance of the surface above the neutral axis (figure 6.3), I is the second moment of area and E is the Young' Modulus.

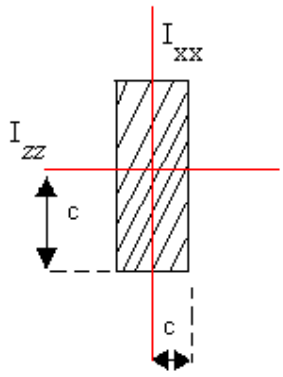


Figure 6.3: The cross section of the lateral bar of the orthosis

The value of the N was considered to be 4 for the strain gauges designed for bending moments and 2.6 for those designed for tension and compression forces. The equation 6.3 was changed as follows.

$$\varepsilon = \frac{V_{out}}{K\, V_{in}} \qquad \text{Eq. 6.5}$$

$$\varepsilon = \frac{V_{out}^{2}}{V_{in}\, 1.3K} \qquad \text{Eq. 6.6}$$

The equation 6.5 was used for the bending moments and equation 6.6 was used for compression and tension forces. For the strain gauge configuration designed for measuring compression and tension forces, another equation could be used which is as follows (Window, 1992).

$$\varepsilon = \frac{V_{out}2}{V_{in}K(1+\upsilon)} \qquad \text{Eq. 6.7}$$

Where, υ is Poisson ratio. If the Poisson ratio be considered as 0.3 for aluminum, the equations 6.7 and 6.6 would be the same. The final equations which can be used for converting the strain gauges output according to the dimensions of the bar were as follows, full details in appendix 6.

$$F_y = 4407V_{out} \text{ (N)} \qquad \text{Eq. 6.8}$$

$$M_x = 15.27V_{out} \text{ (Nm)} \qquad \text{Eq. 6.9}$$

$$M_z = 29.6V_{out} \text{ (Nm)} \qquad \text{Eq. 6.10}$$

Where, V_{out} is in millivolt.

6.1.4.4. II Results

The maximum values of the bending moments and vertical forces applied on the lateral bar of the orthosis during walking of the normal subjects are shown in table 6.6.

The results of the strain gauges showed that the loads applied on the orthosis during walking was more than the threshold of the available transducer, thus it was impossible to use the transducer in order to measure the loads applied on the orthosis. The collected data from the lab view and Vicon system force plate

Parameter	Compression (N)	Tension (N)	Flexing moment (Nm)	Extending moment (Nm)	Adducting moment (Nm)
Mean values	244.5±11.42	37.1±19.8	7.95±1.04	13.72±2.2	50±3.6

Table 6.6: The mean values (±2SD) of the loads applied on the orthosis during walking

amplifiers were identical, so it was possible to collect the data of the strain gauges directly from the force plate amplifiers.

6.1.4.4.III Redesigning the strain gauge system for use in the main project

The preliminary results of the strain gauges showed that it was impossible to use the available transducer for analysing the loads applied on the orthosis during walking. The thickness of the bar of the orthosis was 16 mm which displayed a very small deformation under tension and compression during walking. The sensitivity of the strain gauges to sense the axial loads was not high and had some cross talk with other channels. In order to increase the sensitivity of the strain gauges especially against the axial loads, the thickness of the bar must be decreased or the number of the strain gauges should be increased. The sensitivity of the strain gauges was increased by using more strain gauges. They were attached to the lateral bar of the orthosis according to the same procedure which was used before. A silicon coating was finally applied over the strain gauges to protect them during walking and standing. Figure 6.4 shows the strain gauges attached on the lateral bar of the orthosis.

6.1.4.4.IV Calibration of the strain gauges system

Calibration is a process in which an acceptable standard is compared against an unknown quantity and is used to determine the accuracy of a method or a tool. The accuracy of the calibration depends upon the accuracy of the calibration procedure and is introduced by the errors of the tools and technique. The static calibration which is used routinely for calibration of strain gauged transducers involves the application of known loads along the axes of the transducer and recording the output. The weights are made to a high degree of accuracy which exceeds the value required for the calibration. The output will give information on the calibration coefficients which may be used to convert the output into forces and moments.

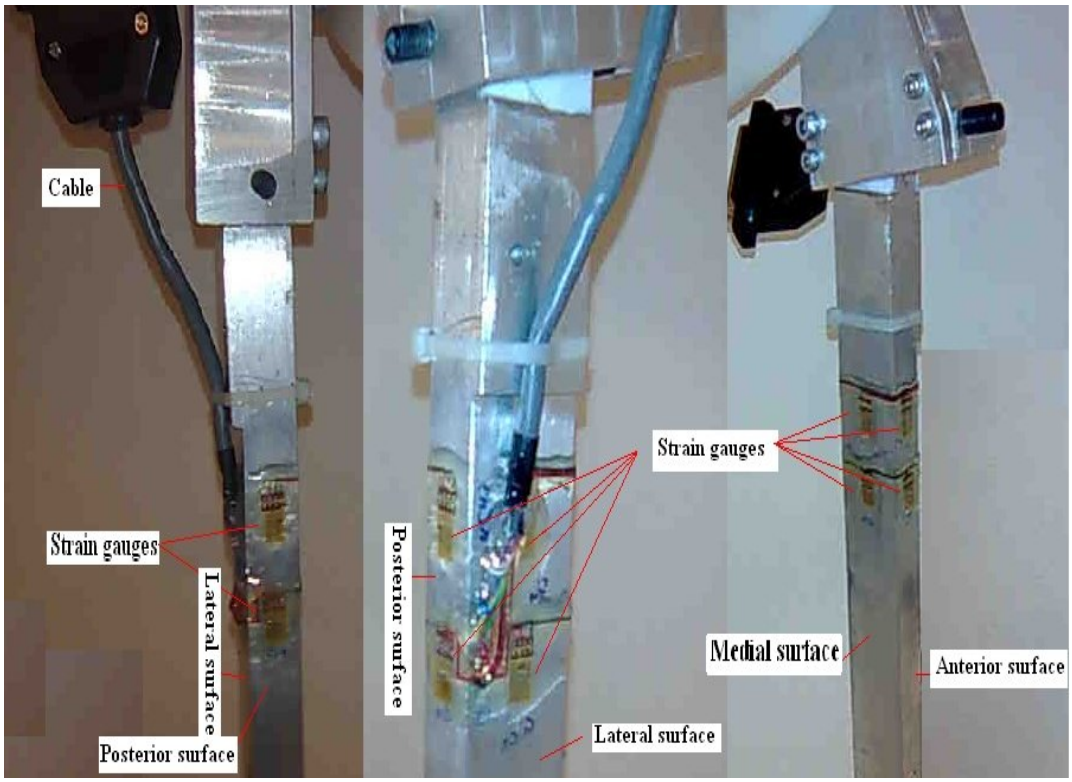


Figure 6.4: The strain gauges attached on the different surfaces of the lateral bar of the orthosis

For the strain gauged system which was used in this research study with three channels, the output signals S_i (i=1, 3), i.e. the measured output voltages, is a direct function of the input signals L_j (j=1, 3), i.e. the applied loads. An accurately designed strain gauge system can provide an output which can be represented as (Gozal, 1986, Maqsood, 1996):

$$S_i = \sum_{j=1}^{3} C_{ij} L_j \qquad \text{Eq. 6.11}$$

The above equation may be represented in a matrix as follows.

$$[S] = [C][L] \qquad \text{Eq. 6.12}$$

Where, $[S]$ is the output signal in volts, $[C]$ is the calibration coefficient and $[L]$ is the input applied loads. The above equation can be expressed into the following matrix.

$$\begin{pmatrix} SF_y \\ SM_x \\ SM_z \end{pmatrix} = \begin{pmatrix} C_{11} & C_{12} & C_{13} \\ C_{21} & C_{22} & C_{23} \\ C_{31} & C_{32} & C33 \end{pmatrix} \begin{pmatrix} F_y \\ M_x \\ M_z \end{pmatrix} \qquad \text{Eq. 6.13}$$

The above matrix can be broken into three component equations, which for example for F_y can be expressed as follows.

$$SF_y = C_{11}F_y + C_{12}M_x + C_{13}M_z \qquad \text{Eq. 6.14}$$

When a multi channel strain gauged system is loaded purely in one channel, there would be an output in that channel related to that loads however, other channels may also have a small apparent strain and output voltage. This is known as cross talk and depends upon the accuracy of the system and a procedure which is used for calibrating it, by applying a known load along different channels, the output of the different channels can be measured and the magnitude of the cross talk can be determined. The coefficients which are shown in the above equations can be determined by the calibration process. This can be repeated for the three channels to produce a full calibration matrix.

During the walking tests the loads applied on the orthosis were unknown however, they were determined using the calibration procedure. The measured output

voltages and predetermined calibration coefficients could be determined by using the following equation.

$$[L] = [C]^{-1}[S] \qquad \text{Eq. 6.15}$$

Where $[C]^{-1}$ was actually the inverse of the calibration matrix.

6.1.4.4. IV Calibration procedure

The following apparatus was used during calibration procedure, figure 6.5:

a) The lateral bar of the orthosis with strain gauges attached on it
b) A digital Voltmeter (DVM)
c) Amplifiers with power supply
d) DAQ card
e) A suitable computer with lab view software
f) Connection cable

A 3 V bridge voltage was supplied to channels 1 and 2 (bending moments) and a 6 V bridge voltage was used for channel 3 (axial load). Before starting the calibration process the outputs of all channels were checked using a DVM. It was important to determine the direction of the proximal and distal ends of the bar and also the medial, lateral, anterior and posterior directions and the direction of the application of the load relative to these surfaces. The reasons for this was that the positive output of the strain gauge did not necessary correspond to a positively applied load. The amplifier gain setting was arranged according to the procedure stated before; it was 10,000 for the axial load and 2,000 for the bending moments.

The bar of the orthosis was located horizontally in the calibration jig using special parts manufactured for this purpose (for anteroposterior moment) and the strain gauged system was connected to the amplifiers and the computer, figure 6.5. The alignment of the bar was checked using a standard laser liner system to be exactly along the horizontal axis. The strain gauges were left to warm up for at least one hour. The channel to be calibrated was preloaded in both positive and negative directions several times to remove any irregularities in the strain gauges and at the coupling of the bar and jig.

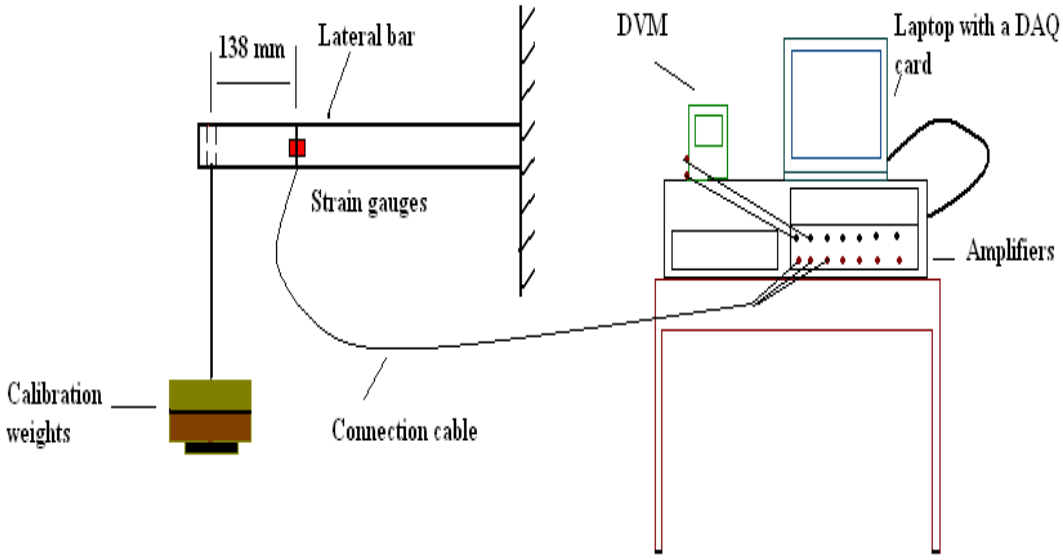


Figure 6.5: The calibration system used for the anteroposterior calibration

The output of the strain gauges for the three channels was reset to zero as was observed by DVM. The weight carrier was hanged at right angle to the longitudinal axis of the bar which was located 138 millimeters away from the centre of the strain gauge arrangement. The output of the three channels reset to zero again. The first load was put on the carrier and this was increased up to 20 kg in steps of 5 kg. The output was recorded continuously by lab view software with a frequency as 120 Hz. The signals were again recorded as the weights were removed. Comparison of ascending and descending signal output allowed any problems to be observed and was used to ensure that the gauges had not yielded. In order to calibrate the strain

gauges against the mediolateral bending moment, the bar was rotated 90 degrees, so the loads applied on the mediolateral surface of the bar.

The same procedure which was used for calibration of the strain gauge for the anteroposterior moment was used for mediolateral moment as well. The calibration of the strain gauges for the bending moment in the mediolateral direction is shown in figure 6.6.

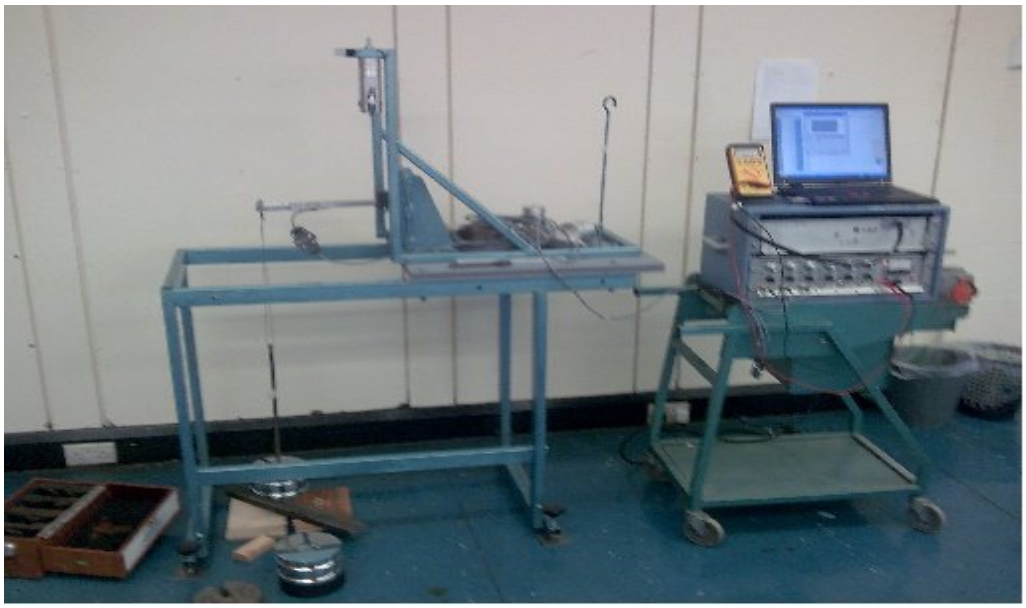


Figure 6.6: Calibration of the strain gauges for the mediolateral bending moment

In order to calibrate the strain gauges for axial force (compression force), the bar of the orthosis was positioned vertically in the special axial loader which was manufactured for this purpose, with the distal end above the proximal end, figure 6.7. This apparatus allowed the application of an absolute compression force to the device. The first load (5 kg) was placed on the loader end and the recording made by checking the output of the DVM and lab view. This was repeated for each 9 weights until a maximum load of 445 N had been applied. As the weights were removed from the loader the measurements were also recorded. Examination of the initial and final reading was used to ensure that the strain gauges had not yielded.

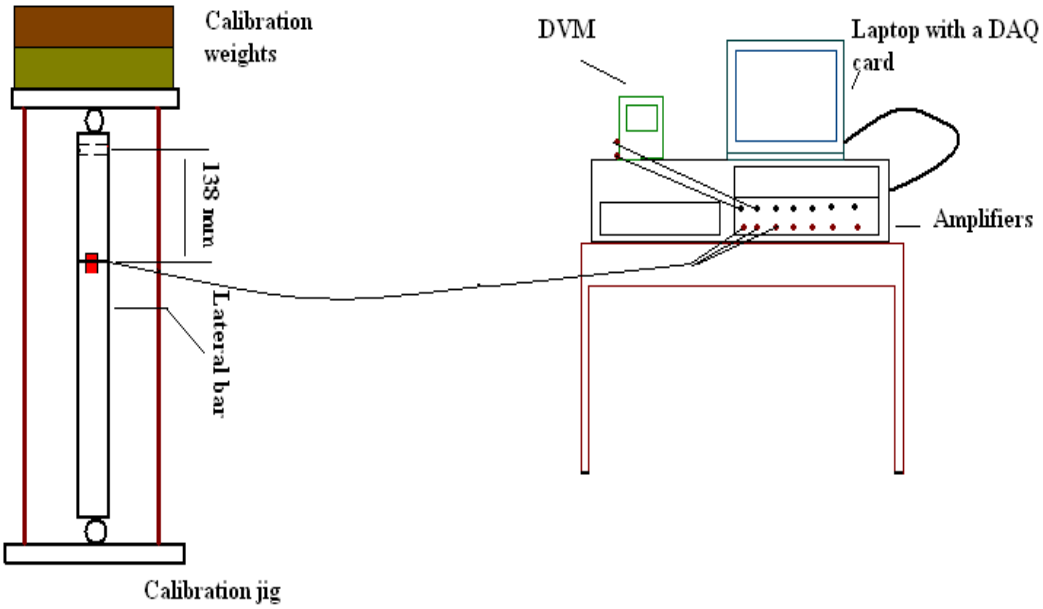


Figure 6.7: Calibration of the strain gauges for the axial force

The numerical output from the lab view software was in millivolts. It was adjusted by considering the bridge voltages and gain for each channel. The calibration factor for each channel was obtained in units of mV/N for axial force and mV/Nm for the bending moments by performing linear regression. The final calibration matrix is shown in table 6.7. A regression line was fitted to the principal calibration coefficient to check for linearity and hysteresis. The voltage output was plotted against the input load to check for linearity, hysteresis, as are shown in figures 6.8 to 6.10 for the vertical force. The calibration figures of other channels are shown in appendix 6. As can be seen in appendix 6, the cross talk of the strain gauges arrangement for the moments was significantly more than that for the vertical force.

6.1.5 Data Analysis

The normal distribution of all mentioned parameters was controlled by using Shapiro-Wilk test. The parameters which had no normal distribution, were

Output (millivolts)	F_y (N)	M_x (Nm)	M_z (Nm)
F_y	0.00021463	0.08226	0.03
M_x	0	0.0604	1
M_z	0	-0.6366	0.032875

Table 6.7: The final matrix found from calibration procedure

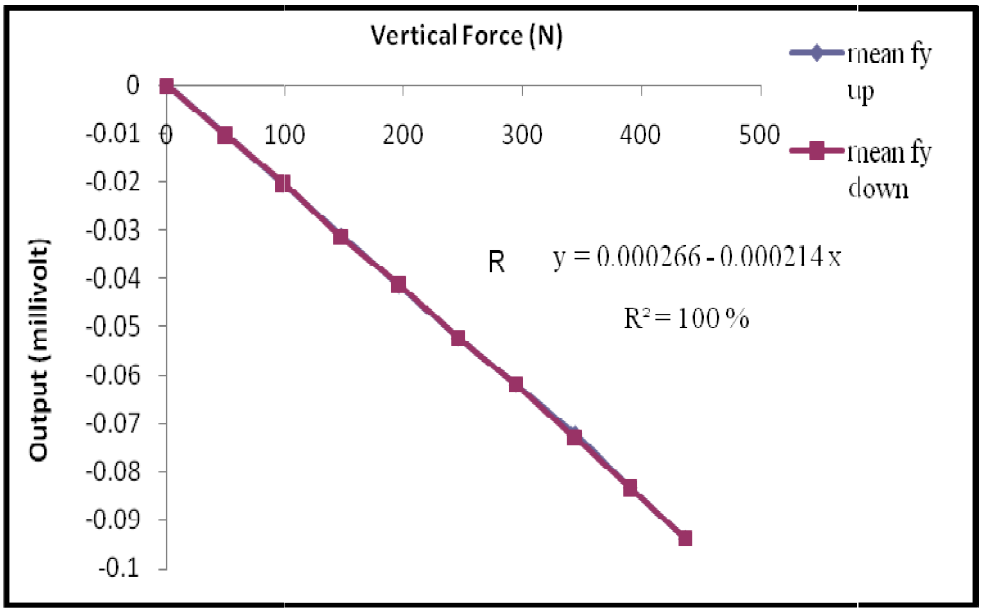


Figure 6.8: Calibration graph of the strain gauge output with F_y as main channel

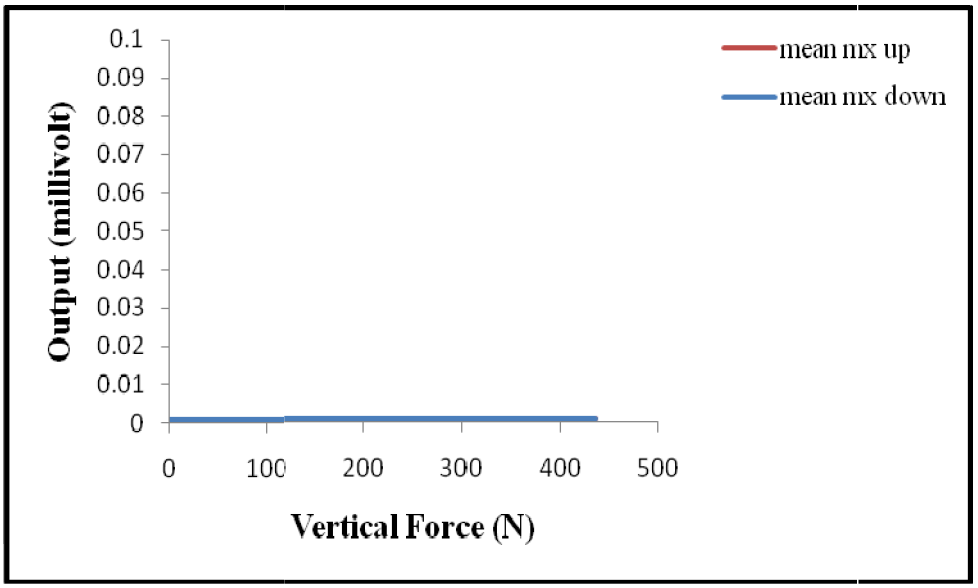


Figure 6.9: Calibration graph of the strain gauge output for F_y as the main channel and showing the cross talk in M_x channel

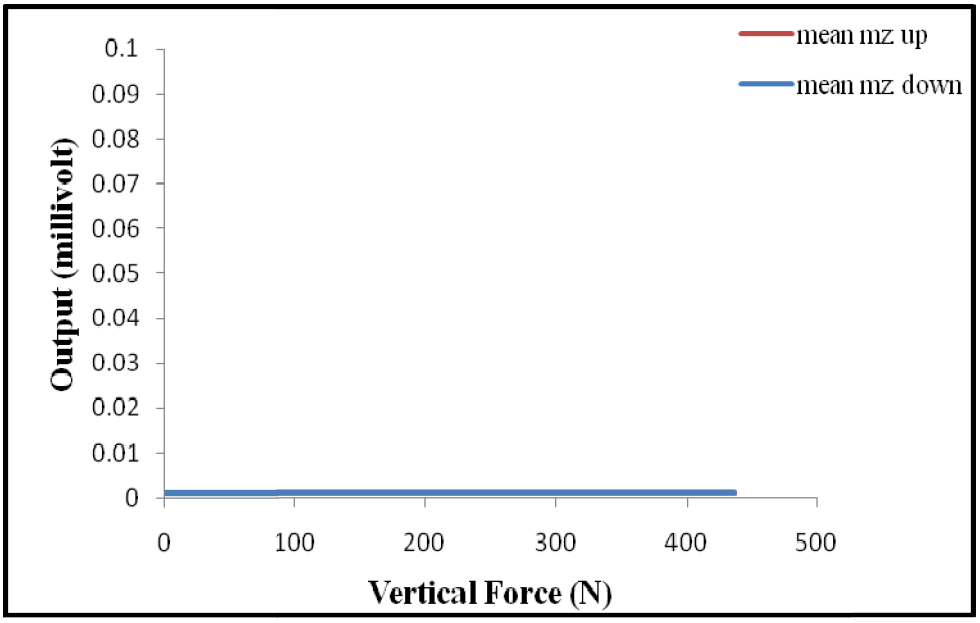


Figure 6.10: Calibration graph of the strain gauge output for F_y as the main channel and showing the cross talk in M_z channel

normalized using a logarithmic transformation procedure. This allowed the use of parametric statistics for final analysis. The difference between the mean values of different parameters during walking with the new RGO orthosis and the HGO orthosis was analyzed by using Paired t test, with a significant level as 0.05.

6.2 RESULTS

The mean values of the different parameters during walking with both orthoses are shown in tables 6.8 to 6.10.

6.2.1 Stability

The mean value of the COP sway in the mediolateral plane in standing with the new RGO orthosis was 8.08 ± 3.28 mm, compared to 10.67 ± 6.34 mm in standing with the HGO orthosis, table 6.8. The excursion of the COP in the anteroposterior plane was 11.5 ± 3.5 and 28.1 ± 26.8 mm in standing with the new orthosis and the HGO orthosis, respectively. Although the stability of the participant during standing with the new orthosis was better than that with the HGO, the difference was not significant.

The stability of the participants during hand function did not differ significantly between both orthoses. The time necessary to do different hand tasks in standing with both orthoses was nearly the same as each others. The mean values of the COP sway in the mediolateral and anteroposterior planes were 76.94±11 and 244.4±88.2 mm, respectively whilst moving the cylindrical weights along a transverse plane in standing with the new orthosis compared with 85.3±9.96 and 213.2±66.4 for the HGO orthosis. As can be seen in table 6.8 the stability of the participants whilst moving the cylindrical weights along the vertical plane was better in the new

Parameters	New RGO orthosis	HGO orthosis	P-value of the difference
COP sway, ML (mm)	8.08 ± 3.28	10.67 ± 6.34	0.288
COP sway, AP (mm)	11.5 ± 3.5	28.1 ± 26.8	0.217
Time transverse (second)	9.53 ± 2.1	9.64 ± 1.97	0.899
Time vertical (second)	9 ± 1.54	9.074 ± 1.99	0.874
COP sway , AP transverse (mm)	76.94 ± 11	85.3 ± 9.96	0.227
COP sway , ML transverse (mm)	244.4 ± 88.2	213.2 ± 66.4	0.644
COP sway, AP vertical (mm)	58.1 ± 15.9	72.6 ± 14.5	0.047
COP sway, ML vertical (mm)	56.1 ± 10.8	72 ± 29.4	0.2

Table 6.8: The mean values of the stability parameters during standing with the HGO and new RGO orthoses

Parameters	New RGO orthosis	HGO orthosis	P-value of the difference
Flexion extension excursion (degree)	29.38 ± 3.56	30.5 ± 4.24	0.41
Abduction adduction excursion (degree)	5.61 ± 2.15	10.8 ± 5.53	0.179
Walking speed (m/min)	35.06 ± 6.28	33.58 ± 11.2	0.688
Cadence (steps/min)	57.61 ± 3.65	50.12 ± 12.77	0.296
Stride length (m)	1.031 ± 0.243	1.1 ± 0.219	0.121
Percentage of the stance phase	61.61 ± 3.04	60.65 ± 3.53	0.477

Table 6.9: The mean values of the gait parameters during walking with the HGO and new RGO orthoses

Parameters	New RGO orthosis	HGO orthosis	P-value of the difference
*Flexing Moment (Nm/kg)	0.54 ± 0.278	0.474 ± 0.203	0.417
*Extending Moment (Nm/kg)	0.437 ± 0.11	0.44 ± 0.05	0.946
*Adducting Moment (Nm/kg)	1.056 ± 0.288	0.893 ± 0.43	0.282
Crutch Force (N/BW)	0.163 ± 0.04	0.179 ± 0.067	0.469
*Foot Force (N/BW)	1 ± 0.03	0.998 ± 0.054	0.82
FTI (crutch force) (N.s)	93.2 ±28.8	121.3 ±94.4	0.543
** PCI (beats/m)	0.46 (0.41-0.625)	0.48 (0.39- 0.83)	0.641

Table 6.10: The mean values of the gait and energy consumption parameters during walking with the HGO and new RGO orthoses

*These moments and forces were applied on the hip joint complex (anatomical and mechanical ones) and foot complex (orthosis and body), respectively

** This parameter did not have a normal distribution, the median and the first and third quarters were represented

orthosis than with the HGO, the difference between the mean values of the COP excursion was significant for the anteroposterior plane.

6.2.2 Gait Analysis

6.2.2.1 The hip joint motions in the sagittal and coronal planes and Spatio-temporal gait parameters

The mean value of the excursion of the hip joint in the sagittal plane was nearly the same for both orthoses (it was 29.4 degrees for the new orthosis and 30.5 for the HGO orthosis). The hip joint abduction/adduction excursion in walking with the new orthosis was less than that with the HGO orthosis. It was 5.61 ± 2.15 degrees for the new orthosis compared to 10.8 ± 5.53 degrees for the HGO. The walking speed of the subjects with the new orthosis was more than that with the HGO orthosis however, the difference between the mean values was not significant. The number of steps per minute (cadence) in walking with the new orthosis was 57.61, which was more than that with the HGO (50.12). There was no difference between the percentages of the stance phase in walking with both orthoses. Figures 6.11 to 6.14 show the motion of the hip joint in the coronal and sagittal planes during walking with the HGO and new RGO orthoses.

6.2.2.2 Hip joint flexing/extending, abducting/adducting moments

The flexing moment applied on the hip joint was 0.54 Nm/kg in walking with the new orthosis, compared to 0.474 Nm/kg in walking with the HGO orthosis (the difference between the flexing moments of both orthoses was not significant). The extending moment of the hip joint in walking with the new orthosis was nearly the same as that with the HGO orthosis. The mean value of the adducting moment was 1.056 ±0.288 Nm/kg in walking with the new orthosis and 0.893±0.43 Nm/kg in walking with the HGO however, the difference between the mean values was not

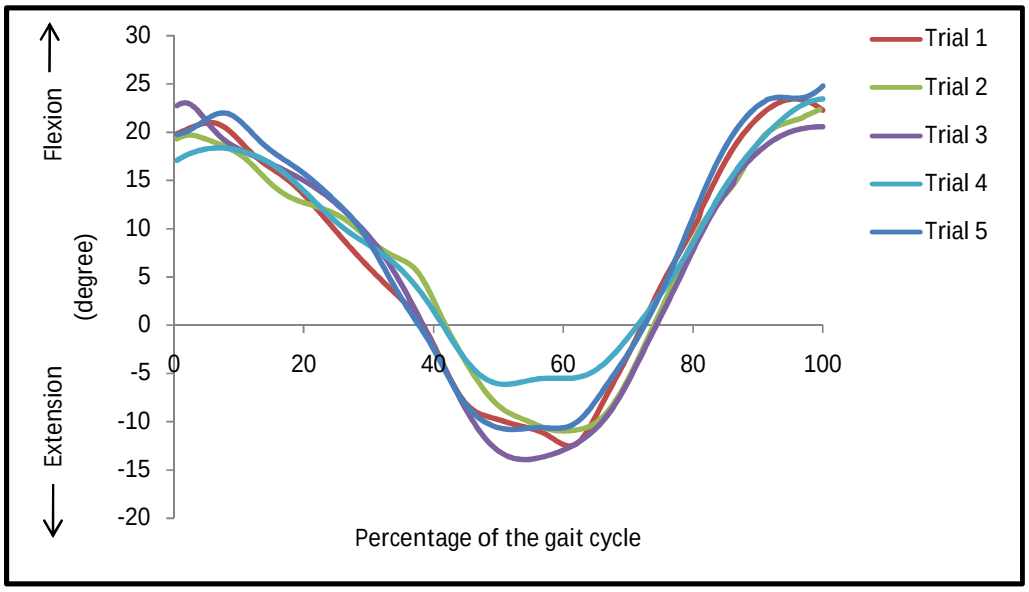


Figure 6.11: Flexion/extension angle of the hip joint during walking with the new RGO orthosis

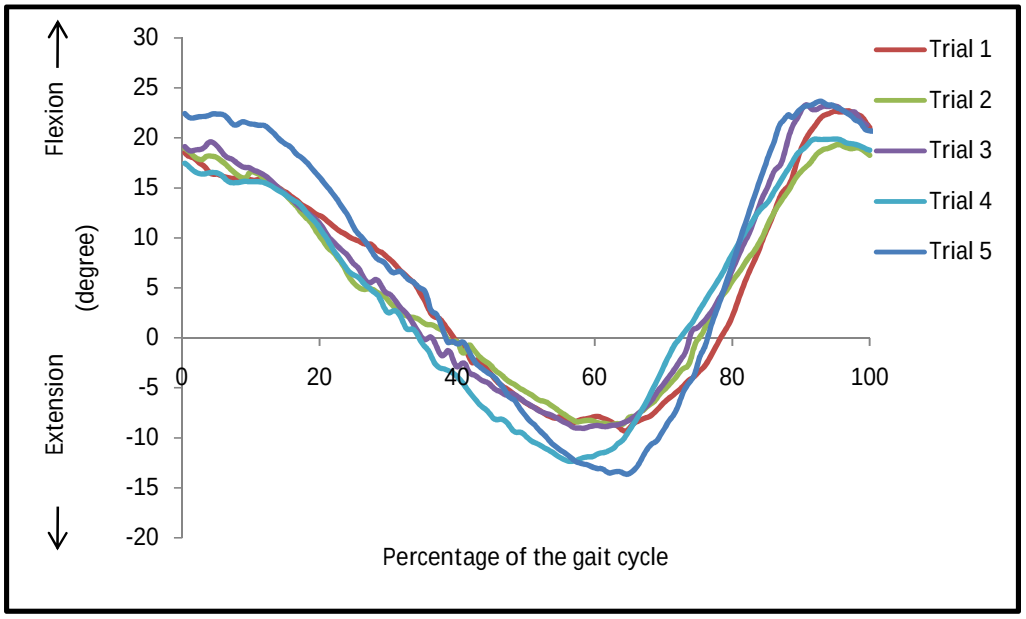


Figure 6.12: Flexion/extension angle of the hip joint during walking with the HGO orthosis

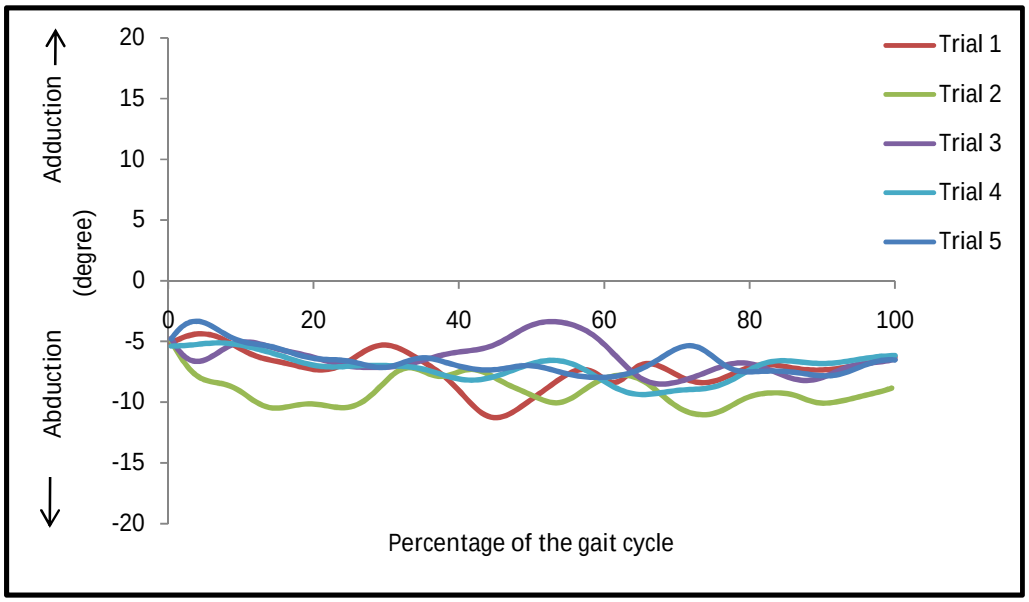


Figure 6.13: The abduction/adduction angle of the hip joint during walking with the new RGO orthosis

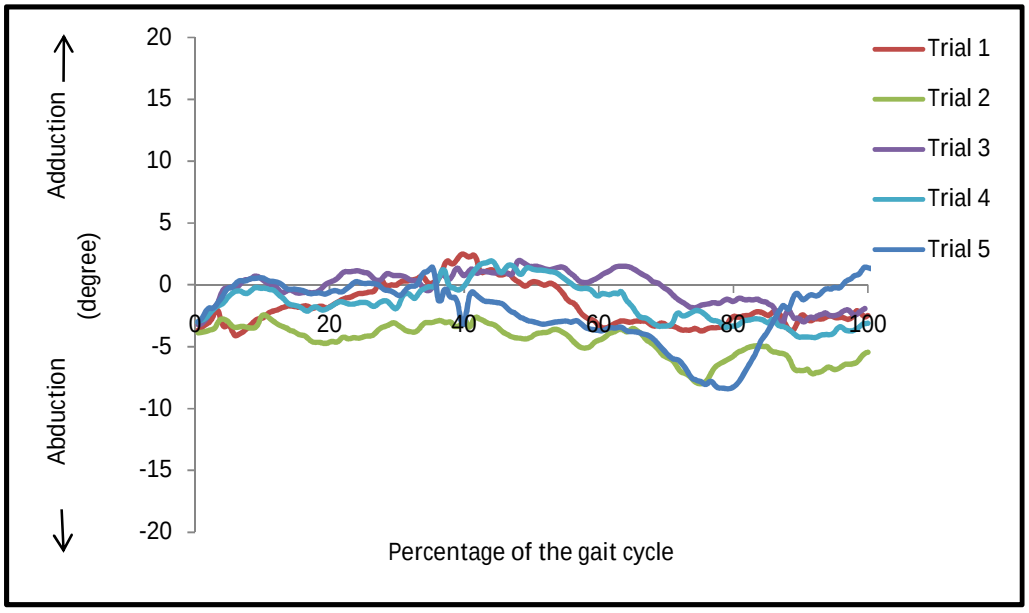


Figure 6.14: The abduction/adduction angle of the hip joint during walking with the HGO orthosis

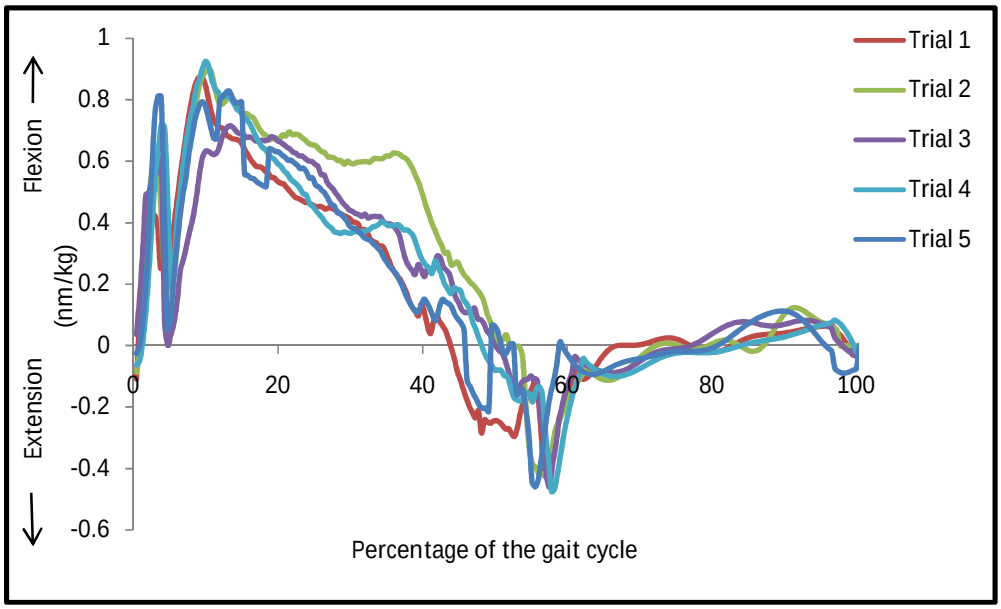


Figure 6.15: The flexing/extending moment of the hip joint during walking with the new RGO orthosis

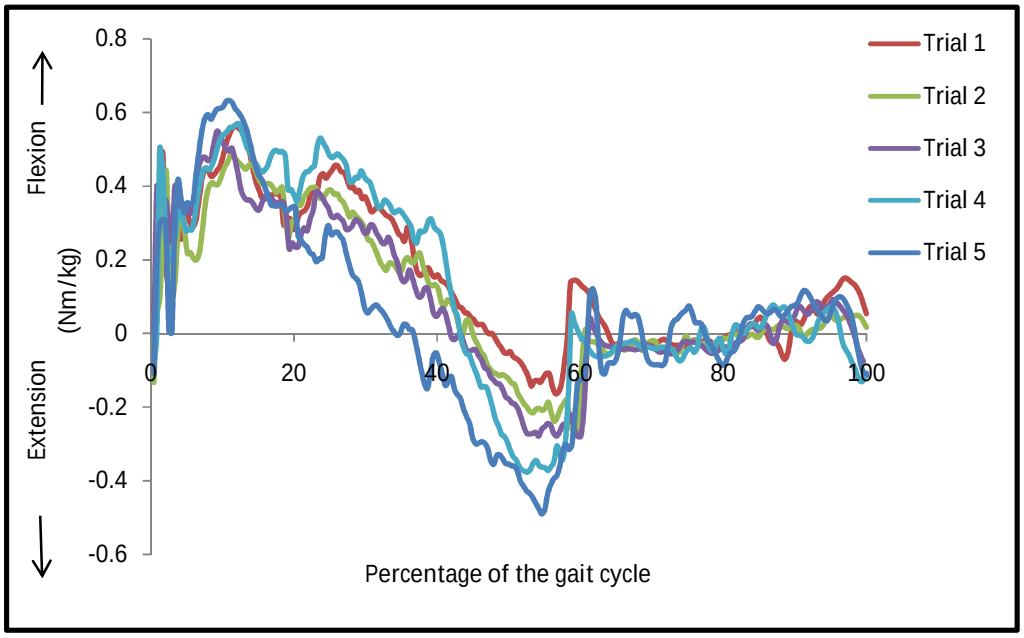


Figure 6.16: The flexing/extending moment of the hip joint during walking with the HGO orthosis

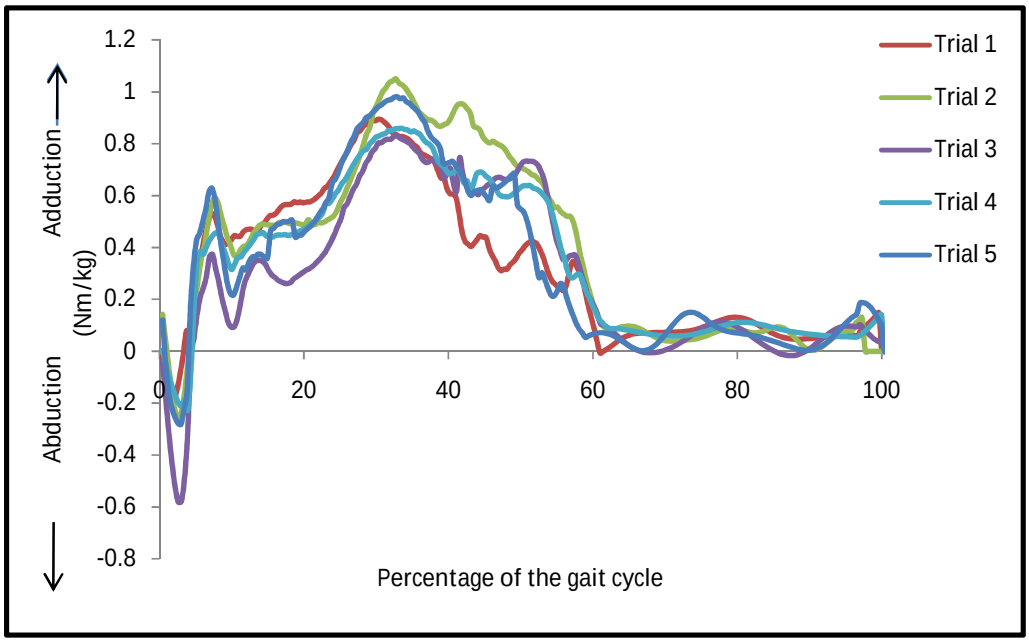


Figure 6.17: The adducting moment applied on the hip joint during walking with the new RGO orthosis

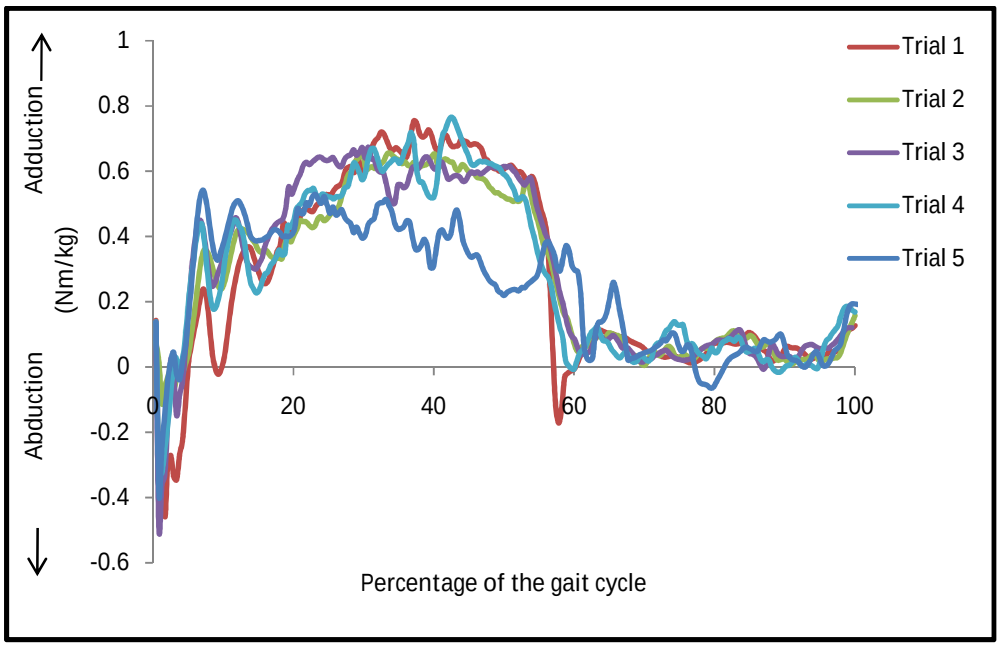


Figure 6.18: The adducting moment applied on the hip joint during walking with the HGO orthosis

significant. The flexing, extending, and adducting moments of the hip joint of both orthoses are shown in figure 6.15 to 6.18.

6.2.2.3 Force applied on the foot and crutch

The magnitude of the force applied on the crutch during walking with the new orthosis was less than that with the HGO orthosis however, the difference was not significant. Force time integral (FTI) was the other parameter selected in this research to represent the effect of the orthosis on the magnitude of the force applied on the upper limbs during walking. The mean value of FTI in walking with the new orthosis was less than that with the HGO orthosis; it was 93.2 and 121.3 Ns for new orthosis and the HGO, respectively. There was no difference between the peaks of the force applied on the foot in walking with both orthoses. The force applied on the foot and crutch during walking with both orthoses are shown in figures 6.19 to 6.22.

6.2.3 Energy Consumption Test Results

The distribution of the PCI in walking with the new orthosis was not normal. It was normalized using a logarithmic transformation. The difference between the mean values of the new PCI was not significant (p-value = 0.726). The heart rate of a subject during walking with the HGO and the new orthoses is shown in figures 6.23.

6.2.4 Results from strain gauge data

The maximum value of the axial compression force applied on the lateral bar of the orthosis was 0.174± 0.055 N/BW, which was very small in comparison with the force applied on the foot. Approximately 0.138±0.05 N/BW axial tension force was applied on the orthosis with the maximum value displayed during the swing phase. The output of the strain gauges regarding the axial force was transferred to the Vicon coordination system, figure 6.24. The mean values of the compression and tension forces applied on the lateral bar during walking were 0.17±0.0745 and 0.107±0.0477 N/BW, respectively. The flexing moment applied at the lateral bar

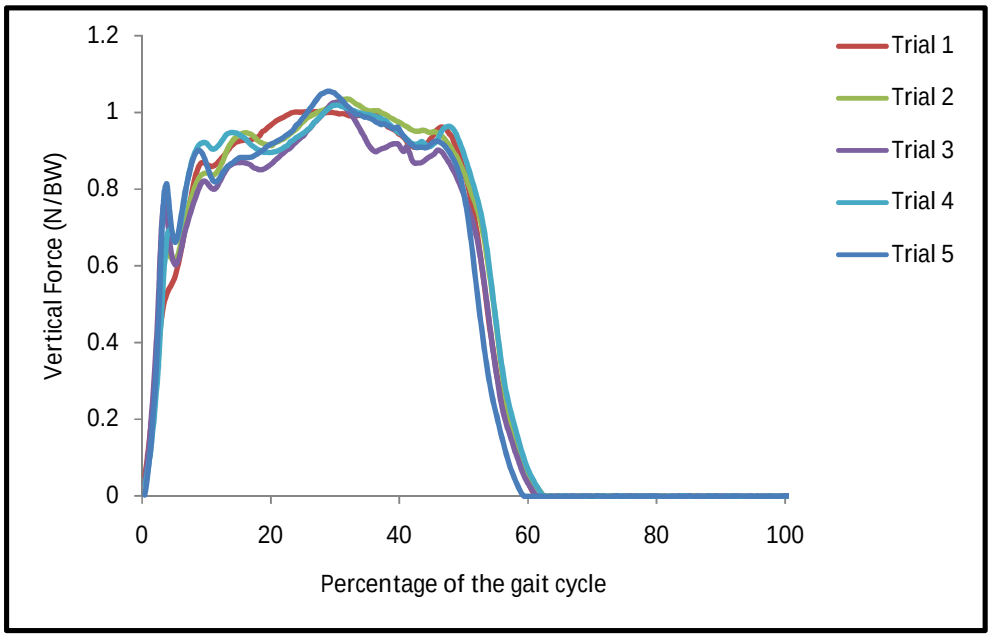


Figure 6.19: The force applied on the foot during walking the subjects with the new orthosis

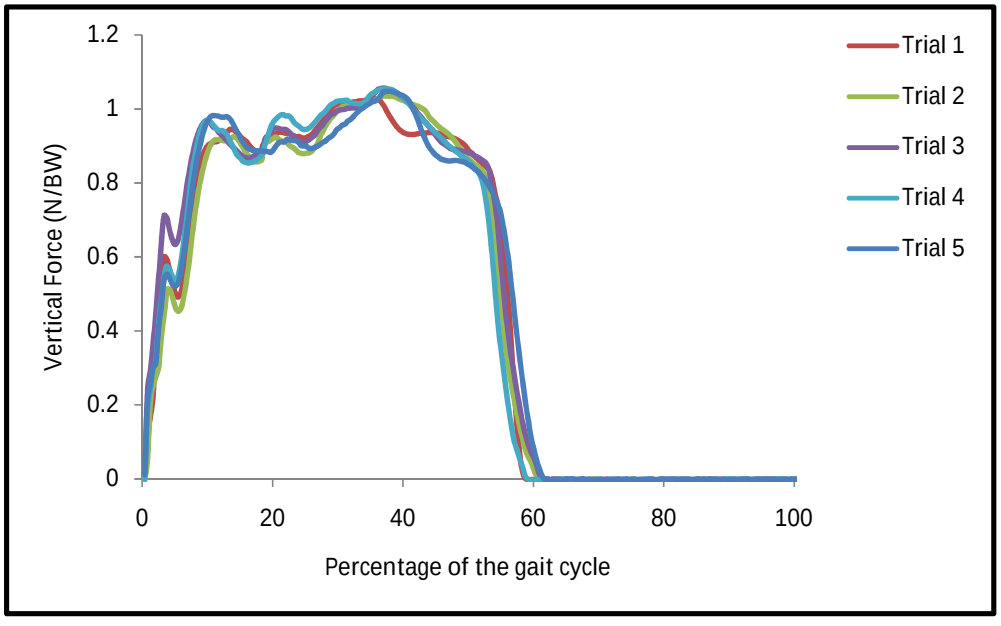


Figure 6.20: The force applied on the foot during walking the subjects with the HGO orthosis

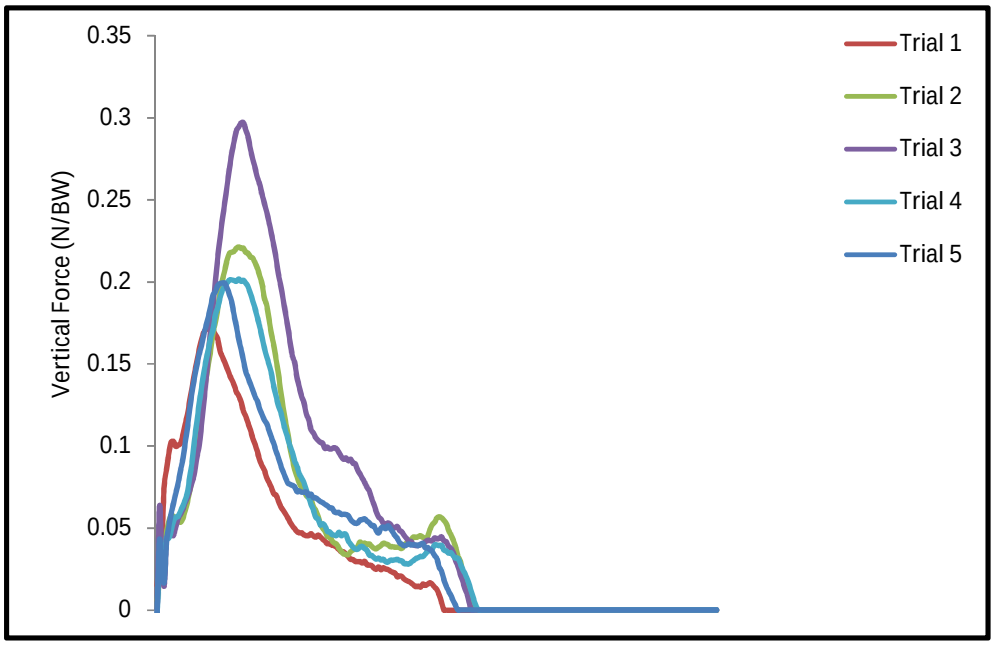


Figure 6.21: The force applied on the crutch during walking with the new orthosis

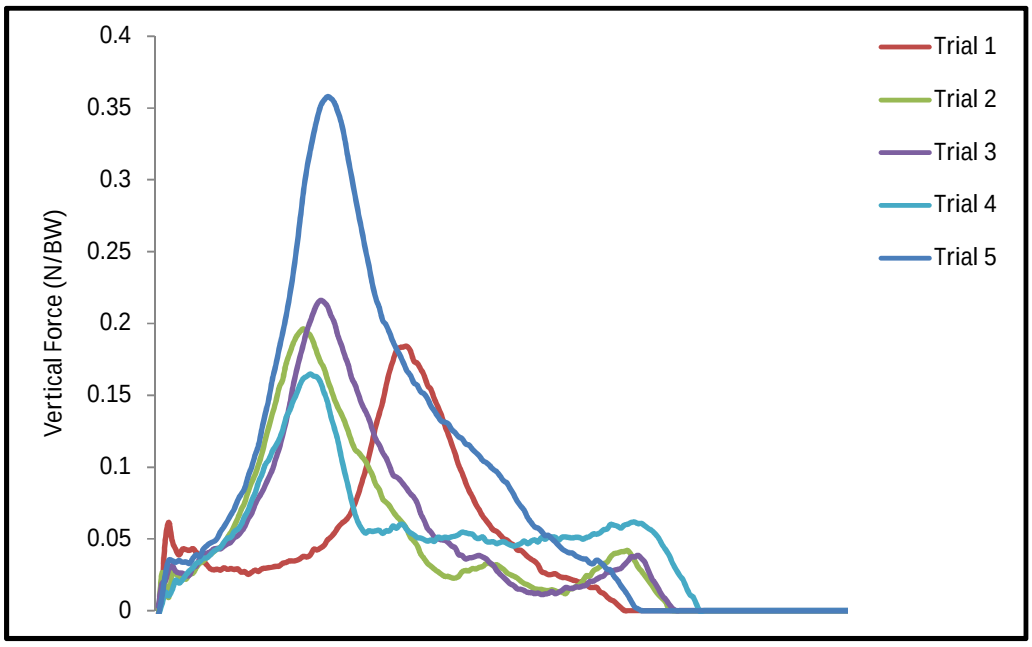


Figure 6.22: The force applied on the crutch during walking with the HGO orthosis

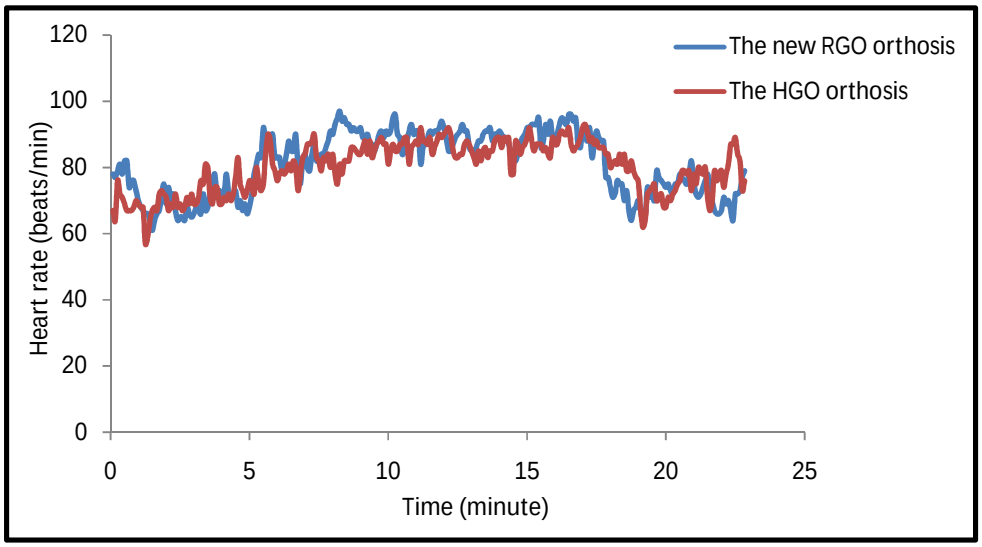


Figure 6.23: The heart rate of a subject 1 during walking with the new RGO and HGO orthoses

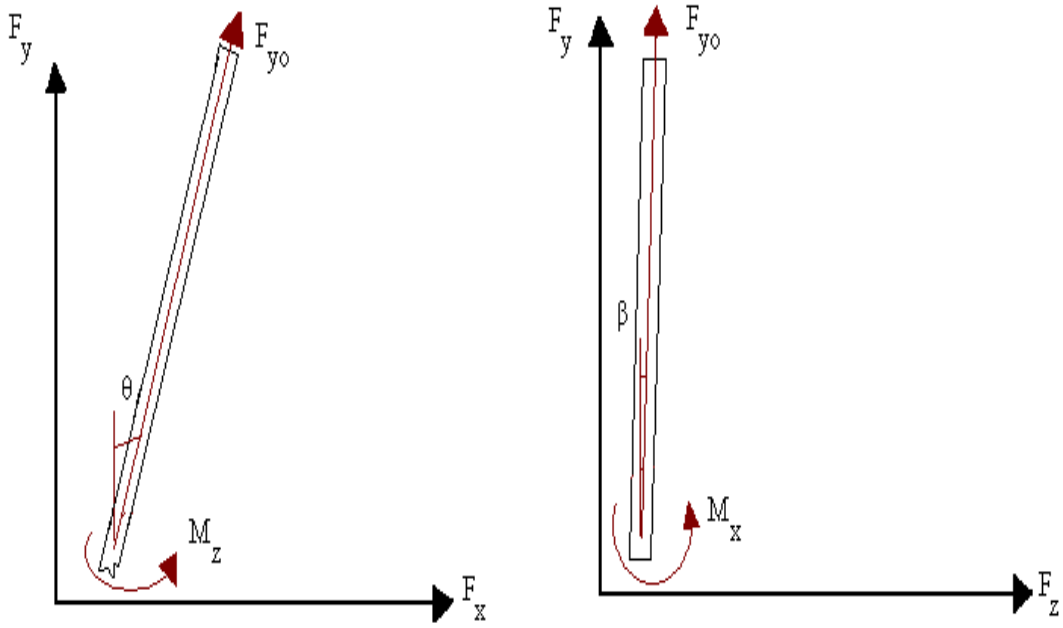


Figure 6.24: The coordination systems of Vicon and the lateral bar of the orthosis, where F_{yo}, θ and β are the vertical axis of the bar and the angle between the vertical axis of the bar and the vertical axis of the Vicon system in the anteroposterior and mediolateral planes, respectively

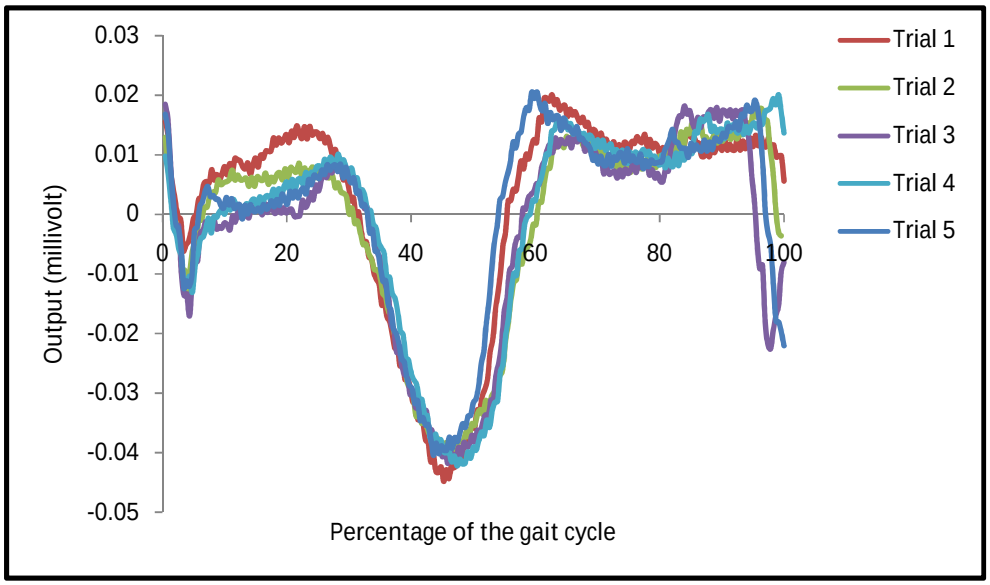


Figure 6.25: The output of the strain gauges, channel 3 corresponding to the axial force, subject 1

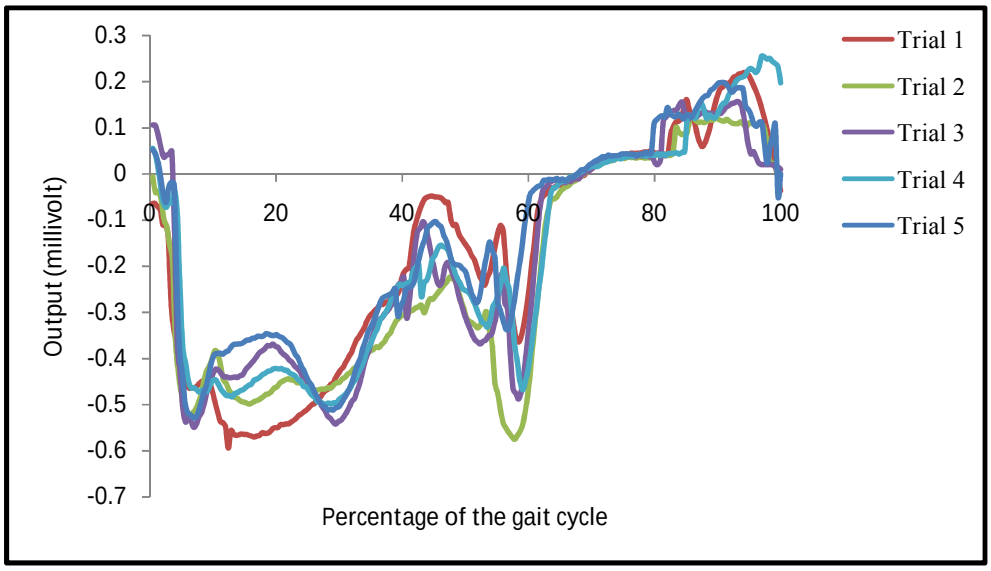


Figure 6.26: The output of the strain gauges, channel 1 corresponding to the flexing extending moment, subject 1

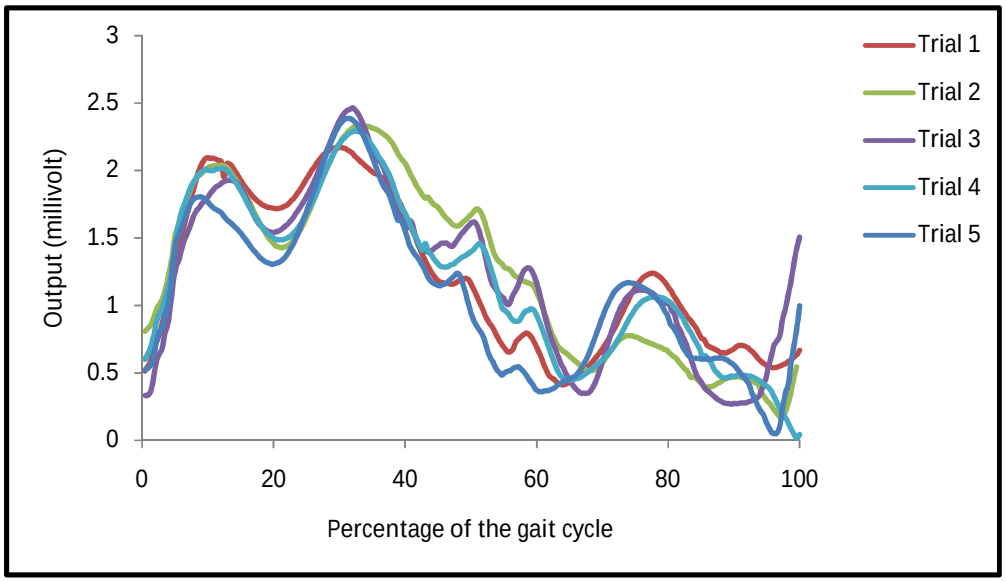


Figure 6.27: The output of the strain gauge, channel 2 corresponding to abducting adducting moment, subject 1

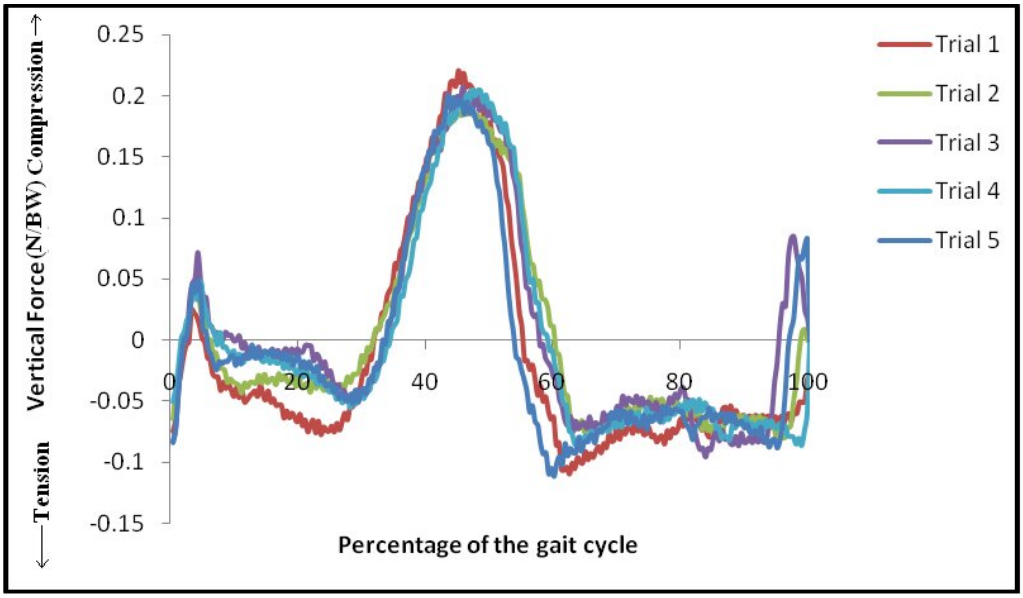


Figure 6.28: The vertical force (normalized by body weight) applied on the lateral bar of the orthosis (in Vicon reference system), subject 1

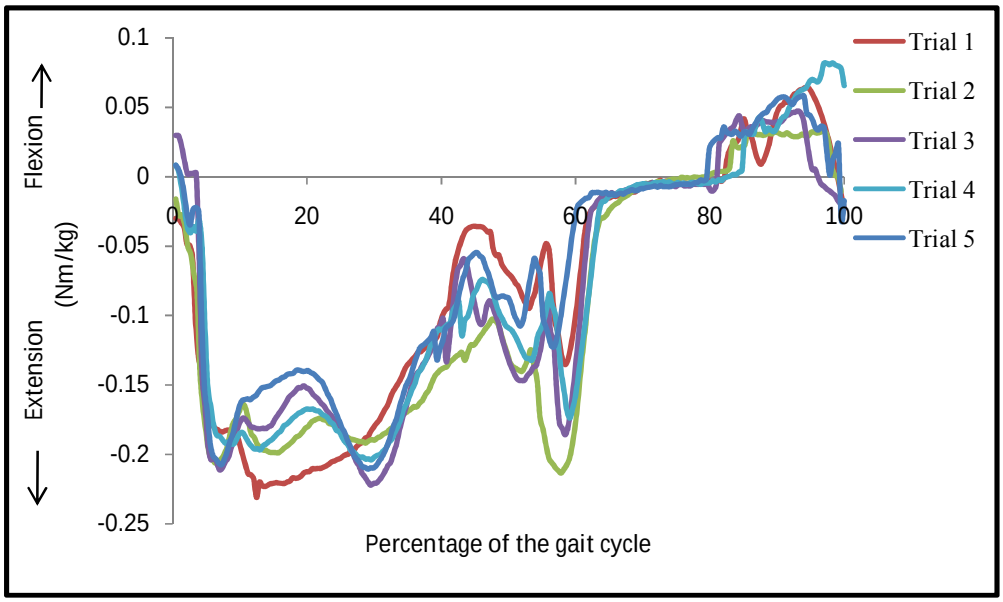


Figure 6.29: The flexing extending moment applied at the lateral bar of the orthosis, subject 1 (in Vicon reference system)

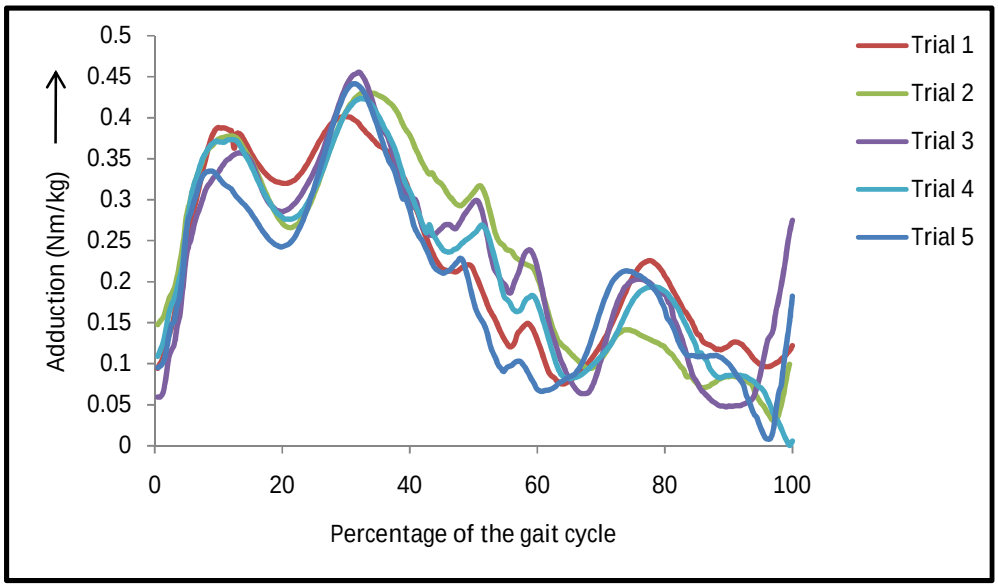


Figure 6.30: The abducting adducting moment applied at the lateral bar of the orthosis, subject1 (in Vicon reference system)

was significantly less than that applied at the hip joint, it was 0.0366±0.0312 Nm/kg for the lateral bar and 0.54±0.278 for the hip joint complex. In contrast to the flexing moment, the extending moment transmitted by the lateral bar was more than flexing moment (0.22±0.0411 Nm/kg). The adducting moment applied at the hip joint complex was 1.056±0.288 Nm/kg however, it was only 0.516±0.051 Nm/kg for the lateral bar. Figures 6.25 to 6.30 show the output of the strain gauges and also the loads applied on the lateral bar of the orthosis. The reason for plotting the output of the strain gauges was to show that their output of did not necessary corresponds to a positive applied load.

6.3 DISCUSSION

In this chapter the functional performance of the new orthosis during walking was compared with that of the HGO orthosis which has been judged to be the best orthosis for paraplegics. Moreover, the stability of the participants during quiet standing and while performing various hand tasks with the new orthosis was compared with that of the HGO orthosis.

The walking speed of the normal subjects with the new orthosis was more than that of the HGO orthosis. The main reason for that was related to the cadence which was more during walking with the new orthosis in contrast to that with the HGO orthosis, as shown in table 6.9. The flexion extension excursions of the hip joint were the same in both orthoses however, it was more than expected. The range of motion of the hip joints was set to be 25 degrees however, the recorded motion was 29-30.5 degrees in both orthoses, table 6.9. It could be concluded that the TLSO acts as a link in both orthoses and transmits the motion from one side to other side. In other words the extension of the ipsilateral side is added to flexion of the contralateral side and vice versa. The role of the TLSO in transmitting the motion between the right and left sides was discussed in detail in chapter 4.

The adduction/abduction excursion of the hip joint during walking with the new orthosis was less than that of the HGO orthosis, figures 6.13 and 6.14. It means that the structural stiffness of the new orthosis was greater than that of the HGO (the loads applied on the foot were nearly the same in walking with both orthoses). The magnitude of the force applied on the crutch was higher in the HGO orthosis in contrast to that with the new orthosis, figures 6.21 and 6.22. Structural stiffness of the orthosis played an important role in decreasing the loads applied on the upper limb through the crutches during walking with the orthosis. The subjects applied less force on the crutch to take the swing leg off the ground if the orthosis is fitted correctly and has good structural stiffness. As the result the shoulder and wrist pain will decrease in walking with the new orthosis

The flexing and extending moments applied on the hip joint were not significantly different in these orthoses, figures 6.15 and 6.16, as there was no difference between the magnitudes of the force applied on the foot in both orthoses. The adducting moment of the hip joint was slightly more in the new orthosis in contrast to that in the HGO orthosis, figures 6.17 and 6.18.

The magnitude of the compression force applied on the lateral bar of the orthosis was very small in contrast to the force applied on the foot. The maximum value of the compression force applied on the lateral bar was before toe off (before the maximum extension angle of the hip joint). Then, it changed to a tension force as the hip joint of the orthosis reached the extension stop. It was expected that the lateral bar of the orthosis subjected to a tensile force during swing phase. As can be seen from figures 6.19 and 6.28 the pattern of the force applied on the bar is completely different from the pattern of the force applied on the foot during walking with the orthosis. It would be expected that the vertical force applied on the lateral bar during walking of paraplegic subjects is the same as that of the normal subjects. The main reason is that the peak of the vertical force applied on the bar occurs when the hip

Parameters	Vertical force (N)	Flexion moment (Nm)	Adduction moment (Nm)
Male	163	-14.28	-1.43
Female	86	6.93	1.43

Table 6.11: The magnitude of the loads applied on the lateral proximal part of a KAFO orthosis (Trappitt and Berme, 1981)

Parameters	Vertical force (N)		Flexion moment (Nm)		Adduction moment (Nm)	
	Max	Min	Max	Min	Max	Min
Magnitude	325	-99	21	-30	6	-4

Table 6.12: The maximum and minimum values of the loads applied on the orthosis (Lim, 1985)

joint is near maximum extension angle of the hip joint. However, it was predicted that the moments applied on the orthosis in walking of paraplegic subjects is more than that of the normal subjects.

The mean value of adducting moment transmitted by the lateral bar of the orthosis was 0.516 Nm/kg which was nearly half of the adducting moment around the hip joint complex. The peak of the adducting moment applied on the bar was near the end of the stance phase. The weight of the orthosis produced an adducting moment during the swing phase which was less than that in the stance phase, figure 6.30. The lateral bar of the orthosis was subjected to an extending moment in the stance phase with a mean value as 0.22 Nm/kg. However, there was a flexing moment applied at the hip joint complex in the first part of the stance phase which changed to an extending moment in the second part of the stance phase, figure 6.29. The extending moment applied on the lateral bar decreased during the swing phase and changed to a flexing moment at the end of this phase.

The patterns of the loads transmitted through the lateral bar of the orthosis differed from the data collected by gait analysis. The data of the strain gauges showed the absolute values of the loads applied on the orthosis which can be used for designing a new orthosis. The results of the strain gauge showed that using the data of the gait analysis for designing a new orthosis is not too practical.

Unfortunately, there is a lack of information in the literature regarding the forces and moments applied on a HKAFO orthosis during walking. However, some researchers carried out different research studies to find out the loads applied on a KAFO orthosis during walking of handicapped subjects. According to the results of the study undertaken by Trappitt and Berme (1981) the magnitudes of the loads transmitted by orthosis (KAFO), lateral proximal part of the orthosis, differed

between female and male participants. Figure 6.31 shows the patterns of the loads applied on the orthosis. Table 6.11 shows some results of this research.

In contrast the magnitude of the loads which were reported by Lim (1985), table 6.12, were more than those of the aforementioned research. According to the results of these researches, the magnitude of the bending moments applied on the HKAFO orthosis is more than that of the KAFO orthosis. In contrast the vertical force transmitted by KAFO orthosis is more than that of the HKAFO orthosis. It seems that the patterns of the bending moments of the KAFO and HKAFO orthoses were the same.

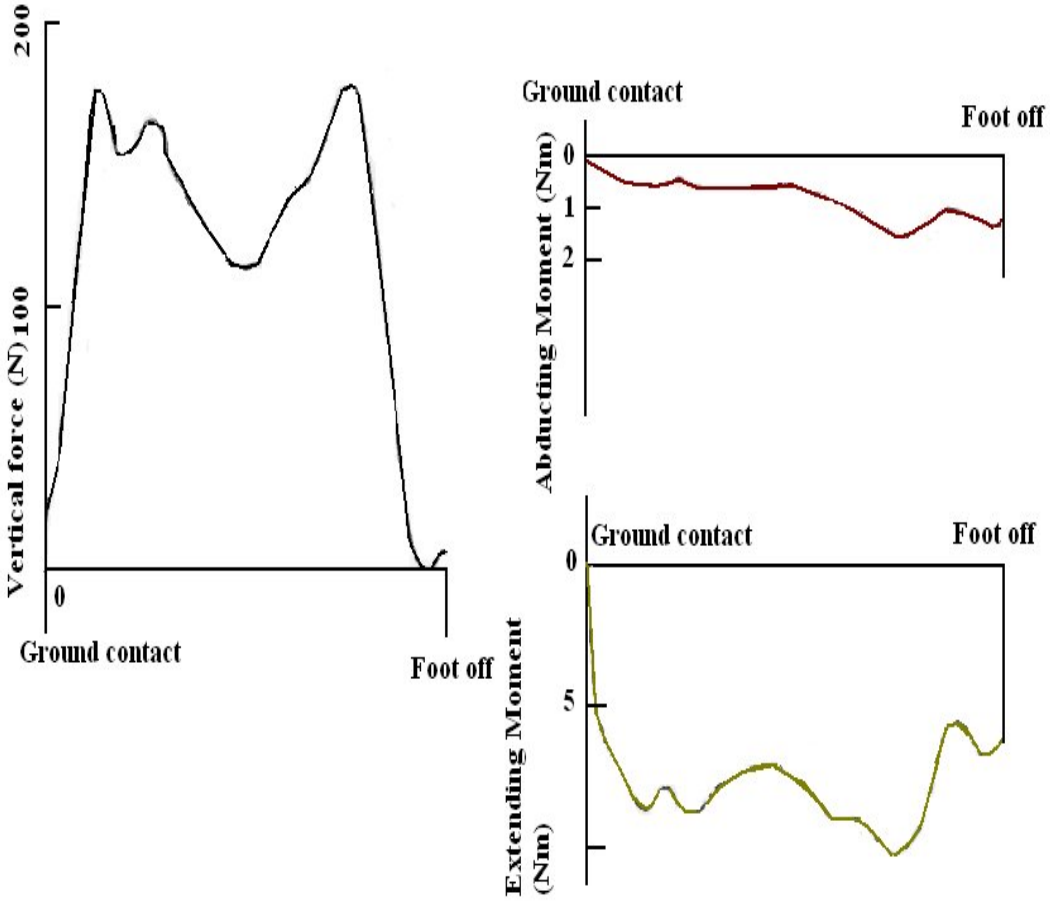


Figure 6.31: The patterns of the loads applied on the lateral proximal part of the KAFO orthosis (Trappitt and Berme, 1981)

6.4 CONCLUSION

The functional performance of the new orthosis during standing and walking could be better than that of the HGO orthosis, because it is stiffer than the HGO and lower force applied on the crutches during walking in contrast to the HGO orthosis. The cosmesis of the new orthosis was better than the HGO and it had an opened structure the same as ARGO orthosis, without thigh bar, and the TLSO and AFO parts of the orthoses are custom moulded. Donning and doffing the orthosis and adjustability of the alignment of the different components of the new orthosis were the other advantages of the new orthosis in contrast to the HGO orthosis.

The force applied on the lateral bar of the orthosis was considerably less than the force applied on the foot during walking with orthosis. The role of the lateral bar of the orthosis in transmitting the adducting moment was significantly more than the flexing and extending moments in the HKAFO orthosis.

6.5 SUGGESTION FOR FURTHER WORK

The data of the strain gauges can be used to redesign the components of the orthosis, especially if the data could be collected from the paraplegic subjects walking with this orthosis, which actually would be lighter and smaller than the second generation.

CHAPTER 7: CONCLUSIONS AND RECOMMENDATIONS

7.1 CONCLUSION

Spinal cord injury is damage to the spinal cord that results in loss of function and mobility below the level of injury. Using orthoses and wheelchairs are two most common mobilization systems selected by the patients. Walking and standing with orthoses brings some benefits for paraplegic subjects in contrast to using a wheelchair however, the energy demands in walking with an orthosis are high and the speed of walking is low compared to normal walking. In this project a new type of the RGO orthosis was designed which aimed to allow easy independent donning and doffing by the users and allows alignment changes of various components whilst the patients are wearing the orthosis.

The results of this research project showed that the performance of the subjects using this orthosis during walking significantly differed from that of normal walking. The walking speed and cadence decreased in walking of the normal subjects with the orthosis. Moreover, the amount of energy consumption was between two to three times more than that of normal walking. The hip joint flexion/extension excursion in walking with the orthosis was less than expected compared to normal walking. It can therefore be concluded that although, the power of the muscles is important, the motions of the hip joint such as abduction, adduction, internal, and external rotations are also important in order to increase the range of motion of the hip joint in the sagittal plane.

The hip joint range of motion, flexion and extension, was more than designed values during walking with the orthosis with configurations 3 and 4 (chapter 4). It was found that the TLSO part of the orthosis acts as a reciprocal link which transmits the

motion from one side to other side. It means that the flexion of the ipsilateral side adds to extension of the contralateral side and vice versa.

In comparison with the performance of the paraplegic subjects in walking with the HGO orthosis, which has been reported to be the best available mechanical orthosis for the paraplegic subjects, the gap between the functions of the normal and paraplegic subjects is as large as expected. It can be concluded that the other motions of the hip joints during walking such as abduction, adduction and rotations, can increase the performance of the subjects in using the orthosis. The results of various researches carried out by some investigators shows that using FES, external power source and using knee flexion and ankle dorsi flexion during walking could not increase the abilities of the paraplegic subjects in using the orthosis. So using other motions of the hip joint during walking can increase the function and improve the performance (according to the results of the first part of this research project).

Building up the orthosis in abduction improved the functional performance of the subjects in walking and standing with the orthosis. Moreover, the force applied on the upper limb through crutches decreased. It was much easier for the subjects to take the swing leg off the ground when the orthosis was aligned with some degrees of abduction. The subjects could use the crutches at a distance from the body and as a result the force applied on the crutch decreased.

This research gave indications to suggest that the performance of subjects in walking with the new RGO orthosis could be better than that with the HGO orthosis. Since the structural stiffness of the new orthosis was greater than the HGO, it had better performance. Moreover, it was more cosmetic, easier to donn and doff and offered alignment change of the orthosis components when the subjects wear the orthosis. The modularity of the new orthosis allowed for easy transportation (according to the results of the third part of this research project).

The locking mechanism of the hip joint in the new orthosis was the same as that in the HGO orthosis; it is operated by applying a pulling force. In contrast to the old system, generation1, which was operated using a pushing force, it was much easier for the subjects to unlock the hip joint. Although the new orthosis consisted of some attachment components in the hip and knee joints, the security of the new orthosis is more than that of the HGO orthosis. The closer fitting of the AFO and TLSO parts of the new orthosis decreased the loads applied on the upper limbs during walking, especially when it was aligned in some degrees of abduction.

The results of the orthotic loads as determined by the strain gauge data showed that the force and moments applied on the lateral bar of the orthosis differed from those expected. As there are no data published regarding the loads transmitted by the orthoses, it has been suggested that the loads determined using motion analysis system could be used for designing orthotic components. The results of the strain gauge tests differed from the results collected from the motion analysis system. The compression force applied on the lateral bar of the orthosis was very small in comparison to the force transmitted by foot. The bar was subjected to a tensile force when the hip joint was locked in extension. The pattern of the force transmitted through the lateral bar of the orthosis and foot complex differed from each others. Although the result of the strain gauges tests were collected during walking of normal subjects with orthosis, it seems that the pattern of the loads applied on the orthosis would be the same as that of the paraplegic subjects, although there would be a significant difference between the maximum magnitude of the loads applied on the orthosis between normal and paraplegic subjects.

The main moment transmitted by the lateral bar of the orthosis was adducting moment (50% of adducting moment applied at the hip joint complex transmitted through the orthosis). The extending moment applied on the lateral bar was more than the flexing moment. In contrast to the flexing and extending moments of the

hip joint complex the role of the lateral bar regarding transmitting theses moments was not too much.

There was no information in the literature regarding the loads applied on a HKAFO orthosis in walking and many researchers used the data collected from the motion analysis system for determining orthotic loads. Many of the orthoses designed for the paraplegic subjects were based only on the flexing moment applied on the hip joint complex; however the results of this research showed that the flexing moment transmitted by the orthosis was significantly less than the moment applied on the hip joint complex. Moreover, the main moment which was transmitted by the orthosis was an adducting moment. Unfortunately, many investigators did not use this moment for designing the orthosis, however the mediolateral stiffness of the orthosis plays a significant role in improving the performance of the orthosis and decreasing the loads transmitted to the upper limb during walking. Thus, it is recommended that in developing any new orthosis for the paraplegic subjects, the main moment to consider in the design should be the adducting moment.

The results of the strain gauges were collected during walking of normal subjects on a level surface. However, it is important to determine the loads applied on the orthosis during walking with orthosis on uneven surfaces and during climbing up/down ramps and stairs. Evaluating the gait performance, energy consumption and stability of the paraplegic subjects while using the new RGO orthosis, is also recommended in order to determine the function of the orthosis and the gap which can be decreased by redesigning a better orthosis.

7.2 RECOMMENDATIONS

As a result of the experience gained from this study, the following recommendations for future work are suggested.

1) It is suggested that the data of orthotic loads should be obtained through strain gauge tests during other activities such as walking on uneven surface and during climbing up/down vamp and stairs.
2) The data of the strain gauge tests be collected during walking of paraplegic subjects with the new RGO orthosis
3) The gait performance, stability analysis and energy consumption be measured during walking of paraplegic subjects with the orthosis with the same procedures used in this study
4) The new RGO orthosis be redesigned according to the data collected from the strain gauge tests
5) The new RGO orthosis be designed and manufactured from other available materials such as carbon fiber

REFERENCES:

Agustsson, A (2002) Two-dimensional Versus three-dimensional kinematics in normal and pathological gait, M.Sc. Thesis, University of Strathclyde, Glasgow.

Aluminum Association. (1982) Aluminum standards and data, Aluminum Association, Washington, D.C.

Aluminum Association. (2000) Aluminum standards and data, Aluminum Association, Washington, D.C.

American Academy of Orthopaedic Surgeons (1985) Atlas of orthotics. 2nd. ed., Mosby, St. Louis, Mo., 199-237.

Andrews, BJ (1990). A modular hybrid FES orthosis for paraplegics, Annual Intemational Conference of the IEEE Engineering in Medicine and Biology Society,

Astrand, PO & Rodahl, K (1986) Textbook of work physiology : physiological bases of exercise, McGraw Hill, New York.

Baardman, G, IJzerman, MJ, Hermens, HJ, Veltink, PH, Boom, G & Zilvold, G (2002a) Knee flexion during the swing phase of orthotic gait: influence on kinematics, kinetics and energy consumption in two paraplegic cases. Saudi Journal of Disability and Rehabilitation 8: 20-32.

Baardman, G, Ijzerman, MJ, Hermens, HJ, Veltink, PH, Boom, HB & Zilvold, G (1997) The influence of the reciprocal hip joint link in the Advanced Reciprocating Gait Orthosis on standing performance in paraplegia. Prosthetics and Orthotics International 21: 210-21.

Baardman, G, IJzerman, MJ, Hermens, HJ, Veltink, PH, Boom, HBK & Zilvold, G (2002b) Augmentation of the knee flexion during the swing phase of orthotic gait in paraplegia by means of functional electrical stimulation. Saudi Journal of Disability and Rehabilitation 8: 73-81.

Bailey, MJ & Ratcliffe, CM (1995) Reliability of physiological cost index measurements in walking normal subjects using steady-state, non-steady-state and post-exercise heart rate recording. Physiotherapy 81: 618-23.

Banta, JV, Bell, KJ, Muik, EA & Fezio, J (1991) Parawalker: energy cost of walking. European Journal of Pediatric Surgery 1: 7-10.

Bar-On, Z & Nene, AV (1990) Relationship between heart rate and oxygen uptake in thoracic level paraplegics. Paraplegia 28: 87-95.

Barnett, RW (1990) Paraplegic standing and reciprocal gait using a floor reaction hybrid F.E.S orthosis, PhD Thesis, University of Strathclyde, Glasgow.

Belforte, G, Gastaldi, L & Sorli, M (2001) Pneumatic active gait orthosis Mechatronics 11: 301-323.

Bell, AL, Pedersen, DR & Brand, RA (1990) A comparison of the accuracy of several hip center location prediction methods. Journal of Biomechanics 23: 617-21.

Bickford, JH & Nassar, S (1998) Handbook of bolts and bolted joints, Marcel Dekker, New York.

Butler, PB & Major, RE (1987) ParaWalker: a rational approach to the provision of reciprocal ambulation for paraplegic patients. Physiotherapy 73: 393-397.

Butler, PB, Major, RE & Patrick, JH (1984) The technique of reciprocal walking using the hip guidance orthosis (hgo) with crutches. Prosthetics and Orthotics International 8 (1): 33-8.

Capaul, M, Zollinger, H, Satz, N, Dietz, V, Lehmann, D & Schurch, B (1994) Analyses of 94 consecutive spinal cord injury patients using ASIA definition and modified Frankel score classification. Paraplegia 32 (9): 583-7.

Cappozzo, A, Catani, F, Croce, UD & Leardini, A (1995) Position and orientation in space of bones during movement: anatomical frame definition and determination. Clinical Biomechanics 10: 171-178.

Carroll, N (1974) The orthotic management of the spina bifida child. Clinical Orthopaedics and Related Research 102: 108-114.

Cerny, D, Waters, R, Hislop, H & Perry, J (1980) Walking and wheelchair energetics in persons with paraplegia. Physical Therapy 60: 1133-9.

Chen, HY, Chen, SS, Chiu, WT, Lee, LS, Hung, CI, Wang, YC, Hung, CC, Lin, LS, Shih, YH & Kuo, CY (1997) A nationwide epidemiological study of spinal cord injury in geriatric patients in Taiwan. Neuroepidmiology 16(5): 241-7.

Cicenia, E & Hoberman, M (1957) Crutches and crutch management. Archives of Physical Medicine and Rehabilitation 36: 359-84.

Cole, GK, Nigg, BM & Ronsky, JL (1995) Application of the joint co-ordinate system to three-dimensional joint attitude and movement representation Journal of Biomechanical Engineering 115: 344-349.

Colombo, G, Wirz, M & Dietz, V (2001) Driven gait orthosis for improvement of locomotor training in paraplegic patients. Spinal Cord 39: 252-255.

Corcoran, PJ, Jebsen, RH, Brengelmann, GL & Simons, BC (1970) Effects of plastic and metal leg braces on speed and energy cost of hemiparetic ambulation. Archives of Physical Medicine and Rehabilitation 51: 69-77.

Crawford, RJ (1998) Plastics engineering, Butterworth-Heinemann, Oxford.

Crosbie, WJ & Nicol, AC (1990) Biomechanical comparison of two paraplegic gait patterns. Clinical Biomechanics 5: 97-108.

Cuddeford, TJ, Freeling, RP, Thomas, SS, Aiona, MD, Rex, D, Sirolli, H, Elliott, J & Magnusson, M (1997) Energy consumption in children with myelomeningocele: a comparison between reciprocating gait orthosis and hip-knee-ankle-foot orthosis ambulators. Developmental Medicine and Child Neurology 39: 239-42.

Cybulski, GR & Jaeger, RJ (1986) Standing performance of persons with paraplegia. Archives of Physical Medicine and Rehabilitation 67: 103-8.

Dall, PM (2004) The function of orthotic hip and knee joints during gait for individuals with thoracic level spinal cord injury, PhD Thesis, University of Strathclyde, Glasgow.

Dall, PM, Muller, B, Stallard, I, Edwards, J & Granat, MH (1999) The functional use of the reciprocal hip mechanism during gait for paraplegic patients walking in the Louisiana State University reciprocating gait orthosis. Prosthetics and Orthotics International 23(2): 152-62.

Dalyan, M, Cardenas, DD & Gerard, B (1999) Upper extremity pain after spinal cord injury. Spinal Cord 37: 191-5.

David, RI & Rolfes, RH (1981) Four-bar gait-control linkage. Physical therapy 61: 912-3.

Davidson, HM (1994) The Isocentric Reciprocating Gait Orthosis. APO newsletter.

Douglas, R, Larson, PF, D' Ambrosia, R & McCall, RE (1983) The LSU Reciprocal-Gait Orthosis. Orthopedics 6: 834-839.

Doyle, TI, Newton, RU & Burnett, AF (2005) Reliability of traditional and fractal dimension measures of quiet stance center of pressure in young, healthy people. Archives of Physical Medicine and Rehabilitation 86: 2034-40.

Dunn, RB, Walter, JS, Lucero, Y, Weaver, F, Langbein, E, Fehr, L, Johnson, P & Riedy, L (1998) Follow-up assessment of standing mobility device users. Assistive Technology 10: 84-93.

Ehara, Y (2002). Comparison of commercial motion analysis systems, Comparison meeting of motion analysis systems, Nippon engineering college in Tokyo.

Eng, JI & Winter, DA (1995) Kinetic analysis of the lower limbs during walking: what information can be gained from a three-dimensional model? Journal of Biomechanics 28: 753-8.

Eng, JJ, Levins, SM, Townson, AF, Mah-Jones, D, Bremner, J & Huston, G (2001) Use of prolonged standing for individuals with spinal cord injuries. Physical Therapy 81: 1392-9.

Engen, T (1989) Lightweight modular orthosis. Prosthetics and Orthotics International 13: 125-9.

Erdemir, A & Piazza, SJ (1999). Simulation-based design of a pointer for accurate determination of anatomical landmarks, Proceedings of the American Society of Biomechanics, Pittsburgh.

Ferguson, KA, Polando, G, Kobetic, R, Triolo, RJ & Marsolais, EB (1999) Walking with a hybrid orthosis system. Spinal Cord 37: 800-4.

Ferrarin, M & Pedotti, A (1994) Restoration of walking for paraplegics : recent advancements and trends, Edizioni Pro Juventute ; Oxford : IOS Press, Milano.

Ferrarin, M, Pedotti, A & Boccardi, S (1993) Biomechanical assessment of paraplegic locomotion with hip guidance orthosis (HGO). Clinical Rehabilitation 7(4): 303-308

Franks, CA, Palisano, RJ & Darbee, JC (1991) The effect of walking with an assistive device and using a wheelchair on school performance in students with myelomeningocele. Physical Therapy 71: 570-7.

Gage, J, Deluca, P & Renshaw, T (1995) Gait analysis: Principle and applications. Journal of Bone and Joint Surgery 77: 1607-1623.

Genda, E, Oota, K, Suzuki, Y, Koyama, K & Kasahara, T (2004) A new walking orthosis for paraplegics: hip and ankle linkage system. Prosthetics and Orthotics International 28: 69-74.

Geurts, AC, Nienhuis, B & Mulder, TW (1993) Intrasubject variability of selected force-platform parameters in the quantification of postural control. Archives of Physical Medicine and Rehabilitation 74: 1144-1450.

Gharooni, S, Heller, B & Tokhi, MO (2001) A new hybrid spring brake orthosis for controlling hip and knee flexion in the swing phase. IEEE transactions on neural systems and rehabilitation engineering 9: 106-7.

Gilbertson, MP (1971) Use of the reciprocating brace with polyplanar hip hinge on spina bifida children. Physiotherapy 57: 67-8.

Goemaere, S, Van Laere, M, De Neve, P & Kaufman, JM (1994) Bone mineral status in paraplegic patients who do or do not perform standing. Osteoporosis International 4: 138-43.

Goldfarb, M & Durfee, WK (1996) Design of a controlled-brake orthosis for FES-aided gait. IEEE Transactions on Rehabilitation Engineering 4: 13-24.

Goldie, PA, Bach, TM & Evans, OM (1989) Force Platform measures for Evaluation postural control:Reliability and Validity. Archives of Physical Medicine and Rehabilitation 70: 510-517.

Goosey, T & Tolfrey, K (2004) The oxygen uptake-heart rate relationship in trained female wheelchair athletes. Journal of Rehabilitation Research and Development 41: 415-20.

Gozal, D (1986) Loads analysis of the knee joints of the cosmetic type Knee Ankle Foot orthosis, M.Sc. Thesis, University of Strathclyde, Glasgow.

Granat, MH, Kirkwood, CA & Andrews, BJ (1990) Problem with the use of total distance travelled and average speed as measures of postural sway. Medical & Biological Engineering & Computing 28: 601-602.

Gray, H, Carter, HV, Pick, TP & Howden, R (1994) Gray's anatomy, Senate, London.

Greene, PJ (2002) Design and evaluation of a knee and ankle flexing hybrid orthosis for paraplegic ambulation, PhD Thesis, University of Strathclyde, Glasgow.

Greene, PJ & Granat, MH (2003) A knee and ankle flexing hybrid orthosis for paraplegic ambulation. Medical Engineering & Physics 25: 539-65.

Hall, MG, Fleming, HE, Dolan, MJ, Millbank, SF & Paul, JP (1996) Static in situ calibration of force plates. Journal of Biomechanics 29: 659-665.

Hammell, KW (1995) Spinal cord injury rehabilitation, Chapman & Hall, London.

Harvey, LA, Smith, MB, Davis, GM & Engel, S (1997) Functional outcomes attained by T9-12 paraplegic patients with the walkabout and the isocentric reciprocal gait orthoses. Archives of Physical Medicine and Rehabilitation 78(7): 706-11.

Hawran, S & Biering, SF (1996) The use of long leg calipers for paraplegic patients: a follow-up study of patients discharged 1973-82. Spinal Cord 34: 666-8.

Hirokawa, S, Solomonow, M, Baratta, R & D'Ambrosia, R (1996) Energy expenditure and fatiguability in paraplegic ambulation using reciprocating gait orthosis and electric stimulation. Disability and Rehabilitation 18(3): 115-22.

Hood, VI, Granat, MH, Maxwell, DJ, Maxwell, DJ & Hasler, JP (2002) A new method of using heart rate to represent energy expenditure: the Total Heart Beat Index. Archives of Physical Medicine and Rehabilitation 83: 1266-73.

Huang, CT, Kuhlemeier, KV, Moore, NB & Fine, PR (1979) Energy cost of ambulation in paraplegic patients using Craig-Scott braces. Archives of Physical Medicine and Rehabilitation 60(12): 595-600.

Ijzerman, MJ, Baardman, G, Hermens, HJ, Veltink, PH, Boom, HB & Zilvold, G (1997a) The influence of the reciprocal cable linkage in the advanced reciprocating gait orthosis on paraplegic gait performance. Prosthetics and Orthotics International 21: 52-61.

Ijzerman, MJ, Baardman, G, Holweg, GGJ, Hermens, HJ, Veltink, PH, Boom, HBK & Zilvold, Z (1997b) The influence of frontal alignment in the Advanced Reciprocating Gait Orthosis on energy cost and crutch force requirements during paraplegic gait. Basic and Applied Myology 7: 123-130.

Ijzerman, MJ, Baardman, G, van 't Hof, MA, Boom, HB, Hermens, HJ & Veltink, PH (1999) Validity and reproducibility of crutch force and heart rate measurements to assess energy expenditure of paraplegic gait. Archives of Physical Medicine and Rehabilitation 80: 1017-23.

Jacobson, GP, Newman, CW & Kartush, JM (1993) Handbook of balance function testing, Mosby Year Book.

Jaiyesimi, AO & Fashakin, OG (2007) Reliability of physiological cost index measurements. African journal of Medicine and Medical Sciences 36: 229-34.

Jefferson, RJ & Whittle, MW (1990) Performance of three walking orthoses for the paralysed: a case study using gait analysis. Prosthetics and Orthotics International 14: 103-110.

Johnson, GR, Ferrarin, M, Harrington, M, Hermens, H, Jonkers, I, Mak, P & Stallard, J (2004) Performance specification for lower limb orthotic devices. Clinical Biomechanics 19: 711-8.

Kadaba, MP, Ramakrishnan, HK & Wootten, ME (1990) Measurement of lower extremity kinematics during level walking. Journal of Orthopaedic Research 8: 383-92.

Kagawa, T, Fukuda, H & Uno, Y (2006) Stability analysis of paraplegic standing while wearing an orthosis. Medical & Biological Engineering & Computing 44: 907-917.

Kagaya, H, Shimada, Y, Sato, K, Sato, M, Iizuka, K & IObinata, G (1996) An electrical knee lock system for functional electrical stimulation. Archives of Physical Medicine and Rehabilitation 77: 870-3.

Kaoru, A (2006) Comparison of Static Balance, Walking Velocity, and Energy Consumption with Knee-Ankle-Foot Orthosis, Walkabout Orthosis, and Reciprocating Gait Orthosis in Thoracic-Level Paraplegic Patients. Journal of Prosthetics and Orthotics 18: 87-91.

Karacan, I, Koyuncu, H, Pekel, O, Sumbuloglu, G, Kirnap, M, Dursun, H, Kalkan, A, Cengiz, A, Yalinkilic, A, Unalan, HI, Nas, K, Orkun, S & Tekeoglu, I (2000) Traumatic spinal cord injuries in Turkey: a nation-wide epidemiological study. Spinal Cord 38 (11): 697-701.

Karamehmetoglu, S, Unal, S, Karacan, I, Yilmaz, H, Togay, HS, Ertekin, M, Dosoglu, M, Ziyal, MI, Kasaro glu, D & Hakan, T (1995) Traumatic spinal cord injuries in Istanbul, Turkey. An epidemiological study. Paraplegia 33 (8): 469-71.

Karimi, MT (2001). The new orthoses for Spinal Cord Injury (SCI) patients, Spinal Cord Injuries, Tehran, Iran.

Kawashima, N, Sone, Y, Nakazawa, K, Akai, M & Yano, H (2003) Energy expenditure during walking with weight-bearing control (WBC) orthosis in thoracic level of paraplegic patients. Spinal Cord 41(9): 506-10.

Kent, HO (1992) Vannini-Rizzoli stabilizing orthosis (boot): preliminary report on a new ambulatory aid for spinal cord injury. Archives of Physical Medicine and Rehabilitation 73: 302-7.

Kirtley, C & McKay, SK (1992). Total design of the walkabout, a new paraplegic walking orthosis, Proceedings, seventh world congress of ISPO, Chicago, Illinois USA.

Kralj, AR & Bajd, T (1989) Functional electrical stimulation : standing and walking after spinal cord injury, CRC Press, Boca Raton, Fla.

Kunkel, CF, Scremin, AM, Eisenberg, B, Garcia, JF, Roberts, S & Martinez, S (1993) Effect of "standing" on spasticity, contracture, and osteoporosis in paralyzed males. Archives of Physical Medicine and Rehabilitation 74: 73-8.

Lafond, DF, Corriveau, H, Hebert, R & Prince, F (2004) Intrasession reliability of center of pressure measures of postural steadiness in healthy elderly people. Archives of Physical Medicine and Rehabilitation 85: 896-901.

Lee, BY (1991) The Spinal cord injured patient : comprehensive management, Saunders, Philadelphia, Pa. ; London.

Leeder Group, I (2000) http://leedergroup.com.

Lehmann, JF (1979) Biomechanics of ankle-foot orthoses: prescription and design. Archives of Physical Medicine and Rehabilitation 60 (5): 200-7.

Lehmann, JF, DeLateur, BJ, Warren, CG, Simons, BC & Guy, AW (1969) Biomechanical evaluation of braces for paraplegics. Archives of Physical Medicine and Rehabilitation 50(4): 179-88.

Lehmann, JF, Warren, CG & DeLateur, BJ (1970) A biomechanical evaluation of knee stability in below knee braces. Archives of Physical Medicine and Rehabilitation 51 (12): 688-695.

Lim, SYE (1985) A study of the biomechanical performance of knee-ankle-foot orthoses in normal ambulatory activities, PhD Thesis, University of Strathclyde, Glasgow.

Liverman, CT (2005) Spinal cord injury : progress, promise, and priorities, National Academies ; Oxford : Oxford Publicity Partnership [distributor], Washington, D.C.

Lobley, S, Rogerson, J, Cullen, J & Freed, M (1985) Orthotic design from the New England Regional Spinal Cord Injury Center. Suggestion from the field. Physical therapy 65: 492-3.

Long, CI & Lawton, EB (1955) Functional significance of spinal cord lesion level. Archives of Physical Medicine and Rehabilitation 36(4): 249-55.

Maharaj, JC (1996) Epidemiology of spinal cord paralysis in Fiji: 1985-1994. Spinal Cord 34 (9): 549-59.

Major, RE, Stallard, J & Farmer, SE (1997) A review of 42 patients of 16 years and over using the ORLAU Parawalker. Prosthetics and Orthotics International 21: 147-52.

Major, RE, Stallard, J & Rose, GK (1981) The dynamics of walking using the hip guidance orthosis (hgo) with crutches. Prosthetics and Orthotics International 7: 19-22.

Maki, BE, Holliday, PJ & Fernie, GR (1987) A posture control model and balance test for the prediction of relative postural stability. IEEE Transactions on Biomedical Engineering 34: 797-810.

Malizos, NK (2006) A study of the optimization of lower extrimity gait analysis, M.Sc. Thesis, University of Strathclyde, Glasgow.

Maqsood, T (1996) Load analysis of a Knee Ankle Foot orthosis, of the cosmetic type, M.Sc. Thesis, University of Strathclyde, Glasgow.

Marieb, EN (1989) Human anatomy and physiology laboratory manual : fetal pig version, Benjamin/Cummings Pub. Co, Redwood City, Calif.

Massucci, M, Brunetti, G, Piperno, R, Betti, L & Franceschini, M (1998) Walking with the advanced reciprocating gait orthosis (ARGO) in thoracic paraplegic patients: energy expenditure and cardiorespiratory performance. Spinal Cord 36(4): 223-7.

Maynard, FM, Jr., Bracken, MB, Creasey, G, Ditunno, JF, Jr., Donovan, WH, Ducker, TB, Garber, SL, Marino, RJ, Stover, SL, Tator, CH, Waters, RL, Wilberger, JE & Young, W (1997) International Standards for Neurological and Functional

Classification of Spinal Cord Injury. American Spinal Injury Association. Spinal Cord 35: 266-74.

Mazur, JM, Shurtleff, D, Menelaus, M & Colliver, J (1989) Orthopaedic management of high-level spina bifida. Early walking compared with early use of a wheelchair. Journal of Bone Joint Surgery 71: 56-61.

McArdle, WD, Katch, FL & Kartch, VL (1996) Exercise physiology: energy, nutrition and human performance, Ba.

McGregor, J (1979) The objective measurement of physical performance with long term ambulatory physiological surveillance equipment (LAPSE). Proceedings of the third international sysmposium on ambulatory monitoring. Academic press 28-38.

Melis, EH, Torres-Moreno, R, Barbeau, H & Lemaire, ED (1999) Analysis of assisted-gait characteristics in persons with incomplete spinal cord injury. Spinal Cord 37: 430-9.

Merati, G, Sarchi, P, Ferrarin, M, Pedotti, A & Veicsteinas, A (2000) Paraplegic adaptation to assisted-walking: energy expenditure during wheelchair versus orthosis use. Spinal Cord 38: 37-44.

Merkel, KD, Miller, NE, Westbrook, PR & Merritt, JL (1984) Energy expenditure of paraplegic patients standing and walking with two knee-ankle-foot orthoses. Archives of Physical Medicine and Rehabilitation 65: 121-4.

Middleton, JW, Fisher, W, Davis, GM & Smith, RM (1998) A medial linkage orthosis to assist ambulation after spinal cord injury. Prosthetics and Orthotics International 22: 258-64.

Middleton, JW, Sinclair, PJ, Smith, RM & Davis, GM (1999) Postural control during stance in paraplegia: effects of medially linked versus unlinked knee-ankle-foot orthoses. Archives of Physical Medicine and Rehabilitation 80: 1558-65.

Middleton, JW, Yeo, JD, Blanch, L, Vare, V, Peterson, K & Brigden, K (1997) Clinical evaluation of a new orthosis, the 'walkabout', for restoration of functional standing and short distance mobility in spinal paralysed individuals. Spinal Cord 35: 574-9.

Moisio, KC, Sumner, DR, Shott, S & Hurwitz, DE (2003) Normalization of joint moments during gait: a comparison of two techniques. Journal of Biomechanics 36: 599-603.

Moore, P & Stallard, J (1991) A clinical review of adult paraplegic patients with complate lesions using the ORLAU Parawalker. Paraplegia 29: 191-196.

Murray, MP, Drought, AB & Kory, RC (1964) WALKING PATTERNS OF NORMAL MEN. Journal of Bone and Joint Surgery 49: 335-60.

Murray, MP, Seireg, AA & Sepic, SB (1975) Normal postural stability and steadiness: quantitative assessment. The Journal of Bone and Joint Surgery 57: 510-6.

Nene, AV (1993) Physiological cost index of walking in able-bodied adolescents and adults. Clinical Rehabilitation 7: 319-326.

Nene, AV & Major, RE (1987) Dynamics of reciprocal gait of adult paraplegics using the Para Walker (Hip Guidance Orthosis). Prosthetics and Orthotics International 11(3): 124-7.

Nene, AV & Patrick, JH (1989) Energy cost of paraplegic locomotion with the ORLAU ParaWalker. Paraplegia 27: 5-18.

Nene, AV & Patrick, JH (1990) Energy cost of paraplegic locomotion using the ParaWalker--electrical stimulation "hybrid" orthosis. Archives of Physical Medicine and Rehabilitation 71: 116-20.

Nixon, V (1985) Spinal cord injury: a guide to functional outcomes in physical therapy management, Heinemann, London.

Noreau, L, Richards, CL, Comeau, F & Tardif, D (1995) Biomechanical analysis of swing-through gait in paraplegic and non-disabled individuals. Journal of Biomechanics 28 (6): 689-700.

NSCISC (2001) Spinal cord injury: facts and figures at a glance. The journal of spinal cord medicine 24 (3): 212-3.

O'Connell, M, George, K & Stock, D (1998) Postural sway and balance testing: a comparison of normal and anterior cruciate ligament deficient knees. Gait & Posture 8: 136-142.

O'Connor, PJ (2005) Prevalence of spinal cord injury in Australia. Spinal Cord 43 (1): 42-6.

O'Connor, RJ & Murray, PC (2006) Review of spinal cord injuries in Ireland. Spinal Cord 44: 445-8.

Odeen, I & Knutsson, E (1981) Evaluation of the effects of muscle stretch and weight load in patients with spastic paraplegia. Scandinavian Journal of Rehabilitation Medicine 13: 117-21.

Ogilvie, C, Bowker, P & Rowley, DI (1993) The physiological benefits of paraplegic orthotically aided walking. Paraplegia 31: 111-5.

Ohta, Y, Yano, H, Suzuki, R, Yoshida, M, Kawashima, N & Nakazawa, K (2007) A two-degree-of-freedom motor-powered gait orthosis for spinal cord injury patients. Proceedings of the Institution of Mechanical Engineers 221: 629-39.

Ozyalcin, H & Ozbasli, E (1992). Hydraulic reciprocation gait hip knee ankle foot orthosis, Proceedings, seventh world congress of ISPO Chicago, Illinois USA.

Parmley, RO (1989) Standard handbook of fastening and joining, McGraw-Hill.

Parmley, RO (1997) Standard handbook of fastening and joining, McGraw-Hill, New York ; London.

Patrick, JH & McClelland, MR (1985) Low energy cost reciprocal walking for the adult paraplegic. Paraplegia 23: 113.-117.

Pickett, W, Simpson, K, Walker, J & Brison, RJ (2003) Traumatic spinal cord injury in Ontario, Canada. Journal of Trauma 55 (6): 1070-6.

Ragnarsson, KT, Sell, GH, McGarrity, M & Ofir, R (1975) Pneumatic orthosis for paraplegic patients: functional evaluation and prescription considerations. Archives of Physical Medicine and Rehabilitation 56: 479-83.

Raymakers, JA, Samson, MM & Verhaar, HJJ (2005) The assessment of body sway and the choice of the stability parameter(s). Gait & Posture 21: 48-58.

Redford, JB (1986) Orthotics etcetera, Williams & Wilkins, Baltimore.

Requejo, PS, Wahl, DP, Bontrager, EL, Newsam, CJ, Gronley, JK, Mulroy, SJ & Perry, J (2005) Upper extremity kinetics during Lofstrand crutch-assisted gait. Medical Engineering & Physics 27: 19-29.

Rose, GK (1979) The principles and practice of hip guidance articulations. Prosthetics and Orthotics International 3: 37-43.

Rose, GK (1986) Orthotics : principles and practice, Heinemann.

Rose, Gk, Sankarankutty, M & Stallard, J (1983) A clinical review of the orthotic treatment of myelomeningocele patients. Journal of Bone Joint Surgery 65: 242-6.

Rose, J & Gamble, JG (2006) Human walking, Lippincott Williams & Wilkins, Philadelphia, Pa. ; London.

Rose, J, Gamble, JG, Burgos, A, Medeiros, J & Haskell, WL (1990) Energy expenditure index of walking for normal children and for children with cerebral palsy. Developmental Medicine and Child Neurology 32: 333-40.

Rose, J, Gamble, JG & Inman, VT (1994) Human walking, Williams & Wilkins, Baltimore ; London.

Rosenstein, BD, Greene, WB, Herrington, RT & Blum, AS (1987) Bone density in myelomeningocele: the effects of ambulatory status and other factors. Developmental Medicine and Child Neurology 29: 486-94.

Rowley, DI & Edwards, J (1987) Helping the paraplegic to walk. Journal of Bone Joint Surgery 69: 173-4.

Ryu, JC, Kang, SJ, Moon, IH, Ryu, JW, Kim, KH & Mun, MS (2004) Foot-pressure distribution during the gait of paraplegic using PGO. Second international conference of Biomedical engineering. Innsbruck, Austria.

Sabo, D, Blaich, S, Wenz, W, Hohmann, M, Loew, M & Gerner, HJ (2001) Osteoporosis in patients with paralysis after spinal cord injury. A cross sectional study in 46 male patients with dual-energy X-ray absorptiometry. Archives of Orthopaedic and Trauma Surgery 121: 75-8.

Sabo, D, Blaich, S, Wenz, W, Hohmann, M, Loew, M & Gerner, HJ (2002) Osteoporosis in patients with paralysis after spinal cord injury. A cross sectional study in 46 male patients with dual-energy X-ray absorptiometry. Spinal Cord 40: 230-5.

Santos, BR, Delisle, A, C., L, Plamondon, A & Imbeau, D (2008) Reliability of centre of pressure summary measures of postural steadiness in healthy young adults. Gait & Posture 27: 408-15.

Scivoletto, G, Mancini, M, Fiorelli, E, Morganti, B & Molinari, M (2003) A prototype of an adjustable advanced reciprocating gait orthosis (ARGO) for spinal cord injury (SCI). Spinal Cord 41: 187-191.

Scrutton, D (1971) A reciprocating brace with polyplanar hip hinges used on spina bifida children. Physiotherapy 57: 61-6.

Shields, RK (2002) Muscular, skeletal, and neural adaptations following spinal cord injury. Journal of Orthopaedic & Sports Physical Therapy 32: 65-74.

Shigley, JE & Mischke, CR (2001) Mechanical engineering design, McGraw Hill, Boston, Mass. ; London.

Shimada, Y, Hatakeyama, K, Minato, T, Matsunaga, T, Sato, M, Chida, S & Itoi, E (2006) Hybrid functional electrical stimulation with medial linkage knee-ankle-foot orthoses in complete paraplegics. The Tohoku Journal of Experimental Medicine 209: 117-23.

Slavens, BA, Frantz, J, Sturm, PF & Harris, GF (2007) Upper extremity dynamics during Lofstrand crutch-assisted gait in children with myelomeningocele. The Journal of Spinal Cord Medicine 30(1): 165-171.

Solomonow, M, Baratta, R, Hirokawa, S, Rightor, N, Walker, W, Beaudette, P, Shoji, H & D'Ambrosia, R (1989) The RGO Generation II: muscle stimulation powered orthosis as a practical walking system for thoracic paraplegics. Orthopedics 12: 1309-15.

Somers, MF (1991) Spinal cord injury : functional rehabilitation, Appleton & Lange, Norwalk, Conn.

Somers, MF (1992) Spinal cord injury : functional rehabilitation, Appleton & Lange, Norwalk, Conn.

Stallard, J (2000) ORLAU, A brief history- The first 25 years 1975 to 2000. ORLAU

Stallard, J & Major, RE (1993) The case for lateral stiffness in walking orthoses for paraplegic patients. Proceedings of the Institution of Mechanical Engineers. Part H 207: 1-6.

Stallard, J & Major, RE (1995) The influence of orthosis stiffness on paraplegic ambulation and its implications for functional electrical stimulation (FES) walking systems. Prosthetics and Orthotics International 19: 108-114.

Stallard, J & Major, RE (1998) A review of reciprocal walking systems for paraplegic patients: factors affecting choice and economic justification. Prosthetics and Orthotics International 22: 240-247.

Stallard, J, Major, RE, Poiner, R, Farmer, IR & Jones, N (1986) Engineering design considerations of the ORLAU Parawalker and FES hybrid system. Engineering in Medicine 15: 123-9.

Stallard, J, McLeod, N, Woollam, PJ & Miller, K (2003) Reciprocal walking orthosis with composite material body brace: initial development. Proceedings of the Institution of Mechanical Engineers. Part H 217: 385-92.

Stallard, J, Woollam, PJ, Miller, K, Farmer, IR, Jones, N & Poiner, R (2001) An infant reciprocal walking orthosis: engineering development. Proceedings of the Institution of Mechanical Engineers. Part H 215: 599-604.

Stolov, WC & Clowers, MR (1981) Handbook of severe disability : a text for rehabilitation counselors, other vocational practitioners, and allied health professionals, U.S. Dept. of Education Rehabilitation Services Administration ; for sale by the Supt. of Docs. U.S. Govt. Print. Off., Washington.

Subbarao, JV, Klopfstein, J & Turpin, R (1995) Prevalence and impact of wrist and shoulder pain in patients with spinal cord injury. The journal of spinal cord medicine 18: 9-13.

Surkin, J, Gilbert, BJ, Harkey, HL, Sniezek, J & Currier, M (2000) Spinal cord injury in Mississippi. Findings and evaluation, 1992-1994. Spine 25 (6): 716-21.

Sutton, NG (1973) Injuries of the spinal cord the management of paraplegia and tetraplegia, Butterworths, London.

Swanenburg, J, de Bruin, ED, Favero, K, Uebelhart, D & Mulder, T (2008) The reliability of postural balance measures in single and dual tasking in elderly fallers and non-fallers. BMC Musculoskeletal Disorders 9: 159-162.

Sykes, L, Edwards, J, Powell, ES & Ross, ER (1995) The reciprocating gait orthosis: long-term usage patterns. Archives of Physical Medicine and Rehabilitation 76: 779-83.

Sykes, L, Ross, ER, Powell, ES & Edwards, J (1996) Objective measurement of use of the reciprocating gait orthosis (RGO) and the electrically augmented RGO in adult patients with spinal cord lesions. Prosthetics and Orthotics International 20: 182-90.

Tashman, S, Zajac, FE & Perkash, I (1995) Modeling and simulation of paraplegic ambulation in a reciprocating gait orthosis. Journal of Biomechanical Engineering 117: 300-8.

Tilley, AR (1993) The measure of man and woman : human factors in design, Whitney Library of Design.

Trappitt, AE & Berme, N (1981) A trasducer for the measurement of lower limb orthotic loads. Eng Med 10: 149-153.

Triolo, RJ, Reilley, B, Mulcahey, MJ, Cohn, J, Betz, RR & Freedman, W (1993) Development and standardization of a clinical evaluation of standing function in children: the functional standing test. IEEE Transactions on Rehabilitation Engineering 1: 18-25.

Ulkar, B, Yavuzer, G, Guner, R & Ergin, S (2003) Energy expenditure of the paraplegic gait: comparison between different walking aids and normal subjects. International Journal of Rehabilitation Research 26: 213-7.

Waters, RI, Hislop, HJ, Perry, J & Antonelli, D (1978) Energetics: application to the study and management of locomotor disabilities. Energy cost of normal and pathologic gait. The Orthopedic Clinics of North America 9(2): 351-6.

Waters, RI & Lunsford, BR (1985) Energy cost of paraplegic locomotion. Journal of Bone, Joint and Surgery 67: 1245-50.

Whittle, M (1996) Gait analysis : an introduction, Butterworth-Heinemann, Oxford ; Boston.

Whittle, MW, Cochrane, GM, Chase, AP, Copping, AV, Jefferson, RJ, Staples, DJ, Fenn, PT & Thomas, DC (1991) A comparative trial of two walking systems for paralysed people. Paraplegia 29: 97-102.

Winchester, PK, Carollo, JJ, Parekh, RN, Lutz, LM & Aston, JW (1993) A comparison of paraplegic gait performance using two types of reciprocating gait orthoses. Prosthetics and Orthotics International 17: 101-106.

Window, AL (1992) Strain gauge technology, Elsevier Applied Science, London.

Winter, DA (1991) The biomechanics and motor control of human gait : normal, elderly and pathological, Waterloo Biomechanics, Waterloo, Ont.

Woollam, PJ, Dominy, J, McCleod, N, Stallard, J & Major, RE (1999) Feasibility study on a composite material construction technique for highly stressed

components in reciprocal walking orthoses for paraplegic patients. proceedings of the Institution of Mechanical Engineers. Part H 213: 355-60.

Woolridge, C (1969) Spina bifida orthotics program presented at the Workshop on Bracing of Children with Paraplegia from Spina Bifida and Cerebral Palsy. National Academy of Sciences, University of Virginia, Charlottesville, VA,

Wyndaele, M & Wyndaele, JJ (2006) Incidence, prevalence and epidemiology of spinal cord injury: what learns a worldwide literature survey? Spinal cord 44 (9): 523-9.

Yang, L, Condie, DN, Granat, MH, Paul, JP & Rowley, DI (1996) Effects of joint motion constraints on the gait of normal subjects and their implications on the further development of hybrid FES orthosis for paraplegic persons. Journal of Biomechanics 29(2): 217-26.

Yano, H, Kaneko, S, Nakazawa, K, Yamamoto, SI & Bettoh, A (1997) A new concept of dynamic orthosis for paraplegia: the weight bearing control (WBC) orthosis. Prosthetics and Orthotics International 21: 222-8.

Yongue, DA, Douglas, R & Roberts, JM (1984) The Reciprocation Gait Orthosis in Myelomeningocele. Journal of Pediatrics 4: 304-10.

Zampa, A, Zacquini, S, Rosini, C, Bizzarini, E, Magrin, P & Saccavini, M (2003) Relationship between neurological level and functional recovery in spinal cord injury patients after rehabilitation. European Journal of Physical and Rehabilitation Medicine 39: 69-78.

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APPENDIX 1: STRESS ANALYSIS OF THE COMPONENTS OF THE HIP JOINT COMPLEX

A.1.1 FORCE ANALYSIS OF THE UPPER BAR OF THE HIP JOINT

The free body diagrams of the upper bar of the hip joint are shown in figure A.1.1 and A.1.2. The forces and moments developed in this bar were analyzed at two different cross sections which included the cross section at the second hip joint centre and 5 cm above the second hip joint centre.

A.1.1.1 Force Analysis of the Upper Bar at the Cross Section at the Second Hip Joint

It was assumed that the adducting moment applied on the hip joint was resisted by the main component of the hip joint complex, so the adducting moment at this cross section was supposed to be zero. The forces and moment applied on this bar at this section are as follows:

F_{xh2} = 6506.65 N
F_{yh2} = 854.88 N
M_{zh2} = 127.18 Nm
M_{xh2} = 0 Nm

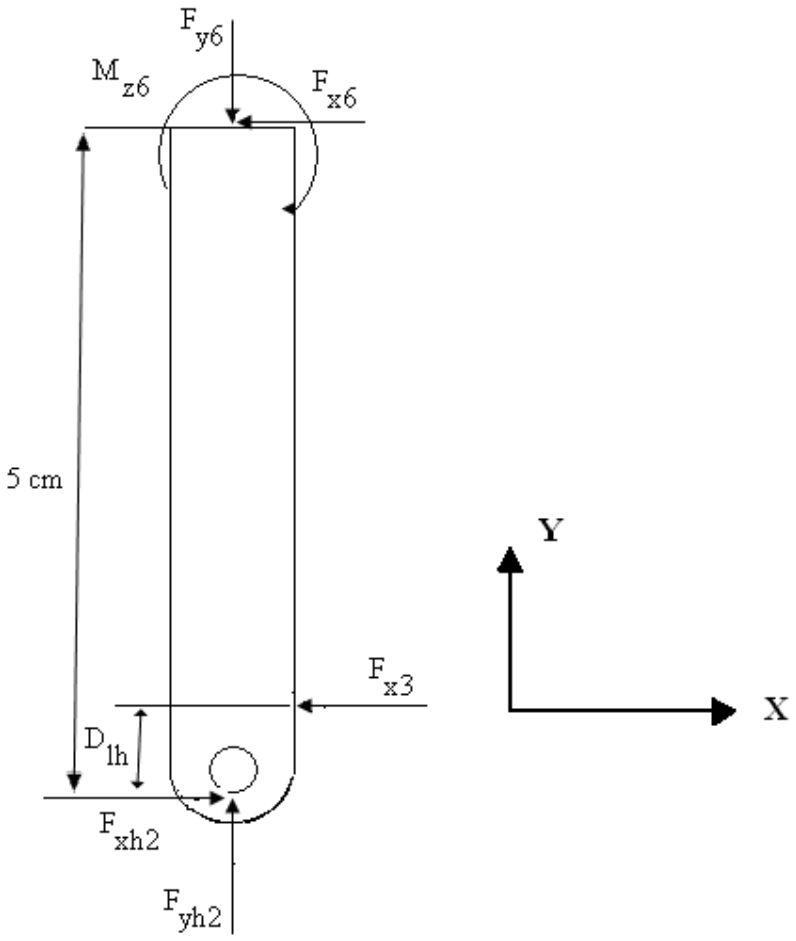

Figure A.1.1: The free body diagram of the upper bar of the hip joint complex in the anteroposterior plane

Where D_{lh} is the distance between the force of the locking system and the second hip joint centre (2 cm)

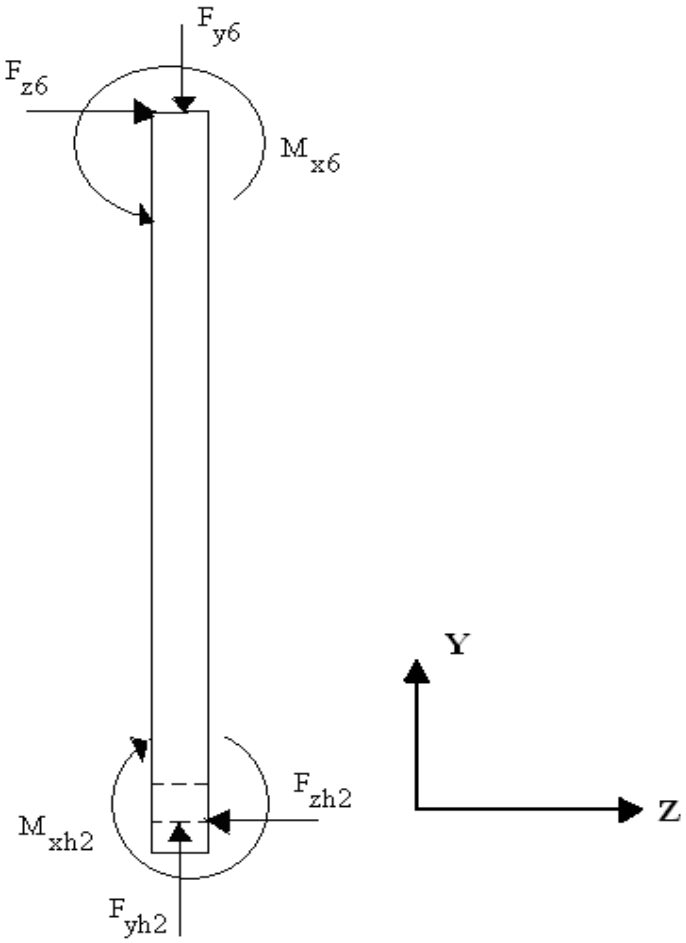

Figure A.1.2: The free body diagram of the upper bar of the hip joint complex in the mediolateral plane

The second moment of the area and area of this cross section, figure A.1.3, were as follows:

$I_{ZZ} = 39.75 \times 10^{-9}\ m^4$, $A = 323 \times 10^{-6}\ m^2$

The combined bending and direct stress in this cross section was determined as follows.

$$\sigma = \frac{127.18 \times 0.0155}{39.756 \times 10^{-9}} + \frac{854.88}{323 \times 10^{-6}} = 52.23 \text{ MP}$$

With a safety factor of 3, it was 156.69 MPa. The shear stress in this cross section was determined as follows.

$$Q = 0.0095 \times 0.017 \times 0.01075 = 1.736 \times 10^{-6} \text{ m}^3$$

$$\tau = \frac{1.736 \times 10^{-6} \times 6506.65}{0.017 \times 39.756 \times 10^{-9}} + \frac{6506.65}{323 \times 10^{-6}} = 36.85 \text{ MPa}$$

With safety factor as 3 it was 110.55 MPa.

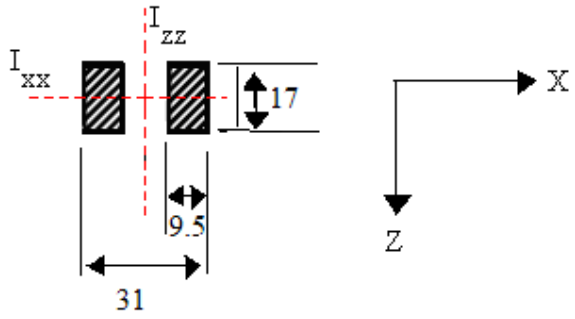

Figure A.1.3: The cross section 1 of the upper bar of the hip joint

A.1.1.2 Force Analysis of the Upper Bar at the Second Cross Section Area

The forces and moment in this cross section, 5 cm above the second hip joint, could be determined as follows.

$$\sum F_x = 0$$

$$F_{xh2} - F_{x3} - F_{x6} = 0$$

$$F_{x6} = F_{xh2} - F_{x3} = 6506.65 - 6359.5$$

$$F_{x6} = 147.15 \text{ N}$$

$$\sum F_y = 0$$

$$F_{yh2} - F_{y6} = 0$$

$$F_{y6} = F_{yh2} = 854.88 \text{ N}$$

$$\sum M_z = 0$$

$$M_{z6} - F_{xh2} \times 0.05 + F_{x3} \times 0.03 = 0$$

$$M_{z6} = 6506.65 \times 0.05 - 6359 \times 0.03$$

$$M_{z6} = 134.56 \text{ Nm}$$

$$\sum M_x = 0$$

$$128 - F_{zh2} 0.05 + M_{x6} = 0$$

$$M_{x6} = 121.3 \text{ Nm}$$

The second moments of the inertia and the area in this section, figure A.1.4, are as follows.

$$I_{zz} = 42.2 \times 10^{-9} \text{ m}^4$$

$$I_{xx} = 12.69 \times 10^{-9} \text{ m}^4$$

$$A = 527 \times 10^{-6} \text{ m}^2$$

The combined bending stress at this cross section could be defined as follows.

$$\sigma = \frac{134.56 \times 0.0155}{42.2 \times 10^{-9}} + \frac{121.3 \times 0.0085}{12.69 \times 10^{-9}} + \frac{854.88}{527 \times 10^{-6}} = 132.29 \text{ MPa}$$

With a safety factor of 3 it was 396.9 MPa. The shear stress in this cross section was determined as follows:

$$Q = 0.0155 \times 0.017 \times 0.01075 = 2.832 \times 10^{-6} \text{ m}^3$$

$$\tau = \frac{147.15 \times 2.832 \times 10^{-6}}{0.017 \times 42.03 \times 10^{-9}} + \frac{147.15}{527 \times 10^{-6}} = 0.865 \text{ MPa}$$

With a safety factor of 3 it was 2.595 MPa.

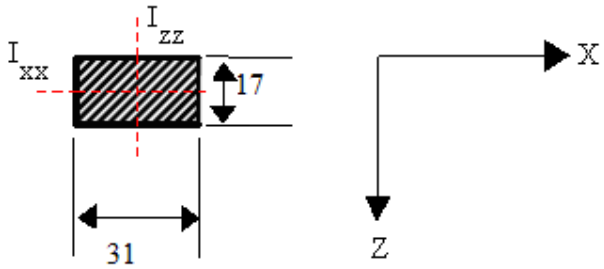

Figure A.1.4: The cross section 2 of the upper bar of the hip joint, all dimensions are in mm

A.1.2 FORCE ANALYSIS OF THE MAIN COMPONENT OF THE HIP JOINT

The force analysis of the main component of the hip joint was done on two cross section areas, which the first one was located at the first hip joint centre and the second one was located at the second hip joint centre.

A.1.2.1 Force Analysis of the Main Component of the Hip Joint at the First Cross Section Area

The maximum loads and moments applied on this cross section were as follows.

$F_{xh1} = 5234.75$ N

$F_{yh1} = 854.88$ N

$M_{zh1} = 254.36$ Nm

$M_{xh1} = 128$ Nm

The second moments of the inertia and the cross section area at this level were as follows.

$I_{zz} = 175.04 \times 10^{-9}$ m^4

$I_{xx} = 86.561 \times 10^{-9}$ m^4

$A = 616 \times 10^{-6}$ m^2

The stress developed in this cross section, figure A.1.5 was measured as follows.

$$\sigma = \frac{254.36 \times 0.0293}{175.04 \times 10^{-9}} + \frac{128 \times 0.016}{86.561 \times 10^{-9}} + \frac{855.88}{616 \times 10^{-6}} = 67.63 \text{ MPa}$$

With a safety factor of 3 it was 202.89 MPa.

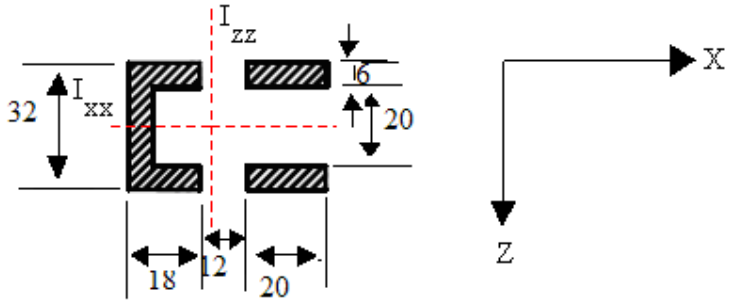

Figure A.1.5: The first cross section area of the main component of the hip joint

A.1.2.2 Force Analysis of the Main Component of the Hip Joint at the Second Cross Section Area

The forces and moments applied on the hip joint at this section were as follows.

F_{xh2} = 6506.65 N
F_{yh2} = 854.88 N
M_{zh2} = 127.18 Nm
M_{xh2} = 128 Nm

The second moments of the area and the cross area at this section, figure A.1.6 are as follows.

$I_{zz} = 168.313 \times 10^{-9}\ m^4$

$I_{xx} = 75.516 \times 10^{-9}\ m^4$

$A = 616 \times 10^{-6}\ m^2$

The stress in this cross section was determined as follows:

$$\sigma = \frac{127.18 \times 0.03274}{168.313 \times 10^{-9}} + \frac{128 \times 0.016}{75.516 \times 10^{-9}} + \frac{854.88}{616 \times 10^{-6}} = 53.24\ MPa$$

With a safety factor of 3 it was 159.74 MPa.

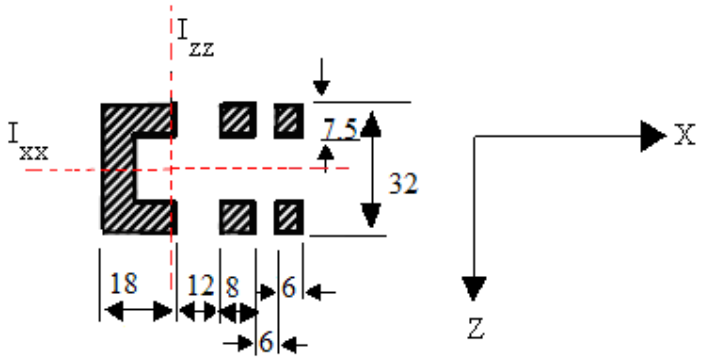

Figure A.1.6: The second cross section area of the main component of the hip joint

A.1.3 FORCE ANALYSIS OF THE FLEXION RESTRICTION SCREW

The flexion restriction screw locates 50 mm below the first hip joint hinge. As was shown before, chapter 3, the amount of the force applied on this screw was 5087.6 N. The stress developed in this screw was measured as follows.

$$\sigma = \frac{F}{A}$$

$F = 5087.6$ N

$A = 36.6 \times 10^{-6}$ m^2

$$\sigma = \frac{5087.6}{36.6 \times 10^{-6}} = 139 \text{ MPa}$$

With a safety factor of 3 it was 417 MPa.

A.1.4 FORCE ANALYSIS OF THE EXTENSION RESTRICTION SCREW

The maximum range of extension in this orthosis was 10 degree, according to the design. The moment applied on the hip joint at this angle according to figure A.1.7 was calculated as follows.

$$\sum M_z = 0$$

$$(F_{y1}L_l)\sin\theta - (F_{x1}L_l)\cos\theta - (W_lD_l)\sin\theta + M_{zh1} = I \times \alpha \qquad \text{Eq. A.1.1}$$

Where, H and W are the height and the weight of total body and W_l is the weight of the leg with the orthosis. Since the speed of walking is not high, especially in the stance phase, the angular acceleration was supposed to be zero.

$$M_{zh1} = (F_{x1}L_l)\cos\theta - (F_{y1}L_l)\sin\theta + (W_lD_l)\sin\theta \qquad \text{Eq. A.1.2}$$

By inserting the values of W_l, L_l and D_l from table 3.2 and the values of F_{x1} and F_{y1}, which supposed to be 15% and 104% of body weight respectively; the applied moment around the hip joint was 18.62 Nm.

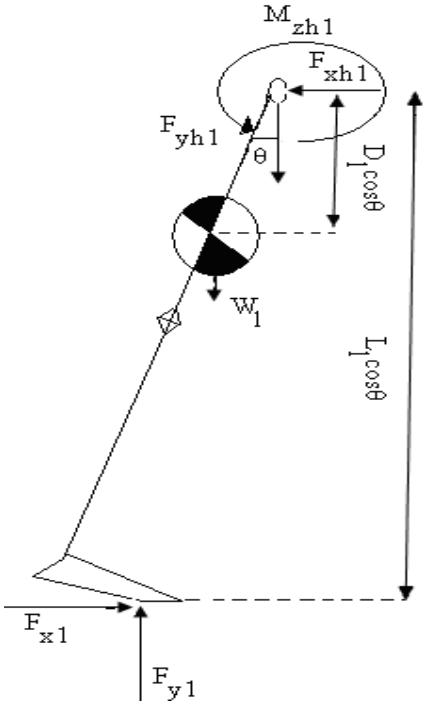

Figure A.1.7: Free body diagram of the leg during toe off

The extension restriction screw was located 20 mm below the first hip joint centre; figure A.1.8. So the force applied on it could be resulted as follows.

$$\sum M_z = 0$$
$$18.62 - 0.02\, F_{x7} = 0$$
$$F_{x7} = 931.0 \text{ N}$$

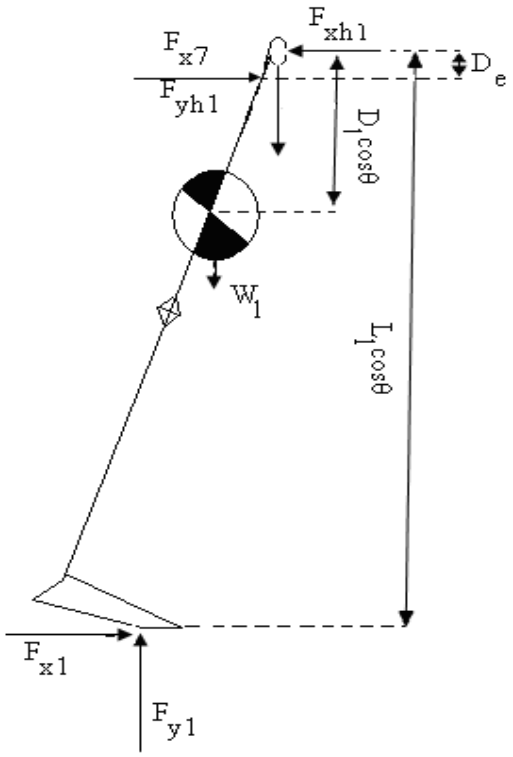

Figure A.1.8: The free body diagram of the leg during toe off

D_e is the distance between the point of application of extension restriction screw and the first hip joint hinge

The maximum stress developed in this screw (with 4 mm diameter) was resulted as follows.

$$\sigma = \frac{F}{A}$$

$F = 931.0$ N, $A = 8.78 \times 10^{-6} m^2$

$$\sigma = \frac{931.0}{8.78 \times 10^{-6}} = 106.03 \text{ MPa}$$

With a safety factor of 3 it was 318.09 MPa.

A.1.5 FORCE ANALYSIS OF THE FIRST HIP JOINT HINGE

The forces applied on the first hip joint hinge were as follows.

$F_{xh1} = 5234.75$ N
$F_{yh1} = 854.88$ N
$R_{h1} = 5303.95$ N
$F_{zh1} = 134.17$ N

The force applied in the anteroposterior and vertical directions produced shear stresses (which R is their resultant force) however, the force applied in the mediolateral direction compressed the hinge. The shear and compression stresses developed in this hinge could be analyzed as follows.

$$\tau = \frac{F}{A}$$

$F = 5303.95$ N, $A = 113 \times 10^{-6}$ m^2

$$\tau = \frac{5303.95}{113 \times 10^{-6}} = 46.93 \text{ MPa}$$

$$\sigma = \frac{134.17}{113 \times 10^{-6}} = 1.18 \text{ MPa}$$

With a safety factor of 3 the shear and bending stress were 140.79 and 3.54 MPa, respectively.

A.1.6 FORCE ANALYSIS OF THE SECOND HIP JOINT HINGE

The forces applied on the second hip joint hinge were as follows.

F_{xh2} = 6506.65 N
F_{yh2} = 854.88 N
R_{h2} = 6562.45 N
F_{zh2} = 134.17 N

Where R_{h2} is the resultant force of the shear forces applied in the anteroposterior and vertical directions and F_{zh2} is the compression force applied on the hinge. The stress developed in this hinge could be determined as follows.

$$\tau = \frac{F}{A}$$

$F = 6562.45$ N, $A = 113 \times 10^{-6}$ m^2

$$\tau = \frac{6562.45}{113 \times 10^{-6}} = 58.07 \text{ MPa}$$

$$\sigma = \frac{134.17}{113 \times 10^{-6}} = 1.18 \text{ MPa}$$

With a safety factor of 3 the shear and bending stress were 174.21 and 3.54 MPa, respectively.

A.1.7 ANALYSIS OF THE STRESS IN THE LOCKING SYSTEM OF THE HIP JOINT

The free body diagram of the forces applied on this component is shown in figure A.1.9. It was shown that the shear force applied on the locking system was 6359.5 N. The shearing stress produced in this component could be determined as follows.

$$\tau = \frac{F}{A}$$

$$F_{x3} = 6359.5 \text{ N and } A = (240 + 28.26) = 268.26 \times 10^{-6} \text{ m}^2$$

$$\tau = \frac{6359.5}{268.26 \times 10^{-6}} = 23.70 \text{ MPa}$$

With a safety factor of 3 it was 71.10 MPa.

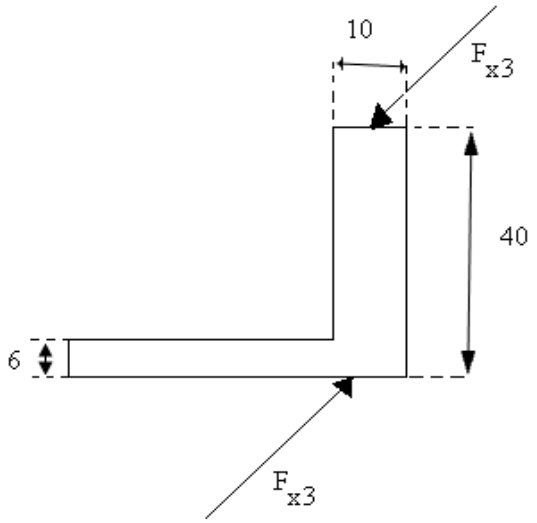

Figure A.1.9: Free body diagram of the locking system

A.1.8 ANALYSIS OF THE STRESS IN THE ATTACHMENT COMPONENTS OF THE HIP JOINT

The hip joint attachment components consisted of a pyramid, which was attached to the upper bar of the hip joint, and an adaptor, which was attached to the TORSO part of the orthosis.

A.1.8.1 Analysis of the Stress in the Pyramid

The pyramid of the hip joint was attached to the adaptor by 5 screws. The free body diagrams of the pyramid are shown in figure A.1.10 and A.1.11. The forces and moments applied on this component were determined as follows.

$$\sum F_x = 0$$
$$F_{xh2} - F_{x3} + F_{x7} = 0$$
$$F_{x7} = F_{x3} - F_{xh2} = 6359.5 - 6506.65 = -147.15 \text{ N}$$

$$\sum F_y = 0$$
$$F_{yh2} - F_{y7} = 0$$
$$F_{y7} = F_{yh2} = 854.88 \text{ N}$$

$$\sum M_z = 0$$
$$-0.075 F_{xh2} + 0.055 F_{x3} - M_{z7} = 0$$
$$M_{z7} = -0.075 \times 6506.65 + 0.055 \times 6359.5$$
$$M_{z7} = 138.23 \text{ Nm}$$

$\sum Mx = 0$

$-128 + 0.075\, F_{zh2} + M_{x7} = 0$

$M_{x7} = 117.94$ Nm

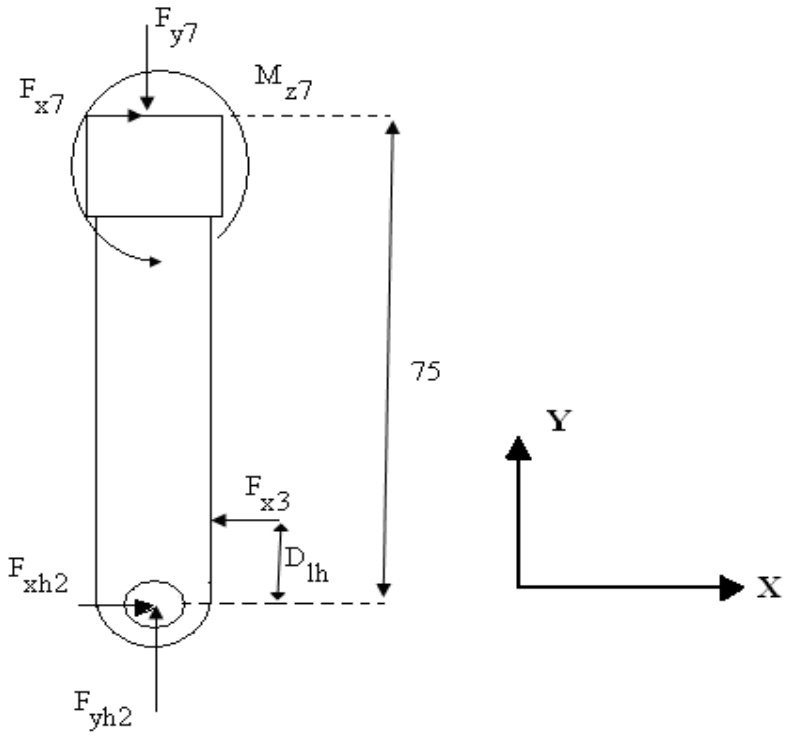

Figure A.1.10: The free body diagram of the pyramid

Where D_{lh} is the distance between the force of the locking system and the second hip joint centre

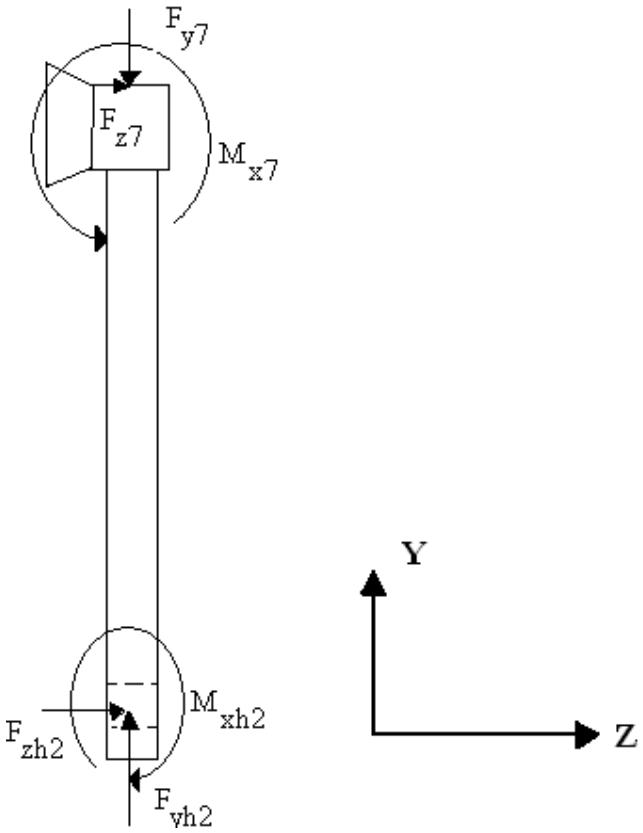

Figure A.1.11: The free body diagram of the pyramid in the mediolateral plane

The second moments of area and the area of this section, figure A.1.12, were as follows.

$I_{xx} = 13.13 \times 10^{-9}\ m^4$

$I_{zz} = 13.13 \times 10^{-9}\ m^4$

$A = 349.76 \times 10^{-6}\ m^2$

The combined bending and direct stress in this cross section was determined as follows.

$$\sigma = \frac{138.23 \times 0.01}{13.13 \times 10^{-9}} + \frac{117.94 \times 0.01}{13.13 \times 10^{-9}} + \frac{134.17}{349.76 \times 10^{-6}} = 195.48 \text{ MPa}$$

With a safety factor of 3 it was 586.44 MPa. The shear force at this section is the resultant force from the forces applied in the vertical and the anteroposterior directions. The shear stress in this cross section was determined as follows.

$$\tau = \frac{F}{A}$$

$F = 867.43$ N and $A = 349.76 \times 10^{-6}$ m^2

$$\tau = \frac{867.43}{349.76 \times 10^{-6}} = 2.48 \text{ MPa}$$

With safety factor as 3 it was 7.44 MPa.

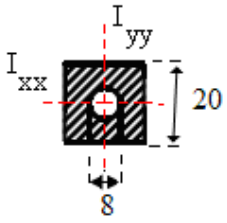

Figure A.1.12: The cross section area of the pyramid

A.1.8.2 Analysis of the Stress in the Adaptor

The adaptor of the hip joint was attached to the pyramid by 5 screws. It was supposed that the force and moment which applied on this component were the same as those applied on the adaptor. The following forces and moments applied on the adaptor.

$F_{x8} = 147.15$ N

$F_{y8} = 854.88$ N

$M_{z8} = 138.23$ Nm

$M_{x8} = 117.94$ Nm

The second moments of area and the area of this cross section, figure A.1.13, were as follows.

$I_{zz} = 348 \times 10^{-9}$ m^4

$I_{xx} = 73.526 \times 10^{-9}$ m^4

$A = 530 \times 10^{-6}$ m^2

The combined bending and direct stress in this section was determined as follows.

$$\sigma = \frac{138.23 \times 0.0515}{348 \times 10^{-9}} + \frac{117.94 \times 0.0155}{73.526 \times 10^{-9}} + \frac{134.17}{530 \times 10^{-6}} = 45.57 \text{ MPa}$$

With a safety factor of 3 it was 136.71 MPa.

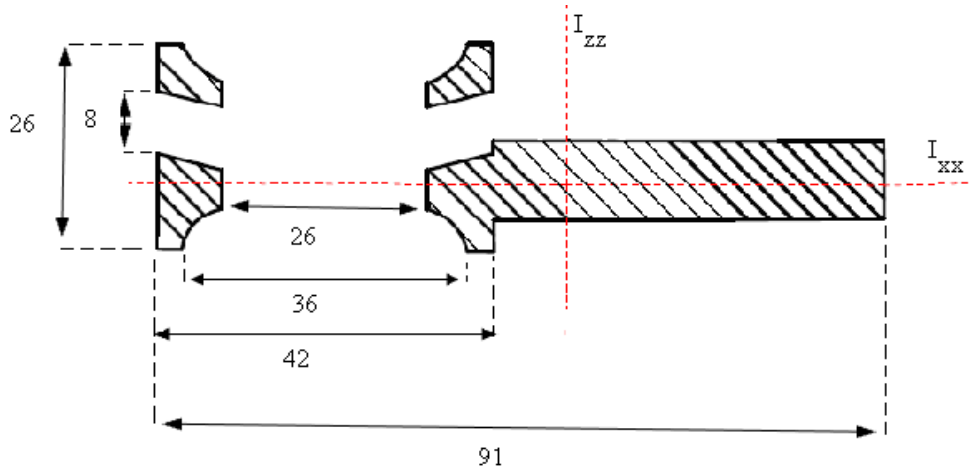

Figure A.1.13: The cross section area of the adaptor, all dimensions are in mm

A.1.8.2.I Analysis of the stress in the screws of the adaptor

The security of the attachment between the adaptor and the pyramid was enhanced by four screws around the adaptor and using another one in the middle. The forces and moments applied on these screws are the same as those applied on the adaptor and pyramid.

F_{x8} = 147.15 N
F_{y8} = 854.88 N
M_{z8} = 138.23 Nm
M_{x8} = 117.94 Nm

These moments produced other forces in the screws. According to the free body diagrams of the screws, as are shown in figure A.1.14 and A.1.15, the forces which were developed as a result of these moments could be determined as follows.

$$M_{z9} = M_{z8} = 138.23 \text{ Nm}, r = 0.013 \text{ m}$$

$$F_9 = \frac{M_{z9}}{4 \times r} = \frac{138.23}{4 \times 0.013}$$

$$F_9 = 2658.27 \text{ N}$$

Which, r is the distance between the screws and the centroid point.

$$M_{x9} = 117.95 \text{ Nm}, r = 0.013 \text{ m}$$

$$F_{z9} = \frac{M_{x9}}{2 \times r} = \frac{117.94}{2 \times 0.013}$$

$$F_{z9} = 4536.5 \text{ N}$$

These forces are shearing forces which apply on all screws but in the different directions. There are some bending moments which are produced as results of these shearing forces. The amount of these moments depends on the distance between the point of contact of the screws with pyramid and the point of their entrance to the adaptor. Figure A.1.16 shows the distance and the moments resulted from applying these forces. It was supposed that the moment arm of these forces be 4 mm. So the above mentioned moments were determined as follows.

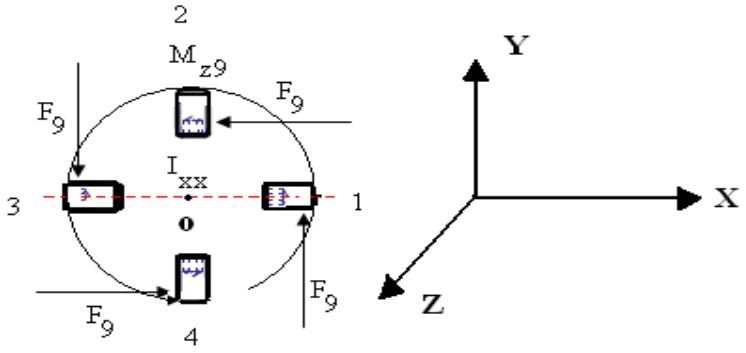

Figure A.1.14: The forces applied on the adaptor screws as a result of a flexing moment (o is the centroid point)

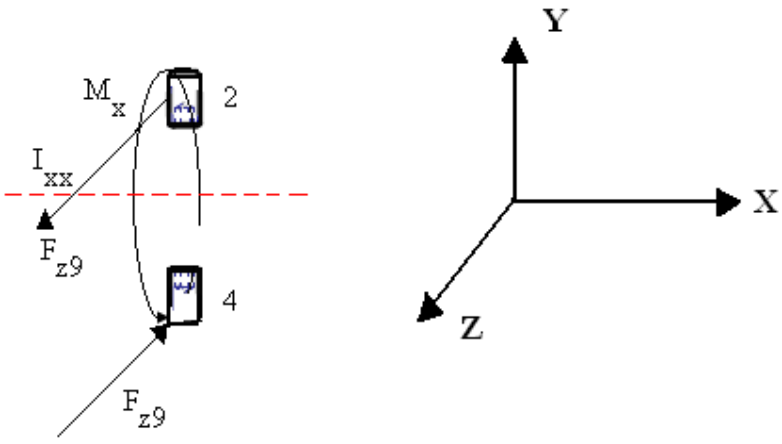

Figure A.1.15: The forces applied on the adaptor screws as a result of an adducting moment

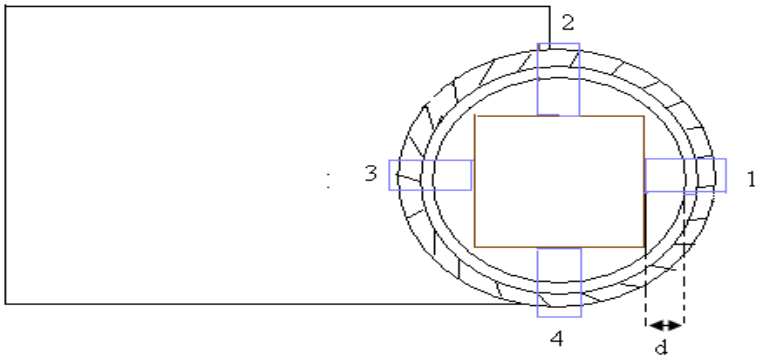

Figure A.1.16: The cross section area of the adaptor when the pyramid was inserted. The distance between the pyramid and adaptor (d) is 4 mm

$M_{z9} = F_{z9} \times d$

$M_{z9} = 2658.27 \times 0.004 = 10.63$ Nm

$M_{x9} = 4536.5 \times 0.004 = 18.14$ Nm

The total forces applied on those screws could be resulted as follows.

Screw 1:

$$F_{xs1} = \frac{-147.15}{2} = -73.57 \text{ N}$$
$$F_{ys1} = 211.5 + F_9$$
$$F_{ys1} = 2869.77 \text{ N}$$
$$F_{zs1} = 0$$

Which F_{xs1} is a compression force and F_{ys1} is a shear force.

Screw 2:

$$F_{xs2} = F_9 = -2658.27 \text{ N}$$
$$F_{ys2} = 211.5 \text{ N}$$
$$F_{zs2} = 4536.5 - \frac{134.17}{2} = 4469.41 \text{ N}$$

Which F_{xs2} and F_{zs2} are shear forces and F_{ys2} is a compression force. The resultant force of the shear force, applied in the vertical and anteroposterior directions, is 5200.2 N.

Screw 3:

$$F_{xs3} = \frac{-147.15}{2} = -73.57 \text{ N}$$
$$F_{ys3} = F_9 - 211.5 \text{ N} = 2446.77 \text{ N}$$
$$F_{zs3} = 0 \text{ N}$$

Which F_{xs3} is a tensile force and F_{ys3} is a shear force.

Screw 4:

$$F_{xs4} = F_9 = 2658.27 \text{ N}$$
$$F_{ys4} = 211.5 \text{ N}$$
$$F_{zs4} = 4536.5 + \frac{134.17}{2} = 4603.58 \text{ N}$$

Which F_{xs4} and F_{zs4} are shear forces and F_{ys4} is a compression force. The resultant shear force applied on this screw would be as 5315.95 N.

The second moments of area and the area of these screws were as follows.

$$I_{xx} = 0.2 \times 10^{-9} \text{ m}^4$$
$$I_{zz} = 0.2 \times 10^{-9} \text{ m}^4$$
$$A = 36.6 \times 10^{-6} \text{ m}^2$$

The stress in these screws could be determined as follows.

Screw 1:

$$\sigma_{s1} = \frac{10.63 \times 0.004}{0.2 \times 10^{-9}} + \frac{73.57}{36.6 \times 10^{-6}} = 214.6 \text{ MPa}$$

$$\tau_{s1} = \frac{2869.77}{36.6 \times 10^{-6}} = 78.41 \text{ MPa}$$

With a safety factor of 3, the maximum shear and bending stress in the first screw were 235.23 and 643.8 MPa, respectively.

Screw 2:

$$\sigma_{s2} = \frac{10.63 \times 0.004}{0.2 \times 10^{-9}} + \frac{18.14 \times 0.004}{0.2 \times 10^{-9}} + \frac{211.5}{36.6 \times 10^{-6}} = 581.17 \text{ MPa}$$

$$\tau_{s2} = \frac{5200.2}{36.6 \times 10^{-6}} = 142.08 \text{ MPa}$$

With a safety factor of 3, the maximum shear and bending stress in the second screw were 426.24 and 1743.51 MPa, respectively.

Screw 3:

$$\sigma_{s3} = \frac{10.63 \times 0.004}{0.2 \times 10^{-9}} + \frac{73.57}{36.6 \times 10^{-6}} = 214.61 \text{ MPa}$$

$$\tau_{s3} = \frac{211.5}{36.6 \times 10^{-6}} = 5.78 \text{ MPa}$$

With a safety factor of 3, the maximum shear and bending stress in the third screw were 17.34 and 643.83 MPa, respectively.

Screw 4:

$$\sigma_{s4} = \frac{10.63 \times 0.004}{0.2 \times 10^{-9}} + \frac{18.14 \times 0.004}{0.2 \times 10^{-9}} + \frac{211.5}{36.6 \times 10^{-6}} = 581.18 \text{ MPa}$$

$$\tau_{s4} = \frac{5315.95}{36.6 \times 10^{-6}} = 145.24 \text{ MPa}$$

With a safety factor of 3, the maximum shear and bending stress in the fourth screw were 435.73 and 1743.54 MPa, respectively.

A.1.8.2.II Analysis of the stress in the middle screw of the adaptor

The middle screw was subjected to an adducting moment which produces a shear force. The length of the screw which is inside the pyramid was nearly 1.5 cm as is shown in figure A.1.17. The shear force resulted from the adducting moment (M_{z10}) could be determined as follows.

$$M_{x10} = M_{x9} = 117.94 \text{ Nm}$$

$$M_{x10} = F_{y10} \times 0.015$$

$$F_{y10} = 7863.33 \text{ N}$$

The forces which applied on this screw were as follows.

$$F_{yms} = F_{y10} + F_{y8} = 8718.2 \text{ MPa}$$

$$F_{xms} = 147.15 \text{ N}$$

$$F_{zms} = 134.17 \text{ N}$$

$R_{ms} = 8719.44$ N

Which R_{ms} is the resultant shear stress developed in this screw.

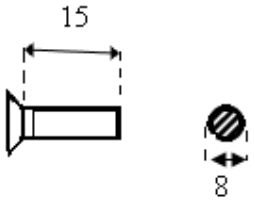

Figure A.1.17: The middle screw of the pyramid

The maximum shear and bending stress developed in this screw could be determined as follows.

$$\tau = \frac{R_{ms}}{A}$$

$$A = 36.6 \times 10^{-6}\ m^2$$

$$\tau = \frac{8719.44}{36.6 \times 10^{-6}} = 238.23\ MPa$$

$$\sigma = \frac{F_{z10}}{A}$$

$$\sigma = \frac{134.17}{36.6 \times 10^{-6}} = 3.66\ MPa$$

With a safety factor of 3 the shear and bending stress were 714.69 and 10.98 MPa.

A.1.9 ANALYSIS OF THE STRESS IN THE LATERAL BAR OF TORSO

A.1.9.1 Analysis of the Stress in the Body of the Lateral Bar of the TORSO

The lateral bar of the TORSO was attached to the hip joint attachment unit by four screws. It was expected that the forces and the moments applied on the lateral bar of the orthosis were the same as those applied on the hip joint attachment unit. The second moment of area and the area of this cross section, figure A.1.18, were:

$$I_{xx} = 13.65 \times 10^{-9}\ m^4$$

$$I_{zz} = 85.33 \times 10^{-9}\ m^4$$

$$A = 640 \times 10^{-6}\ m^2$$

The bending stress in the body of the lateral bar was as follows.

$$\sigma = \frac{0.02 \times 138.23}{85.33 \times 10^{-9}} + \frac{0.008 \times 117.94}{13.653 \times 10^{-9}} + \frac{854.88}{640 \times 10^{-9}} = 102.83\ MPa$$

With a safety factor of 3 it was 308.49 MPa. The shear stress in the body of the lateral bar was resulted as follows.

$$Q = 0.016 \times 0.02 \times 0.01 = 3.2 \times 10^{-6}\ m^3$$

$$\tau = \frac{3.2 \times 10^{-6} \times 147.15}{85.33 \times 10^{-9} \times 0.016} + \frac{147.15}{640 \times 10^{-6}} = 0.573\ MPa$$

With a safety factor of 3 it was 1.72 MPa.

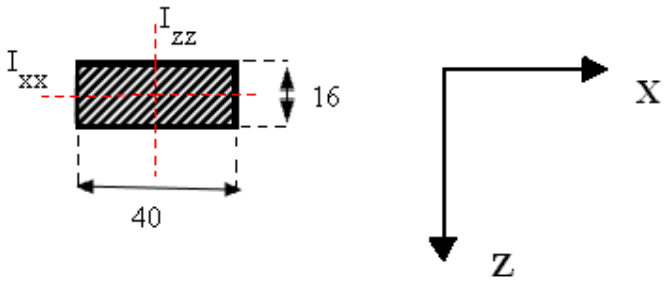

Figure A.1.18: The cross section area of the lateral bar of the TLSO

A.1.9.2 Analysis of the Stress in the Screws Used to Attach the Lateral Bar to the TORSO

The forces and moments applied on the screws were as follows.

$F_{x11} = F_{x10} = 147.15$ N
$F_{y11} = F_{y10} = 854.88$ N
$F_{z11} = F_{z10} = 134.17$ N
$M_{z11} = M_{z10} = 138.23$ Nm
$M_{x11} = M_{x10} = 117.94$ Nm

These moments produced some forces in the screws. According to the free body diagram of the screws, as is shown in figure A.1.19, the forces which were developed as a result of these moments could be determined as follows.

$M_{z11} = 138.23$ Nm, $r_1 = 0.018$ m

$$F_{11} = \frac{M_{z11}}{4 \times r_1} = \frac{138.23}{4 \times 0.018}$$

$F_{11} = 1919.86$ N

$M_{x11} = 117.95$ Nm, $r_2 = .015$ m

$$F_{z11} = \frac{M_{x11}}{4 \times r_2} = \frac{117.94}{4 \times 0.015}$$

$F_{z11} = 1965.8$ N

Which r_1 and r_2 are the distance between the centre of screws and the centroid points, as are shown in figure A.1.19. The total forces applied on the screws could be resulted as follows.

Screw 1:

$$F_{xs1} = \frac{-147.15}{4} - F_{11}\sin 56.3 = -1634.25 \text{ N}$$

$$F_{ys1} = \frac{854.88}{4} + F_{11}\cos 56.3 = 1278.94 \text{ N}$$

$$F_{zs1} = \frac{134.17}{4} - 1965.8 = -1932.25 \text{ N}$$

Which F_{xs1} and F_{ys1} were shear forces and F_{zs1} was a compression force. The angle between the force applied on the screws (F_{11}) and the vertical axis was 56.3 degrees. The resultant shear force applied on this screw was 2017.7 N.

Screw 2:

$$F_{xs2} = 36.75 + F_{11}\sin 56.3 = 1634.25 \text{ N}$$

$$F_{ys2} = 213.72 - F_{11}\cos 56.3 = -851.8 \text{ N}$$

$$F_{zs2} = \frac{134.17}{4} - 1965.8 = 1932.25 \text{ N}$$

Which F_{xs2} and F_{ys2} were shear forces and F_{zs2} was a compression force. The resultant shear force applied on this screw was 1842.9 N.

Screw 3:

$$F_{xs3} = -36.75 + F_{11}\sin 56.3 = 1560.57 \text{ N}$$
$$F_{ys3} = 213.72 - F_{11}\cos 56.3 = -851.8 \text{ N}$$
$$F_{zs3} = \frac{134.17}{4} + 1965.8 = 1999.34 \text{ N}$$

Which F_{xs3} and F_{ys3} were shear forces and F_{zs3} was a tensile force. The resultant shear force applied on this screw was 1777.9 N.

Screw 4:

$$F_{xs4} = -36.75 + F_{11}\sin 56.3 = 1560.57 \text{ N}$$
$$F_{ys4} = 213.72 + F_{11}\cos 56.3 = 1278.94 \text{ N}$$
$$F_{zs4} = \frac{134.17}{4} + 1965.8 = 1999.34 \text{ N}$$

Which F_{xs4} and F_{ys4} were shear forces and F_{zs4} was a tensile force. The resultant shear force applied on this screw was 2017.7 N.

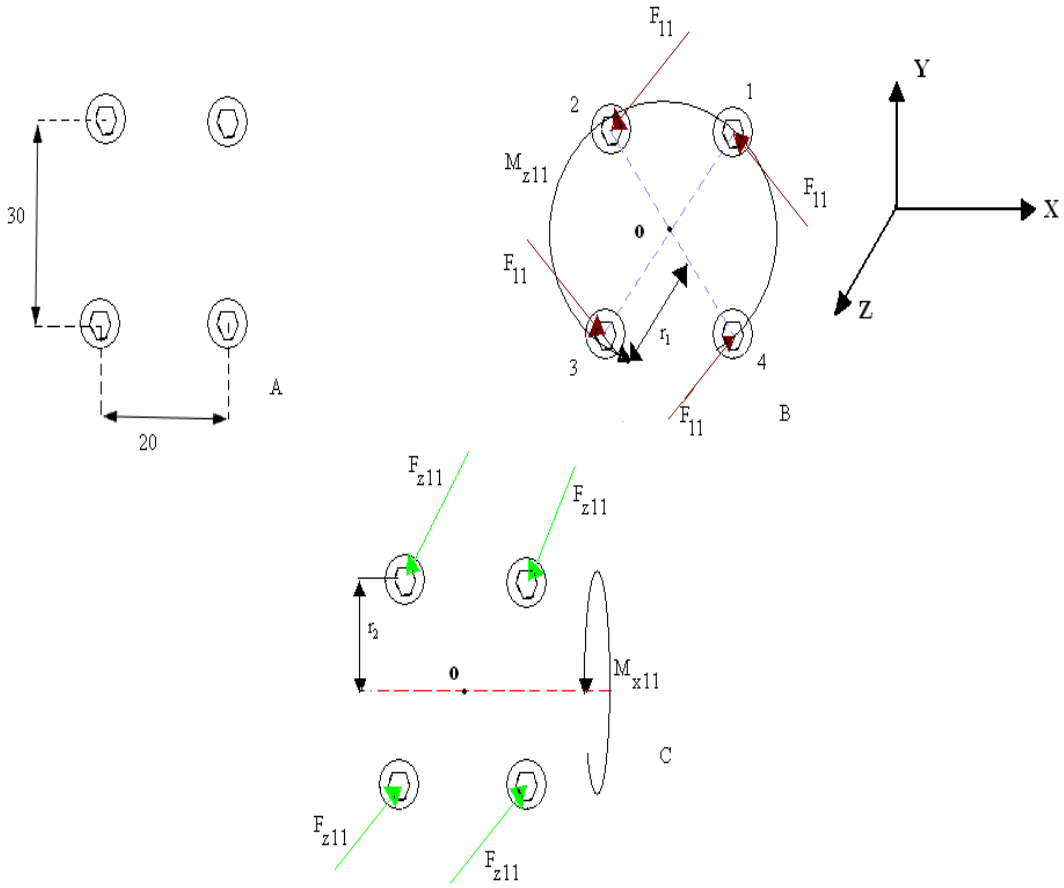

Figure A.1.19: The free body diagram of the lateral bar screws, A shows the arrangement of the screws, B shows the forces applied on the screws as a result of applying a flexing moment, and C shows the force developed as a results of using an adducting moment

The stress in the screws could be determined as follows.

Screw 1:

$$\sigma_{s1} = \frac{1932.25}{20.1 \times 10^{-6}} = 96.13 \text{ MPa}$$

$$\tau_{s1} = \frac{2017.7}{20.1 \times 10^{-6}} = 100.38 \text{ MPa}$$

With a safety factor of 3, the maximum shear and bending stress in the first screw were 301.14 and 288.39 MPa, respectively.

Screw 2:

$$\sigma_{s2} = \frac{1932.25}{20.1 \times 10^{-6}} = 96.13 \text{ MPa}$$
$$\tau_{s2} = \frac{1842.9}{20.1 \times 10^{-6}} = 91.68 \text{ MPa}$$

With a safety factor of 3, the maximum shear and bending stress in the second screw were 275.04 and 288.39 MPa, respectively.

Screw 3:

$$\sigma_{s3} = \frac{1999.34}{20.1 \times 10^{-6}} = 99.46 \text{ MPa}$$
$$\tau_{s3} = \frac{1777.9}{20.1 \times 10^{-6}} = 88.45 \text{ MPa}$$

With a safety factor of 3, the maximum shear and bending stress in the third screw were 265.35 and 298.38 MPa, respectively.

Screw 4:

$$\sigma_{s4} = \frac{1999.34}{20.1 \times 10^{-6}} = 99.46 \text{ MPa}$$
$$\tau_{s4} = \frac{2017.7}{20.1 \times 10^{-6}} = 100.38 \text{ MPa}$$

With a safety factor of 3, the maximum shear and bending stress in the fourth screw were 301.14 and 298.38 MPa, respectively.

APPENDIX 2: COPY OF EHICAL APPROVAL APPLICATION

A.2.1: APPLICATION FORM TO UNIVERSITY ETHICS COMMITTEE AND DEPARTMENTAL ETHICS COMMITTEES

This form applies to all investigations within the remit of the University's Code of Practice on Investigations on Human Beings. This includes all investigations with human participants undertaken by staff or students of the University of Strathclyde which falls within the remit of the University Ethics Committee (see Code of Practice, para 5.1) or the Departmental Ethics Committees (see Code of Practice, para 5.2). However, this form should NOT be used for any investigation involving clinical trials (see Code of Practice, para 6.4) or medicinal products, nor for investigations involving staff, patients, facilities, data, tissue, blood or organ samples from the National Health Service. Applications for ethical approval for investigations involving the National Health Service in any way must be made under the governance arrangements for National Health Service Research Ethics Committees (see Code of Practice, para 3.2(d)) and where ethical approval is required from the NHS using the form issued by COREC (see Code of Practice, para 6.1). Information sheets for volunteers and consent forms to be used in this study should be submitted with the application form for consideration by the Committee.

The application will be judged entirely on the information provided in this form and any accompanying documentation - full grant proposals to funding bodies should not be attached. Please explain any abbreviations, acronyms etc that you use. The Code of Practice (http://www.mis.strath.ac.uk/Secretariat/Ethics.htm) contains guidance on completing this application, on information sheets and on consent forms.

Applications which are not signed and/or do not include the required additional forms (e.g. participant information sheet and consent form) will not be considered by the University Ethics Committee and will be referred back to the Chief Investigator. The form is designed for completion in Word, and should in any case be typed rather than handwritten. The grey-shaded text boxes on the form will expand to allow you to enter as much information as you require. If you have difficulty filling out the form in Word, please contact Fiona Campbell in the Secretariat (ext. 2101).

Document	Enclosed	N/A
Participant information sheet(s)	*	
Consent form(s)	*	
Sample questionnaire(s)		
Sample interview format(s)		
Sample advertisement(s)		
Any other documents (please specify below)		

Table1: Checklist of enclosed documents

1. Chief Investigator (for the purposes of this application, this should always be the person responsible for the study at Strathclyde)

Name: Mr William Spence

Status (e.g. professor, senior lecturer): Lecturer

Department: Bioengineering

Contact details: Telephone: ++44 (0) 141 548 3027/6/5

E-mail: w.d.spence@strath.ac.uk

2. Other Strathclyde Investigator(s)

Name(s): Mohammad Taghi Karimi

Status (e.g. lecturer, post-/undergraduate): PhD student.

Department(s): Bioengineering

If student(s), name of supervisor: Mr William Spence

Contact details: Telephone: ++44 (0)141 548 3027/6/5

E-mail: w.d.spence@strath.ac.uk

Please provide details for all investigators involved in the study (*the text box below will expand to allow details to be entered*):

Name: Professor Alexander Nicol

Status: Professor

Department: Bioengineering

Contact details: Telephone: +44 (0)141 548 3028

E-mail: a.c.nicol@strath.ac.uk

3. Non-Strathclyde collaborating investigator(s)

Name(s):

Status:

Department/Institution:

If student(s), name of supervisor:

Contact details: Telephone:

E-mail:

Please provide details for all investigators involved in the study (*the text box below will expand to allow details to be entered*):

4. Title of the investigation:

A pilot study to quantify the impact of a new Reciprocal Gait Orthosis on the functional performance of subjects during walking

5. Where will the investigation be conducted? (Note that the Committee reserves the right to visit testing sites and facilities)

Gait analysis laboratory of the Bioengineering Unit of Strathclyde University

6. Duration of the investigation (years/months)

(Expected) start date: 3 years from September 2007

(Expected) completion date: September 2010

7. Sponsor

University of Strathclyde

8. Funding body (if applicable)

Status of proposal – if seeking funding (Please cross as appropriate):

i) In preparation

ii) Submitted

iii) Proposal accepted by funding body

Date of submission of proposal:

Date of commencement of funding:

9. Objectives of investigation

Brief outline of the background, purpose and possible benefits of the investigation.

Spinal cord injury (SCI) patients often undergo different rehabilitation programs for walking and exercises. It is accepted that walking is a good exercise for paraplegics in order to maintain good health (Moore and Stallard 1991; Ogilvie, et al. 1993; Major, et al. 1997; Stallard and Major 1998); urinary tract infections decrease (Douglas, et al.1983); cardiovascular and digestive functions improve and psycological health improves (Thoumie, et al. 1995).

Several types of orthosis have been designed to enable SCI patients to walk, however they are not without problems which include: independent donning and doffing is difficult (Stallard and Major 1998), transporting the orthosis from place to place is difficult, walking speed is reduced compared with 'normal' subjects, cosmesis is poor and the style of walking is abnormal (Ragnarsson, et al. 1975).

This project aims to design an orthosis which will overcome some of the aforementioned problems. Specifically the design will allow for easy, independent, donning and doffing by the user; it will allow alignment of the various segments while the user is wearing the orthosis; the modularity of the orthosis will allow for easy transportation.

Before attempting to fit SCI patients with this device this particular study is aimed at establishing: the ease of donning and doffing, the ease of performing alignment changes and establishing the quality of gait achieved by able bodied subjects whilst wearing the device. The logic for this is that a benchmark will be established for an able bodied subject to walk with the device which will be the best that an SCI subject could hope to achieve whilst wearing the orthosis. The benefit of this study is that it will provide the benchmark as described above.

10. Nature of the participants:

Number:

Three able bodied subjects will be recruited

Age (range): 20 to 60

Gender of volunteers: male

Recruitment method(s):

The able bodied subjects will be recruited from the student/ staff body of the Bioengineering Unit, University of Strathclyde.

Inclusion/exclusion criteria (if appropriate)

The subjects should all be able bodied.

Screening procedure (if appropriate)

Any special skills, attributes, medical conditions:

Any vulnerable participants (see Code of Practice, section 5.1(ii) and annex 2)

Justifications for sample size (e.g. power calculations)

Three subjects are deemed sufficient to enable the pilot study to be completed.

Will data be anonymised and destroyed after use? If not, please give reasons.

Yes.

11. What consents will be sought and how?

(Consent forms and participator information sheets (and questionnaires where used) must be appended to this application.

Informed consent will be sought, based on a form and information sheet.

Appendix 1: Form of consent for volunteers in a research project

Appendix 2: Information sheet for volunteers in a research project

12. Methodology

Design: what kind of design is to be used in the investigation (e.g. interview, experimental, observation, randomized control trial, etc.)?

The experimental work carried out will involve the use of a number of pieces of equipment. Those will be used together and in isolation. A motion analyzer (Vicon & camera system) will be used to monitor the location of the subject within the Biomechanics laboratory of the Bioengineering Unit. The forces between the subjects and the ground will be measured using a force platform (Kistler). A heart rate monitor will record pulse rate (Polar).

Techniques: what methods will be employed and what exactly is required of participants?

For motion analysis:

Light reflective markers will be attached to anatomical landmarks on the subject, using double sided tape or contoured plates will be strapped onto the subjects limbs. Subject motion will be monitored in the laboratory using infra red and visible light cameras. The subject will walk normally at a comfortable pace across the gait laboratory, passing over the force platform. Software will be used to record the ground reaction force and the subject's motion.

The heart rate monitor is a commercially available, light weight, device worn by the subject, akin to a wrist watch.

Reference should be made to any of the following to be used in the investigation (see Code of Practice, section 5.1):

Invasive techniques

DNA testing

Administration of drugs, foods, liquids, additives, other substances

Any deception

Physical exertion/exercise*

Manipulation of cognitive or affective human responses, possibly causing stress/anxiety

Highly personal, intimate and/or confidential information being sought

Acquisition of bodily fluids or tissue

Access to confidential data (e.g. medical reports)

Description of the use of any of the above:

The duration of the study for participants and frequency of testing (if repeat testing is necessary.

The duration of involvement for each participant will be four months during which time they will undergo the test regime eight times. Each test regime will last no more than 2 hours most of which will involve the participant sitting down or resting between walking exercises.

13. Potential risks or hazards

1) Adverse effect of adhesive tape

2) Discomfort from wearing the orthosis

5) Slight risk of falling

Procedures to minimize risk caused by hazards:

1) If subjects have an adverse reaction to the adhesive tape the testing will be stopped and all equipment will removed from the subjects, skin will be cleaned and the skin reaction monitored.

2) All attempts will be made during the fitting of the orthosis to ensure that the device is as comfortable to wear as is practicable. The orthosis will be worn for maximum duration of 2 hours during which time skin condition will be monitored by visual inspection and by asking the subjects to describe any discomfort. Before testing commences the fit of orthosis will have been optimized for the individual subject to ensure that potential damage to the subject is minimized.

3) The subject will be provided with elbow crutches and will be guided/accompanied by two trained members of the research team.

4) Electrical equipment is subject to annual departmental safety checks. All equipment will have been checked for electrical safety before use.

5) Subjects will be instructed on how to perform the activities and will be allowed to familiarize themselves with the environment in which the testing will occur.

14. Ethical issues

What do you consider to be the main ethical issues which may arise during the investigation, and how do you propose to address them (please refer in particular to Code of Practice, section 5.1).

The main ethical issues are physical exertion and the use of an orthosis with able bodied subjects. The subjects will be fully informed of the purpose of testing which is establishing walking capabilities in able bodied subjects in order that subsequent data from SCI subjects may be compared.

15. Any payment to be made

Include reference to reimbursements for time or expenses incurred, plus any additional fee/incentive for participation.

Their expenses will be reimbursed.

16. What debriefing, if any, will be given to volunteers?

Volunteers will be informed of the result of the tests.

17. What are the expected outcomes of the investigation? How will these be disseminated? Will you seek to publish the results?

The results will be published in the appropriate journals.

How long will data (incl. e.g. photographs) be kept, and how will it be stored?

Data will be stored electronically until September 2010.

18. Nominated person (and contact details) to whom participants' concerns/questions should be directed before, during or after the investigation (in the case of student projects, both the supervisor (Ord 16 staff member) and the student should be named); in all cases a member of University staff should be named.

Mr William Spence, Lecturer, Bioengineering Unit, Wolfson Centre.

Contact details: Telephone: ++44 (0) 141 548 3027/6/5

E-mail: w.d.spence@strath.ac.uk

Professor Alexander Nicol, Professor, Bioengineering Unit, Wolfson Centre

Contact details: Telephone: ++44 (0) 141 548 3028 (EXT. 3028)

E-mail: a.c.nicol@strath.ac.uk

Mr Mohammad Taghi Karimi, PhD student, Bioengineering Unit, Wolfson Centre

Contact details: Telephone: ++44 07912893136

E-mail: mohammad.karimi@strath.ac.uk

19. Previous experience of the investigator(s) with the procedures involved

Mr. William Spence, 30 years experience of prosthetic and orthotic patient handling, device design, manufacture, fitting and testing of subjects.

20. Generic approval

If approval is sought for several separate investigations, or a series of investigations, all employing the same basic methodology and serving the same overall objective, then generic approval can be sought for a 3-year period. Give, on a separate sheet, further details about additional studies to be covered by this approval application, using the relevant headings (1-17 above), and drawing attention to any variations in methodology, participants, risks, etc. Student projects can also be submitted via Generic approval – see Code of Practice on Investigations on Human Beings, Section 6.3.

21. Sponsorship

This application requires the University to sponsor the investigation. I am aware of the implications of University sponsorship of the investigation and have assessed this investigation with respect to sponsorship and management risk. As this particular investigation is within the remit of the DEC and has no external funding and no NHS involvement, I agree on behalf of the University that the University is the appropriate sponsor of the investigation and there are no management risks posed by the investigation.

If not applicable, cross here

Signature of Head of Department. Please also print name below

Professor Alexander Nicol

Date:12/10/2007

22. Declaration

I have read the University's Code of Practice on Investigations on Human Beings and have completed this application accordingly.

Signature of Chief Investigator. Please also print name below

William Spence

Signature of Head of Department. Please also print name below

Professor Alexander Nicol

Date:12/10/2010

* *

Notes:

1. If there is any variation to any aspect of the investigation (location, investigators, methodology, risks, etc.) then the Secretary to the Ethics Committee should be notified in writing immediately.

2. Should anything occur during the project which may prompt ethical questions for any similar projects the Chief Investigator should notify the Ethics Committee.

3. Insurance and other approval requirements from appropriate external bodies must also be in place **before** the project can commence.

* *

For applications to the University Ethics Committee this completed form should be sent (electronically, with signed hard copy to follow) to Research and Innovation in the first instance.

A.2.2 FORM OF CONSENT FOR VOLUNTEERS IN A RESEARCH PROJECT

Title of Project:

A pilot study to quantify the impact of a new Reciprocal Gait Orthosis on the functional performance of subjects during walking.

Name of researcher: Mohammad Karimi

1. I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
3. I agree that the data resulting from my participation in this study may be stored in digital format, without my identity being revealed, and may be used in scientific publications.
4. I agree that photographic and video images may be stored in a digital format, without my identity being revealed.
5. I agree to take part in the above study.

Name of participant: Date: Signature:

Name of person taking consent Date: Signature:

1 copy for participant and 1 copy for researcher's file.

Contact details:

Name: Mr. William Spence

Telephone: ++44 (0) 141 548 3027/6/5

E-mail address: w.d.spence@strath.ac.uk

Mr Mohammad Karimi

Research student

Bioengineering Unit

As above.

A.2.3. INFORMATION SHEET FOR VOLUNTEERS IN A RESEARCH PROJECT

Title of Project:

A pilot study to quantify the impact of a new Reciprocal Gait Orthosis on the functional performance of subjects during walking.

Invitation:

We would like to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about study if you wish.

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 to take part.

Purpose of the study:

This study is to observe the amount of functional performance of normal, able bodied people during walking whilst wearing a new type of orthosis (brace/caliper) which will encompass the legs. This orthosis is classified as a Hip Knee Ankle Foot Orthosis (HKAFO) which allows reciprocating gait to be achieved by the wearer. It consists of tow plastic sections which are fitted to the feet and shanks, knee joints connect the shank sections via aluminum bars to hip joints which in turn are connected to section made from aluminum and plastic which encompasses the pelvis. The data acquired from this study will be compared with data acquired from paraplegic subjects in a later study.

Participants:

It is not compulsory that you take part. It is up to you to decide. We will describe the study and go through this information sheet, which we will give to you. We will then ask you to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

Procedure:

You will be asked to attend for a maximum of 8 sessions, spending a maximum of 2 hours each time at the Biomechanics Laboratory of the Bioengineering Unit, University of Strathclyde. You will be fitted with a new type of orthosis which you will wear and walk with in the Biomechanics laboratory. A variety of small light reflective markers and other lightweight devices will be attached to your body whilst you perform walking activities on a flat level surface.

You will have training for 4 sessions and then take part in the test procedure. You will be asked to walk at a comfortable speed across Biomechanics Laboratory of the Bioengineering Unit. Your movement will be tracked by a motion capture system with only sees the light reflective markers and the amount of load that you impart to the floor will be measured using rigid platforms built into the floor. Your heart rate will also be monitored during both resting and walking using a simple device which consists of a wristwatch and an expandable strap around your chest.

There should be minimal if any discomfort or irritation involved with these testing procedures. You will not be asked to do any activities that are uncomfortable or too difficult. You may withdraw from the study at any time before or during the testing, without having to provide a reason.

All of your personal and experimental information will be kept anonymous to all except the investigators directly involved in the project.

The results of this testing may be submitted for publication so that others can use the information. The data that are used will not allow identification of participants. Any use of images of participants will be edited to ensure identification is not possible.

Expenses:

No fees are payable for your participation in this study, however reasonable travel costs will be reimbursed if appropriate.

Risks:

The risks associated with this study are minor and regarded as low. Some minimal discomfort may be experienced from wearing the orthosis as this is not a normal device for you to use. We will endeavor to minimize discomfort during fitting of the device. Whilst it may be a strange thing to wear it should not cause any level of distress other than some interface with your normal walking pattern. There is a possibility of a reaction to the double sided adhesive tape used to adhere the markers to your skin. Should this occur, the tape will be removed immediately and the skin cleaned.

Again, whilst this is an unusual device for you to walk in there is a risk of falling, however you are also provided with a pair of elbow crutches and the purpose of the training sessions is to allow you to become familiar with the constraints/operation of the device. During all sessions you will be carefully guided and monitored by two trained members of the research team.

Benefits of participation:

There are no benefits to you of taking part in this study but the information we get will help to improve the treatment of people who have had a spinal cord injury.

What if there is a problem?

Any compliant about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. Please see contact details at the end of this information document.

What will happen if I don't want to carry on with the study?

You may withdraw from the study without giving a reason. Any data that has been obtained as a result of your participation will be retained but you will not be identified.

Complaints:

If you have a concern about any aspect of this study, you should ask to speak to the researchers (details at the end of the document) who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting:

Professor A C Nicol

Head of Department

Bioengineering Unit

University of Strathclyde

Wolfson Centre

106 Rottenrow

Glasgow

G4 0NW

Use of the results of the study:

The results from this study will be compared to results obtained from a study of paraplegic subjects which will be conducted at a later date. There is a possibility that the results will be published in scientific publications and at scientific meeting. Your identity will not be revealed to anyone out with the research team.

Data storage:

The data obtained from this study will be stored as digital media on a computer and on digital storage media. These data will be identified by a code known only to the researchers.

Contact details:

Name: Mr. William Spence

Telephone: ++44 (0) 141 548 3027/6/5

E-mail address: w.d.spence@strath.ac.uk

Mr Mohammad Karimi

Research student

Bioengineering Unit

As above.

APPENDIX 3: BODYBUILDER CODE

```
{*Start of macro section*}
{*======================*}

macro LINVELACC(Point, Segment)
{*When called, this macro calculates the linear velocity in m/s
and the linear acceleration in m/s^2 of a point, using numerical
differentiation.  For numerical differentiation, reference one
of the following:
Hildebrand, F.B. (1974).  Introduction to Numerical Analysis,
2nd Edition, pp.111
Kreyszig, Erwin (1983).  Advanced Engineering Mathematics, 5th
Edition, pp.793
Yakowitz, Sydney and Szidarovsky, Ferenc (1989).  An
Introduction to Numerical Computations, 2nd Edition, pp.185*}

$Sampling Rate= 120
$Frame Time Length=1/$ Sampling Rate
LVel#Point= ((Point [-2]-(8*Point [-1]) + (8*Point [1])-Point
[2])/ (12*$FrameTimeLength))/1000
LAccel#Point= ((LVel#Point [-2]-(8*LVel#Point [-1]) +
(8*LVel#Point [1])-LVel#Point [2])/ (12*$FrameTimeLength))

{*%LVel#Point=LVel#Point/Segment
%LAccel#Point=LAccel#Point/Segment*}
Output (LVel#Point,LAccel#Point)
param($FrameTimeLength)

endmacro
macro SUBSTITUTE4(p1,p2,p3,p4)
{*Replaces any point missing from set of four fixed in a
segment*}
s234 = [p3, p2-p3, p3-p4]
p1V = Average (p1/s234)*s234
s341 = [p4, p3-p4, p4-p1]
p2V = Average (p2/s341)*s341
s412 = [p1, p4-p1, p1-p2]
p3V = Average (p3/s412)*s412
s123 = [p2, p1-p2, p2-p3]
p4V = Average (p4/s123)*s123

p1 = p1? p1V
p2 = p2? p2V
p3 = p3? p3V
p4 = p4? p4V
endmacro


macro POINTER(Anatomy, Segment)
{*Calculates the position of the end of the pointer for
calibration in the technical frame it belongs to*}
{*1st determine the "point" in the Global system and outputs it
as point#Calib. Then converts the point into*}
```

```
{*the appropriate technical reference frame and stores it as
parameter $%#point#Calib*}

Unit Pointer= ((Pointer1-Pointer2)/DIST (Pointer1, Pointer2))
Anatomy#Calib=Pointer1+123*unit Pointer
OUTPUT (Anatomy#Calib)
PARAM (Anatomy#Calib)
%#Anatomy#Calib=Anatomy#Calib/Segment
PARAM (%#Anatomy#Calib)
end macro

Macro DYNPOINTER (AnatPoint,Segment)
AnatPoint=%#AnatPoint#Calib*Segment
OUTPUT (AnatPoint)
PARAM (AnatPoint)
EndMacro

macro SEGVIS(Segment)
{*outputs a visual representaion of the segment to be viewed in
the Workspace*}
{*0(Segment) is the origin of the segment*}
ORIGIN#Segment=0(Segment)
XAXIS#Segment=0(Segment) + (1(Segment)*100)
YAXIS#Segment=0(Segment) + (2(Segment)*100)
ZAXIS#Segment=0(Segment) + (3(Segment)*100)
OUTPUT
(ORIGIN#Segment,XAXIS#Segment,YAXIS#Segment,ZAXIS#Segment)
endmacro

macro ColeJCS(seg1,seg2,joint)
{* Procedure to calculate the rotations about defined embedded
axes using the joint
Co-ordinate system.

References: Cole,G.K. et al (1993).  Application of the Joint Co-
ordinate System to Three-dimensional Joint Attitude and Movement
Representation: A Standardization Proposal.  Journal of
Biomechanical Engineering. November 1993: Vol 115: pp 344-349

aEone,aEtwo,aEthree =unit vector describing the attitude of the
1st,2nd and 3rd axis of the joint co-ordinate system between the
reference segment (seg1) and the target segment(seg2), relative
to an inertial reference system.

If the axes of a body segment co-ordinate system are identified
as an axis of Flexion, a longitudinal axis and a Third axis,
then Fone, Lone, Tone are unit vectors that describe the
attitude of the Flexion, Longitudinal and Third axes
respectively, in an inertial reference system.

Input:     'seg1', 'seg2' describing the axes of the co-ordinate
systems embedded in each segment.
      Fone, Lone, Tone describe the flexion, longitudinal and
third co-ordinate axes of the proximal segment.
      Ftwo, Ltwo, Ttwo describe the flexion, longitudinal and
third co-ordinate axes of the distal segment.
```

```
     'Joint' is the name given to the joint at which the
specified segments interact.

Output:    Angles of rotation about axes aEone,aEtwo,aEthree,
flexion, abduction and rotation respectively. Counterclockwise
rotations are chosen as positive*}

Fone=3(seg1)
Lone=2(seg1)
Tone=1(seg1)
Ftwo=3(seg2)
Ltwo=2(seg2)
Ttwo=1(seg2)


{*Defines e1 and e3*}
aEone=Fone
aEthree=Ltwo

{*Calculate the Vector or Cross Product between the Vectors*}
Va= {2(aEthree)*3(aEone)-3(aEthree)*2(aEone),
3(aEthree)*1(aEone)-1(aEthree)*3(aEone), 1(aEthree)*2(aEone)-
2(aEthree)*1(aEone)}
Vb=DIST ({2(aEone)*3(aEthree)-3(aEone)*2(aEthree),
3(aEone)*1(aEthree)-1(aEone)*3(aEthree), 1(aEone)*2(aEthree)-
2(aEone)*1(aEthree)}, {0, 0, 0})
Vc={2(Va)*3(aEthree)-3(Va)*2(aEthree),3(Va)*1(aEthree)-
1(Va)*3(aEthree),1(Va)*2(aEthree)-2(Va)*1(aEthree)}

{*Calculate the Scalar or Dot Product between the Vectors*}
DPone= (1(Va)*1(Ttwo)) + (2(Va)*2(Ttwo)) + (3(Va)*3(Ttwo))
DPtwo= (1(Vc)*1(Ftwo)) + (2(Vc)*2(Ftwo)) + (3(Vc)*3(Ftwo))

{*Calculates A (AA) and then e2*}
IF DPone < 0 AND DPtwo > 0 THEN AA=-1 ELSE AA=1 ENDIF
aEtwo=(Va/Vb)*AA

{*Calculate the value of r.*}
Rone= {2(Fone)*3(aEtwo)-3(Fone)*2(aEtwo), 3(Fone)*1(aEtwo)-
1(Fone)*3(aEtwo), 1(Fone)*2(aEtwo)-2(Fone)*1(aEtwo)}
Rtwo=DIST (Rone, {0, 0, 0})
r=Rone/Rtwo

{*Calculate the Scalar or Dot Product between the Vectors.*}
aEtwoTonedp=(1(aEtwo)*1(Tone))+(2(aEtwo)*2(Tone))+(3(aEtwo)*3(To
ne))
aEtwoLonedp=(1(aEtwo)*1(Lone))+(2(aEtwo)*2(Lone))+(3(aEtwo)*3(Lo
ne))
rLtwodp=(1(r)*1(Ltwo))+(2(r)*2(Ltwo))+(3(r)*3(Ltwo))
FoneLtwodp=(1(Fone)*1(Ltwo))+(2(Fone)*2(Ltwo))+(3(Fone)*3(Ltwo))
aEtwoTtwodp=(1(aEtwo)*1(Ttwo))+(2(aEtwo)*2(Ttwo))+(3(aEtwo)*3(Tt
wo))
aEtwoFtwodp=(1(aEtwo)*1(Ftwo))+(2(aEtwo)*2(Ftwo))+(3(aEtwo)*3(Ft
wo))

IF aEtwoLonedp >= 0 THEN aEtwoLonesign=1 ENDIF
```

```
IF aEtwoLonedp < 0 THEN aEtwoLonesign=-1 ENDIF
IF FoneLtwodp >= 0 THEN FoneLtwosign=1 ENDIF
IF FoneLtwodp < 0 THEN FoneLtwosign=-1 ENDIF
IF aEtwoFtwodp >= 0 THEN aEtwoFtwosign=1 ENDIF
IF aEtwoFtwodp < 0 THEN aEtwoFtwosign=-1 ENDIF

joint#Flex=(acos(aEtwoTonedp))*(aEtwoLonesign)
joint#Abd=(acos(rLtwodp))*(FoneLtwosign)
joint#Rot=(acos(aEtwoTtwodp))*(aEtwoFtwosign)
joint#angles=<joint#Flex,joint#Abd,joint#Rot>

OUTPUT (joint#angles)

joint#JCS=[joint,aEtwo,aEone,xyz]

ORIGIN#joint#jcs=0(joint#jcs)
XAXIS#joint#jcs=0(joint#jcs) + (1(joint#jcs)*100)
YAXIS#joint#jcs=0(joint#jcs) + (2(joint#jcs)*100)
ZAXIS#joint#jcs=0(joint#jcs) + (3(joint#jcs)*100)
OUTPUT
(ORIGIN#joint#jcs,XAXIS#joint#jcs,YAXIS#joint#jcs,ZAXIS#joint#jc
s)

ENDMACRO

macro FORCEVECTOR(FP)
{*This defines the quantities of force (F), moment (M) and
Centre(C) from the reaction (FP)*}
{*P_#FP is the centre of pressure and is set at the forceplate
centre if load is below 10N*}

If ExistAtAll( FP )
      F_#FP = FP(1)
      M_#FP = FP(2)
      C_#FP = FP(3)
      if ( ABS ( F_#FP ) > 10 )
            P_#FP = C_#FP + {-M_#FP(2)/F_#FP(3),
M_#FP(1)/F_#FP(3), -C_#FP(3) }
      else
            P_#FP = C_#FP
      endif
      F_#FP = F_#FP + P_#FP
      OUTPUT ( P_#FP, F_#FP )
EndIf
endmacro


{*Macro for Dot Product*}

MACRO DotProduct (One,Two,DotProd)
      DotProd = (1(One)*1(Two)+2(One)*2(Two)+3(One)*3(Two))
ENDMACRO

{* Macro to do a cross product *}

MACRO CrossProduct (First, Second, Result)
```

```
      Result = {First (2)*Second (3)-First (3)*Second (2),
      First (3)*Second (1)-First (1)*Second (3),
      First (1)*Second (2)-First (2)*Second (1)}

ENDMACRO

macro LINVELACC(Point,Segment)
{*When called, this macro calculates the linear velocity in m/s
and the linear acceleration in m/s^2 of appoint, using numerical
differentiation.  For numerical differentiation, reference one
of the following:
Hildebrand, F.B. (1974).  Introduction to Numerical Analysis,
2nd Edition, pp.111
Kreyszig, Erwin (1983).  Advanced Engineering Mathematics, 5th
Edition, pp.793
Yakowitz, Sydney and Szidarovsky, Ferenc (1989).  An
Introduction to Numerical Computations, 2nd Edition, pp.185*}

$SamplingRate= 120
$FrameTimeLength=1/$SamplingRate
LVel#Point=((Point[-2]-(8*Point[-1])+(8*Point[1])-
Point[2])/(12*$FrameTimeLength))/1000
LAccel#Point=((LVel#Point[-2]-(8*LVel#Point[-
1])+(8*LVel#Point[1])-LVel#Point[2])/(12*$FrameTimeLength))

{*%LVel#Point=LVel#Point/Segment
%LAccel#Point=LAccel#Point/Segment*}
output(LVel#Point,LAccel#Point)
param($FrameTimeLength)

endmacro

macro ANGVELACC(child,parent,Joint)
{*When called, this macro calculates the angular velocity in
rad/s and the angular acceleration in rad/s^2 at a joint, using
numerical differentiation.  For numerical differentiation,
reference one of the following:
Hildebrand, F.B. (1974).  Introduction to Numerical Analysis,
2nd Edition, pp.111
Kreyszig, Erwin (1983).  Advanced Engineering Mathematics, 5th
Edition, pp.793
Yakowitz, Sydney and Szidarovsky, Ferenc (1989).  An
Introduction to Numerical Computations, 2nd Edition, pp.185*}

$SamplingRate= 120
$FrameTimeLength=1/$SamplingRate
Pi=3.1415927
Joint#Angle= joint#angles
Joint= {Joint#Angle (1),Joint#Angle(2),Joint#Angle(3)}
Rad#Joint=Joint*pi/180
AVel#Joint=((Rad#Joint[-2]-(8*Rad#Joint[-1])+(8*Rad#Joint[1])-
Rad#Joint[2])/(12*$FrameTimeLength))
AAccel#Joint=((AVel#Joint[-2]-(8*AVel#Joint[-
1])+(8*AVel#Joint[1])-AVel#Joint[2])/(12*$FrameTimeLength))

output(AVel#Joint,AAccel#Joint)
```

```
param($FrameTimeLength)
endmacro


{*End of macro section*}
{* Anthropometric Data: From DA Winter, Biomechanics and Motor
Control of Human Movement *}

AnthropometricData
DefaultPelvis 0.142 0.865 0.5 0.3
DefaultFemur 0.1 0.567 0.323 0
DefaultTibia 0.0465 0.567 0.302 0
DefaultFoot 0.0195 0.5 0.475 0
EndAnthropometricData

{*Optional points are points which may not be present in every
trial*}

OptionalPoints(Pointer1,Pointer2)
OptionalPoints(RASIS,LASIS,RPSIS,LPSIS,PELF)
OptionalPoints(RTH1,RTH2,RTH3,RTH4)
OptionalPoints(LTH1,LTH2,LTH3,LTH4)
OptionalPoints(RSH1,RSH2,RSH3,RSH4)
OptionalPoints(LSH1,LSH2,LSH3,LSH4)
OptionalPoints(RMET1,RMET5,RHEEL,LMET1,LMET5,LHEEL)
OptionalPoints(RHJC,LHJC,RKJC,LKJC,RAJC,LAJC)
OptionalPoints(CalRLEPI,CalRMEPI,CalLLEPI,CalLMEPI)
OptionalPoints(RLMAL,RMMAL,LLMAL,LMMAL)

{*Substitutes missing markers based on clusters of 4 markers*}
SUBSTITUTE4(RASIS,LASIS,RPSIS,LPSIS)
SUBSTITUTE4(RTH1,RTH2,RTH3,RTH4)
SUBSTITUTE4(LTH1,LTH2,LTH3,LTH4)
SUBSTITUTE4(RSH1,RSH2,RSH3,RSH4)
SUBSTITUTE4(LSH1,LSH2,LSH3,LSH4)

{*Marker cluster axis definitions…..CHECK DIRECTIONS WITH
RESPECT TO MARKERS*}

RThighSeg=[RTH1,RTH1-RTH3,RTH3-RTH2,zyx]
RShinSeg=[RSH1,RSH1-RSH4,RSH2-RSH4,zxy]
LThighSeg=[LTH1,LTH1-LTH3,LTH3-LTH2,zyx]
LShinSeg=[LSH1,LSH1-LSH4,LSH2-LSH4,zxy]

{*STATIC CALIBRATIONS*}

If $Static==1

If EXIST(CalRLEPI)
Pointer (RLEPI,RThighSeg)
EndIf

If EXIST(CalRMEPI)
Pointer (RMEPI,RThighSeg)
EndIf
```

```
If EXIST(CalLLEPI)
Pointer (LLEPI,LThighSeg)
EndIf

If EXIST(CalLMEPI)
Pointer (LMEPI,LThighSeg)
EndIf

%RMMAL=RMMAL/RShinSeg
%LMMAL=LMMAL/LShinSeg
%RLMAL=RLMAL/RShinSeg
%LLMAL=LLMAL/LShinSeg

PARAM (%LMMAL,%LLMAL,%RLMAL,%RMMAL)

DISTRToes= (RMET1- RMET5)
PARAM(DISTRToes)

EndIf

{*Dynamic Trials*}

If $Static==0

{*Anatomical frame definition*}

RMMAL=%RMMAL*RShinSeg
RLMAL=%RLMAL*RShinSeg
LMMAL=%LMMAL*LShinSeg
LLMAL=%LLMAL*LShinSeg
OUTPUT (RMMAL,RLMAL,LMMAL,LLMAL)


DYNPOINTER (RLEPI, RThighSeg)

DYNPOINTER (RMEPI, RThighSeg)

DYNPOINTER (LLEPI, LThighSeg)

DYNPOINTER (LMEPI, LThighSeg)

{*Pelvis Segment…Using "Bell et al. 1990"..Hip Offset*}
{*Hip joint centre is 14%, 30% and 19% From interAsis Distance*}
{*0.36 represents 50% from the ASIS less the 14%*}

SACR=(LPSIS+RPSIS)/2
OUTPUT(SACR)
PARAM(SACR)

PELF=(LASIS+RASIS)/2
OUTPUT(PELF)
PARAM(PELF)
Pelvis=[PELF, RASIS-LASIS, SACR-PELF, zyx]
SEGVIS(Pelvis)

%RHipOffsetFactor={-0.19,-0.3,0.36}
```

```
%LHipOffsetFactor={-0.19,-0.3,-0.36}

InterASISDist=DIST(LASIS, RASIS)

RHJC= (InterASISDist*%RHipOffsetFactor)*Pelvis
LHJC= (InterASISDist*%LHipOffsetFactor)*Pelvis

OUTPUT (RHJC, LHJC)
PARAM (RHJC, LHJC)

RHipSeg=[RHJC, RASIS-LASIS, SACR-PELF, zyx]
LHipSeg=[LHJC, RASIS-LASIS, SACR-PELF, zyx]
SEGVIS(RHipSeg)
SEGVIS(LHipSeg)

{*Right Thigh Segment*}
RKJC=(RLEPI+RMEPI)/2
OUTPUT(RKJC)
PARAM(RKJC)

RFemur=[RKJC, RHJC-RKJC, RMEPI-RLEPI, yxz]
SEGVIS(RFemur)

{*Left Thigh Segment*}
LKJC=(LLEPI+LMEPI)/2
OUTPUT(LKJC)
PARAM(LKJC)
LFemur=[LKJC, LHJC-LKJC, LLEPI-LMEPI, yxz]
SEGVIS(LFemur)

{*Right Shin System*}
RAJC=(RMMAL+RLMAL)/2
OUTPUT(RAJC)
PARAM(RAJC)
RTibia=[RAJC, RKJC-RAJC, RMMAL-RLMAL, yxz]
SEGVIS(RTibia)

{*Left Shin System*}
LAJC=(LMMAL+LLMAL)/2
OUTPUT(LAJC)
PARAM(LAJC)
LTibia=[LAJC, LKJC-LAJC, LLMAL-LMMAL, yxz]
SEGVIS(LTibia)

{*Foot System*}
{*Considered to represent a shoe rather than a foot. The markers
are put on so that they lie in a plane perpendicular to the
floor in a neutral position. This can be considered as ankle
joint neutral*}

{*Right Foot System*}
RmidFOOT=(RMET1+RMET5)/2
IF EXIST(RMET5)
ELSE
      RMET5=RMET1-DISTRToes
ENDIF
```

```
RFootSeg=[RHEEL, RHEEL-RmidFOOT, RMET1-RMET5, yxz]
OUTPUT(RmidFOOT)
SEGVIS(RFootSeg)

{*Left Foot System*}
LmidFOOT=(LMET1+LMET5)/2
LFootSeg=[LHEEL, LHEEL-LmidFOOT, LMET5-LMET1, yxz]
OUTPUT(LmidFOOT)
SEGVIS(LFootSeg)


{*The joint names are given values to allow the creation of
dummy JCS*}

LHip=LHJC
RHip=RHJC
LKnee=LKJC
RKnee=RKJC
LAnkle=LAJC
RAnkle=RAJC

ColeJCS(LHipSeg,LFemur,LHip)
SEGVIS(LHipJCS)
ColeJCS(RHipSeg,RFemur,RHip)
SEGVIS(RHipJCS)
ColeJCS(LFemur,LTibia,LKnee)
SEGVIS(LKneeJCS)
ColeJCS(RFemur,RTibia,RKnee)
SEGVIS(RKneeJCS)
ColeJCS(LTibia,LFootSeg,LAnkle)
SEGVIS(LAnkleJCS)
ColeJCS(RTibia,RFootSeg,RAnkle)
SEGVIS(RAnkleJCS)

{*corrects so that flexion, adduction and internal rotation are
positive*}
{*Order of angles is flexion, add, IR*}

RHipangles=<1(RHipangles),2(RHipangles),3(RHipangles)>
LHipangles=<1(LHipangles),-2(LHipangles),-3(LHipangles)>
RKneeangles=<-1(RKneeangles),2(RKneeangles),3(RKneeangles)>
LKneeangles=<-1(LKneeangles),-2(LKneeangles),-3(LKneeangles)>
RAnkleangles=<(1(RAnkleangles)-90),2(RAnkleangles*-
1),3(RAnkleangles)>
LAnkleangles=<(1(LAnkleangles)-90),2(LAnkleangles),-
3(LAnkleangles)>

Output(RHipangles,LHipangles,LKneeangles,RKneeangles,LAnkleangle
s,RAnkleangles)


LINVELACC(SACR,Pelvis)
OUTPUT(LVelSACR,LAccelSACR)
PARAM(LVelSACR,LAccelSACR)
```

```
EndIF


{*KINETIC CALCULATIONS*}
{*====================*}



Pelvis = [Pelvis,0.142*$BodyMass,{0,0,0},{0,0,0}]
{*Hierarchy*}

RFemur=[RFemur,Pelvis,RHJC, DefaultFemur]
LFemur=[LFemur,Pelvis,LHJC, DefaultFemur]
RTibia=[RTibia,RFemur,RKJC, DefaultTibia]
LTibia=[LTibia,LFemur,LKJC, DefaultTibia]
RFootSeg=[RFootSeg,RTibia,RAJC, DefaultFoot]
LFootSeg=[LFootSeg,LTibia,LAJC, DefaultFoot]


{*Force Vectors*}
{*=============*}
OptionalReactions(ForcePlate1, ForcePlate2, ForcePlate3,
ForcePlate4)
ForceVector(ForcePlate1)
ForceVector(ForcePlate2)
ForceVector(ForcePlate3)
ForceVector(ForcePlate4)

{* Forces and Moments *}
{*====================*}

{* These moments are external moments*}
{* Not Normalised to body mass (NN)*}

{*NN=$BODYMASS*}

{*LOWER LIMB*}

RAnkleForce = 1(REACTION(RFootSeg))
RAnkleMoment = 2(REACTION(RFootSeg))
RAnkleMoment = RAnkleMoment/(1000)

RKneeForce = 1(REACTION(RTibia))
RKneeMoment = 2(REACTION(RTibia))
RKneeMoment = RKneeMoment/(1000)

RHipForce = 1 (REACTION(RFemur))
RHipMoment = 2(REACTION(RFemur))
RHipMoment = RHipMoment/(1000)

LAnkleForce = 1(REACTION(LFootSeg))
LAnkleMoment = 2(REACTION(LFootSeg))
LAnkleMoment = LAnkleMoment/(1000)

LKneeForce = 1(REACTION(LTibia))
LKneeMoment = 2(REACTION(LTibia))
```

```
LKneeMoment = LKneeMoment/(1000)

LHipForce = 1(REACTION(LFemur))
LHipMoment = 2(REACTION(LFemur))
LHipMoment = LHipMoment/(1000)

{*Corrects for inverse sign for right side of body in frontal
and transverse plane*}

RHipMoment = {1(RHipMoment), 2(RHipMoment), -3(RHipMoment)}

RKneeMoment = {1(RKneeMoment), 2(RKneeMoment), 3(RKneeMoment)}
RAnkleMoment = {1(RAnkleMoment), 2(RAnkleMoment), -
3(RAnkleMoment)}
LHipMoment = {-1(LHipMoment), -2(LHipMoment), -3(LHipMoment)}

LKneeMoment = {-1(LKneeMoment), -2(LKneeMoment), 3(LKneeMoment)}

LAnkleMoment = {-1(LAnkleMoment), -2(LAnkleMoment), -
3(LAnkleMoment)}


OUTPUT(LHipForce, LKneeForce, LAnkleForce, RHipForce,
RKneeForce, RAnkleForce,
RHipMoment,RKneeMoment,RAnkleMoment,LHipMoment,LKneeMoment,LAnkl
eMoment)


{*Joint Powers (W/kg)*}
{*==================*}
LHipPower =  POWER(Pelvis, LFemur)
RHipPower =  POWER(Pelvis, RFemur)
LKneePower = POWER(LFemur, LTibia)
RKneePower = POWER(RFemur, RTibia)
LAnklePower = POWER(LTibia, LFootSeg)
RAnklePower = POWER(RTibia, RFootSeg)

OUTPUT(LHipPower,RHipPower,LKneePower,RKneePower,LAnklePower,RAn
klePower)
```

Marker File:

```
!MKR#2

[Autolabel]

Pointer1
Pointer2

RASIS
LASIS
```

```
RPSIS
LPSIS

RTH1
RTH2
RTH3
RTH4

RSH1
RSH2
RSH3
RSH4

RMET1
RMET5
RHEEL

LTH1
LTH2
LTH3
LTH4

LSH1
LSH2
LSH3
LSH4

LMET1
LMET5
LHEEL

LMMAL
LLMAL
RMMAL
RLMAL

Pointer1, Pointer2

RASIS,LASIS
LASIS,LPSIS
LPSIS,RPSIS
RPSIS,RASIS

RTH1,RTH2
RTH2,RTH3
RTH3,RTH4
RTH4,RTH1

LTH1,LTH2
LTH2,LTH3
LTH3,LTH4
LTH4,LTH1

RSH1,RSH2
RSH2,RSH3
RSH3,RSH4
```

```
RSH4,RSH1

LSH1,LSH2
LSH2,LSH3
LSH3,LSH4
LSH4,LSH1

RMET1,RMET5
RMET5,RHEEL
RHEEL,RMET1

LMET1,LMET5
LMET5,LHEEL
LHEEL,LMET1

Pelvis

RThighSeg
RShinSeg
RFootSeg

LThighSeg
LShinSeg
LFootSeg

Pelvis,RThighSeg
RThighSeg,RShinSeg
RShinSeg,RFootSeg

Pelvis,LThighSeg
LThighSeg,LShinSeg
LShinSeg,LFootSeg

Pelvis=RASIS,LASIS,RPSIS,LPSIS

RThighSeg=RTH1,RTH2,RTH3,RTH4
RShinSeg=RSH1,RSH2,RSH3,RSH4
RFootSeg=RMET1,RMET5,RHEEL

LThighSeg=LTH1,LTH2,LTH3,LTH4
LShinSeg=LSH1,LSH2,LSH3,LSH4
LFootSeg=LMET1,LMET5,LHEEL

[Virtual Points]

RASIS
LASIS
RPSIS
LPSIS
SACR
PELF

RMET1
RMET5
RHEEL
```

```
LMET1
LMET5
LHEEL
RLEPI
RMEPI
LLEPI
LMEPI

RLMAL
RMMAL
LLMAL
LMMAL

RHJC
LHJC

RKJC
LKJC

RAJC
LAJC

RASIS,LASIS
LASIS,SACR
SACR,RASIS

RHJC,RKJC
RKJC,RAJC

LHJC,LKJC
LKJC,LAJC

RMET1,RMET5
RMET5,RHEEL
RHEEL,RMET1

LMET1,LMET5
LMET5,LHEEL
LHEEL,LMET1

[Calib points]

CalRLEPI
CalRMEPI

CalLLEPI
CalLMEPI

[Kinematics]

LHipangles
LKneeangles
LAnkleangles
RHipangles
RKneeangles
RAnkleangles
```

```
[Force Vectors]
P_ForcePlate1    Base of Plate1 Vector
F_ForcePlate1    Tip of Plate1 Vector
P_ForcePlate2    Base of Plate2 Vector
F_ForcePlate2    Tip of Plate2 Vector

LHipForce
LKneeForce
LAnkleForce
RHipForce
RKneeForce
RAnkleForce

P_ForcePlate1, F_ForcePlate1
P_ForcePlate2, F_ForcePlate2


[Moments from model]
RHipMoment
RKneeMoment
RAnkleMoment
LHipMoment
LKneeMoment
LAnkleMoment

[POWER]

LHipPower
LKneePower
LAnklePower
RHipPower
RKneePower
RAnklePower

[OTHER]
LVelSACR
LAccelSACR
```

APPENDIX 4: RESULTS OF STABILITY, GAIT, AND ENERGY CONSUMPTION TESTS FOR RIGHT LEG OF 3 NORMAL SUBJECTS IN WALKING AND STANDING WITH AND WITHOUT ORTHOSIS (GENERATION 1)

A.4.1: STANDING STABILITY ANALYSIS RESULTS

Parameters	Normal standing	Standing with orthosis (1)	Standing with orthosis (2)	Standing with orthosis (3)	Standing with Orthosis (4)
Subject 1	16.37 ±5.49	16.96 ±5.98	14.77 ±3.3	13 ±5.1	17.93±14.12
Subject 2	40 ±5.98	27.1 ±9.57	33.17 ±9.57	25.28±12.86	9.03 ±2.37
Subject 3	35.95 ±15.6	21.8 ±5.52	17.1± 3	11.52 ±5.86	14.82 ±6.2

Table A.4.1: The mean values of the **anteroposterior** COP sway (mm) during standing with and without the orthosis

Parameters	Normal standing	Standing with orthosis (1)	Standing with orthosis (2)	Standing with orthosis (3)	Standing with Orthosis (4)
Subject 1	8.15 ±1.85	11.1 ±1.63	9.66 ±6	7.61 ±4.1	12.79 ±9.64
Subject 2	26 ±5.12	12.4 ±2.8	9.26 ±2.74	10.2 ±6.59	6.04 ±0.986
Subject 3	19 ±10.38	10.62 ±2.2	12± 2.5	16.65±14.34	8.04 ±4.48

Table A.4.2: The mean values of the **mediolateral** COP sway during standing with and without the orthosis

A.4.2: GAIT ANALYSIS RESULTS

Mean value	Subject 1	Subject 2	Subject 3
Normal walking	86.51± 8.7	70.76 ±1.55	109.04± 3.12
Orthosis with configuration 1	29.4 ±2.54	33.99± 1.089	44.12± 1.73
Orthosis with configuration 2	37.91± 2.59	39.68± 1.242	45.24 ± 1.723
Orthosis with configuration 3	35±0 .69	32.699± 1.086	38.464± 1.163
Orthosis with configuration 4	34.76± 2.59	36.8 ± 2.69	34.45 ±2.24

Table A.4.3: The mean values of **walking speed (m/min)** of all participants during walking with the orthosis with different hip joint configurations and without orthosis

Mean value	Subject 1	Subject 2	Subject 3
Normal walking	107.02 ±5.18	98.64± 1.067	109.96 ±2.71
Orthosis with configuration 1	49.5± 3.23	54.298 ± 1.686	55.05± 1.792
Orthosis with configuration 2	56.71± 3.21	59.94 ± 2.55	59.17± 2.058
Orthosis with configuration 3	60.1± 2.04	60.78 ± 4.41	57.98± 2.5
Orthosis with configuration 4	61.36± 3.47	58.96 ±2.61	54.77 ±2.147

Table A.4.4: The mean values of **cadence (steps/min)** of all participants during walking with the orthosis with different hip joint configurations and without orthosis

Mean value	Subject 1	Subject 2	Subject 3
Normal walking	60.52 ±2.28	63.39 ±2.01	58.49 ± 0.611
Orthosis with configuration 1	67.19± 5.16	62.21± 2.49	58.46 ± 0.611
Orthosis with configuration 2	62.19 ± 3.11	63.46 ± 1.358	59.14 ±1.847
Orthosis with configuration 3	64.112± 1.68	64.89 ±2.1	58.08 ± 3.89
Orthosis with configuration 4	63.92± 1.897	62.16± 2.37	63.75 ±0.912

Table A.4.5: The percentage of the **stance phase duration** during walking with and without the orthosis

Mean value	Subject 1	Subject 2	Subject 3
Normal walking	1.616± 0.1257	1.456 ±0.00871	1.918 ± 0.0256
Orthosis with configuration 1	1.024 ± 0.114	1.09 ±0.0597	1.5± 0.0491
Orthosis with configuration 2	1.336 ±0.0415	1.0596 ±0.0629	1.419 ±0.0553
Orthosis with configuration 3	1.058 ±0.027	0.908± 0.0326	1.258± 0.0396
Orthosis with configuration 4	1.0312± 0.074	1.1186 ±0.1339	1.1284 ± 0.0648

Table A.4.6: The **stride length (m)** of all participants during normal walking and walking with the orthosis with different hip joint configurations

Mean value	Subject 1	Subject 2	Subject 3
Orthosis with configuration 1	299.4± 10.84	119± 18.2	84.273 ±11.57
Orthosis with configuration 2	90.75 ±15.98	134.53± 25.14	62.6±6.98
Orthosis with configuration 3	84.24 ±11.12	171.9± 9.59	63.83± 14.75
Orthosis with configuration 4	108± 7.65	156.24± 23.05	83.76± 19.72

Table A.4.7: The **force time integral (N.s)** of the crutch force during walking with the orthosis with different hip joint configurations

Mean value	Subject 1	Subject 2	Subject 3
Orthosis with configuration 1	0.35 ±0.0377	0.1727± 0.066	0.146± 0.0295
Orthosis with configuration 2	0.241 ±0.0455	0.1816 ±0.0315	0.134±0.0193
Orthosis with configuration 3	0.261± 0.03	0.22 ±0.024	0.136± 0.02
Orthosis with configuration 4	0.265 ±0.0263	0.192± 0.0176	0.123 ±0.012

Table A.4.8: The **Force applied on the crutch (N/BW)** during walking with the orthosis, with different hip joint configurations

Mean value	Subject 1	Subject 2	Subject 3
Normal walking	1.2± 0.06	1.205 ±0.0166	1.164± 0.053
Orthosis with configuration 1	0.914± 0.079	1 ±0.0127	1.067 ±0.0263
Orthosis with configuration 2	1.0312 ±0.0131	0.924 ±0.019	1.062± 0.0678
Orthosis with configuration 3	0.996± 0.01	0.976 ±0.0256	1.085± 0.068
Orthosis with configuration 4	1 ±0.012	0.961 ±0.0218	1.09± 0.047

Table A.4.9: The **peak of the force applied on the foot (N/BW)** during walking with the orthosis

Mean value	Subject 1	Subject 2	Subject 3
Normal walking	40.24± 6.81	45.07± 2.94	43.78 ±3.72
Orthosis with configuration 1	32.63± 2.46	29.64 ±1.145	33.5 ±1.6
Orthosis with configuration 2	29.17± 3.22	26.95± 1.96	31.43 ±2.1
Orthosis with configuration 3	26.97± 0.46	26.21 ± 2.91	28.3± 1.725
Orthosis with configuration 4	20.518 ±1.37	31.48 ± 3.19	25.26 ± 1.735

Table A.4.10: The mean values of **flexion/extension excursions (degree)** of the hip joint of all participants during walking with orthosis with different hip joint configurations and without the orthosis

Mean value	Subject 1	Subject 2	Subject 3
Normal walking	10.49 ± 3.91	12.9 ±0.846	13.62 ±2.024
Orthosis with configuration 1	5.5 ± 3.76	6.12 ±0.767	8.66 ±2.6
Orthosis with configuration 2	4.94± 0.9	5.4 ±1.035	7.94± 2.64
Orthosis with configuration 3	4.68 ±1.55	6.356 ± 1.38	7.79± 1.712
Orthosis with configuration 4	4.438 ± 0.716	6.355± 1.027	8.63 ± 2.89

Table A.4.11: The mean values of **abduction/adduction excursions (degree)** of the hip joint of all participants during walking with and without the orthosis

Mean value	Subject 1	Subject 2	Subject 3
Normal walking	0.99± 0.261	0.7973 ±0.0586	0.772 ±0.0626
Orthosis with configuration 1	0.477 ±0.1342	0.78± 0.0744	0.588± 0.0879
Orthosis with configuration 2	0.385± 0.1245	1.012 ±0.1081	0.458 ±0.0764
Orthosis with configuration 3	0.44 ±0.079	1.149 ±0.161	0.261± 0.0844
Orthosis with configuration 4	0.485 ±0.0938	1.0172± 0.0825	0.542 ± 0.119

Table A.4.12: The mean values of **flexing moment (Nm/kg)** of the hip joint of all participants during walking with and without the orthosis

Mean value	Subject 1	Subject 2	Subject 3
Normal walking	0.999 ±0.272	0.621± 0.158	1.02 ±0.297
Orthosis with configuration 1	0.3228± 0.1254	0.3817 ± 0.1354	0.6368 ±0.1298
Orthosis with configuration 2	0.477± 0.2177	0.435 ± 0.1634	0.5176± 0.205
Orthosis with configuration 3	0.565± 0.0766	0.429 ±0.1192	0.945 ±0.186
Orthosis with configuration 4	0.4696 ± 0.1293	0.494 ± 0.1052	0.4022± 0.1568

Table A.4.13: The mean values of **extending moment (Nm/kg)** of the hip joint of all participants during walking with and without the orthosis

Mean value	Subject 1	Subject 2	Subject 3
Normal walking	1.1± 0.392	1.08± 0.07	1.217 ±0.176
Orthosis with configuration 1	1.1± 0.097	1.08 ±0.0613	0.857 ±0.151
Orthosis with configuration 2	1.187 ±0.07	1.05 ±0.1	0.837 ±0.641
Orthosis with configuration 3	0.899± 0.0213	0.852 ±0.099	0.776± 0.0638
Orthosis with configuration 4	0.873 ±0.0764	0.83 ±0.036	0.753 ±0.0793

Table A.4.14: The mean values of **adducting moment (Nm/kg)** of the hip joint of all participants during walking with and without the orthosis

A.4.3: ENERGY CONSUMPTION TEST RESULTS

Parameters	Resting heart rate (beats/min)	Walking heart rate (beats/min)	Walking speed (m/min)	PCI (beats/min)
Normal walking	77.33	92.62	79.066	0.1933
Orthosis with configuration 1	76.06	96.02	24.328	0.823
Orthosis with configuration 2	71.89	92.13	40.546	0.445
Orthosis with configuration 3	71.73	93.86	26.922	0.8257
Orthosis with configuration 4	70.53	100.37	36.95	0.807

Table A.4.15: The **heart rate during walking, resting and walking speed** of subject 1 in normal walking and walking with the orthosis with different hip joint configurations

Parameters	Resting heart rate (beats/min)	Walking heart rate (beats/min)	Walking speed (m/min)	PCI
Normal walking	69.33	110.6	78.63	0.525
Orthosis with configuration 1	83.29	117.43	33.01	1.03
Orthosis with configuration 2	77.13	121.27	37.41	1.17
Orthosis with configuration 3	64.21	115.29	35.6	1.43
Orthosis with configuration 4	77.09	127.51	46.4	1.08

Table A.4.16: The **heart rate during walking, resting and walking speed** of subject 2 in normal walking and walking with orthosis with different hip joint configurations

Parameters	Resting heart rate (beats/min)	Walking heart rate (beats/min)	Walking speed (m/min)	PCI (beats/metre)
Normal walking	78.361	98.9	94.271	0.215
Orthosis with configuration 1	92.3	117.78	36.492	0.698
Orthosis with configuration 2	82.97	107.32	40.216	0.605
Orthosis with configuration 3	82.28	115.92	33.451	1.005
Orthosis with configuration 4	78	102.56	34.75	0.602

Table A.4.17: The **heart rate during walking, resting and walking speed** of subject 3 in normal walking and walking with orthosis with different hip joint configurations

A.5: RESULTS OF STABILITY, GAIT, AND ENERGY CONSUMPTION TESTS FOR RIGHT LEG OF 3 NORMAL SUBJECTS IN WALKING AND STANDING WITH AND WITHOUT ORTHOSIS (GENERATION 2)

A.5.1: STABILITY ANALYSIS RESULTS

Parameters	ML COP sway (mm)	AP COP sway (mm)
Subject 1	9.98 ± 4.15	12.46 ± 8
Subject 2	9.85 ± 7.55	13.6 ± 5.45
Subject 3	11.194 ± 8.73	13.55 ± 6.4

Table A.5.1: The mean values of the **COP sway** in standing with the second generation of the new orthosis

A.5.2: GAIT ANALYSIS RESULTS

Parameters	Flexion extension excursion (degree)	Abduction adduction excursion (degree)	Walking velocity (m/min)	Stride length (m)	Cadence (steps/min)	Percentage of stance phase (%)
Subject 1	29.4± 4.5	5.85± 2.3	40.6 ±1.7	1.2±0.06	62.1±2.14	58±2.43
Subject 2	33.3± 7.9	9.1 ±3.58	38.9 ±2.7	1.21±0.07	52.43±2.9	54.46 ±5.3
Subject 3	28.6 ±6.9	9.73±3.8	38.03±2.5	1.21±0.026	58.7±1.34	59.3 ±2.25

Table A.5.2: The mean values of the **gait parameters** during walking with the second generation of the new orthosis

Parameters	Flexion Moment (Nm/kg)	Extension Moment (Nm/kg)	Abduction Moment (Nm/kg)	Crutch Force (N/BW)	Foot Force (N/BW)	FTI (N.s)
Subject 1	0.585 ±0.1	0.344 ±0.2	0.78 ±0.07	0.18 ±0.04	0.99 ±0.006	70.7 ±14.2
Subject 2	0.987 ±0.1	0.49 ±0.17	1.05 ±0.11	0.106 ±0.02	0.98 ±0.04	58.678 ±8.9
Subject 3	0.663 ±0.1	0.718 ±0.1	0.873 ±0.1	0.121 ±0.04	1 ± 0.038	52.81 ±16.7

Table A.5.3: The mean values of the **gait parameters** during walking with the second designed orthosis

Parameters	Resting heart rate (beats/min)	Walking heart rate (beats/min)	Walking speed (m/min)	PCI (beats/metre)
Subject 1	70.373	89.45	40.33	0.473
Subject 2	92	117.48	34.75	0.733
Subject 3	80	97.52	36.516	0.4798

Table A.5.4: The **heart rate during walking and resting and walking speed** of the participants walked with the new generation of the orthosis

APPENDIX 6: CALIBRATION RESULTS FOR THE STRAIN GAUGE ARRANGMENT

Before starting calibrating the final strain gauge system designed for this research study, the magnitude of the force applied on the lateral bar of the orthosis was determined according to following equations:

$$\varepsilon = \frac{V_{out}\,2}{V_{in}\,1.3K} \qquad \text{Eq. 6.6}$$

$$\sigma = \frac{F_{yo}}{A} \qquad \text{Eq. A.6.1}$$

$$\sigma = \varepsilon . E \qquad \text{Eq. A.6.2}$$

$$\varepsilon = \frac{F_{yo} . E}{A} \qquad \text{Eq. A.6.3}$$

Where, σ, ε, K, A, E, F_{yo} are stress, strain, gauge factor, area, young modulus and the axial force applied on the orthosis, respectively. Thus, the magnitude of the axial force applied on the bar can be determined by following equation:

$$F_{yo} = \frac{A. E. V_{out} . 2}{V_{in} . 1.3. K} \qquad \text{Eq. A.6.4}$$

The magnitude of V_{in} for the axial force was 6 volts. By using the values of A, E and K, which are shown in tables A.6.1, the final value of the axial force applied on the orthosis can be determined by using the following equation:

$$F_{yo} = 4407.\, V_{out}\ (N) \qquad \text{Eq. 6.8}$$

Where, V_{out} is in millivolt.

Parameters	K	A	E (Pa)	I_{xx}	I_{zz}
Value	2.02	496×10^{-6} m^2	70×10^{9}	10.581 $\times10^{-9}m^4$	39.721 $\times10^{-9}m^4$

Table A.6.1: The value of the parameters used to calculated the loads applied on the orthosis from strain gauge data

For the anteroposterior bending moment (M_z) the following equations was used.

$$\sigma = E\varepsilon = \frac{M_z c}{I_{zz}} \qquad \text{Eq. 6.4}$$

$$\varepsilon = \frac{V_{out}}{V_{in}.\, K} \qquad \text{Eq. 6.5}$$

Thus, the applied moment would be:

$$M_z = \frac{V_{out}\ .\, I_{zz}.\, E}{c.\, K.\, V_{in}} \qquad \text{Eq. A.6.5}$$

The value of c is 15.5 millimetres for the anteroposterior bending moment. The magnitude of V_{in} for the bending moment was 3 volts, so the final equation according to the parameters shown in table A.6.1 would be as follows:

$$M_z = 29.6V_{out} \text{ (Nm)} \qquad \text{Eq. 6.10}$$

Where, V_{out} is in millivolt.

For the mediolateral bending moment (M_x) the following equation was used.

$$M_x = \frac{V_{out} \cdot I_{xx} \cdot E}{c. K. V_{in}} \qquad \text{Eq. A.6.6}$$

The value of c is 8 millimetres for the mediolateral bending moment so the final equation according to the parameters shown in table A.6.1 was as follows:

$$M_x = 15.27V_{out} \text{ (Nm)} \qquad \text{Eq. 6.9}$$

Where, V_{out} is in millivolt.

A.6.1: CALIBRATION GRAPHS FOR M_z

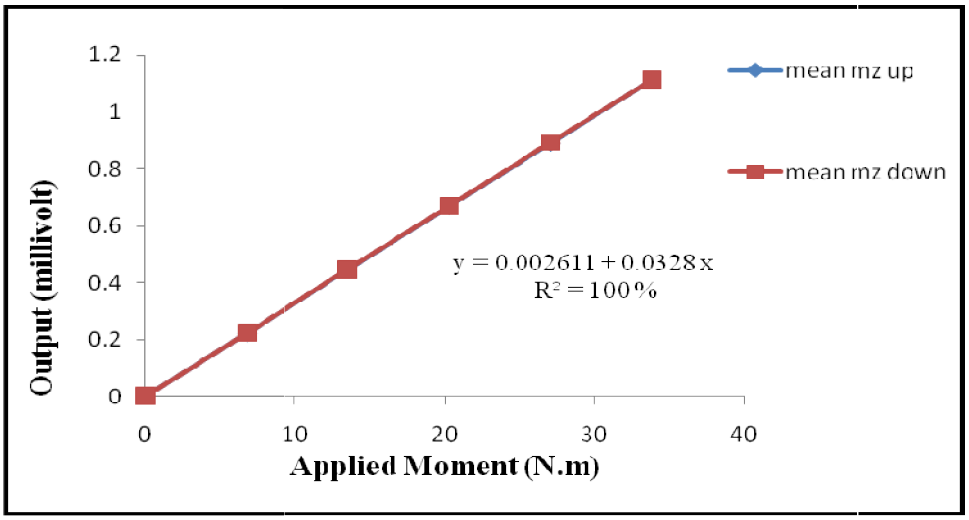

Figure A.6.1: Calibration graph of the strain gauge bridge output with M_z as the main channel

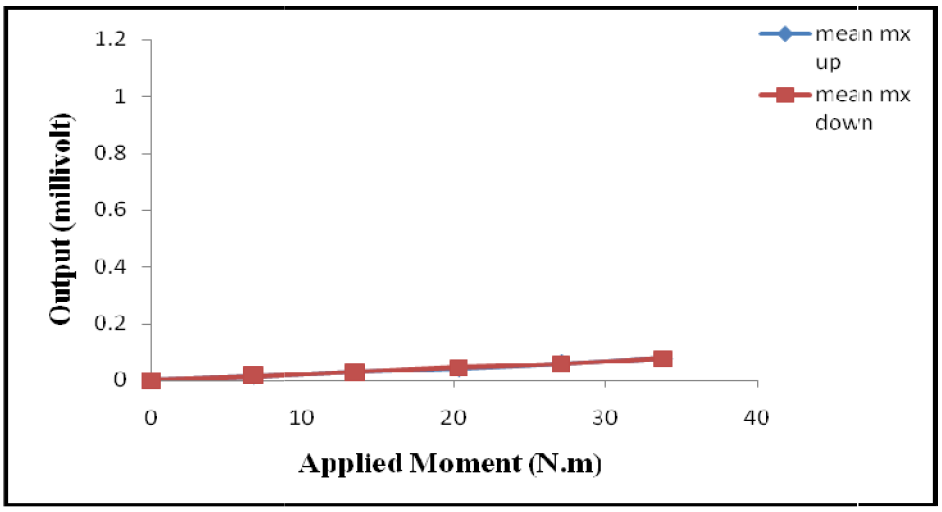

Figure A.6.2: Calibration graph of the strain gauge bridge output for M_z as the main channel and showing the cross talk in M_x channel

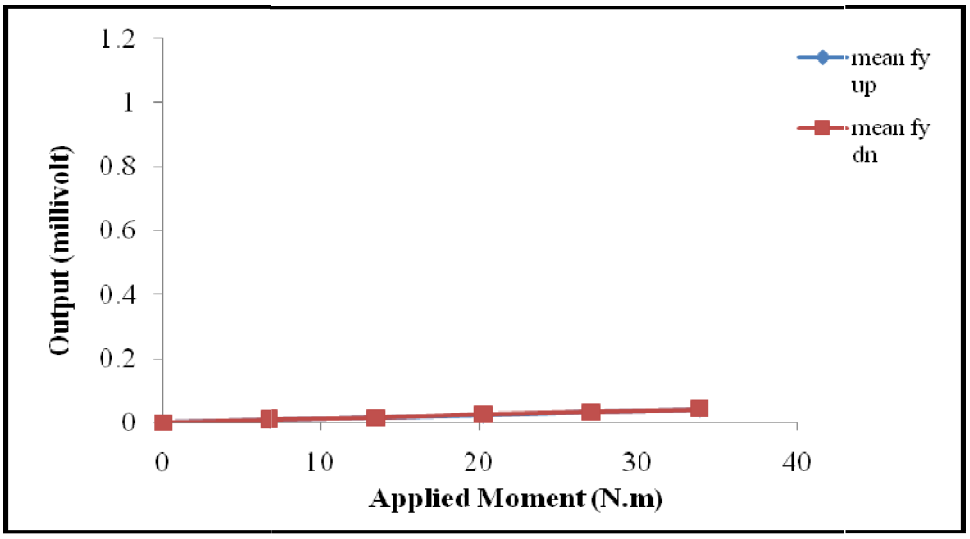

Figure A.6.3: Calibration graph of the strain gauge bridge output for M_z as the main channel and showing the cross talk in F_y channel

A.6.2: CALIBRATION GRAPHS FOR M_x

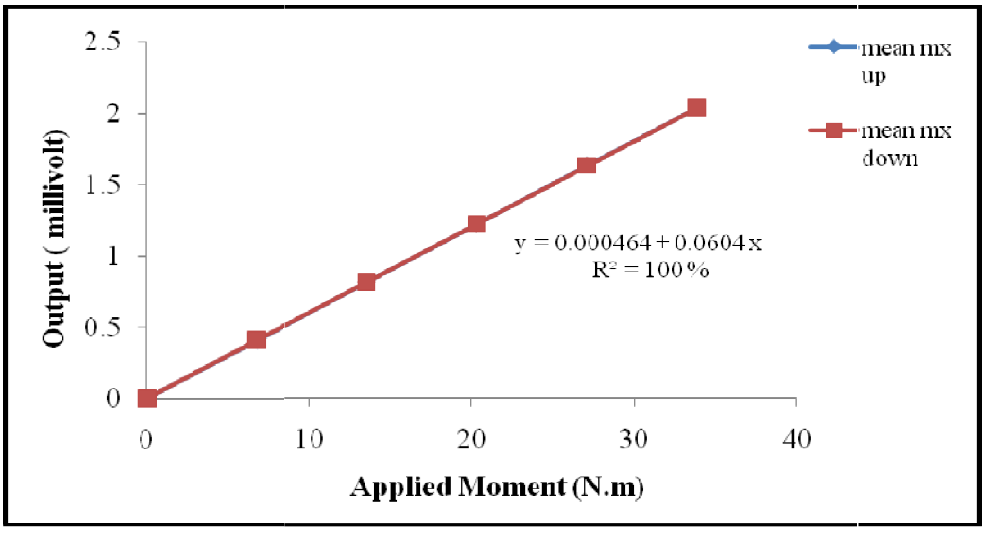

Figure A.6.4: Calibration graph of the strain gauge for M_x as the main channel

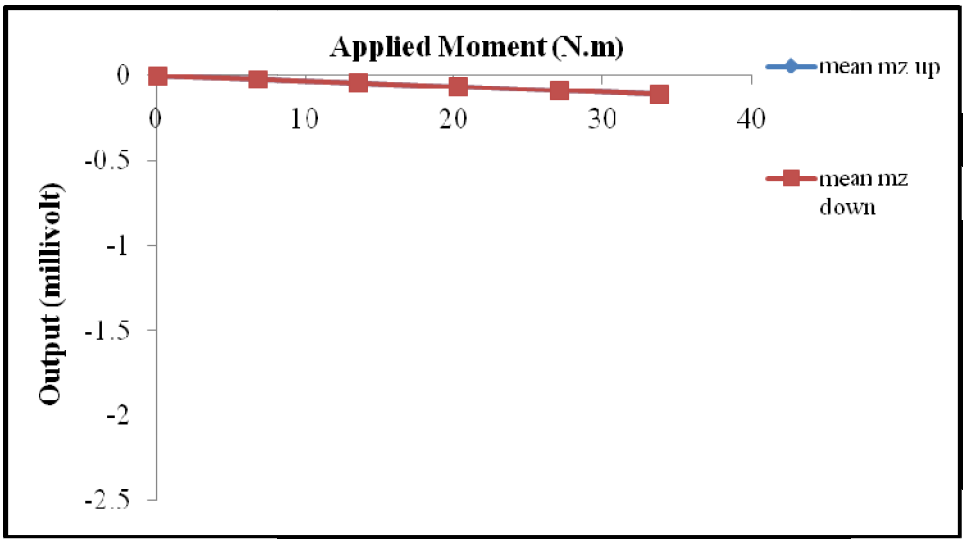

Figure A.6.5: Calibration graph of the strain gauge output for M_x as the main channel and showing the cross talk in M_z channel

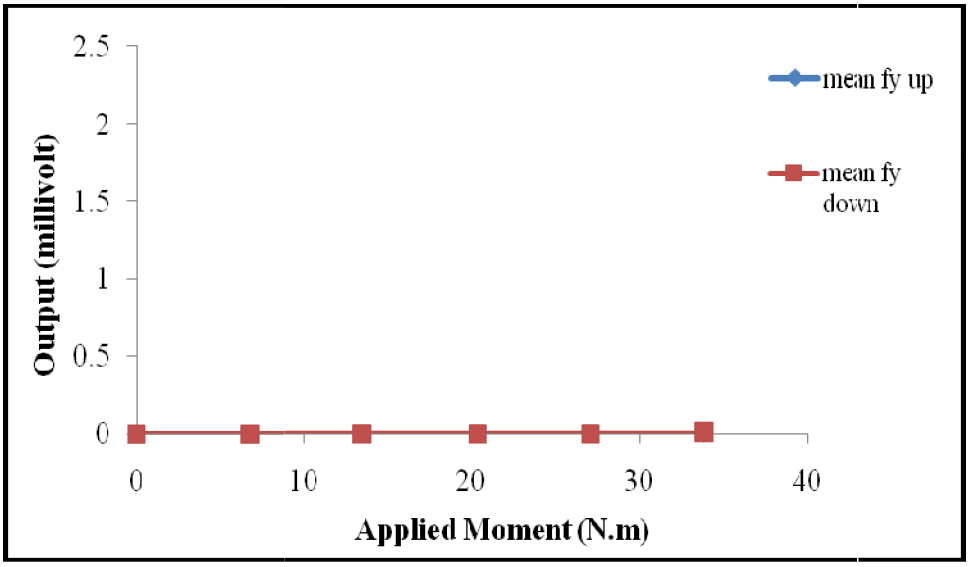

Figure A.6.6: Calibration graph of the strain gauge output for M_x as the main channel and showing the cross talk in F_y channel

APPENDIX 7: RESULTS OF STABILITY, GAIT AND ENERGY CONSUMPTION FOR LEFT LEG OF 5 NORMAL SUBJECTS IN WALKING AND STANDING WITH THE HGO AND THE NEW RGO ORTHOSES

A.7.1 STABILITY ANALYSIS RESULTS

Parameters	ML COP sway (mm)	AP COP sway (mm)
Subject 1	9.98 ± 4.15	12.46 ± 8
Subject 2	9.85 ± 7.55	13.6 ± 5.45
Subject 3	11.194 ± 8.73	13.55 ± 6.4
Subject 4	6.06 ± 1.94	12.62 ± 6.79
Subject 5	3.33 ± 1.13	5.33 ± 1.31

Table A.7.1: The mean values of the **COP sways** during standing with the new **RGO** orthosis

Parameters	ML COP sway (mm)	AP COP sway (mm)
Subject 1	12.92 ±7.97	19.59 ±6.48
Subject 2	5.9 ±1.95	18.58 ±7.46
Subject 3	20.1± 6.76	75.5± 22.93
Subject 4	10.41 ±8.74	17.26 ±11.5
Subject 5	4.02 ±1.13	9.76± 2.6

Table A.7.2: The mean values of the **COP sways** during standing with the **HGO** orthosis

Parameters	Time transverse (s)	Time vertical (s)	COP AP transverse (mm)	COP ML transverse (mm)	COP AP vertical (mm)	COP ML vertical (mm)
Subject 1	8.03 ± 0.47	8.04 ± 0.4	72.2 ± 8.85	178.9 ±15.7	43.2 ± 9.6	50.94 ± 9.71
Subject 2	7.4 ± 0.81	7.34 ±0.228	77.75 ± 39.8	343.9 ±29.3	58.06 ± 24	60 1 ± 0.06
Subject 3	9.32 ± 1.08	8.5 ± 0.478	73 ± 39.43	335.6 ± 25.5	82.89 ± 19	72.74 ± 15.2
Subject 4	12.76 ± 0.27	10 ± 0.875	95.25 ±15.7	201.6 ± 21.2	61 ± 7.82	52.7 ± 8.72
Subject 5	10.16 ± 0.432	11.142 ±1.1	66.49 ± 8.3	161.96 ± 9.6	45.34 ±2.64	44.25 ± 2.4

Table A.7.3: The mean values of the **stability parameters** during carrying out hand tasks with the **new RGO orthosis**

Parameters	Time transverse (S)	Time vertical (S)	COP AP transverse (mm)	COP ML transverse (mm)	COP AP vertical (mm)	COP ML vertical (mm)
Subject 1	8.36 ±1.53	8.1 ±0.657	69.26 ±10.5	184.7 ±14.4	53.64 ±4.93	60.27 ±4.43
Subject 2	7.2 ±0.55	7.31 ± 0.49	96.9 ±16.13	273.9 ±10	86.8 ±11.8	64.72 ±4.6
Subject 3	10.15 ±0.58	8.75 ±0.458	86.94 ± 29.1	280.2 ±13.3	80.85 ± 15.8	101.5 ±46.3
Subject 4	10.2 ±0.6	8.8 ±0.44	88 ±28	280 ±15	79 ±15	100 ±45
Subject 5	12.35 ±1.05	12.47 ±0.85	86.41 ±8.66	137.1 ± 5.96	60.86 ±6.9	32.55 ±3.33

Table A.7.4: The mean values of the **stability parameters** during carrying out hand tasks with the **HGO orthosis**

A.7.2 GAIT ANALYSIS RESULTS

Parameters	Flexion extension excursion (degree)	Abduction adduction excursion (degree)	Walking velocity (m/min)	Stride length (m)	Cadence (steps/min)	Percentage of stance phase (%)
Subject 1	34.12 ±2.92	5.35 ±1	41.43 ±2.47	1.21 ±0.047	62.19 ±1.77	59.77 ±1.23
Subject 2	29.6 ±5	4.98 ±1.5	39.25 ±3.6	1.17 ±0.04	52.87 ±4.95	59.21 ±0.96
Subject 3	31.26 ±2.95	9.38 ±2.8	38 ±0.786	1.23 ±0.024	57.17 ± 3	59.36 ±2.17
Subject 4	26.84 ±3.5	4.2 ±0.78	28.66 ±1.77	0.696 ±0.03	60.1 ± 2.3	63.9 ±3.7
Subject 5	25.1 ±1.02	4.6 ±0.88	27.97 ±1.36	0.85 ±0.0805	55.74 ±2.04	65.8 ± 1.2

Table A.7.5: The mean values of the **Spatio-temporal gait parameters** during walking with the **new RGO orthosis**

Parameters	Flexion extension excursion (degree)	Abduction adduction excursion (degree)	Walking velocity (m/min)	Stride length (m)	Cadence (steps/min)	Percentage of stance phase (%)
Subject 1	32.3 ±3.3	6.68 ±1.84	39.6 ±0.88	1.2 ±0.02	60.4 ±0.99	59.13 ±1.2
Subject 2	33 ±7.93	19.23 ±3.63	41.35 ±2.84	1.23 ±0.06	54.67 ±2.45	60.57 ±2.43
Subject 3	35.1 ± 5.1	5.23 ±1.35	39.3 ±2.35	1.28 ±0.035	55.7 ±3.42	56.2 ±4.3
Subject 4	25.23 ±6.13	12.52 ±1.92	14.28 ±2.64	0.74 ±0.128	27.94 ±5.9	65.85 ±11.03
Subject 5	26.85 ±2.45	10.31 ±2.12	33.4 ± 5	1.05 ±0.078	51.9 ±6.43	61.5 ±2.8

Table A.7.6: The mean values of the **Spatio-temporal gait parameters** during walking with the **HGO orthosis**

Parameters	Flexion Moment (Nm/kg)	Extension Moment (Nm/kg)	Abduction Moment (Nm/kg)	Crutch Force (N/BW)	Foot Force (N/BW)	FTI (N.s)
Subject 1	0.848 ± 0.08	0.447 ±0.024	0.92 ±0.084	0.21 ±0.045	1.027 ±0.02	84.3 ± 18.8
Subject 2	0.758 ±0.196	0.467 ±0.253	1.43 ±0.091	0.127 ±0.019	1.02 ±0.043	113.4 ±26.6
Subject 3	0.584 ±0.12	0.574 ±0.1	0.76 ±0.054	0.141 ±0.03	1.02 ±0.014	57.64 ±7.3
Subject 4	0.224 ±0.053	0.439 ±0.055	1.29 ±0.25	0.203 ±0.035	0.957 ±0.043	108.7 ±14
Subject 5	0.29 ± 0.103	0.26 ±0.086	0.879 ±0.146	0.133 ±0.017	0.985 ±0.376	82.2 ±18.2

Table A.7.7: The mean values of the **gait parameters** during walking with the **new RGO orthosis**

Parameters	Flexion Moment (Nm/kg)	Extension Moment (Nm/kg)	Abduction Moment (Nm/kg)	Crutch Force (N/BW)	Foot Force (N/BW)	FTI (N.s)
Subject 1	0.56 ±0.054	0.316 ±0.12	0.67 ±0.09	0.22 ±0.077	1.04 ±0.012	77.36 ±27
Subject 2	0.66 ±0.25	0.59 ±0.097	1.64 ±0.07	0.08 ±0.006	1.06 ±0.034	46.37 ±12.5
Subject 3	0.565 ±0.13	0.725 ±0.17	0.57 ±0.17	0.14 ±0.013	0.99 ±0.032	63.1 ±7.87
Subject 4	0.136 ±0.06	0.24 ±0.078	0.71 ±0.15	0.24 ±0.045	0.92 ±0.059	277.1 ±107
Subject 5	0.45 ±0.076	0.33 ±0.107	0.86 ±0.26	0.21 ±0.039	0.97 ±0.027	142.7 ±14.8

Table A.7.8: The mean values of the **gait parameters** during walking with the **HGO orthosis**

A.7.3: ENERGY CONSUMPTION RESULTS

Parameters	Resting heart rate (beats/min)	Walking heart rate (beats/min)	Walking speed (m/min)	PCI (beats/meter)
Subject 1	70.62	89.13	40.33	0.459
Subject 2	93.97	120.83	34.75	0.772
Subject 3	83.38	99.16	36.516	0.432
Subject 4	67.09	75.32	21.1	0.389
Subject 5	66.99	79.59	26.2	0.48

Table A.7.9: The **energy consumption parameters** during walking with the **new RGO orthosis**

Parameters	Resting heart rate (beats/min)e	Walking heart rate (beats/min)	Walking speed (m/min)	PCI (beats/meter)
Subject 1	72.53	86.64	39.56	0.356
Subject 2	79.36	102.4	32.63	0.706
Subject 3	91.4	105.5	33.97	0.415
Subject 4	63	76.22	13.95	0.947
Subject 5	74.6	87.21	25.78	0.478

Table A.7.10: The **energy consumption parameters** during walking with the **HGO orthosis**

A.7.4: Loads applied on the orthosis

Parameters	Tension (N/BW)	Compression (N/BW)	Adduction Moment (Nm/kg)	Flexion Moment (Nm/kg)	Extension Moment (Nm/kg)
Subject 1	0.0967 ± 0.014	0.205 ± 0.009	0.43 ± 0.02	0.057 ± 0.017	0.216 ± 0.017
Subject 2	0.056 ± 0.019	0.279 ± 0.0046	0.547 ± 0.027	0.009 ± 0.005	0.215 ± 0.108
Subject 3	0.164 ±0.014	0.099 ±0.013	0.518 ± 0.033	0.073 ± 0.032	0.239 ± 0.011
Subject 4	0.0695 ± 0.029	0.161 ± 0.038	0.56 ± 0.06	0	0.278 ± 0.044
Subject 5	0.149 ± 0.011	0.107 ± 0.033	0.525 ± 0.049	0.044 ± 0.011	0.165 ± 0.023

Table A.7.11: The mean values of the loads applied on the lateral bar of the orthosis, near the hip joint, during walking the normal subjects with the new RGO orthosis