COMPUTER INTEGRATED DESIGN AND MANUFACTURING OF PATIENT SPECIFIC LOWER LIMB ORTHOSES THROUGH 3D RECONSTRUCTION

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DISSERTATION SUBMITTED IN FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF ENGINEERING SCIENCE

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ABSTRACT

Patients with stroke and other neurological disorders like trauma, multiple sclerosis (MS) experience different lower limb disabilities due to various damages in neuromuscular system. Orthotic devices are prescribed to compensate muscle weakness, prevent unwanted movement of the impaired limb. Design and manufacturing methods of lower limb orthoses involve manual techniques e.g. casting and moulding of the limbs to be treated, vacuum forming etc. Such methods are time consuming, require skilful labour and often based on trial and error rather than systematic engineering and evidence based principles.

In recent years, 3D scanning and reconstruction of medical images facilitate making 3D computer models of lower limb, which allows computer aided design (CAD) tools to be incorporated in orthotic design. All these approaches rely on the external model of lower limb and limited to single piece plastic ankle foot orthosis (AFO) only. To design orthosis with articulated joint, precise alignment of anatomical joint and mechanical axis is necessary. However, it is difficult to infer joint axes from external models as it is partially specified by skeletal structure. In our research, a design approach for custom knee ankle foot orthosis and ankle foot orthosis with commercially available joints has been demonstrated, which involves skeletal structure of lower limb for locating anatomical axes to ensure accurate alignment of orthotic mechanical joint. CAD models of the orthotic components were developed based on the 3D models of a healthy subject's lower limb, which were developed through 3D reconstruction. Components of the orthotics were fabricated by rapid prototyping and machining to demonstrate the new approach. The fabricated orthoses were evaluated by a certified orthotist and the performance of the custom made AFO was compared statistically with a pre-fabricated AFO with similar ankle joint.

The manufacturing process requires approximately 50% lesser time to develop AFO and 70% lesser time to develop KAFO compared to Brace and Limb laboratory of University Malaya. Unlike traditional approaches, the design technique facilitates exact positioning of articulated joint. The developed orthoses are light in weight, comfortable and easy to don and doff. Biomechanical test implies that the fabricated AFO provides better range of motion than a pre-fabricated AFO with same ankle joint. Although the custom AFO allowed significantly higher plantar flexion during pre-swing compared to pre-fabricated AFO condition (MD = 1.734, MSD = 1.55), the subject's ankle required to generate significantly higher power with the pre-fabricated AFO (MD = 0.141, MSD = 0.035). These findings suggest that the subject had to overcome higher resistance with pre-fabricated AFO compared to custom made AFO. Simultaneous viewing of exterior and skeletal geometry might help the clinicians modify the design to enhance performance of the orthotic device.

ABSTRAK

Pesakit strok dan penyakit gangguan neurologi yang lain seperti trauma, multiple sclerosis (MS) mempunyai pengalaman berbeza mengenai upaya anggota badan bahagian bawah disebabkan oleh pelbagai kerosakan di dalam sistem saraf. Peranti ortotik ditetapkan untuk mengimbangi kelemahan otot, mengelakkan pergerakan yang tidak diingini daripada anggota badan yang terjejas. Reka bentuk dan pembuatan kaedah orthoses anggota badan bahagian bawah melibatkan teknik manual contohnya pemutus dan pembentukan anggota badan untuk dirawat, pembentukan vakum dan lain-lain. Kaedah seperti ini memakan masa, memerlukan tenaga buruh yang mahir dan sering bergantung kepada kaedah percubaan dan kesilapan dan bukannya kepada prinsip-prinsip kejuruteraan yang sistematik dan berasaskan bukti.

Dalam tahun-tahun kebelakangan ini, imbasan 3D dan pembinaan semula imej perubatan memudahkan dalam pembuatan model komputer 3D anggota badan bahagian bawah, yang membolehkan reka bentuk bantuan komputer (CAD) alat untuk dimasukkan ke dalam reka bentuk ortotik. Semua pendekatan ini bergantung kepada model luar anggota badan bahagian bawah dan terhad kepada buku lali plastik orthosis kaki (AFO) sahaja. Merekabentuk orthosis yang mempunyai sendi, penjajaran tepat bersama anatomi dan paksi mekanikal adalah perlu. Walau bagaimanapun, ia adalah sukar untuk membuat kesimpulan paksi model dari luar kerana ia sebahagiannya ditentukan oleh struktur tulang. Dalam kajian kami, pendekatan reka bentuk untuk pergelangan kaki lutut, orthosis kaki dan buku lali kaki orthosis dengan sendi boleh didapati secara komersial telah berjaya ditunjukkan, yang melibatkan struktur rangka anggota badan bahagian bawah untuk mencari paksi anatomi untuk memastikan penjajaran tepat sendi mekanikal ortotik. Model CAD komponen ortotik telah dibangunkan berdasarkan model 3D daripada anggota sihat, yang dibangunkan melalui pembinaan semula 3D. Komponen orthotics telah dipalsukan oleh prototaip pantas dan pemesinan untuk

menunjukkan pendekatan yang baru. Orthoses fabrikasi telah dinilai oleh orthotist yang diperakui dan pelaksanaan yang dibuat AFO telah dibandingkan dengan statistik AFO pasang siap dengan sendi buku lali yang sama.

Masa untuk proses pembuatan memerlukan kira-kira 50% lebih rendah untuk membangunkan AFO dan 70% lebih rendah untuk membangunkan KAFO berbanding dan masa diperlukan oleh makmal Anggota Badan Universiti Malaya. Tidak seperti pendekatan tradisional, teknik reka bentuk yang memudahkan kedudukan sebenar bersama dinyatakan. Orthoses ini dibangunkan lebih ringan, selesa dan mudah untuk dipakai dan dibuka. Ujian biomekanik menunjukkan bahawa AFO fabrikasi menyediakan rangkaian yang lebih baik daripada gerakan daripada AFO pra-fabrikasi dengan sendi buku lali. Walaupun AFO akhiran plantar dibenarkan adalah lebih tinggi semasa pra-swing berbanding keadaan AFO pasang siap (MD = 1,734, MSD = 1.55). Pergelangan kaki subjek yang diperlukan untuk menjana kuasa yang lebih tinggi adalah dengan AFO pasang siap (MD = 0,141, MSD = 0.035). Penemuan ini menunjukkan bahawa subjek terpaksa mengatasi rintangan yang lebih tinggi dengan pasang siap AFO berbanding alat dibuat untuk AFO. Tontonan serentak geometri luar dan rangka mungkin membantu doktor mengubah suai reka bentuk untuk meningkatkan prestasi peranti ortotik.

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LIST OF SYMBOLS AND ABBREVIATIONS

AFO	Ankle foot orthosis
KAFO	Knee ankle foot orthosis
HKAFO	Hip knee and foot orthosis
CT	Computed tomography
MRI	Magnetic resonance imaging
ISB	International Society of Biomechanics
IST	Standardization and Terminology Committee
ist	Information Society Technologies
VAKHUM	Virtual animation of the kinematics of the human for industrial, educational and research purposes
AM	Additive manufacturing
STL	Stereolithography
SLS	Selective laser sintering

CHAPTER 1

INTRODUCTION

1.1 Introduction

Stroke is considered as the most common cause of disability (Adamson, Beswick, & Ebrahim, 2004). According to Feigin et al. (2014), in 2010 there were 16.9 million people who had a stroke for the first time, and 33 million stroke survivors. Patients surviving after stroke and other neurological disorder like trauma, multiple Sclerosis (MS) have reduced walking capacity, which has a great impact on daily life (Kalron et al., 2013). Various damages in neuromuscular system, presence of spasticity, contracture, and weakness can also result in walking speed reduction, elevation in energy cost, and an increased risk of falling. Individuals with gait disabilities require either rehabilitation or permanent assistance. There are various types of treatments for lower limb disabilities such as surgical, therapeutic, or orthotic. However, among these approaches, orthotic treatment is the most common practice (Stein et al., 2010).

The word "orthotics" originated from Greek word "ortho" which means "align" or "to straighten". Orthotic study has two aspects: clinical aspect including knowledge of biomechanics, physiology, anatomy and application, and engineering aspect including knowledge of design and manufacturing of orthosis. Orthosis is an assistive device that is applied to the impaired limbs externally to correct and enhance functionality. The objectives of the orthoses prescription are presented below:

- To restrict unwanted movement of impaired limbs
- To assist movement by providing torque in a desired direction
- To assist rehabilitation
- In case of deformed body parts, it corrects the shape and alleviates the pain
- Prevent progression of permanent deformity

In general, an orthosis is named by the acronym of the body parts which it covers. There are various types of lower limb orthosis e.g. foot orthosis, ankle foot orthosis (AFO), knee ankle foot orthosis (KAFO) and hip knee ankle foot orthosis (HKAFO). For musculoskeletal disorders the most commonly used orthoses are ankle foot orthosis (AFO) and knee ankle foot orthosis (KAFO). The focus of this research will be limited to these two orthoses only.

AFOs are usually prescribed for plantar flexor, dorsiflexor muscle weakness or joint deformity to ameliorate the walking capability by providing push-off assistance as well as adequate clearance during swing phase of the gait cycle. There are enormous variations of AFO design varying on the basis of purpose and pathology of the patient e.g. passive single piece plastic non-articulated AFO, passive articulated AFO, semi active AFO and active AFO. Among them passive AFOs are most popular for their compactness, light weight and simple design. Active and semi-active AFOs are yet come out of laboratory and mostly used for rehabilitation purpose.

KAFO is prescribed to the patients with knee arthritis or quadriceps weakness to prevent knee collapse during weight bearing. It provides partial solution by maintaining alignments, controlling knee and ankle joint mechanically, and providing stability in stance phase. There are different types of KAFOs depending on knee joint variations. Some knee joints lock the knee entirely and some other facilitate knee motion during swing phase of the gait cycle.

Patient specific orthotic device fabrication requires manual techniques e.g. casting, making molds of the limbs to be treated and vacuum forming (International Committee of Red Cross, 2006 and 2010). Such design and fabrication approaches are time consuming, require skilled labor and often cumbersome for the patients. These techniques are based on trial and error rather than systematic engineering and evidence-based principles. Properties and performance of orthotic devices in these techniques rely on experience of the orthotists.

Since 1960s computer-aided design and manufacturing (CAD/CAM) has been used as an alternative approach of fabrication in prosthetic industry (Kaufman & Irby, 2006). However, only in recent years CAD/CAM is seen to be used in orthotic industry. Development of digital models of freeform surface anatomy of human body parts, by using 3D scanning or medical imaging, such as CT (computed tomography) and MRI (magnetic resonance imaging), allows incorporation of computer aided design (CAD) in orthotic device design. Several researchers explored the feasibility of computer aided design and manufacturing of passive non-articulated AFOs based on external modeling (Mavroidis et al., 2011; Benabid et al., 20012; Faustini et al., 2008), however, the feasibility of KAFO design and fabrication using CAD/CAM tools is yet to be explored.

As the axes of anatomical joints are partially specified by the skeletal structure, it is difficult to infer those axes only from external observations. However, in traditional manufacturing process the placement of articulated joint depends on the limb's cast only, and in computer aided approaches it also depends on external modeling.

1.2 Research Problem

The issues, this dissertation focuses on, regarding manufacturing and design of lower limb orthoses can be summarized as below:

- Lack of computer aided design and manufacturing application in orthotic industry
- Dependence of design on virtual external model or bony prominence in limb's cast to detect anatomical axis
- High product development time

1.3 Objectives

- To demonstrate a computer integrated approach in design and manufacturing of an articulated AFO and KAFO.
- To develop 3D models (triangular mesh format) of skeletal structure and external geometry of lower limb of a healthy subject using 3D reconstruction of CT-images.
- To design and fabricate a custom articulated AFO and a KAFO with accurate joint alignment using computer aided design and manufacturing technique
- To evaluate the performance of newly designed AFO and KAFO

1.4 Motivation

The main motivation behind this study is to help the individuals with lower limb disabilities. The objective is to demonstrate a computer aided technique for AFO and KAFO design and fabrication. This technique would be able to discard manual techniques such as casting, vacuum forming etc. The commonly followed manufacturing process takes at least ten days to deliver an orthotic device by a commercial orthotic center. The demonstrated technique would be able to reduce the product development time.

Another motivation was to involve the skeletal structure of lower limb in orthotic design, which would allow the clinicians simultaneous observations of internal and external geometry of the individuals. Moreover, it would help infer the anatomical axis accurately for articulated orthosis design.

1.5 Contribution of the Study

In this dissertation a design and fabrication process of a simple light weight custom articulated AFO and a custom drop lock KAFO with free motion knee joint has been demonstrated. Through 3D reconstruction solid model of external and skeletal structure were developed from CT-scan data of one healthy subject's lower limb and then dimensions of the orthotic devices were acquired based on the established reference frame. After designing different components with the help of CAD software, prototypes of the devices were fabricated by CNC machining and rapid prototyping. The design of the orthoses were assessed by a certified orthotist and the performance of developed AFO was compared with a pre-fabricated AFO with same ankle joint.

The demonstrated design and fabrication approach requires less time than other processes and ensures proper alignment of anatomical axis and mechanical axis of articulated joint.

1.6 Arrangement of the Dissertation

This dissertation consists of five chapters. The descriptions of the chapters are as below:

Chapter 1 presents a brief introduction of the study, it also sheds light on the research problems, outlines the objectives and provides a summary of the work and its contribution.

Chapter 2 is the literature review section, which includes description of the human gait cycle, lower limb physiology and pathology, and required reference frames for orthotic design. It also presents detailed literature review on existing lower limb orthoses, orthotic design issues and describes manufacturing techniques for AFO and KAFO.

Chapter 3 presents the methodology of the study. It provides a detailed description of design and manufacturing method, which includes data acquisition, orthotic design, fabrication and orthotic evaluation.

Chapter 4 exhibits results and discussion, which includes AFO and KAFO assessment and performance result. It also presents detailed discussion and limitation of the manufacturing process.

Chapter 5 summarizes the findings and contributions of this dissertation and suggests the future direction for research.

CHAPTER 2

RESEARCH BACKGROUND AND LITERATURE REVIEW

2.1 Human Gait Cycle

2.1.1 Phases gait cycle

The sequential repetition of the movements of the major joints of human body during ambulation is referred to as the gait cycle (Smidt, 1990). There are various types of gaits e.g. running, walking and other pathological gaits. The function of the devices in this dissertation is suitable for walking gait only. A gait cycle is divided into two periods starting with stance, which is 60% of the total gait cycle followed by the swing (Shurr & Michael, 2002). Stance denotes the period when foot is in contact with the ground, while swing means foot is in the air. Gait cycle starts with the heel strike of one leg, referred to as initial contact, and ends when the same leg hits the ground again. These periods are also divided into phases as depicted in Figure 2.1.

Through different phases the lower limb accomplishes three important tasks. The first and most important one, weight acceptance, is accomplished in initial contact and loading response phase. During these phases the limb absorbs the shock of the free-falling body to preserve the forward momentum. In the following phases, midstance and terminal stance, the body weight is supported by stance leg because other leg stays in the swing phases. After that the limb starts to move forward in the final phases of the stance and progresses forward through swing phases (Perry, 1992).

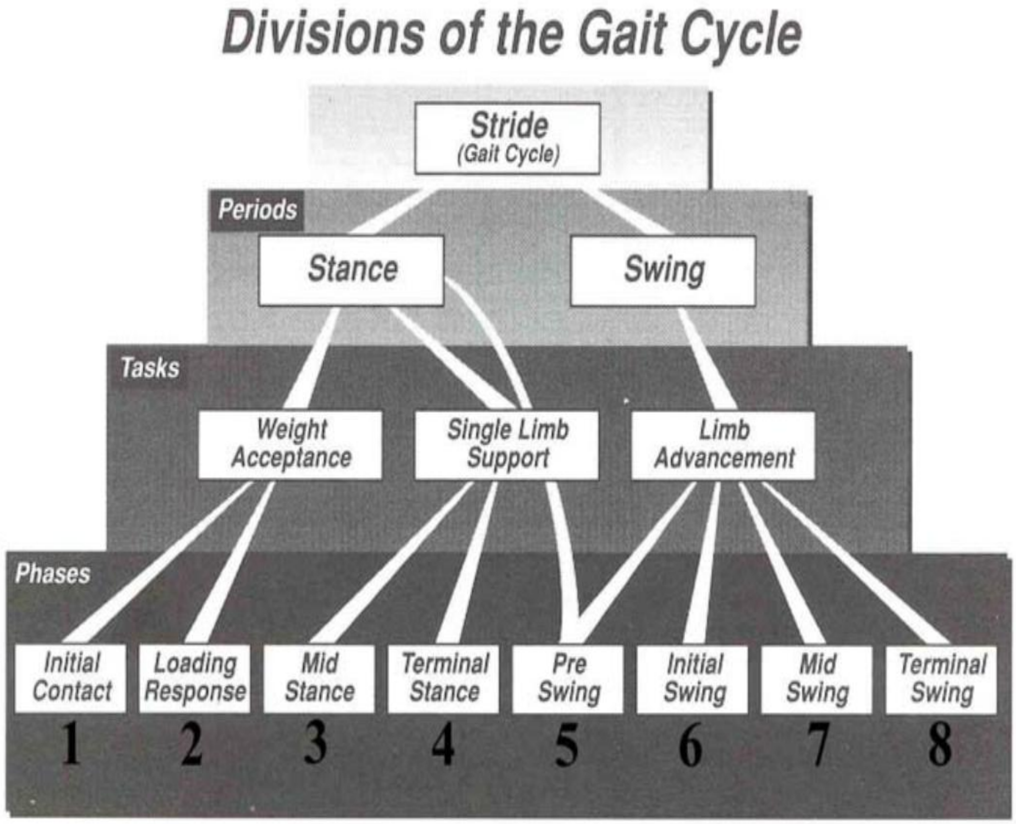

Figure 2.1: Divisions of gait cycle (Perry 1992)

2.1.2 Gait physiology

To design an orthotic device, it is very important to analyze the functionality of the anatomical part that is being assisted by the orthosis. The easiest way to analyze gait is to look into each joint motion in sagittal plane. Following sections describe the ankle and knee functions in a gait cycle.

2.1.2.1 Ankle physiology

During ambulation the ankle, heel and forefoot play important role by absorbing shock in stance phases, creating pivotal system to move the body forward. At the beginning of the gait cycle heel strikes the ground at initial contact with the ankle in neutral position (Figure 2.2). Immediately following after initial contact, the phase denoted as loading response, there is approximately 10 degrees of plantar flexion of the ankle by the eccentric contraction of the dorsiflexor musculature. At the end of this phase the body weight is transferred to single limb support. This phase occurs during first 10% of the gait cycle. The following phase is continuation of single limb support and it is called midstance. It occupies 10-30% of the gait cycle. Terminal stance completes the single support period and it is 30-50% of the gait cycle. The final phase of the stance is pre-swing, it starts with the heel strike of opposite limb and ends with toe-off. It occupies 50-60% of the gait cycle. Most of the power during walking is generated by the calf muscles in terminal stance and pre-swing. The volley of power that is generated around ankle in this phase is known as ankle push-off. The subsequent period of the gait cycle is swing and it is divided into three phases: initial swing (60-73%), mid-swing (73-87%) and terminal swing (87-100%). Initial swing begins with the lift of the foot and continues till maximum knee flexion. The subsequent mid-swing ends while the tibia is in vertical position. At the final phase, terminal swing, knee becomes fully extended and prepares for heel strike (Winter, 1991; Perry, 1992). Ankle range of motion in sagittal plane is presented in Figure 2.3.

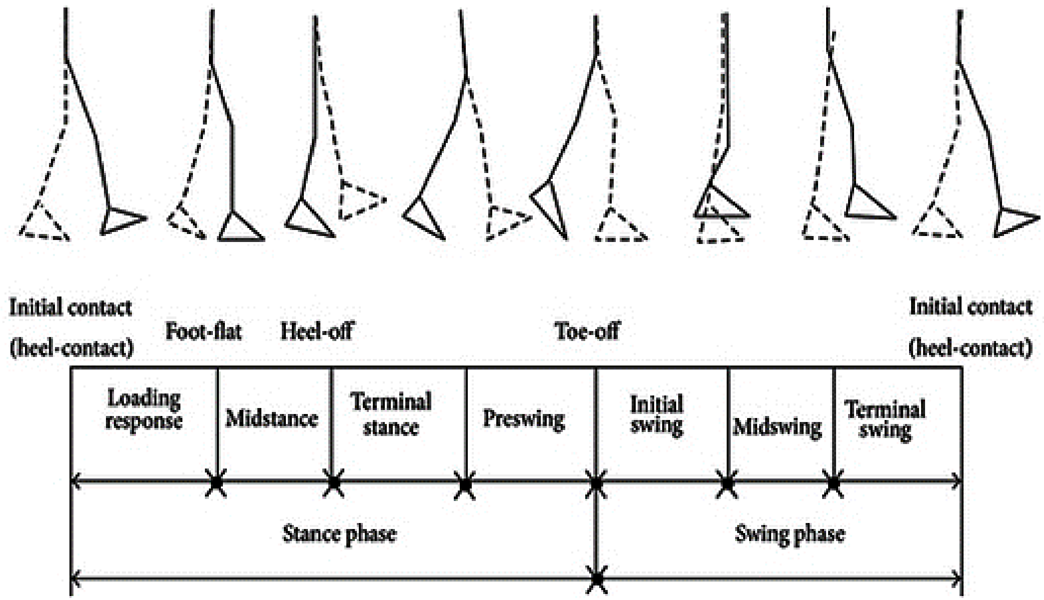

Figure 2.2: Different phases of normal gait cycle (Alam, Choudhury, & Mamat, 2014)

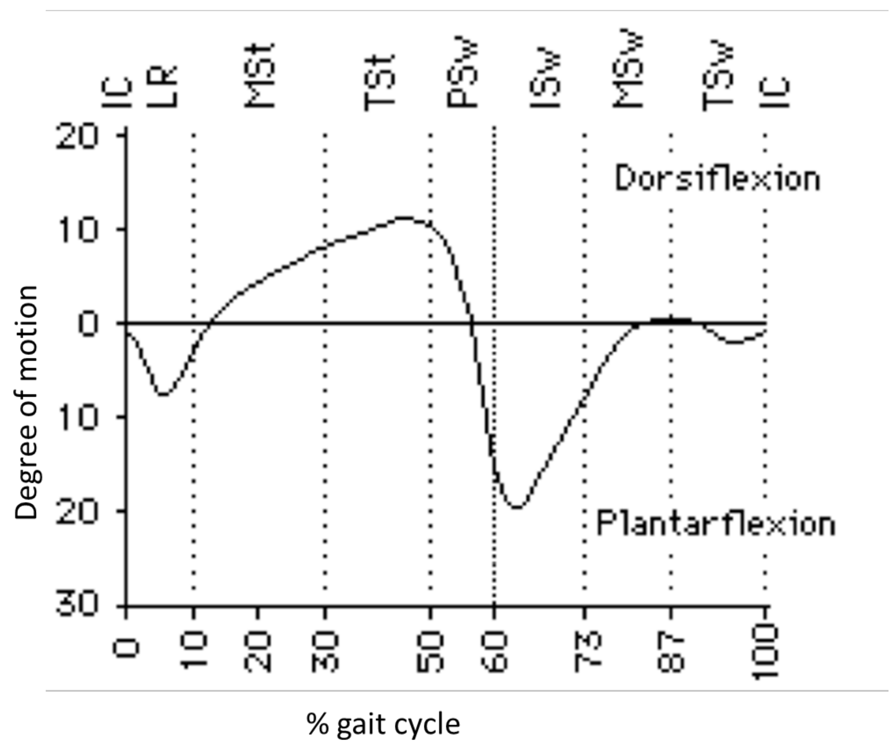

Figure 2.3: (a) Ankle range of motion in sagittal plane (Winter, 1991)

2.1.2.2 Knee physiology

Knee plays the main role to provide limb stability in stance. The primary determinant for limb's ability to move forward in swing phases is the knee flexibility (Perry, 1992). As the gait cycle starts with initial contact there is about two to five degrees of flexion. At loading response ideally the knee absorbs the shock and accomplishes the weight acceptance task. The flexion goes underway as the ground reaction force moves posterior and produces flexion moment. As loading response phases progresses the knee continues to flex, reaching a position close to 20 degrees of flexion. Very early in midstance the flexion ceases as the flexion moment is weaken by quadriceps contraction and eventually the knee begins to extend. Thus during midstance it reaches about eight degrees of flexion. In terminal stance the knee continues to extend and reaches about five degrees of flexion and then in pre-swing the motion is reversed due to the counteraction of quadriceps and strong plantar flexion of ankle. At the end of pre-swing there is a rapid flexion up to about 40 degrees of flexion. The flexion has to be sufficient at this stage as the body weight shift to the opposite limb and the thigh starts to advance. At initial swing the knee reaches to the flexion of about 60 degree to provide toe clearance and then knee starts to reverse and extension begins. In mid-swing there is a rapid extension, which continues until terminal swing reaching to almost (0 deg) neutral position. The knee range of motion in sagittal plane is shown in Figure 2.4.

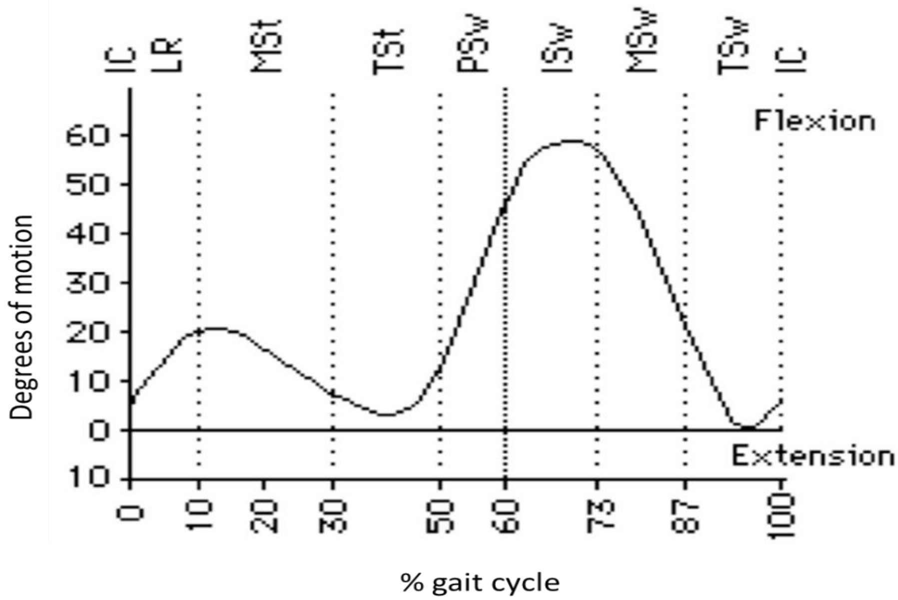

Figure 2.4: Knee range of motion in sagittal plane (Winter, 1991)

2.1.3 Pathological gait

2.1.3.1 Ankle pathology

Proper understanding of pathological gait is the prerequisite of lower limb orthotic device design. The normal gait is impaired by injuries or muscular and neurological disorders. Such disorders include stroke, muscular dystrophies, multiple sclerosis, spinal cord injury, cerebral palsy and trauma (Burridge et al., 2001; Patterson et al., 2007). Plantar flexor and dorsiflexor muscle weaknesses are the main causes of ankle pathological gait. Plantar flexor muscle group is located posterior to the ankle joint which includes gastrocnemias, peroneal, soleus and posterior tibial muscles. As most of the power in walking generates during ankle push-off (Nadeau et al., 1999; Winter, 1991), plantar flexor muscle weakness results in reduction of push-off power and consequently it reduces walking speed, shortens step length and elevates energy cost of walking. Dorsiflexor muscle group is located anterior to the ankle joint and includes extensor digitorum longus, extensor hallucius longus and tibialis anterior

(Perry, 1992). Due to dorsal muscle weakness the foot cannot be lifted adequately in mid-swing, which results in toe-dragging, lowering walking speed, shortening of step length, elevation of energy cost and the gait pattern is known as “drop foot”. In addition to that during loading response the weak dorsal muscle group fail to decelerate the plantar flexion and result in abrupt foot slap (Chin et al., 2009; Stein et al., 2010).

2.1.3.2 Knee pathology

Neuromuscular disorders like amyotrophic lateral sclerosis, polio, femoral neuropathy, Guillain-Barre and other abnormalities can cause lower limb musculoskeletal impairments and paralysis (Taylor, 2006). Lower limb with quadriceps weakness fail to attenuate the compressive forces at the knee as they are responsible for shock absorption during ambulation. This phenomenon leads to the development of knee osteoarthritis (Earl, Piazza, & Hert, 2004; Lewek et al., 2004). Individuals having weak muscle or paralysis are not able to walk efficiently and safely as their knee becomes unstable and it collapses during stance phase of the gait (Fatone, 2006; Yakimovich, Lemaire, & Kofman, 2009)

2.1.4 Gait analysis

The systematic study of human ambulation is called gait analysis. The gait pattern and abnormalities of an individual can be determined through gait analysis. The functional analysis of prosthetic/orthotic devices can also be accomplished by using gait analysis. There are several types of determinants to measure in order to analyze gait cycle: time-distance dependent parameter, kinetic and kinematic parameter, physiological parameter (metabolic energy expenditure), and electromyography (muscle activation). In this dissertation, time-distance dependent parameters, kinetics and kinematic parameters were measured to analyze the performance of fabricated articulated AFO. Definitions of some gait factors are given below:

- Time-distance dependent factor/ spatial-temporal parameter – It is the global aspect of gait as gait is a cyclical activity and a factor like “walking speed” is supposed to be the characteristic of a person’s overall walking performance.
- Kinematic parameter – It describes the movement of the body without accounting the force that moves the body parts (Winter, 1996). It includes angular and linear displacement, accelerations etc. In this study the kinematic parameter used was ankle joint angle.
- Kinetic parameter – It denotes the relationship of mass and force that produce the motion. It mainly includes torques and powers involved in the gait cycle.

2.2 Joint Reference System

To describe the anatomical joint axis and joint motion it is necessary to follow a standard reference system. It was Grood and Suntay (1983), who first proposed joint coordinate system for knee joint. Following the proposal The International Society of Biomechanics (ISB) proposed a general reporting standard for joint motion based on joint coordinate system in 2002 (Wu et al., 2002). According to those recommendations, information society technologies (ist) defined a reference frame and joint coordinate system for different segments of human lower limb anatomy in their VAKHUM (Virtual animation of the kinematics of the human for industrial, educational and research purposes) project (Hilal et al., 2002).

To begin the description of reference system the anatomical reference planes, which are used to describe the human movements, must be defined. The description of three reference planes (Figure 2.5), in accordance with Rose and Gamble (1994) is given below.

- Transverse plane – A horizontal plane, which bisects the body into superior and inferior (head and tail) portions. It is also known as axial plane.
- Coronal plane/frontal plane – It bisects the body in anterior and posterior portions (back and front).
- Sagittal plane – it separates the left and right portions of the body.

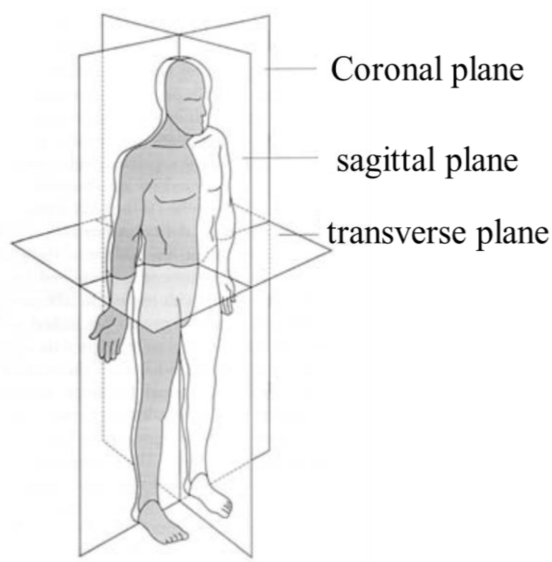

Figure 2.5: Three planes to describe body motion (Rose and Gamble, 1994).

The reference frames, defined by Hilal et al. (2002), are dependent on quasi-coronal plane, quasi-sagittal plane and quasi-transverse plane of the respective segments. Figure 2.6, 2.7, 2.8 and following descriptions present the required anatomical frames of femur, tibia/fibula and foot to acquire fitting dimensions of the orthotic

2.2.1 Reference system for the femur segment

- Anatomical landmarks required to define the femoral reference frame

  fh – center of femoral head

  le – lateral epicondyle

  me – medial epicondyle

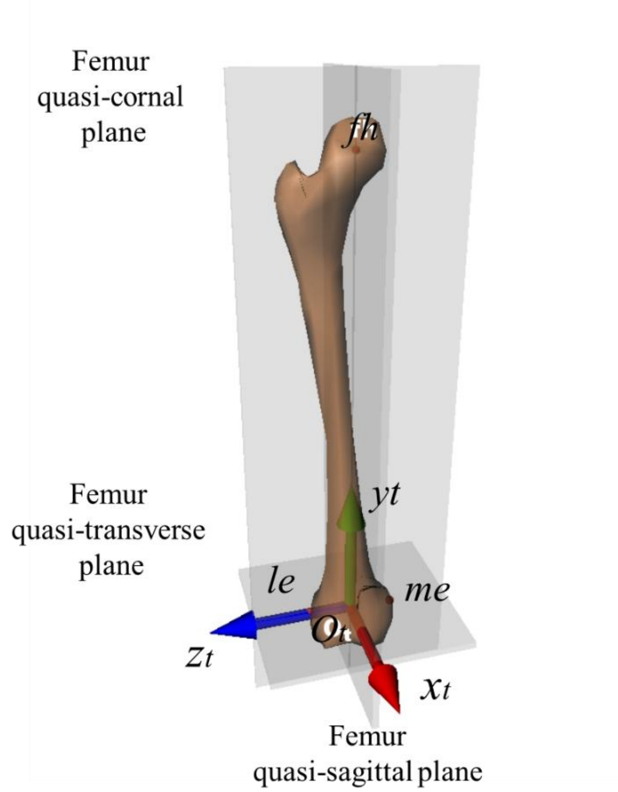

Figure 2.6: Femur anatomical frame (Hilal et al., 2002)

- Femure anatomical plane

  Quasi-coronal plane - the plane containing *fh*, *le* and *me*

  Quasi-sagittal plane - the plane perpendicular to quasi-coronal plane and containing *Ot* (mid point between *le* and *me*) and *fh*.

  Quasi transverse plane- mutually perpendicular plane to other two planes.

- Femur anatomical frame

  O_t – Origin of the femur anatomical frame

  y_t – axis - a line connecting *Ot* and *fh* with upward positive direction.

  z_t – axis – a line perpendicular to y_t – axis and lying in quasi coronal plane, with positive direction pointing right. This axis defines the flexion/extension axis of the knee.

  x_t – axis – mutually perpendicular to other two axes and pointing anterior.

2.2.2 Reference system for the tibia/fibula segment

- Anatomical landmarks required to define the tibia/fibula reference frame

  hf – tip of fibula head

  tt – tibial tuberosity prominence

  lm – distal tip of lateral malleoli

  mm – distal tip of medial malleoli

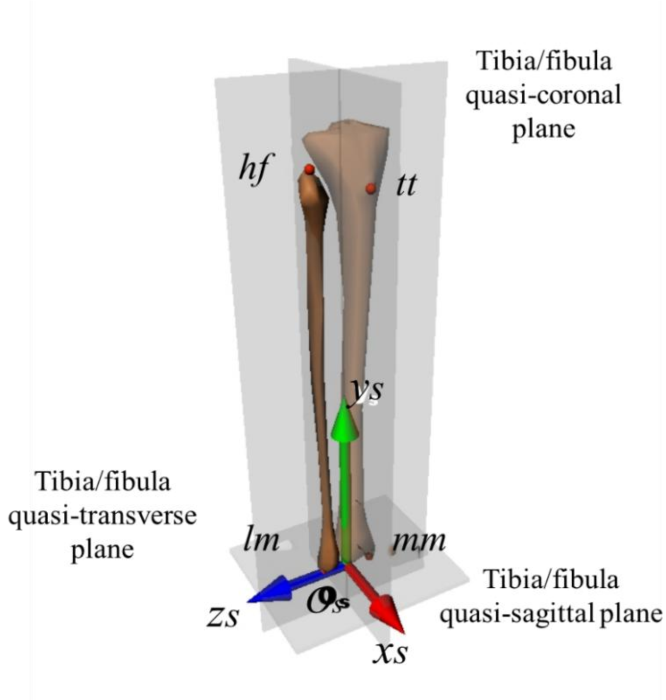

Figure 2.7: Tibia/fibula reference frame (Hilal et al. 2002)

- Tibia/fibula anatomical plane

  Quasi-coronal plane - the plane containing O_s, *lm* and *hf*

  Quasi-sagittal plane - the plane perpendicular to quasi-coronal plane and containing *Os* (mid point between *mm* and *lm*) and *tt*.

  Quasi transverse plane- mutually perpendicular plane to other two planes.

- Tibia/fibula reference frame

  O_s – origin of the tibia/fibula frame of the shank segment.

  y_s axis – the line in upward direction at intersection between quasi-coronal plane and quasi-sagittal plane.

  z_s axis – the perpendicular line to y_s axis and lying in the quasi-coronal plane pointing right. This axis also defines plantar flexion and dorsiflexion around it.

  x_s – mutually perpendicular line to y_s and z_s and pointing to the anterior.

2.2.3 Reference system for the foot segment

- Anaomical landmarks required to define the foot reference frame

  ca – upper ridge of the calcaneus

  fm – point on first metatarsal head (dorsal side)

  sm – point on second metatarsal head (dorsal side)

  vm – point on fifth metatarsal head (dorsal side)

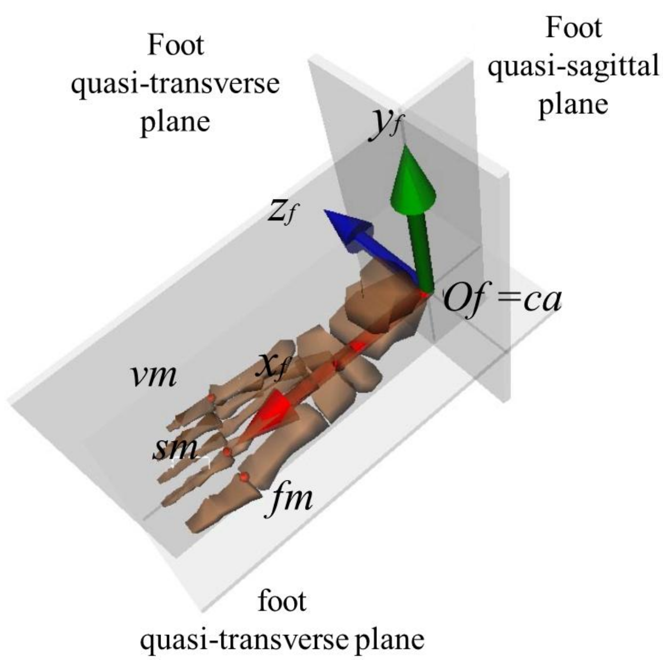

Figure 2.8 foot reference frame (Hilal et al., 2002)

- Foot anatomical plane

  Quasi-transverse plane - the plane containing *vm*, *fm* and *ca*

  Quasi-sagittal plane - perpendicular to quasi-transverse plane and containing *sm* and *ca*

  Quasi transverse plane- mutually perpendicular to other two planes

- Foot reference frame

  O_f – origin of the foot frame of the shank segment, which is actually point *ca*.

  y_f axis – the line in upward direction at intersection between quasi-coronal plane and quasi-sagittal plane.

  z_f axis – the perpendicular line to y_f - axis and lying in the quasi-transverse plane pointing right.

  x_f – mutually perpendicular line to y_f and z_f and pointing to the anterior.

2.3 Existing Lower Limb Orthosis

There are a number of treatments for lower limb disabilities such as surgical, therapeutic, or orthotic. Applying functional-electrical stimulation (FES) is another active approach. It is a technique that uses electrical current to contract damaged muscles. Besides FES, this technique has different names such as electrical stimulation and functional neuromuscular stimulation (FNS). However, all of them have the same goal to stimulate damaged muscle contraction and enhance functionality. FES is applied to the common peroneal (CP) nerve during the swing phase of the gait cycle, which stimulates the functionality of the dorsiflexor muscles (Springer et al., 2012). Through this stimulation the ankle can be flexed beyond neutral angle, which helps the ankle foot complex maintain toe-clearance during the swing phase (Stein et al., 2010). However, activated muscle mass by FES is the fraction of available muscles resulting in less effectiveness for drop-foot prevention, which is a disadvantage of this approach (Polinkovsky et al., 2012). However, among these approaches, orthotic treatment is the most common practice. Foot orthosis, ankle foot orthosis (AFO), knee ankle foot orthosis (KAFO), hip knee ankle foot orthosis (HKFO) are commonly prescribed orthotic devices for different types of disorders. Among these devices KAFO and AFO are within the interest of this dissertation.

2.3.1 Knee ankle foot orthosis

Knee ankle foot orthosis (KAFO) is an assistive device, which extends from the thigh to foot and usually used to control lower limb instability (Shamaei, Napolitano, & Dollar, 2014). KAFO is usually prescribed to the patients having either skeletal problems: arthritic joints, broken bones, knock-knee, knee hyperextension, bowleg, or muscular weakness. It provides partial solution by maintaining alignments, controlling knee and ankle joint mechanically and providing stability during stance phase (Yakimovich, Lemaire, & Kofman, 2009).

Due to paucity of technology for many years mechanical knee joints were restricted to be entirely locked or entirely unlocked. Bail lock (Figure 2.9a) and drop lock (Figure 2.9b) knee joints are example of entirely locked joints, which keep the knee extended throughout the gait cycle. Offset knee joint (Figure 2.9c) remains unlocked during ambulation, maintains the knee stability by moving the mechanical knee axis posterior to anatomic knee joint (Lin VW, 2003). Entirely locked knee joint increases the energy consumption as knee is unable to flex during swing phase, while offset knee joint possess the advantage in this regard. However, offset knee joint fails to provide stability in walking on inclined or uneven surface. Advancement of technology has facilitated development of stance control knee joint (Hebert & Liggins, 2005). It locks the knee in stance phase and allows free motion in swing phase. Both mechanical and electronic actuated stance control knee joints are available (Yakimovich, Lemaire, & Kofman, 2009). KAFO that extends up to hip joint to provide further trunk stability are called hip knee ankle foot orthosis (HKFO). In this research drop lock knee joint was used to fabricate a custom knee ankle foot orthosis.

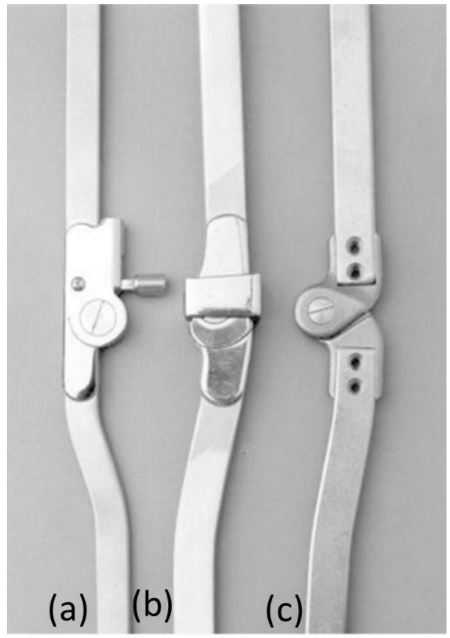

Figure 2.9: Knee joint (a) bail lock (b) drop lock (c) offset

2.3.2 Ankle foot orthosis

Ankle foot orthosis is an assistive device that restricts or controls the ankle motion at any preferred orientation. In general, there are three types of ankle foot orthotic (AFO) devices: passive devices, semi-active devices, and active devices. Passive AFO device does not comprise any electrical or electronic elements or in other words it is not controlled by external power sources. These devices are of two types: articulated and non-articulated. Non-articulated AFO is usually a single piece plastic encompassing the dorsal part of the leg and bottom of the foot, and fabricated out of lightweight thermoformable or thermosetting materials (Figure 2.10a, 2.10b, 2.10c). The design of the AFO varies from highly rigid to flexible. Passive articulated AFOs are designed combining lightweight thermoplastic or carbon composite shells and articulated joints. There are different designs of articulated joints with a variety of hinges, flexion stops, and stiffness control elements like spring, oil damper, one-way friction clutch, and so forth. Commercial hinge joints like Tamarack flexure joint and Klenzak ankle joint with pin or spring are used to control the motion of ankle in sagittal plane (Yamamoto et al., 1997). AFOs with commercial joints and mechanical stops are capable of preventing drop-foot successfully by providing dorsiflexion assisting force or locking the ankle in a suitable position, however, they also inhibit other normal movement of the ankle. To overcome this problem researchers have introduced different motion control elements e.g. spring, one way frictional clutch, oil damper etc. for providing normal gait motion (Figure 2.10d, 2.10e, 2.10f). Articulated AFOs with those elements can provide adjustability of initial ankle angle and joint stiffness, better motion control of foot, assistive force in dorsiflexion direction, resistive force in plantar flexion direction, and desirable range of motion of the ankle joint. There are some innovative passive AFOs those utilize the energy from gait to provide assistive motion. These AFOs are called power harvesting AFOs in which some pneumatic components like bellow pump, passive pneumatic element, and so forth are used for locking the foot or providing assistive torque.

Figure 2.10: (a) Rigid AFO (b) posterior leaf spring AFO (c) Carbon fiber AFO (d) Metal and plastic type articulated AFO (e) AFO with oil damper (f) AFO with one way frictional clutch (dream brace)

Semi-active AFO devices are capable of varying flexibility of the ankle joint by using computer control. Active AFOs contain onboard power source, control system, sensors, and actuators. Among these devices, passive AFO is the most popular daily-wear device due to its compactness, durability, and simplicity of the design. Active and semi-active AFOs have the limited usage only for rehabilitation purpose due to the need of improvement of actuator weight, portable power supply, and general control strategy. Table 2.1 presents some features of different types of AFO.

Table 2.1: Features of different types of AFO

Passive AFO		Active/semi-active AFO
Non articulated	Articulated	Active AFOs possess the ability to interact with the walking environment and act accordingly. Most of the active AFOs compensate dorsiflexor muscle weakness and some designs are found to assist plantar flexor muscles. Active AFOs are comprised of electronic control system, actuator, tethered or untethered power system, and stiffness control element like magneto rheological brake for better control of ankle motion. The control system usually includes components like force sensor, angle measuring sensor, accelerometer, and microprocessor (Kikuchi et al., 2010; Naito et al., 2009; Takaiwa & Noritsugu, 2008).
• Rigid AFO – holds the ankle foot complex in rigid position and prevents drop-foot. • Posterior leaf spring AFO – semi-rigid single piece plastic AFO, assists push-off. • Carbon fiber orthosis – It possesses the ability to store energy during tibial advancement and able to compensate plantar flexor muscle weakness by dissipating energy during push-off. (Wolf, Alimusaj et al., 2008; Bregman, et al., 2012)	• Conventional AFO - It comprises of an articulated ankle joint with a mechanical stop to control motion using pins or adjustable springs to assist push-off, a metal band at the calf covering with leather, two metallic uprights and often a leather strap at the ankle. • AFO with oil damper - Yamamoto et al. (2005) developed an AFO with oil damper that provides adjustable resistance to plantar flexion in order to prevent foot drop. • Dream Brace AFO – An AFO with one way frictional clutch, which provides constant resistance to prevent foot drop (Wong, Wong, & Wong, 2010). • Power harvesting AFO – Some AFOs are found those harvest energy during gait cycle by means of pneumatic elements (Chin et al., 2009). These are non-commercial and still under development.	

In this research a commercially available ankle joint named “Dream joint” was used to fabricate a custom ankle foot orthosis (Figure 2.11). ORTHO Incorporation, Japan, first developed “Dream brace,” whose function is to provide ankle movement according to the gait cycle. The active element for the innovative mechanism of the articulated joint in this AFO is a one-way frictional bearing clutch. This joint is of two types; type A and type B. Type A joint has a dial rock mechanism with three different angle settings to adjust plantar flexion at position of angle 13°, 38°, or −7° (for knee brace), and type B joint has free plantar flexion. Dorsiflexion is maximum 100° and same for both types of joints. Resistance strength of the frictional bearing is fixed and resistance torque can be selected from the chart provided by the manufacturer for different sizes. The weight of the brace is approximately 350 g and the material used for this joint is SUS304 stainless Steel.

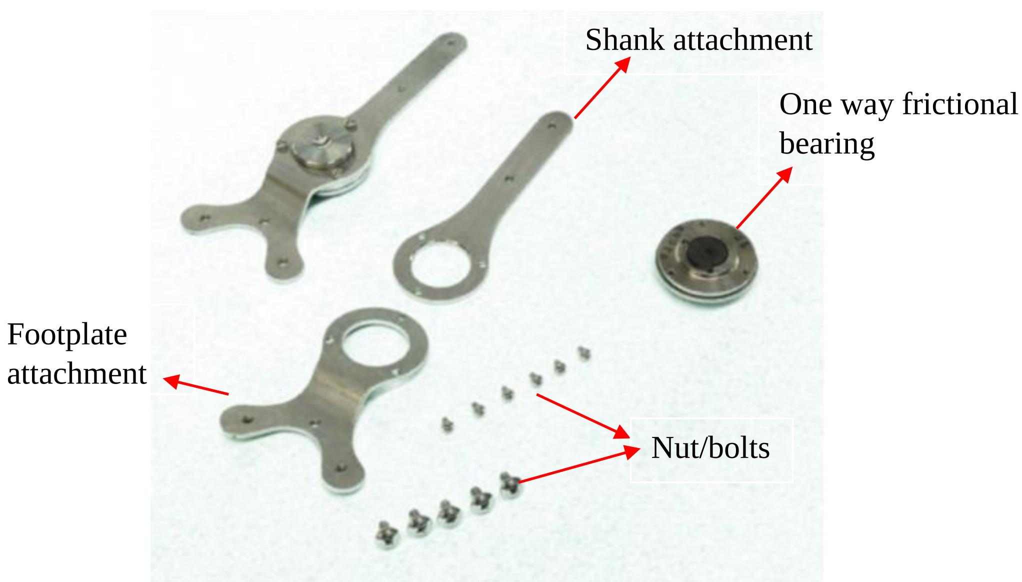

Figure 2.11: Dream joint kit (ORTHO Incorporation, Japan, 2008)

During heel strike at initial contact, the friction of the dream joint dampens the foot-slap by providing resistance to planter flexion. Unlike spring-loaded AFO the resistance torque of the joint does not increase as the foot approaches the ground. During stance phase the body moves forward and the ankle joint allows free dorsiflexion motion as there is no frictional resistance in this direction. During swing phase the joint holds the foot to ensure clearance between toe and ground (ORTHO Incorporation, Japan, 2008; Wong & Hernandez, 2012). No published literature was found describing clinical assessment of the AFO joint.

2.4 Design Considerations of AFO and KAFO

Orthotic device design requires consideration of the dynamics of the original limb, which makes it more challenging than designing prosthetic devices. For the treatment of drop-foot, an ideal AFO should compensate dorsiflexor muscle weakness by preventing unwanted plantar flexion motion of ankle without affecting normal movement. AFO should provide moderate resistance during loading response to prevent foot-slap, no resistance during stance for free ankle motion, and large resistance to plantar flexion during swing phase to prevent drop-foot (Shorter et al., 2013). The objective of the KAFO design is to prevent knee collapse during stance.

An ideal orthotic device should be compact in size and light in weight to facilitate daily life use. Moreover, it is very important to maintain the alignment and mechanical properties; otherwise it could hamper functional activities of the patients. For example misalignment of KAFO might break shank upright and hurt the patient. If an AFO is less stiff, plantar flexion resisting moment will not be sufficient enough to hold the foot and keep clearance during swing. Conversely, an ankle foot orthosis with excessive stiffness can also delay the rehabilitation of patients with neurological damage. The orthotic devices has to be cosmetically attractive and should be designed to use under the clothing (Alam, Choudhury and Mamat, 2014).

Accurate alignment of anatomical ankle joint and rotational axis of mechanical joint is one of the important concerns of AFO design with articulated joint. Gao et al. (2011) reported that optimal alignment of ankle joint provides minimal ankle stiffness, while posterior and anterior alignment provide significantly higher stiffness. Fatone and Hansen (2007) described that with ankle joint misalignment can cause significant calf band movement which might injure the skin.

Precise alignment of anatomical and mechanical axis of knee is one of the most important concerns of KAFO design (Lin and Cutter 2003). During flexion and extension rotary force produces torque, which is absorbed by the orthosis and it must be balanced by ensuring proper alignment. If it is not properly balanced the device will not be stable and it might rotate abnormally causing misalignment and malfunction. Misalignment also creates shear forces which transmit to the limb and increase shear stress on the knee joint. These forces might break the sidebar component of the device and it also has impact on the comfort, performance and longevity of the KAFO (Kaufman and Irby. 2006).

2.5 Manufacturing Process of Lower Limb Orthoses

2.5.1 Traditional process

The traditional techniques of lower limb orthotic device manufacturing are limited by materials and the method used for fabrication. The most followed procedure in orthotic manufacturing is the guidelines published by International committee of Red Cross (ICRC) in 2006 and 2010 for both KAFO and AFO. In AFO guideline manual, instructions for rigid AFO, flexible and articulated AFO with Tamarack Flexure Joint ™ were demonstrated.

Every AFO fabrication starts with making cast of the limb to be treated (Figure 2.12 a, 2.12b). Marking trimline and joint position is then accomplished on the positive cast (Figure 2.12c). To place the articulated joint it is instructed to locate the ankle anatomical axis on the plaster cast by marking the apex of the lateral malleoli and distal tip of the medial malleoli in slightly posterior direction. A dummy joint is then installed on the marked position (Figure 2.12 d), which is followed by vacuum forming of a thermoplastic sheet around a positive cast (Figure 2.12e), cutting away materials to gain proper shape (Figure 2.12f), and installation of the ankle joint (Figure 2.12g). The process flow chart of the AFO (with Tamarack joint) is presented in Figure 2.13.

Figure 2.12: (a) Negative cast (b) Positive cast (c) Marking trimline on positive cast (d) Placing Joint on the cast (e) Vcuum forming (f) Marking separation line (g) Assembled AFO (The International Committee of Red Cross, 2010)

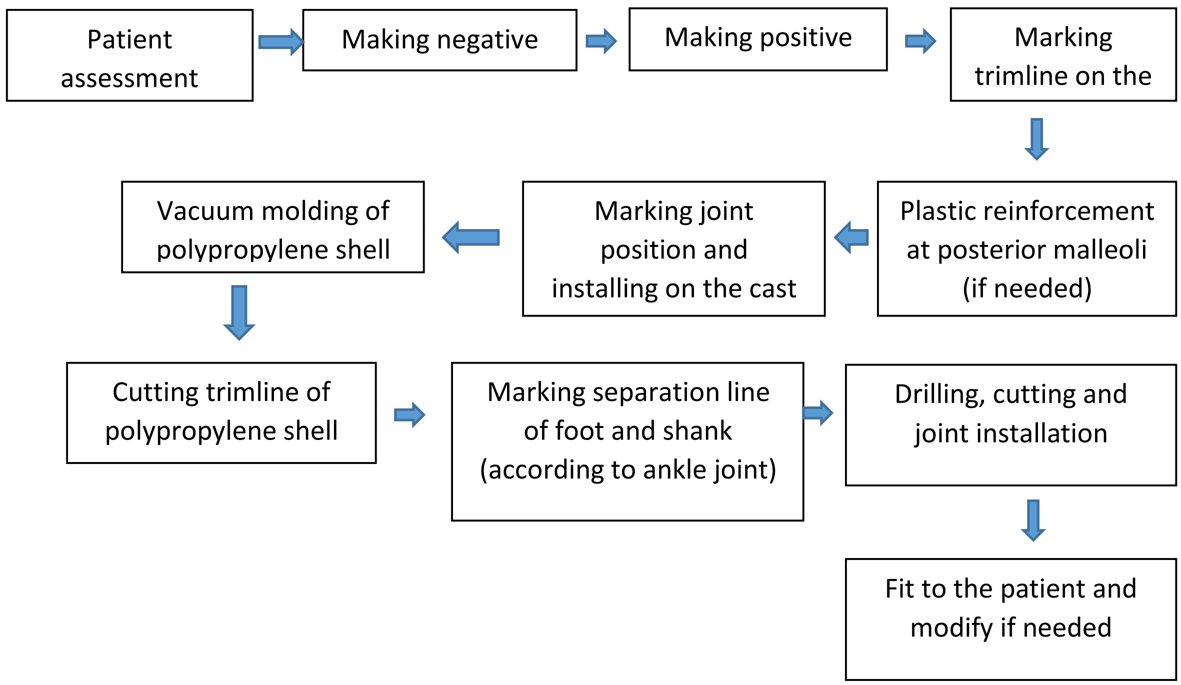

Figure 2.13: Flow chart of traditional process of passive articulated AFO

For custom dream brace AFO fabrication the Ortho Inc. Tokyo, 2011 provided a manual, in which a custom jig was used to maintain the ankle joint alignment. It was instructed to insert a cylindrical shaft through the low end of the medial malleoli and center of the lateral malleoli into the negative cast (Figure 2.14a), then make the positive cast keeping the shaft in its position (Figure 2.14b). The next step is to take out the shaft from the cast and insert a hexel-bolt (Figure 2.14c) to install a dummy joint (Figure 2.14d). Following after vacuum forming cutting trimline and installation of the Dream joint ends the fabrication process (Figure 2.14e, 2.14f, 2.14g, and 2.14h).

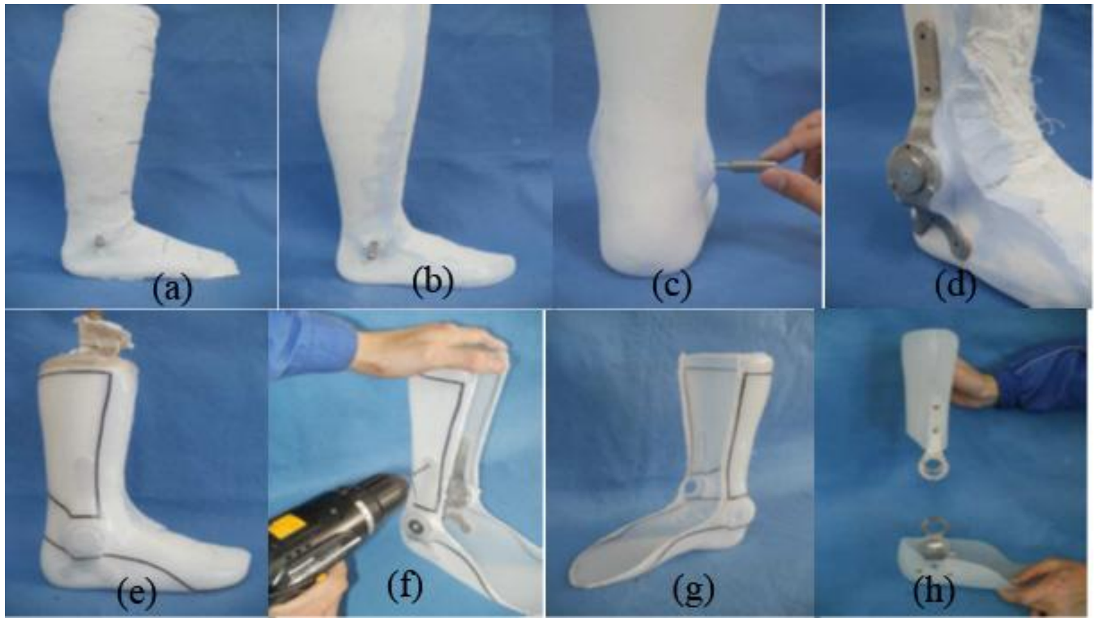

Figure 2.14: (a) Cylindrical shaft in negative cast at the ankle (b) Positive cast with the shaft at ankle (c) insertion of hexel-bolt through the hole (d) Placing dummy joint on the positive cast (e) Vacuum forming and marking trimline (f) drilling on plastic shell (g) prepared plastic shell (h) assembled AFO (ORTHO Incorporation, 2011)

Like AFO fabrication KAFO fabrication also involves casting (Figure 2.15a) and vacuum forming, except its alignment is not only determined by the ankle motion control but also the knee motion. The ICRC instruction (2006) guideline demonstrated fabrication of KAFO with rigid ankle. To maintain the alignment and placement of the knee joint, it requires anatomical landmarking of following bony prominences: great trochanter, medial tibial plateau, head of fibula malleoli, the 1st and 5th metatarsal heads, navicular bone, and base of 5th metatarsal, if prominent. After marking anatomical locations it was instructed to verify the positive cast by ensuring the lateral line passes through great trochanter to the middle of the lateral malleolus, posterior line passes through the middle of the thigh, knee and ankle, and heel and forefoot remain flat on the ground (Figure 2.15b). Following after vacuum forming (Figure 2.15c) the metallic components are shaped (Figure 2.15d) according to the cast shape and installed as shown in Figure 2.15e.The knee joint was placed 20 millimeter above the medial tibial plateau (Figure 2.16). The overall procedure is demonstrated in a flowchart in Figure 2.17.

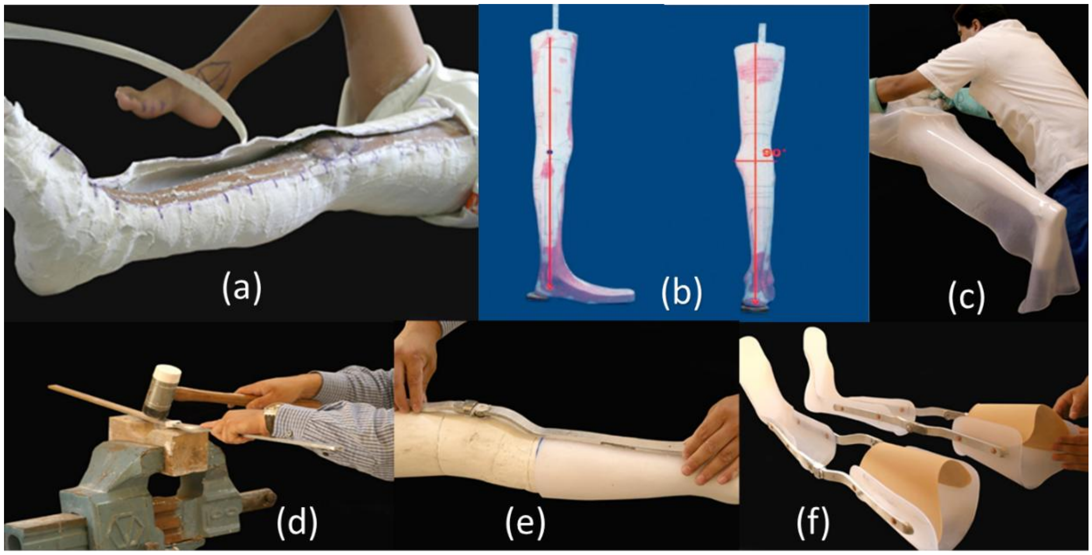

Figure 2.15: (a) Making negative cast (b) Positive cast verification (c) Vacuum forming (d) Metallic upright preparation (e) placement of uprights (f) assembled KAFO (International Committee of Red Cross, 2006)

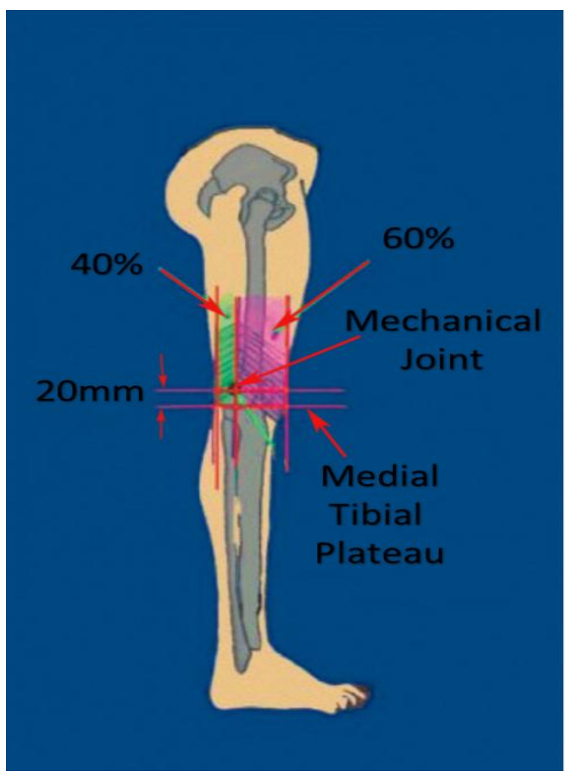

Figure 2.16: Mechanical knee joint location (Internationa Committee of Red Cross, 2006)

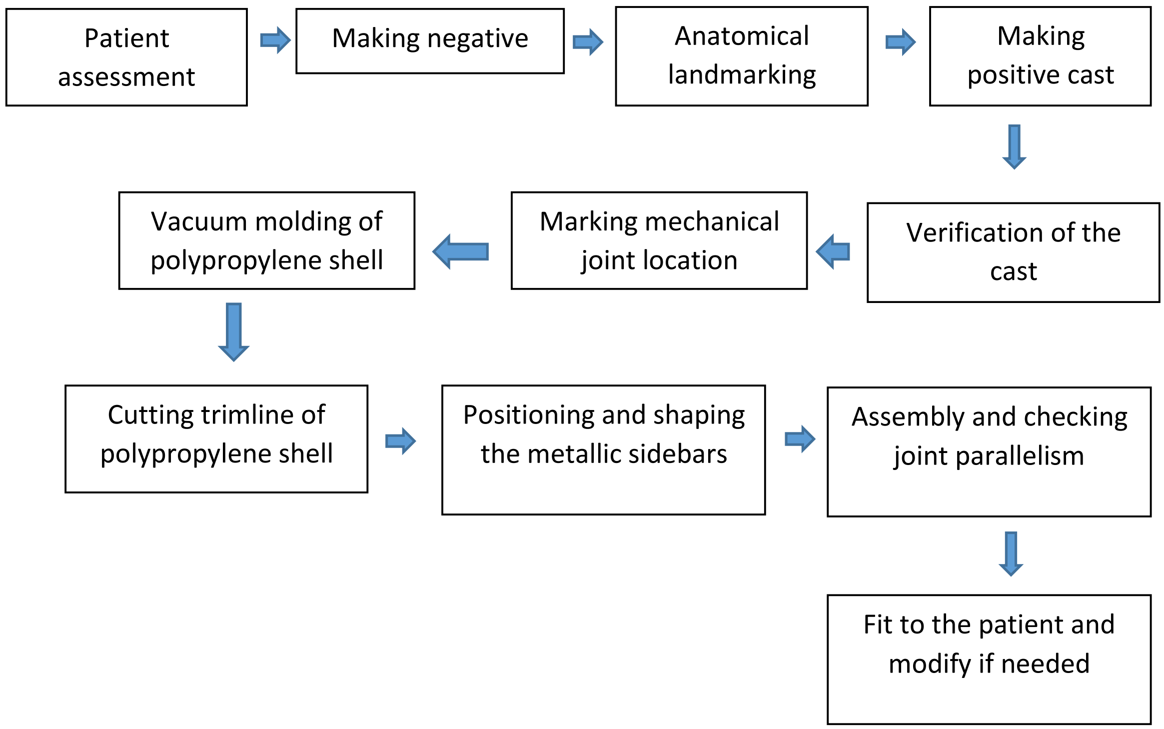

Figure 2.17: Flow chart of traditional process of KAFO fabrication

2.5.2 Computer aided manufacturing of lower limb orthosis

Development of digital models of freeform surfaces of human anatomy has made it feasible to apply computer aided design and manufacturing tools in medical field. Such advancement helps reduce product development time and facilitate freedom to design intricate devices. Two types of technologies are found those are used for computer modeling of human body parts: using medical images and using 3D scanner to collect surface data. Through medical imaging technologies e. g. CT-scan (computed tomography), MRI (magnetic resonance imaging) solid models of body parts are developed by 3D reconstruction. Such images especially CT images can differentiate the anatomical components, like soft tissue, bones by density difference. There are some software like MIMICS (Materialise NV) those have the ability to choose specific area based on density, which is known as thresholding. The software then reconstruct the 3D surface from 2D slice images of that particular area. Such 3D models provide detail information regarding skeletal structure and soft tissues. Through 3D scanner cloud data of the anatomical surface are collected to develop virtual models. Such digital models are compatible with additive manufacturing (AM) which provides exact description of the anatomical part. AM is widely used in data visualization, product development, specialized manufacturing, and rapid prototyping. In this process one can fabricte objects from 3D computer model of stereolithography (STL) format, which instructs the manufacturing machine to fabricate the intended object (Wong & Hernandez, 2012). Selective laser sintering (SLS) and stereolithography (SLA) approaches of AM process requires a reduced amount of build time while fused deposition modeling (FDM) is a low cost approach but less capable of creating intricate designs (Telfer et al., 2012).

Using radiographic images for complex orthopedic surgery is a common practice. However, additive manufacturing allows clinicians greater visualization through making rapid prototypes of damaged body parts, provides opportunity to fabricate accurate surgical implants, plan and simulate the surgery beforehand (James et al., 1998; Chaput & Lafon, 2011). Brown (2003) described few case studies regarding the use of rapid prototyping in trauma surgery. In a case study of acetabular fracture, a three dimensional model of pelvis with complex fracture was developed from CT-scan images (Figure 2.18a). Another computer-reversed wax model without fracture was developed to form contours of pelvic reconstruction plate and establish drilling trajectories. This implant template was then tested on the fractured model before execution of the surgery (Brown, 2002).

Another case study of surgery of left acetabular fracture of a 27 year old man was described, where the three rapid prototype model was used to detect the type of fracture. The fracture was then fixed and reduced in that model with a ten-hole pre-contoured plate and lag screws. The plate was finally applied to patient's pelvis (Figure 2.18b and 2.18c).

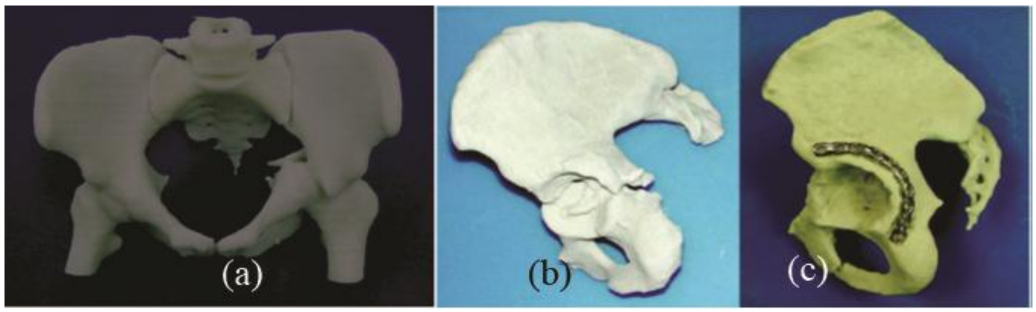

Figure 2.18: (a) A rapid prototype three-dimensional model of a pelvis with a left acetabular fracture Brown (2002) (b) A rapid prototype three-dimensional model of a pelvis with a left acetabular fracture (c) A rapid prototype three-dimensional model of the acetabular fracture after realigning of the fracture components and contouring of the plate for fixation (Brown, 2003).

Additive manufacturing is a popular tool in dental industry as the dentists can build dental implants, CAD model of teeth or even mouth to practice or simulate the surgery (Noort, 2012; Hollister, 2005). AM tools are also widely used in prosthetic field. Cost effective and comfortable prosthetic socket development by 3D printing from 3D scan data of residual limb (Herbert et al., 2005), reconstruction of customized in-the- ear hearing aid shells from three dimensional laser scanning data (Tognola et al., 2003) are the examples of AM technology application.

The application of 3D scanning and AM in lower limb orthotic design is being introduced in recent years. Few articles are found describing the application of digital models in plastic orthotic design and analysis. The process involves scanning of the limb to be treated or any existing AFO and rapid prototyping. The overall work flow chart of computer aided manufacturing of AFO is given in Figure 2.19.

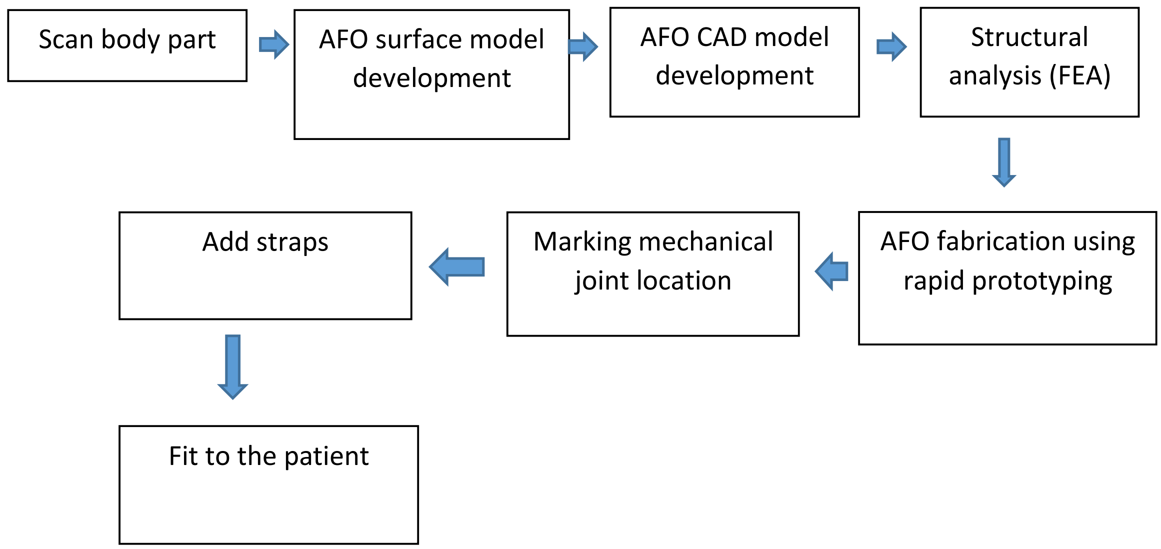

Figure 2.19: Flow chart of AFO fabrication using additive manufacturing

Faustini et al. (2008) explored the feasibility of rapid production of patient-specific passive dynamic AFOs using selective laser sintering based analysis, design and manufacturing framework. The study was designed to manufacture passive dynamic AFO with the shape and mechanical damping properties similar to spring like carbon fiber orthosis. A CAD model was developed to replicate the geometric properties of carbon fiber AFO and FEM analysis was employed to achieve desired stiffness. There were three different SLS material (Nylon 12, glass-filled Nylon 12 and Nylon 11) for manufacturing AFO and evaluating their relative damping properties with carbon fiber AFO. The authors found from the experiment that Nylon-11 AFO had the best damping characteristics while glass filled Nylon-12 had the worst. Destruction test showed that only Nylon-11 AFO did not experience fracture in large deformation.

Schrank & Stanhope, (2011) developed an automated manufacturing process that supports functional customization of AFO and evaluated the dimensional accuracy of passive dynamic orthosis fabricated via selective laser sintering manufacturing process and fit customization. The authors reported that no dimension divergence was greater than 1.5mm with majority divergence less than 0.5mm.

Mavroidis et al. (2011) explored the feasibility of SLA approach for fabricating AFO. The authors produced one personalized rigid AFO and one personalized flexible AFO with different materials. The orthoses were tested by conducting gait analysis of a healthy subject in different conditions and resemblance was found with a commercially available polypropylene AFO over a number of gait parameters.

Telfer et al. (2012) demonstrated the potential of additive manufacturing process by developing prototype of one foot orthosis with adjustable metatarsal support elements and one ankle foot orthosis with adjustable stiffness. The intricate design of the AFO consisted of four AM components: foot section, strut, slider and shank section. Additionally, two bearings, two gas springs were used. Additive manufacturing technique provided geometrical freedom to fabricate the novel AFO with three advantageous features over traditional AFO. The design allowed two different settings of gas spring for adjusting stiffness; intricate design of the strut allowed adjusting the angle between foot and shank; and the slider was useful to compensate friction generated due to misalignment of hinge axis and ankle axis.

Benabid et al. (2012) applied medical imaging data to develop a passive dynamic ankle foot orthosis. They developed foot and shank part of an AFO on the basis of 3D model of lower limb, through 3D reconstruction of MRI images, and connected them with a stainless steel spring blade. They also carried out finite element analysis of the blade to anticipate the behavior of the orthosis.

2.6 Orthotic Materials

It is very important to select the proper material for orthotic design to ensure performance, safety, comfort and cosmetic. There are wide variety of materials used in orthotic fabrication. The characteristics of orthotic materials to be considered are stiffness, strength, fatigue resistance corrosion resistance, density and machinability (Shurr & Michael 2002).

2.6.1 KAFO Materials

Traditional knee ankle foot orthoses are made of steel (uprights) and lather (calf bands). However, new materials with better strength, design, cosmetics have emerged. In KAFO design uprights are usually made of metals such as steel, titanium alloy, aluminum (Kaufman and Irby, 2006). The most common material is steel due to its strength, availability, cost effectiveness and easy machinability. However, Aluminum possesses advantages over steel in context of strength to weight ratio, but its fatigue resistance is lower than steel. Titanium alloys are better than steel and aluminum in every aspect, however, the cost of them is negative factor for selection.

Although steel is still in use for uprights, but the calf band materials are being changed from metal and leather to plastic and carbon fiber materials. Polypropylene and polyethylene are commonly used for their light weight, cosmetic appearance, ease of fabrication and hygiene.

2.6.2 AFO Materials

In general, articulated AFOs comprise of posterior cover or anterior shank component and a foot plate attached by various hinges at the ankle that can control or restrict the motion of the ankle. In the beginning, articulated AFO shank components were metallic uprights attached with leather calf band and ankle joint. Such AFOs are less expensive and provide accommodation for swelling of limb. Carbon fiber uprights in combination with plastic calf bands are light in weight but costlier than metal leather counterpart. In recent years, AFO components are manufactured mostly from thermoplastic or polypropylene. Carbon fiber material or fiber glass reinforced materials are also being used for their energy storage capability and high strength to weight ratio. However, these materials can cause problems like irritation of skin, respiratory tract and eyes (Na Rungsri & Meesane, 2012). Material selection for non-articulated single piece AFO such as rigid AFO, posterior leaf spring AFO is very important as their mechanical characteristics and overall performance depend on the geometrical shape as well as material properties. They are usually made of thermoplastic (polypropylene) or thermosetting (Carbon composite) materials. Incorporation of additive manufacturing technology has facilitated scope for newer materials (Table 2.2) like Nylon base SLS materials (Faustini et al., 2008) and SLA based materials (Accura SI 40 Somos®, 9120 UV) (Mavroidis et al., 2012).

Table 2.2 Material properties of some additive manufacturing materials used for AFO fabrication

Description	Tensile strength (MPa)	Elastic modulus (GPa)	Elongation (%)
Unfilled Polypropylene[1]	31 - 37.2	1.1 - 1.5	7 - 13
Accura SI 40[1]	57.2 - 58.7	2.6 - 3.3	4.8 - 5.1
Somos ® 9120 UV[1]	30 -32	1.2 - 1.4	15 - 25
Rilsan D80[2]	45	1.4	25
DuraForm PA[2]	44	1.6	9
DuraForm GF[2]	38.1	5.91	2

[1] Mavroidis et al. (2011), [2] Faustini et al. (2008)

2.7 Summary

From the literatures, it is evident that application of computer aided design and manufacturing approaches has begun in recent years with few works on plastic single piece non-articulated AFO. Traditional approaches are time consuming and depends largely on orthotist's experience. Moreover, in those techniques the placement of articulated joint depends on limb's cast, however, the anatomical joint is partially specified by skeleton. The objective of the study is to address these issues and demonstrate a computer aided approach of developing a custom articulated AFO and a custom KAFO.

CHAPTER 3

RESEARCH DESIGN AND METHODOLOGY

3.1 Introduction

The objective of this study is to develop light weight, compact custom articulated AFO and a custom drop lock KAFO with free motion ankle joint using computer aided design and fabrication tools. To discard manual casting in orthotic design it is possible to develop virtual cast of the limb to be treated by 3D-scanning or 3D reconstruction of CT or MRI images. 3D reconstruction of CT images facilitates involvement of skeletal structure of the limb, which is important to find anatomical axis. This chapter presents a detailed description of design and fabrication procedure of an AFO and a KAFO through 3D reconstruction.

3.2 3D Reconstruction

The objective of 3D reconstruction is to convert the CT-scan images of a healthy subject's lower limb to a solid model and develop a virtual positive cast, which will be rescaled to fit the orthotic device with the help of an established reference system. CT-scanning of a 26 years old male healthy subject's lower limb was accomplished in University Malaya medical center. During scanning the ankle was kept in neutral position and knee in full extension. The imaging data of the left leg was collected in DICOM format and 3D reconstruction of those images was accomplished using MIMICS software (Materialise NV). For soft tissue and bony tissue two separate models were developed (Figure 3.1a, 3.1b). To get noise free models segmentation, region growing, edit mask operations were performed. The work flow chart of 3D reconstruction in MIMICS is presented below (Figure 3.2).

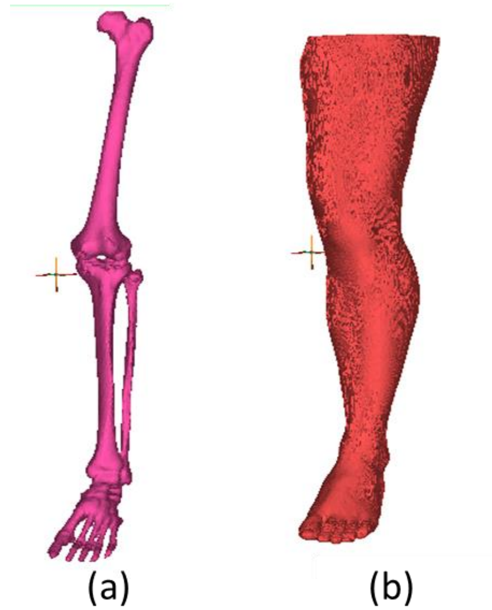

Figure 3.1: (a) 3D skeletal model (triangular mesh format) (b) 3D soft tissue model

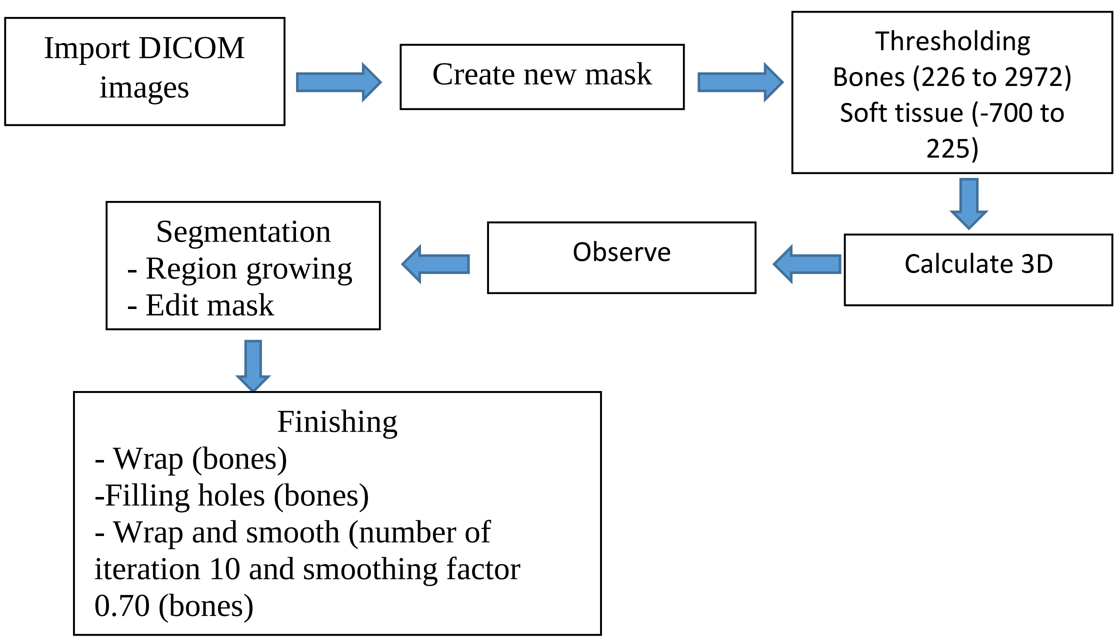

Figure 3.2: Work flow chart in MIMICS software

3.3 Establishment of Reference Frame

3D models were then exported to Abaqus (ABAQUS Inc.) in mesh (.inp) format for landmarking, reference system establishment and data acquisition. Both MIMICS and Abaqus software shared the common coordinate system. As described in section 2.2, bony landmarks such as tip of lateral epicondyle (*le*), fibula head (*hf*) etc. were marked in Abaqus by using "Create datum point" tool. Based on those landmarks, required anatomical reference system for each segments were established. Figure 3.3, 3.4 and 3.5 present reference frames of femur, tibia/fibula and foot respectively. z_t – axis in the figure 3.3 represents knee flexion/extension axis, which is perpendicular to the line connecting O_t *a*nd *fh,* and lying on femur quasi-coronal plane. z_s – axis in figure 3.4 is ankle dorsiflexion and plantar flexion axis, which is perpendicular to the interaction line in between tibia/fibula quasi-coronal and tibia/fibula quasi-sagittal planes, and lying in the tibia/fibula quasi-coronal plane.

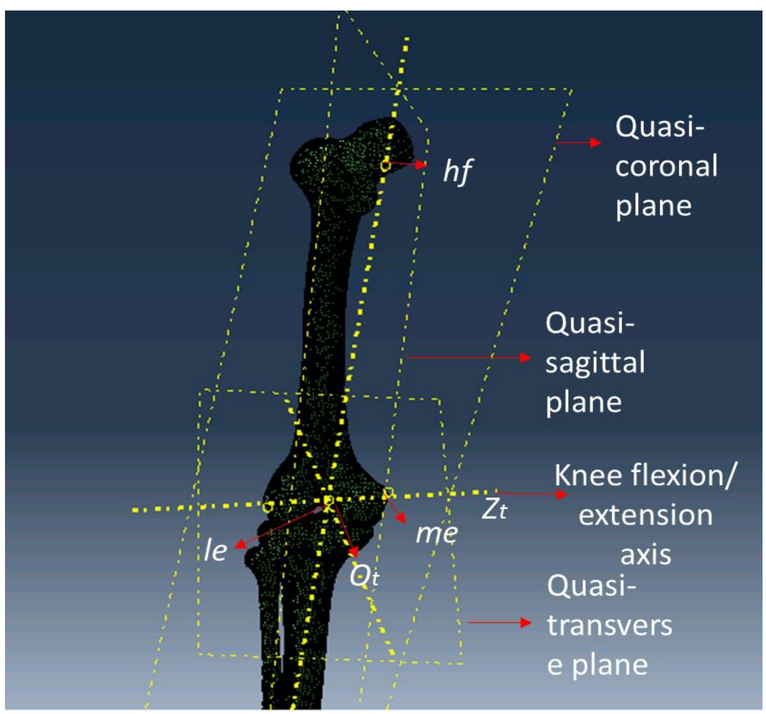

Figure 3.3: Landmarks and reference frame of femur

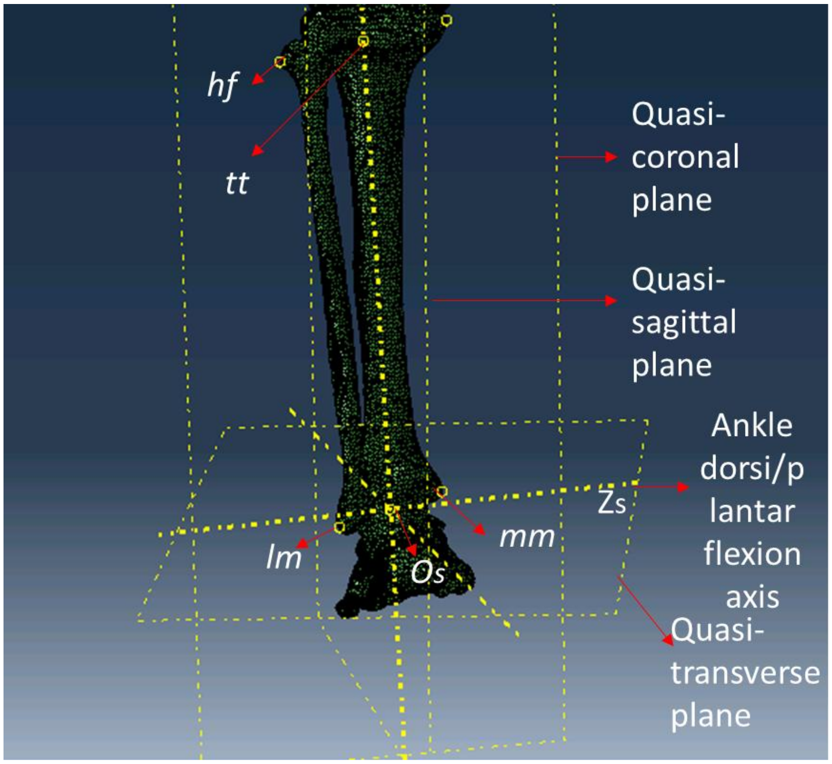

Figure 3.4: Landmarks and reference frame of tibia/ fibula

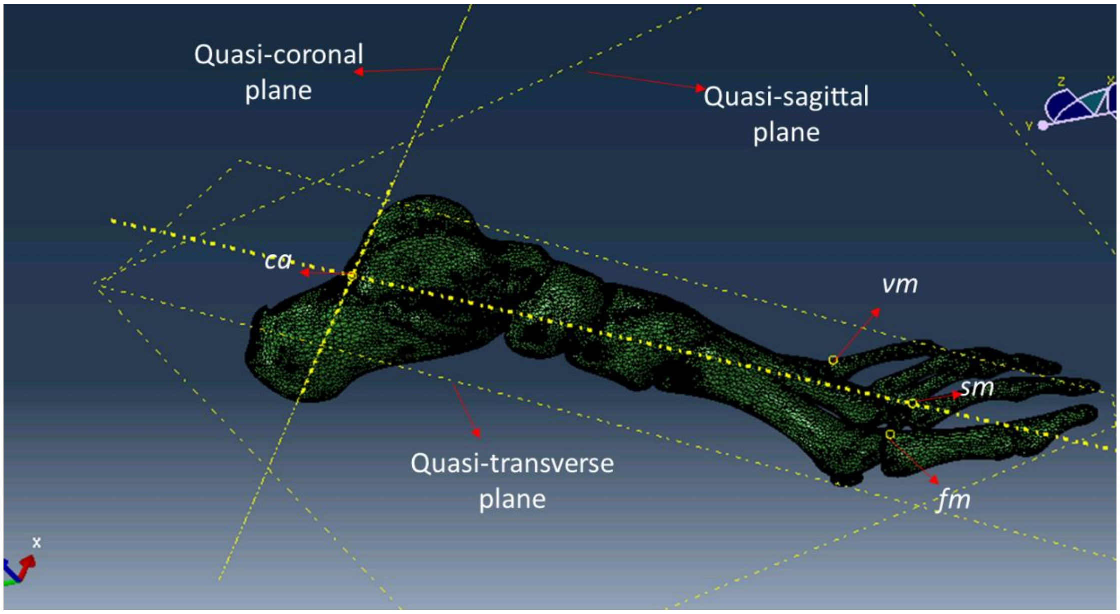

Figure 3.5: Landmarks and reference frame of foot

3.4 Data Acquisition and Orthotic Design

3.4.1 AFO design

The dimensions of the orthotic were acquired from the 3D models in Abaqus software. The lower leg of the subject was treated as two rigid components (foot and shank) affixed by one degree of freedom hinge. On the basis of VAKHUM definitions respective reference frames have been established on the tibia/fibula and foot segment (Figure 3.4, 3.5). The reference frames were imposed on both soft tissue model and skeletal model.

There were three components in the ankle foot orthotic device: foot plate, side bar/shank upright and calf band. Each of the components were designed separately. To acquire the dimensions of the foot plate some planes offset to the foot anatomical planes were drawn (Figure 3.6a, 3.6b, 3.6c). All the features of the foot plate are dependent on the offset distances of the planes from those base planes. The length of the foot plate is two third of the foot length. Planes offset to quasi-coronal plane measure the length of the component, quasi-sagittal plane offsets determine the width and planes offset to quasi-transverse plane measure the height of the ankle upright. The description of the offset planes are given in Table 3.1. The ankle uprights of the foot plate is designed in accordance with the dimension of the dream brace ankle joint so that the z_s - axis (plantar flexion/dorsiflexion axis) matches the axis of articulated joint. The CAD model of foot plate is shown in Figure 3.6d.

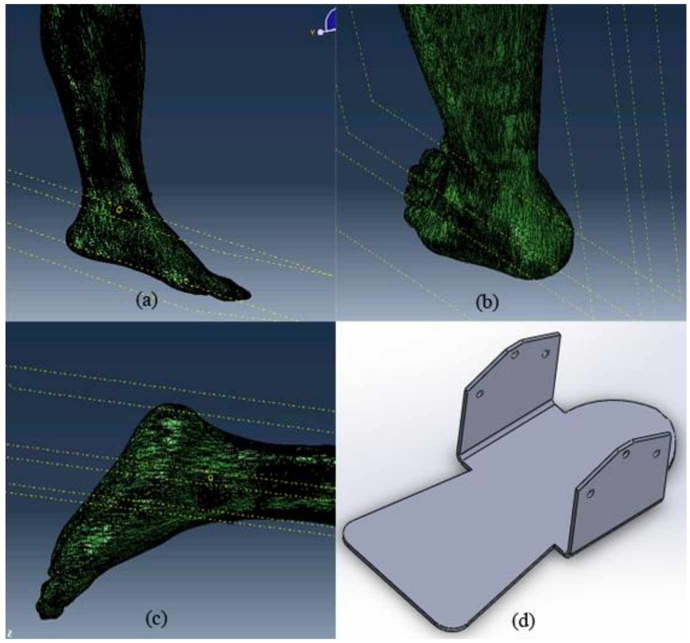

Figure 3.6: (a) Offset planes from quasi- transverse plane to determine the height of the orthotic (b) offset planes from quasi-sagittal plane to determine width of the orthotic (c) offset planes from quasi-coronal plane to determine the length of the foot (d) CAD model of foot plate

Table 3.1 Offset planes for foot plate

Foot anatomical plane	Offset planes	Offset distance (mm)
Quasi sagittal plane	At the lateral edge of the foot	34.4
	At the lateral edge of the heel	14.4
	The medial edge of the hill	38.6
	Medial edge of the foot	50.6
Quasi-transverse plane	Horizontal plane tangent to sole of the foot	65.19
	A plane containing axis of rotation for dorsiflexion and plantar flexion, z_s	20.46
Quasi-coronal plane	Tangent to the posterior edge of heel	77.64
	A plane containing axis of rotation for dorsiflexion and plantar flexion, z_s	10.64
	The edge first metatarsal head	157.36
	Derived dimension, foot plate length (3/4 distance between offset planes at edge of the heel and first metatarsal head)	176.30

The CAD model of the calf band component was developed on the basis of the calf profile of the subject. As advised by a certified orthotist, the component was placed 30 millimeter below the proximal deepest point of the lower leg. The circumference of the band was half of the adjacent calf circumference, which was elongated 20 millimeter at both ends for Velcro attachment. Two planes parallel to quasi-transverse plane, 35 millimeter apart, were drawn at the intended top and bottom of the component to determine its freeform shape. The coordinates of few points on those planes in posterior side of the shank were marked, where the contours connecting those points form the freeform profile of the component (Figure 3.7a, 3.87). The CAD model of the calf band is shown in Figure 3.7c.

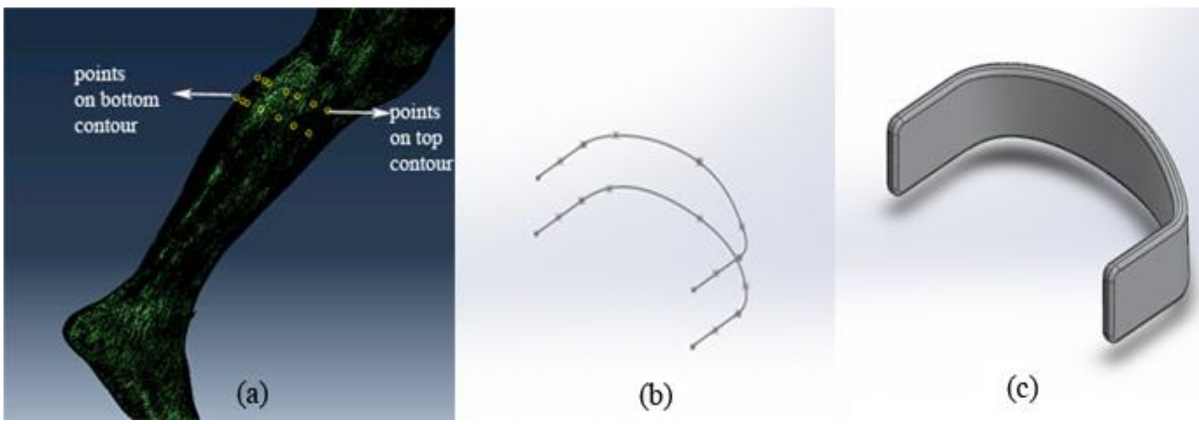

Figure 3.7: (a) Points on top and bottom contour of the calf band component (b) CAD model of the calf band

The sidebar components were designed on the basis of anterior-posterior (A - P) midlines of the shank, which are contours constructed by connecting A - P midpoints. The A – P midpoints on both lateral and medial sides were marked at equal interval along y_s-axis of the tibia/fibula reference frame (Figure 3.8a). The distal end of both sidebars were perpendicular on the ankle anatomical axis for attaching ankle joint and the proximal end was kept vertical for calf band attachment. The profiles of both lateral and medial sidebar were generated in CAD software (Figure 3.8b, 3.8c).

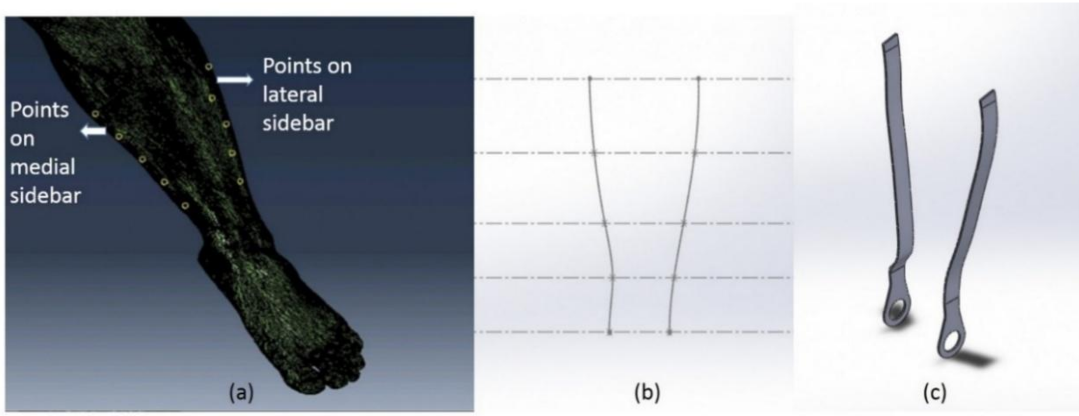

Figure 3.8: (a) Points on anterior-posterior midline contour (b) contours in CAD software (c) CAD model of sidebars

3.4.2 KAFO design

The dimensions of the KAFO were also acquired from 3D models in Abaqus software on the basis of established reference system. The thigh, shank and foot were treated as three rigid components affixed to the adjacent component by one-degree-of-freedom hinge, while the axis of the hinge in between foot and shank is the plantar flexion/dorsiflexion axis and flexion/extension axis of knee is the axis of hinge in between thigh and shank. For foot, tibia and femur segments respective reference frames were established (Figure 3.3, 3.4, 3.5). Same frames were also imposed on soft tissue models to get the fitting dimensions.

The orthotic consists of foot plate, free motion ankle joint, shank sidebar, drop-lock knee joint, calf band, thigh sidebar and proximal thigh band components. For knee and ankle joint commercially available joints were used. The foot plate design procedure was similar to the AFO foot plate design as described in 3.4.1 section.

The sidebars of the KAFO were designed on the basis of A - P midlines of the thigh and shank. The acquisition of the profile of these components were accomplished in a similar procedure as described in 3.4.1 for shank uprights.

The size and shape of the proximal thigh and calf band components are dependent on the outer profile of thigh and calf respectively. The circumference of the components was taken as half of the respective thigh and calf circumference, which was elongated 20 millimeter at each end for Velcro attachment. Two planes offset to femur quasi-transverse plane, 50 millimeter apart, were drawn on the soft tissue model at the intended top and bottom of the thigh band to determine its freeform profile. Then coordinate of few points on those planes in posterior side were marked (Figure 3.9). The curves connecting those points form the top and bottom contour of the component. The CAD model was developed on the basis of these contours. The calf band component, with 35 millimeter width, was designed in similar way. The position of the components with reference of intended top are shown in the Figure 3.9.

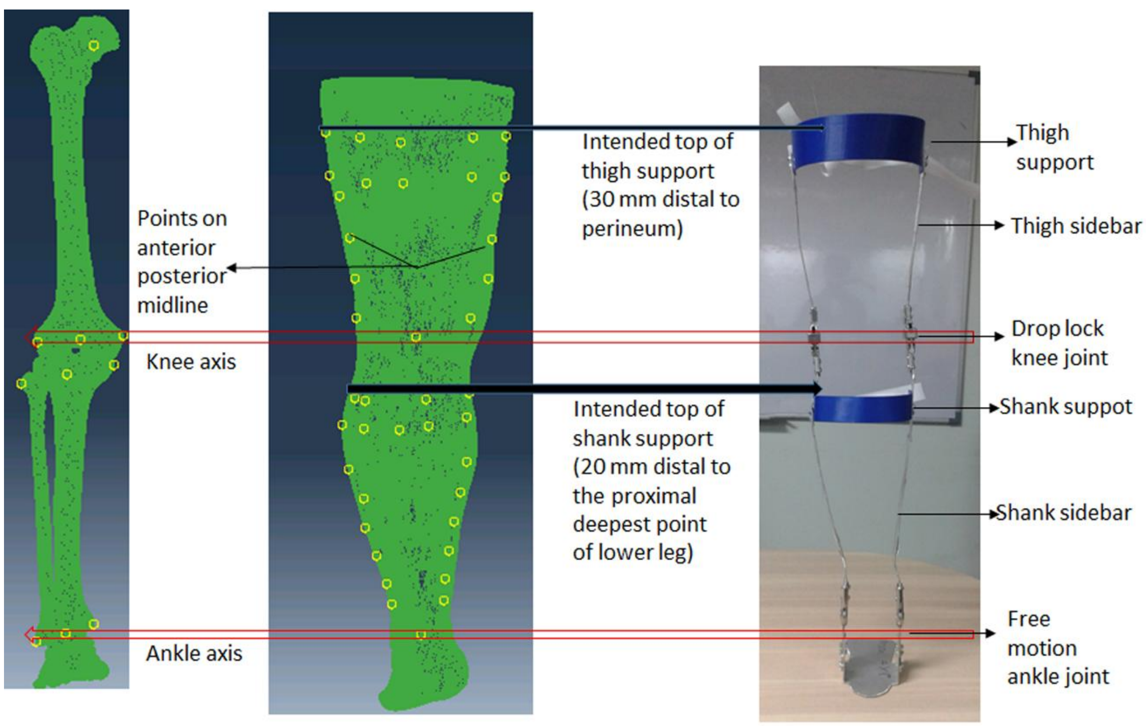

Figure 3.9: KAFO design

The CAD model of the components of both orthotic devices were developed in Solidworks 2011 (Dassault Systèmes SolidWorks Corp.). CAD drawings are presented in Appendix A. Three millimeter gap was maintained between the skin surface and the orthotic.

3.5 Material Selection

For metallic component fabrication Aluminum alloy 6061-T6 was selected due to its high strength to weight ratio, availability, low cost, excellent resistance to corrosion and machinability. For plastic calf band and thigh components 3D printing material PLA was selected for its low cost and compatible properties such as biodegradability (De Silva et al., 2013) and mechanical properties. The tensile strength and elastic modulus of PLA was 54-57 MPa and 3-3.4 GPa respectively and percentage elongation 4-7% (as provided by the supplier), which is coherent with the material properties used in other literatures for plastic AFO manufacturing as described in section 2.6.2.

3.6 Orthotic Fabrication

One prototype of AFO and KAFO were fabricated based on the developed CAD model. Flat pattern of sidebars were cut from Aluminum alloy 6061-T6 plate using Sodick Mark 21wire cut EDM machine. The size of the metallic sidebars was 5 x 19 millimeter, which is most commonly used size for the sidebars (Irby & Kaufman, 2006). A two millimeter thick plate was used for foot plate fabrication. These components were then bent using the bending machine.

To fabricate the calf and thigh component Ultimaker 3D printing machine was used. The CAD files were first converted to .STL (standard tessellation language) file format and then exported to 3D printing machine. The freeform components were then built automatically using biodegradable material PLA (25% infill, 200 microns layer resolution). Different steps of the design and fabrication process is showed in the Figure 3.10.

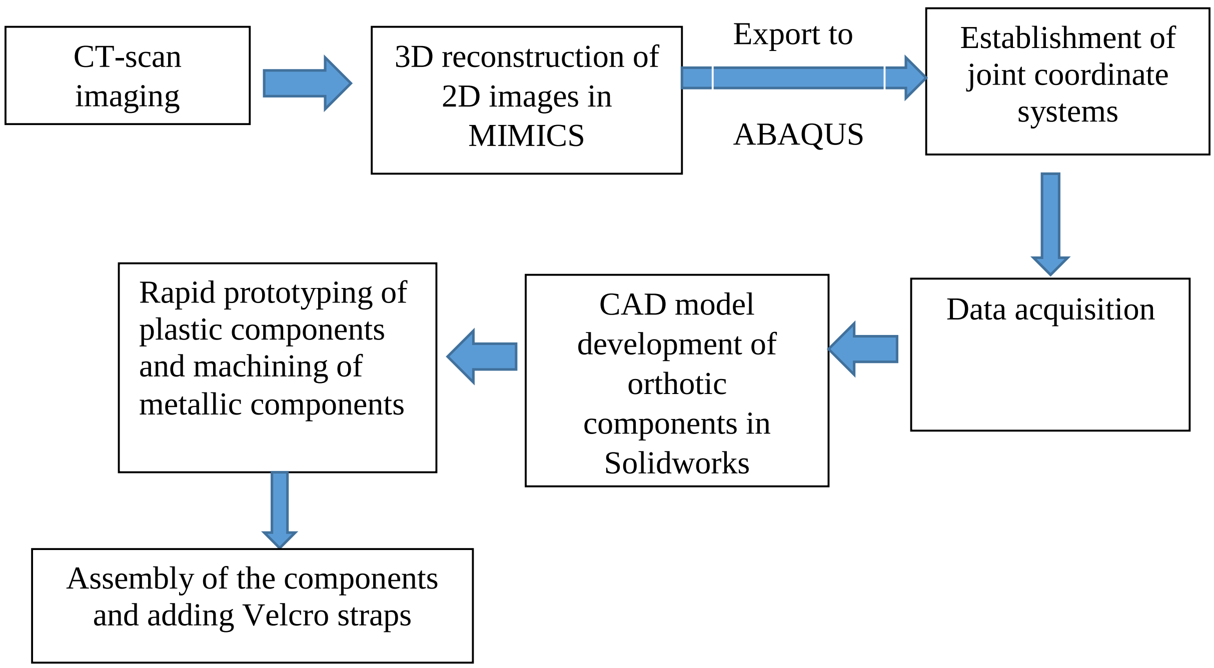

Figure 3.10: Overall flowchart of the orthotic design and fabrication

3.7 Orthotic Evaluation

3.7.1 Orthotist evaluation

The design and functionality of the orthotic devices was assessed by a certified orthotist. He evaluated orthotic characteristics in a scale of three based on a questionnaire, which is presented in Appendix B. Details of assessed characteristics are given below:

- Weight - If the orthotic device is heavy and too rigid, the patients are likely to reject the device as it does not comfort them. According to previous studies KAFO should be less than 2 kg and AFO must be less than 1 Kg (Leerdam & Cool, 1992). KAFO with less than 1 Kg weight and AFO with weight less than 500g get the maximum mark.

- Height – Height of the orthotic device must ensure precise alignment of anatomical axis and mechanical axis of articulated joint. The calf band must be distal to fibula head to avoid peroneal nerve. The top of thigh band must be at least 30 millimeter distal to perineum.

- Joint parallelism – it is checked by using Vermeer calipers. The lateral and medial knee and ankle joint must be vertical and lie on the same horizontal line.

- Trimline - Trimline defines the shape of the orthotic components. It is important for controlling motion and ensuring comfort. The trimline must ensure that no components touches to the bony prominences and put pressure on nerves. Foot plate trimline for lower limb orthotic device with articulated ankle joint should maintain mediolateral stability.

- Edges – All the components should have great finishing with smoothened, chamfered and contoured edges to ensure patient's safety.

- Stability - It is related to the strength of the components, straps, alignment, structure of the device, and contact area of the support components of the orthotic device. If the components are not strong enough during ambulation they might buckle and there could be unwanted movement. Inaccurate alignment leads to calf and thigh band pistoning. Greater contact are of the shank and thigh components provide better stability.

- Belts/straps – Must have proper width and strength to hold the limb firmly. It should not cause any injury to the patient's skin.

- Time use - It is related the activity level and comfort. If the orthosis is heavy and do not have a compact size the patient is likely to reject the device. The orthotist prescribes orthosis with good characteristics for 20 hours a day and 12 hours for moderate and 6 hours for the least.

- Distance travelled – It is also related to the activity level and denotes the performance of the device. To measure this characteristic the orthotist instructed the subject to walk through a 30 meter plane walkway with and without the orthotic devices and then he checked the required effort, time and walking pattern of the subject.

The orthotist assessed the above characteristics for both KAFO and AFO and compare them with standard quality and ranked them as good, moderate and poor.

3.7.2 Motion analysis

Motion analysis was also carried out to evaluate the performance of AFO. It was conducted with the healthy subject, whose CT-scan data of lower limb were used to manufacture the orthoses. The performance of the custom AFO was compared with a pre-fabricated AFO. The position of the ankle joint of the pre-fabricated AFO was six millimeter distal and three millimeter anterior compared to the fabricated AFO. The adjustable plantar flexion stop was set at 13° in both AFOs.

Gait analysis was performed in motion analysis laboratory having a three-dimensional motion analysis system (Vicon 460, Vicon Motion System Ltd., UK) and two force plates (Kistler Instrument AG, Switzerland). Reflective markers were set on the different anatomical landmarks (Figure 3.11); lateral malleoli, second metatarsal heads, heels, tibia (one third distal), knee (lateral femoral condyles), femur (one third distal), anterior superior iliac spines, posterior superior iliac spines. Gait analysis was conducted in three conditions: 1) with custom AFO 2) with a pre-fabricated AFO and 3) without AFO. The subject was instructed to walk at a comfortable speed through a walkway on which force plates are installed.

Data were collected at a rate of 100 Hz for six trials of each conditions. Time-distance dependent factors (walking speed, step length), kinetic (ankle angle) and kinematic (ankle moment, ankle power) parameters were measured as shown in Table 3.2. Bonferroni t-test was performed at $\alpha = 0.05$ to compare the data statistically in three conditions. All the pairwise mean differences (MD) were compared with minimum significant difference (MSD) (Portney & Watkins, 2009).

Table 3.2 Data table for motion analysis

Gait determinants	Variables
Time-distance dependent factors	Walking velocity (m/s) Step length (m) Double support time (s)
Kinetic parameters	Ankle angle (°)
Kinematic parameters	Ankle moment (Nm) Ankle power (W)

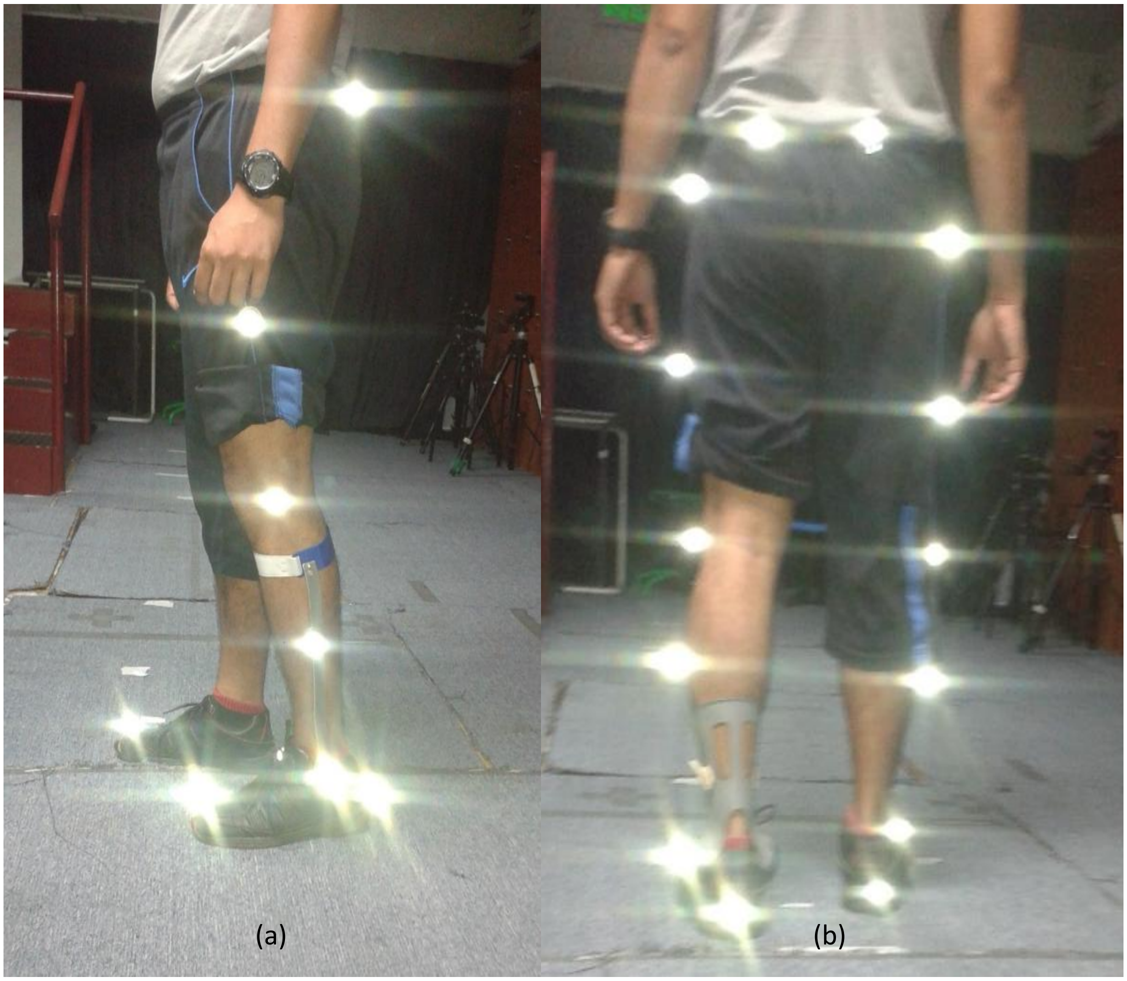

Figure 3.11: Reflective markers at different positions for gait analysis with (a) custom AFO and (b) pre-fabricated AFO

CHAPTER 4

RESULTS AND DISCUSSIONS

4.1 Orthotic Fabrication

The CAD model of different components of the orthotic devices are compatible with computer integrated manufacturing techniques. The metallic components were fabricated using wire cut EDM machine and plastic components were fabricated using rapid prototyping. Rapid prototyping allowed fabrication of freeform shaped thigh and calf band components, which provided good fitting and comfort. The prototypes of each orthotic device are presented in figure 4.1. The time required for design and fabrication of different components are show in Table 4.1. Total time required for AFO and KAFO was a 3.65 hours and 5.6 hours respectively.

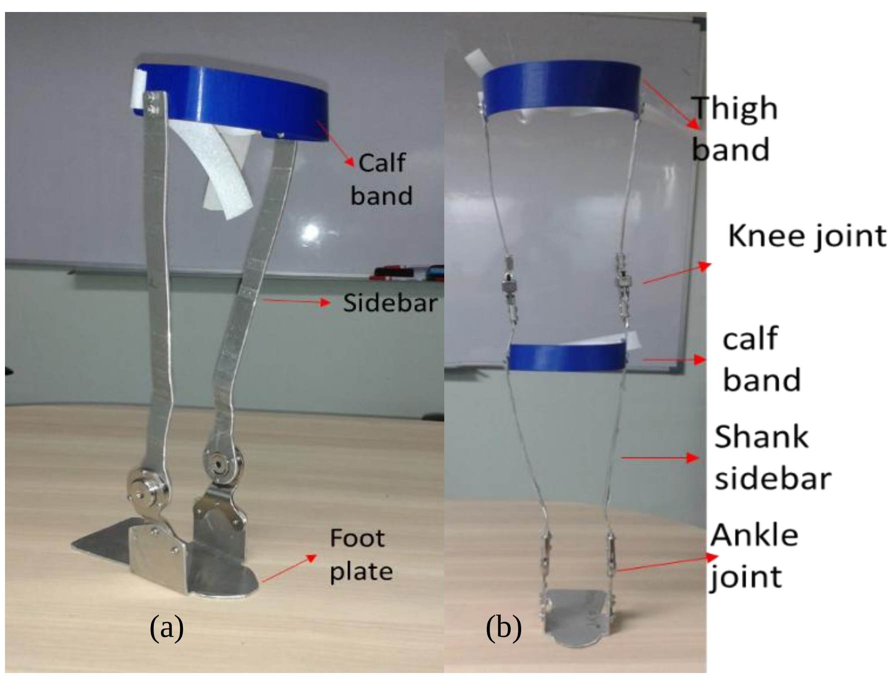

Figure 4.1: (a) AFO prototype (b) KAFO prototype

Table 4.1 Required time for design and fabrication of orthotic components

Orthotic device	Task	Time
AFO	3D reconstruction, data acquisition and CAD model development	45 minutes
	Foot plate fabrication	25 minutes
	Shank uprights fabrication	105 minutes
	Calf band fabrication	44 minutes
KAFO	3D reconstruction, data acquisition and CAD model development	60 minutes
	Foot plate fabrication	25 minutes
	Uprights fabrication	135 minutes
	Calf band and thigh fabrication	115 minutes

4.2 AFO Evaluation

4.2.1 Orthotist evaluation

A certified orthotist assessed different characteristics of AFO in a scale of three. The assessment chart is presented in table 4.2.

Table 4.2. AFO assessment chart

Aspects	Factors	Good (3)	Moderate (2)	Poor (1)
General characteristics	Weight	✓		
	Strength	✓		
	Height	✓		
	Joint parallelism	✓		
Finishing	Trimline	✓		
	Edges	✓		
	Belts/straps		✓	
Functionality	Stability		✓	
	Donning	✓		
	Doffing	✓		
	Time use	✓		
	Distance travelled	✓		

The weight of the AFO was 0.36 Kg only and the strength of the components were marked as good. The computer aided design technique ensured exact height, joint position and joint parallelism. Trimlines and edges of the components were well finished. The stability of the device was marked as moderate and it was suggested to use a distal calf support to improve the stability. The device was comfortable and easy to use and it can be prescribed to use maximum time of the day. Overall, the assessment implies the credential of the manufacturing process.

4.2.2 Motion Analysis

Table 4.3 presents the time-distance dependent gait factors. The mean differences (MD) between each factors in different conditions were found less than minimum significant difference (MSD) in every comparison, which means that the time distance dependent factors were not affected by the AFOs and the subject walked very consistently in every walking condition.

Table 4.3. Time-distance dependent factors (Mean ± SD) of the subject's left leg in three different conditions and significant differences (*) from the Bonferroni t-test

Factors	No AFO	Custom AFO	Pre-fabricated AFO	MSD	MD
Walking velocity (m/s)	0.84±0.08	0.82±0.17	0.82±0.08	0.202	0.02_a 0.02_b 0.00_c
Step length (m)	0.61±0.03	0.62±0.0002	0.60±0.001	0.024	0.01_a 0.01_b 0.02_c
Double support time (s)	0.41±0.008	0.42±0.0004	0.42±0.0002	0.046	0.01_a 0.01_b 0.00_c

MSD – Minimum significant difference; MD – mean difference
a – Mean difference between No AFO and Custom AFO
b – Mean difference between No AFO and Pre-fabricated AFO
c– Mean difference between custom AFO and Pre-fabricated AFO

The kinematics and kinetics of the ankle in three conditions are presented in Figure 4.2, 4.3 and 4.4. Bonferroni t-test comparisons for kinematic and kinetic parameters are presented in Table 4.4, which reveal that both AFOs have significant influence on gait. Figure 4.2a shows that with both AFOs the ankle was more in a neutral position at initial contact compared to no AFO condition. The peak plantar flexion with pre-fabricated AFO was slightly lower than the other two conditions, which likely resulted in least peak dorsiflexion in stance (Figure 4.2b, 4.2c). In pre-swing the plantar flexion angle was significantly different in every condition, as the mean difference in every pairwise comparison (MD no AFO – custom AFO > MSD, MD no AFO – pre-fabricated AFO > MSD, MD custom AFO – pre-fabricated AFO > MSD) was higher than minimum significant difference (Table 4.4). It is due to the resistance of ankle joint of the AFOs. Overall, throughout the gait cycle it was found that the custom AFO provided better range of motion compared to the pre-fabricated AFO.

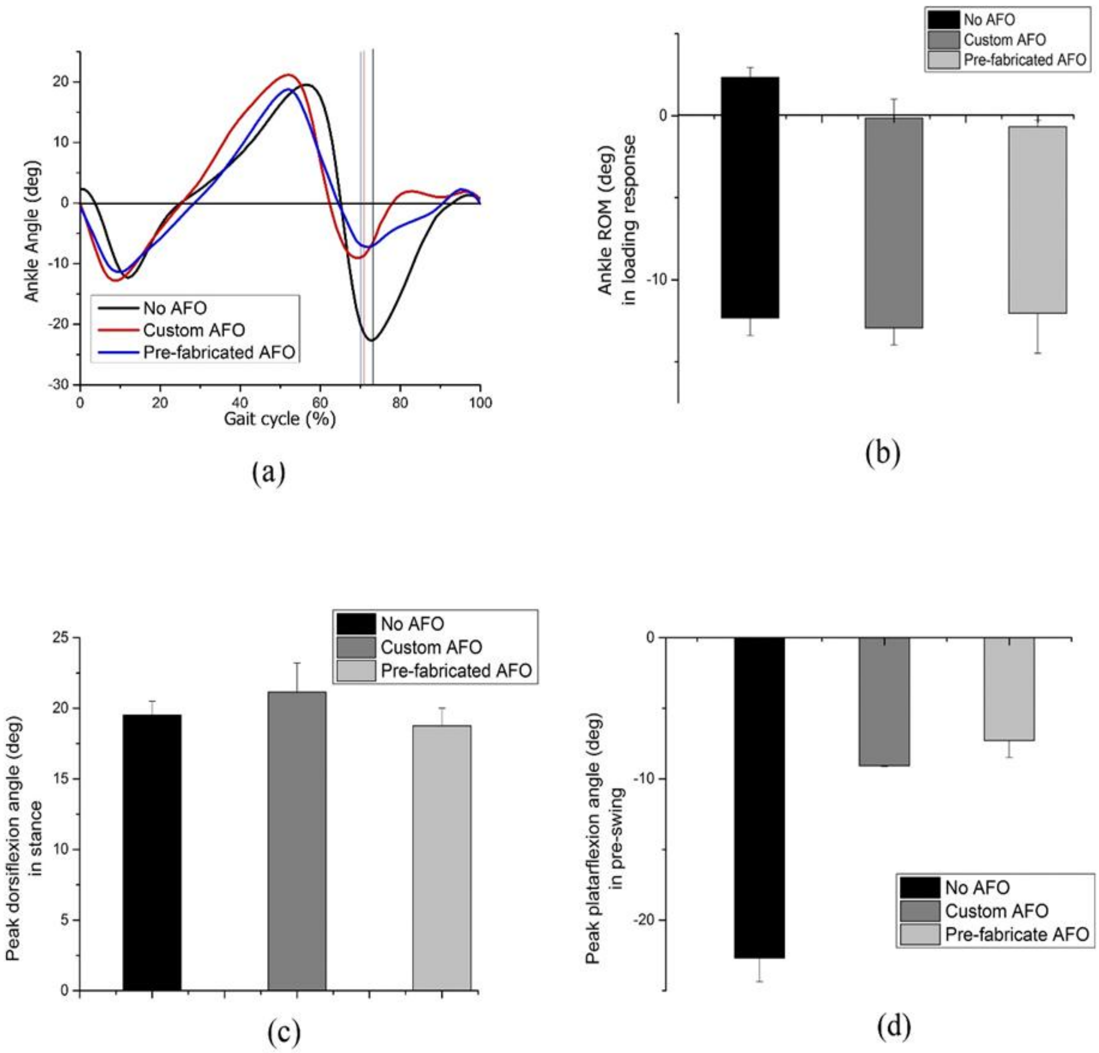

Figure 4.2: Ankle kinematics in three conditions (a) mean ankle angle (b) mean (±SD) range of motion during loading response (c) mean (±SD) peak dorsiflexion angle during stance (d) mean (±SD) peak plantar flexion angle in pre-swing

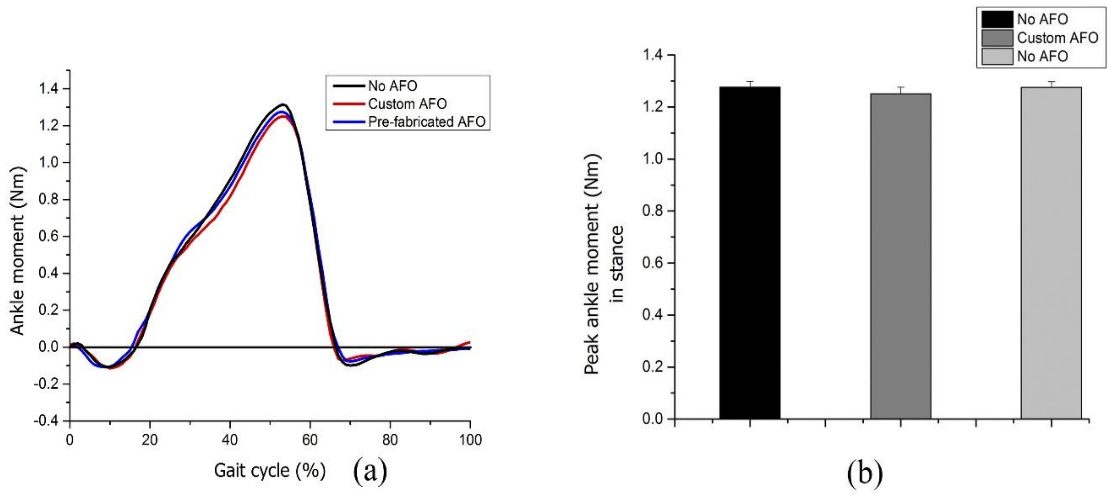

Figure 4.3: Ankle kinetics in three conditions (a) mean (±SD) ankle moment throughout the gait (b) mean (±SD) peak ankle moment in stance

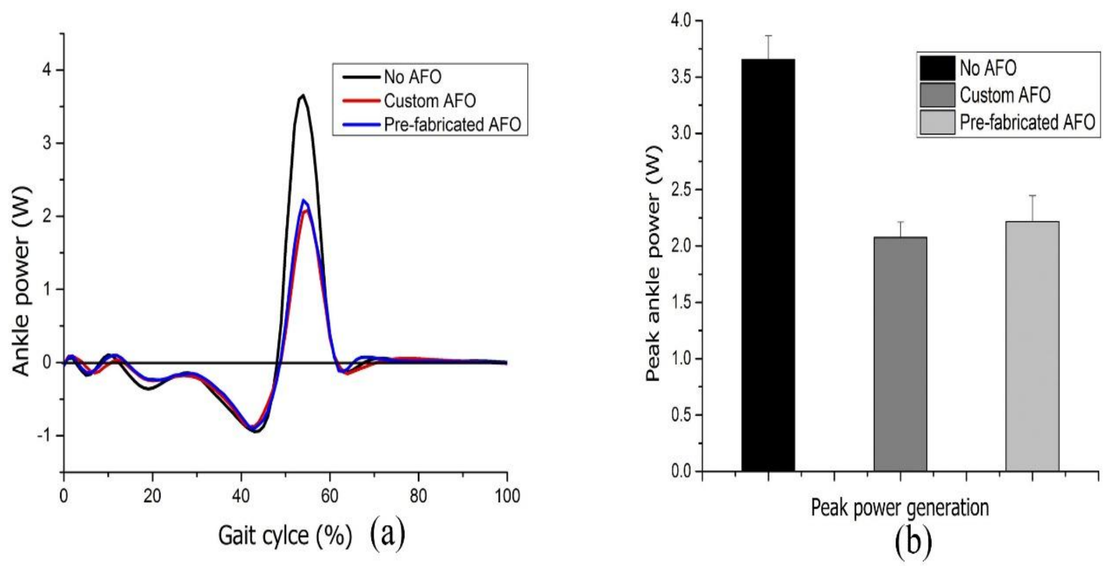

Figure 4.4: Ankle power in three conditions (a) Mean ankle power throughout the gait cycle (b) Mean (±SD) peak ankle power generation

Table 4.4 Significant differences (*) from Bonferroni t-test comparisons for kinematic and kinetic parameters of gait cycle

Variables	No AFO	Custom AFO	Pre-fabricated AFO	MSD	MD
Peak plantar flexion angle in loading response (°)	12.337±3.05	12.726±1.02	11.378±0.07	2.879	0.389_a 0.959_b 1.348_c
Peak dorsiflexion angle in stance (°)	19.603±0.92	21.149±2.07	18.767±1.18	2.285	1.546_a 0.836_b 2.382_c
Peak plantar flexion angle in pre-swing (°)	22.686±1.46	9.017±2.07	7.283±1.18	1.550	13.669_a* 15.403_b* 1.734_c*
Peak ankle moment in stance (Nm)	1.302±0.008	1.253±0.025	1.272±0.017	0.028	0.049_a* 0.030_b* 0.019_c
Peak ankle power (W)	3.659±0.04	2.074±0.007	2.215±0.01	0.035	1.585_a* 1.444_b* 0.141_c*

Value ± SD
a – Mean difference between No AFO and Custom AFO
b – Mean difference between No AFO and Pre-fabricated AFO
c – Mean difference between custom AFO and Pre-fabricated AFO

Kinetics results reveal that both AFO affect the gait in a similar way. The flexion/extension moment curve profile for different conditions are similar (Figure 4.3a and 4.3b). However, the peak flexion moments with AFOs are significantly lower than peak flexion moment in no AFO condition (MD no AFO – custom AFO > MSD, MD no AFO – pre-fabricated AFO > MSD) (Table 4.4). The ankle power curves (Figure 4.4) show that with AFO there was a significant reduction in peak ankle power (MD no AFO – custom AFO > MSD, MD no AFO

– pre-fabricated AFO > MSD, MD custom AFO – pre-fabricated AFO > MSD) (Table 4.4), which is probably due to the lesser plantar flexion during push-off. Although in pre-fabricated AFO the peak plantar flexion during push-off was significantly lower than the custom AFO condition but the peak power generation was significantly higher than the custom AFO condition. It is likely due to the ankle generated greater power to overcome the greater resistance of pre-fabricated AFO. The lesser range of motion and higher power generation in pre-fabricated AFO condition might be attributed to the greater resistance offered by the AFO due to ankle joint misalignment as Gao, Carlton, & Kapp, (2011) reported that stiffness of articulated ankle joint increases with misalignment. Other than joint alignment, the shank upright of the custom AFO was bigger than the pre-fabricated AFO, which might also be one of the reasons behind the difference of kinematics and kinetics in two AFO conditions.

4.3 KAFO Assessment

The fabricated KAFO was also assessed by a certified orthotist, who considered three aspects and evaluated different characteristics of the device in a scale of three. Motion analysis was not conducted to evaluate the KAFO's functionality as functional characteristics measured by the orthotist provides enough evidence. The assessment chart is shown in Table 4.5.

Table 4.5. KAFO assessment chart

Aspects	Factors	Good (3)	Moderate (2)	Poor (1)
General characteristics	Weight	✓		
	Strength		✓	
	Height	✓		
	Joint parallelism	✓		
Finishing	Trimline	✓		
	Edges	✓		
	Belts/straps		✓	
Functionality	Stability		✓	
	Doffing	✓		
	Donning	✓		
	Time use	✓		
	Distance travelled	✓		

All the general characteristics were marked as good except the strength of the device. The strength of the components were enough for the healthy subject, however, increasing the sidebar thickness and using different material with greater strength for thigh and calf support component might be needed for patients with heavy weight. Total weight of the device is 0.75 kg which is very light compared to other common KAFOs. Height, joint position and joint parallelism were exact, which demonstrate credibility of the manufacturing process. Trimlines and edges of the components were up to the mark and it was suggested to increase the width of the straps, attached with thigh and calf support components, from 2.50 inches to 4.0 inches to enhance the stability. The donning and doffing of the device was easy. While checking the functionality the orthotist instructed the subject to walk through a 30m walkway with locked KAFO and unlocked KAFO. The orthotist concluded that there was no calf band movement due to misalignment, moreover, as the KAFO is light in weight, compact and comfortable so it can be prescribed for maximum time in a day. The stability of the KAFO was marked as moderate. Enhancing strength and introducing a distal calf support component might enhance the stability of the device. The overall characteristics of the KAFO implies that the design and fabrication technique is also suitable for other KAFOs like stance control knee ankle foot orhtosis, which provide knee motion in swing, and might enhance the performance.

4.4 Overall Discussion on Manufacturing Process

The design technique demonstrated in this article has advantages over the traditional design techniques. Unlike external modeling methods, it allows the clinicians to observe external and skeletal geometry simultaneously. The placement of mechanical joints and fitting dimensions were exact, which ensured the subject's comfort. Acquisition of fitting dimensions, designing of CAD model and fabrication process took approximately 3.5 hours for AFO and 5.5 hours for KAFO, while in traditional approach it takes 8-12 and 16-18 hours respectively in Brace and Limb laboratory of University Malaya. Creylman et al. (2013) reported that average delivery time of a commercial laboratory for a custom made polypropylene AFO is 10 days. Other than reduction of production time, the manufacturing process discards manual casting of patient's limb and incorporates machining and rapid prototyping. The functional analysis of the AFO shows that the demonstrated process can enhance the performance of the orthotic device. Overall, the assessment results of the orthoses suggest that the design and fabrication process could be a beneficial for the experts in the orthotic industry.

Although there are numbers of literature regarding structural analysis of single piece plastic AFO, however, no literatures were found on articulated AFO or KAFO. It might be due to the lack of standardization of structure of such orthotic devices. Unlike lower limb orthotic devices, for prosthetic component design and material selection Ottobock developed a classification matrix based on body weight and functional demand (Figure 4.5). However, it is difficult to determine the structural demand of lower limb orthoses, especially for KAFO, straight from activity level and weight, because it depends on some additional number of factors such as pathology, BMI, age, residual muscle strength, and alignment. Incorporation of CAD model might facilitate the orthotists to do structural analysis of the orthotic components as needed prior to fabrication based on the individuals. It will also help to find the optimum weight and strength of the device.

Figure 4.5: Ottobock classification matrix

In the data acquisition process the ankle joint was kept in neutral position at time of CT-scanning but the orthotists usually keep the toe in 5-7° outward rotation during casting for AFO manufacturing (International Committee of the Red Cross, 2006). As the lower limb was treated a two rigid components attached with one degree of motion hinge and all dimensions for shank and foot section were taken separately based on respective reference frames of the components, this might discount the necessity of keeping the toe in outward rotation. However, further investigation on this issue needs to be conducted. Another issue of concern might be holding the ankle foot in neutral position during CT-scanning. For actual patients with drop-foot it might deform and a support might be needed to maintain the position.

Considering the knee and ankle joint as one degree of freedom hinge joint might be oversimplification. To describe the ankle geometry and mechanics Leardini (2001) modeled ankle joint as two dimensional four bar linkage model where the rotational axis itself travels during ambulation. Flexion and extension of knee occur about a constantly changing center of rotation or in a “J” shaped polycentric path. The knee joint was also modeled as two dimensional four-bar linkage model (Zavatsky and Wright 2001), wheree the flexion/extension axis passes through the instantaneous center of the four-bar linkage model. According to Goodfellow and O’Connor (1978) the instantaneous center is located where the two ligaments cross each other. However, in most of the knee joint studies (Penrose et al., 2002; Trilha Junior et al., 2009) a lateral medial axis is considered as the flexion/extension axis for convenience.

CHAPTER 5

CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusion

In this dissertation, a new design and manufacturing approach of custom articulated ankle foot orthosis and knee ankle foot orthosis has been demonstrated. 3D models of a healthy subject's lower limb were developed through 3D reconstruction. CAD model of the orthotic components were developed on the basis of fitting dimension acquired from those models. One prototype was fabricated for each orthoses by means of machining and rapid prototyping. The outcome of the research can be summarized as below:

- From literature review it is evident that in lower limb orthotic design and manufacturing, computer aided design approaches are limited to single piece custom AFO. This dissertation demonstrates a technique for articulated AFO and KAFO.
- Unlike traditional approaches, the demonstrated technique involves skeletal structure of lower limb for locating anatomical axes to ensure accurate alignment of orthotic mechanical joint.
- The demonstrated method requires approximately 50% lesser time to develop AFO and 70% lesser time to develop KAFO compared to Brace and Limb laboratory of University Malaya.
- The performance of the fabricated AFO was compared with a pre-fabricated AFO and no AFO condition. The time-distance dependent factors were not affected by the AFO conditions. The statistical analysis reveals that both AFOs did not significantly alter plantar flexion angle in loading response and dorsiflexion angle in stance but significantly decreased plantar flexion in pre-swing compared to no AFO condition

due to the resistance of the ankle joint. Although the custom AFO allowed significantly higher plantar flexion during pre-swing compared to pre-fabricated AFO condition (MD = 1.734, MSD = 1.55), the subject's ankle required to generate significantly higher power with the pre-fabricated AFO (MD = 0.141, MSD = 0.035). These findings suggest that the subject had to overcome higher resistance with pre-fabricated AFO compared to custom made AFO.

5.2 Recommendation for future work

Development of lower limb orthoses through 3D reconstruction is the initial move of our research project. Some future works based on the demonstrated design and manufacturing approach are listed below:

- Since the orthoses were designed for healthy subject, there should be a wide range of clinical study with real patient to implement this manufacturing technique.
- Mechanical behavior of knee and ankle joint with articulated orthotic devices are yet to be explored. As misalignment of mechanical joint of orthosis creates shear forces which eventually transmits to the limb and increases shear stress on the joint, it is imperative to understand its effect on skeleton, muscle and ligaments. The new design approach posits a possibility of developing finite element models of knee and ankle joint to understand their mechanical behavior with articulations.
- In this research the dimension of sidebars or uprights was 5x19 millimeter, which is most commonly used. However, a structural analysis using finite element tools might facilitate finding the optimum size with proper mechanical properties like stiffness, fatigue etc. depending on the pathology and weight of the patient.

- In this research a KAFO with drop lock knee joint has been developed, however, the manufacturing process is more appropriate for KAFOs those are not entirely locked e. g. stance control knee orthosis. Further biomechanical investigation is necessary with those KAFOs to implement the demonstrated manufacturing process.
- Some features could be added to the orthotic devices developed. For instance introduction of an arched plastic foot plate might improve the patient's comfort. Additional calf and thigh support component may improve the stability.

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List of Publications

Alam, M., Choudhury, I. A., & Mamat, A. B. (2014). Mechanism and Design Analysis of Articulated Ankle Foot Orthoses for Drop-Foot. *The Scientific World Journal, 2014*, 14.

Alam, M., Choudhury, I. A., & Azuddin, M. & Hussain, S. (2014). Computer aided design and fabrication of a custom articulated ankle foot orthosis; Journal of mechanics in medicine and biology; Accepted

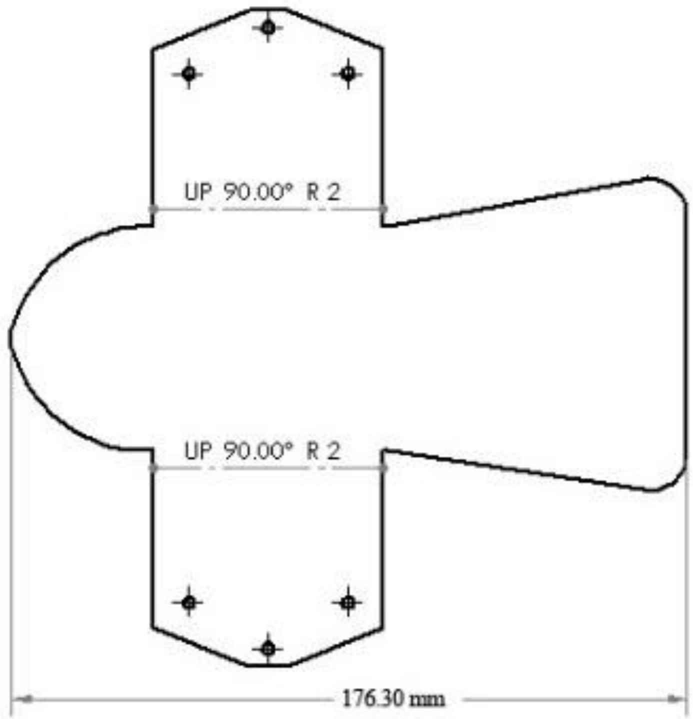
Alam, M., Choudhury, I. A., & Azuddin, M. & Hussain, S. Development of custom knee ankle foot orthosis through 3D reconstruction. Computer Methods in Biomechanics and Biomedical Engineering. Under Review

Alam, M., Choudhury, I. A., & Azuddin, M. (2014). Development of Patient Specific Ankle Foot Orthosis through 3D Reconstruction. *International Proceedings of Chemical, Biological & Environmental Engineering, 70*, Bangkok, Thailand.

APPENDIX A

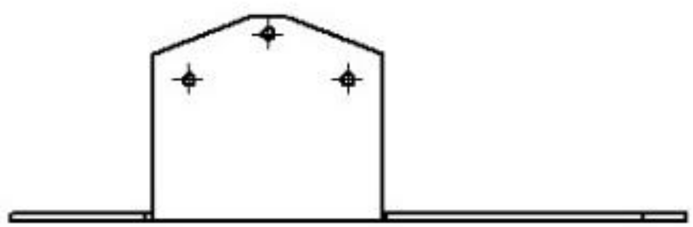
CAD DRAWING OF PRTHOTIC COMPONENTS

CAD drawing of AFO Foot plate

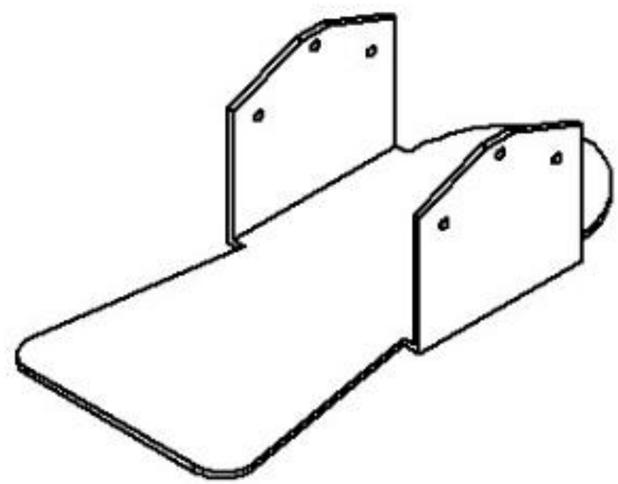


Flat pattern

Front view

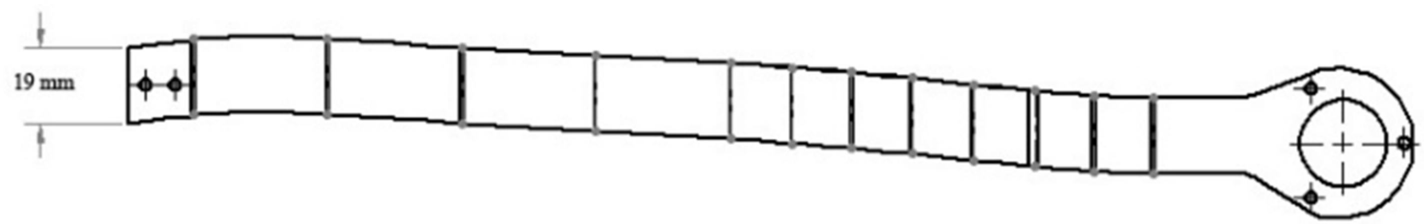


Right hand side view



Right hand side view

CAD drawing of AFO lateral side bar



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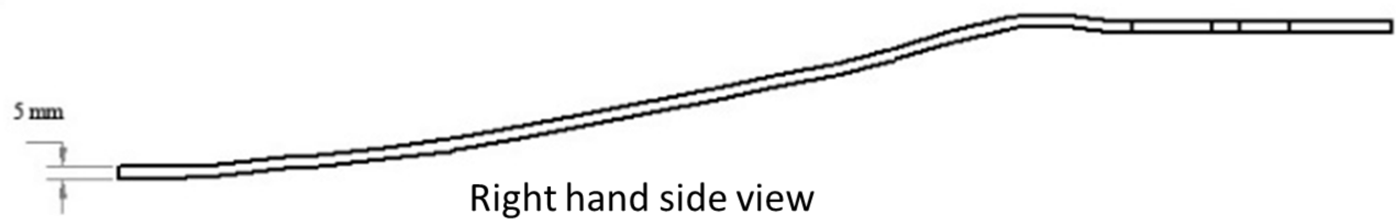
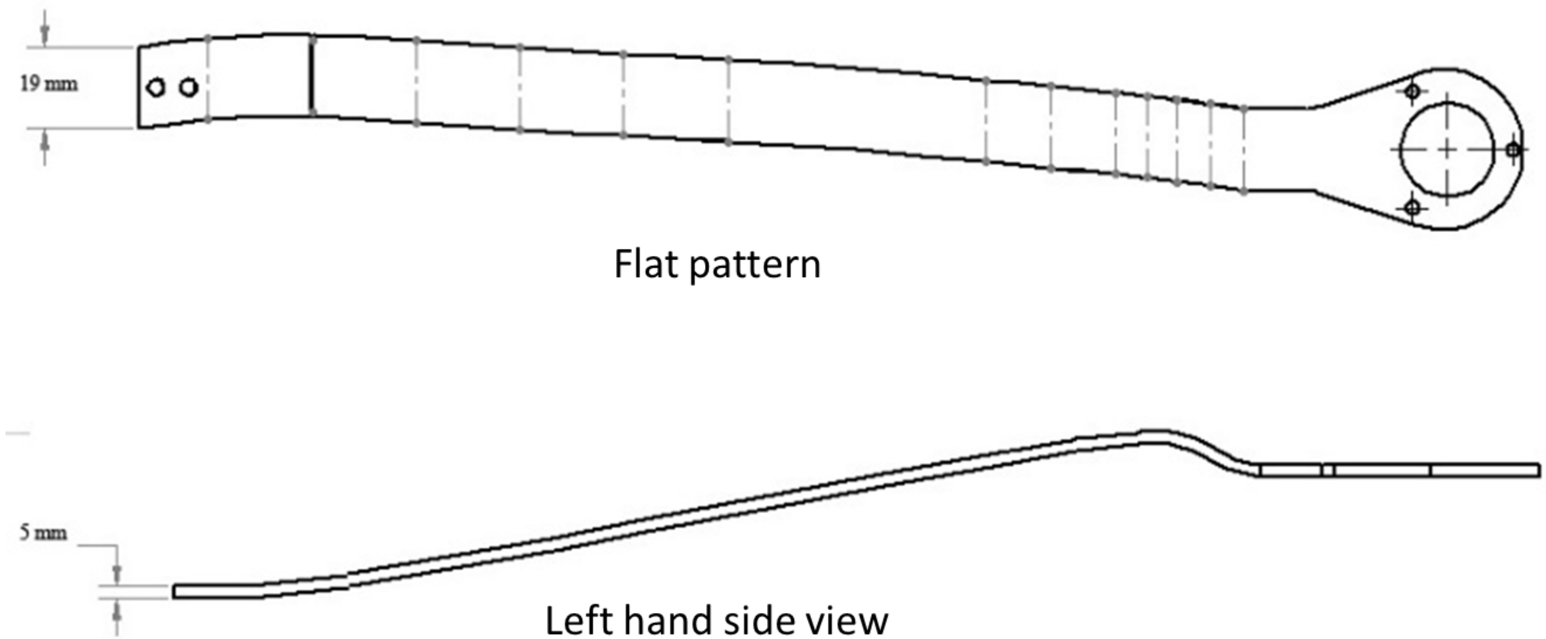


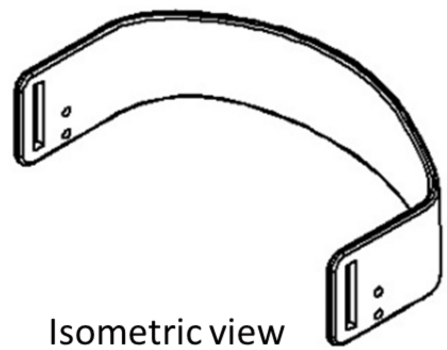
Right hand side view

CAD drawing of AFO medial side bar

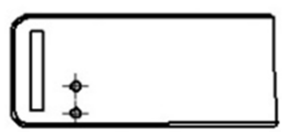


CAD drawing of AFO calf band

Top view

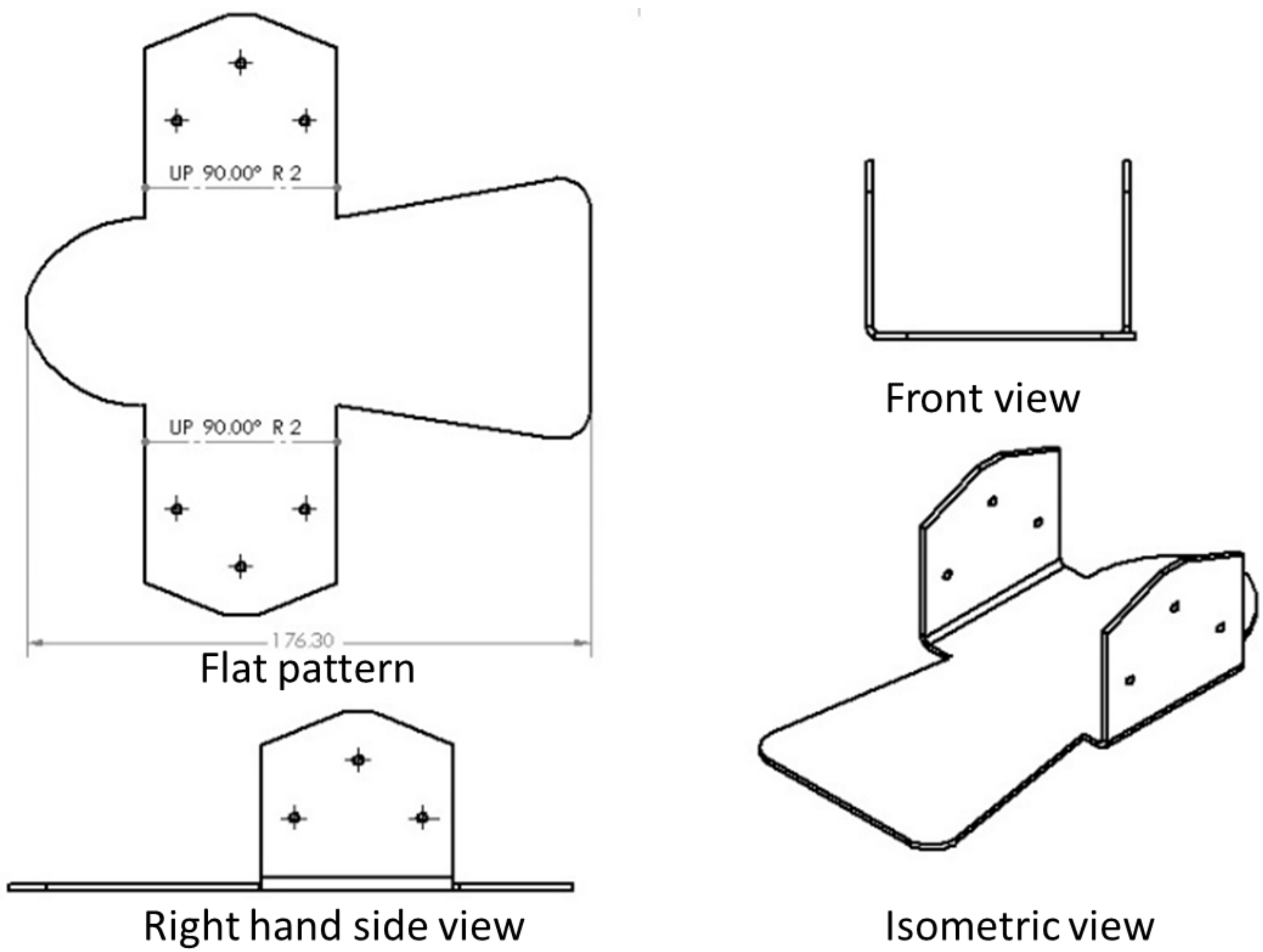


Isometric view

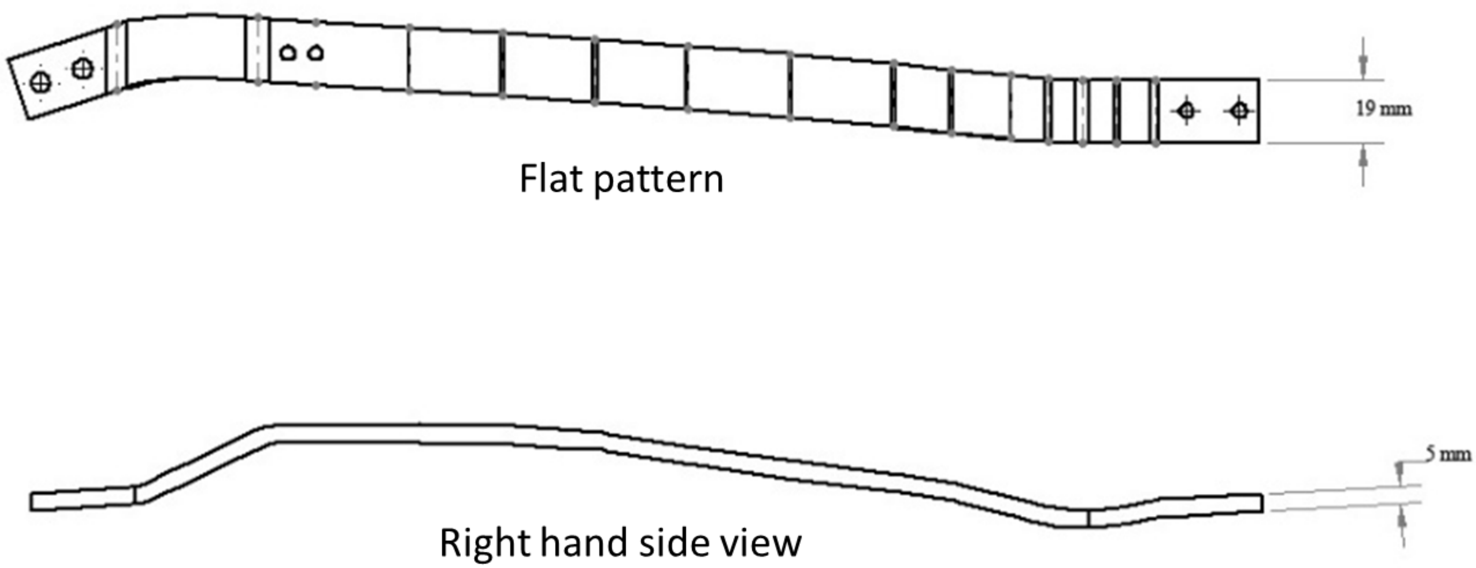


Right hand side view

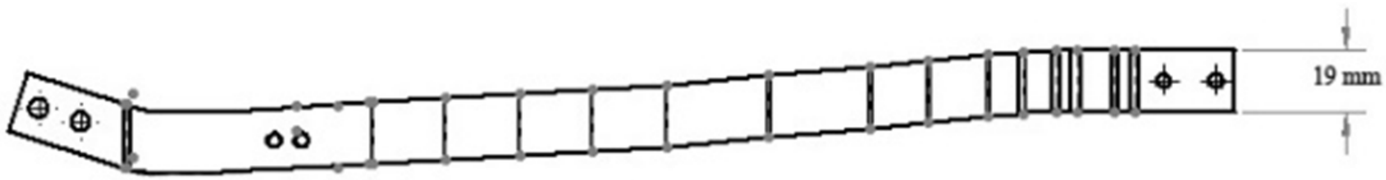
CAD drawing of KAFO foot plate



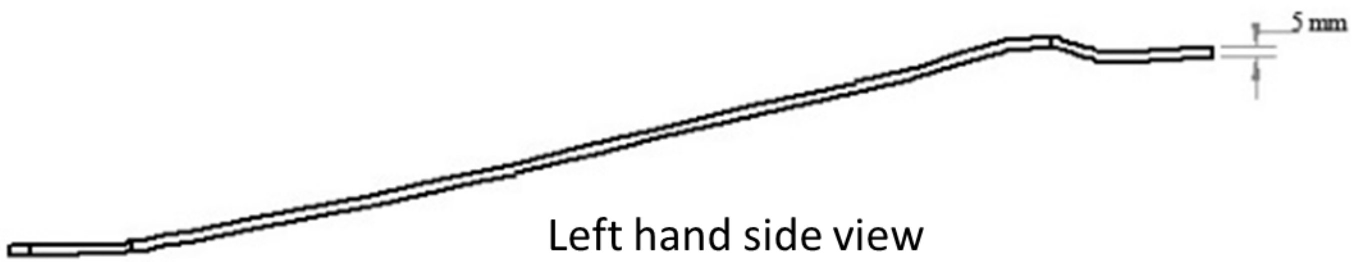
CAD drawing of KAFO lateral sidebar



CAD drawing of KAFO medial sidebar

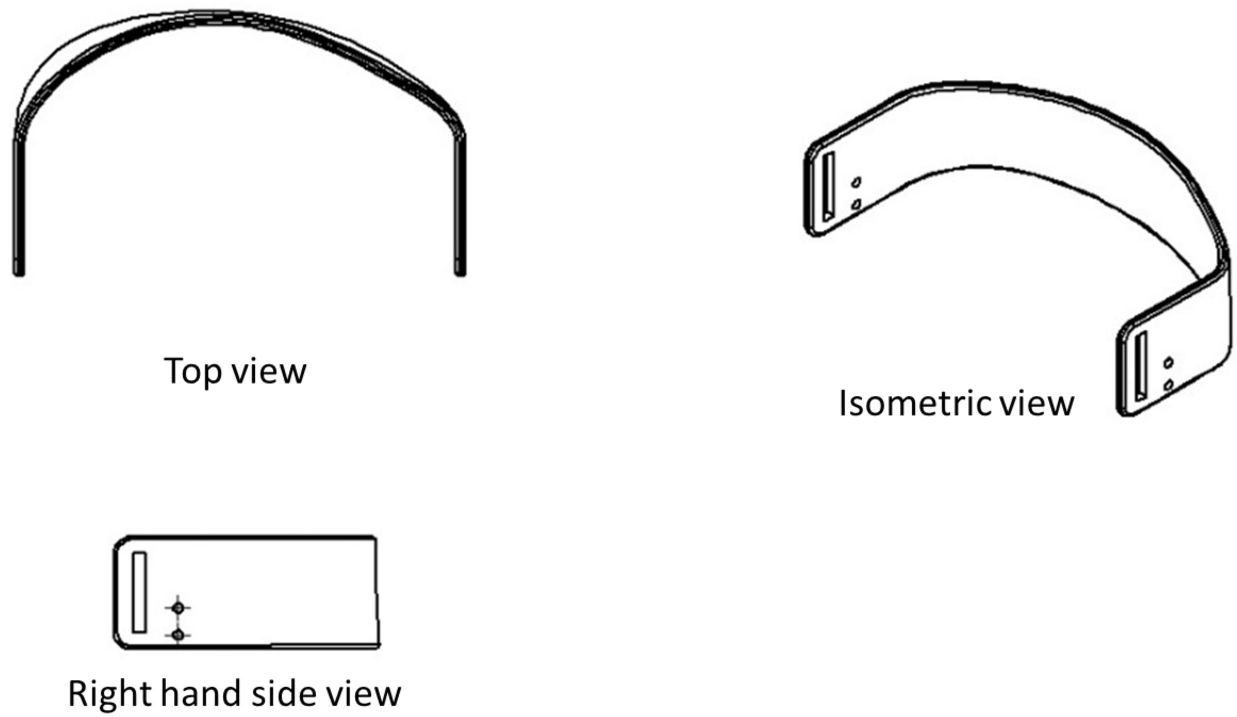


Flat pattern

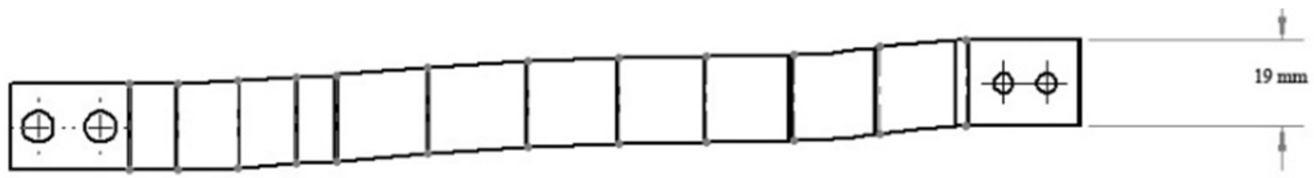


Left hand side view

CAD drawing of KAFO shank support



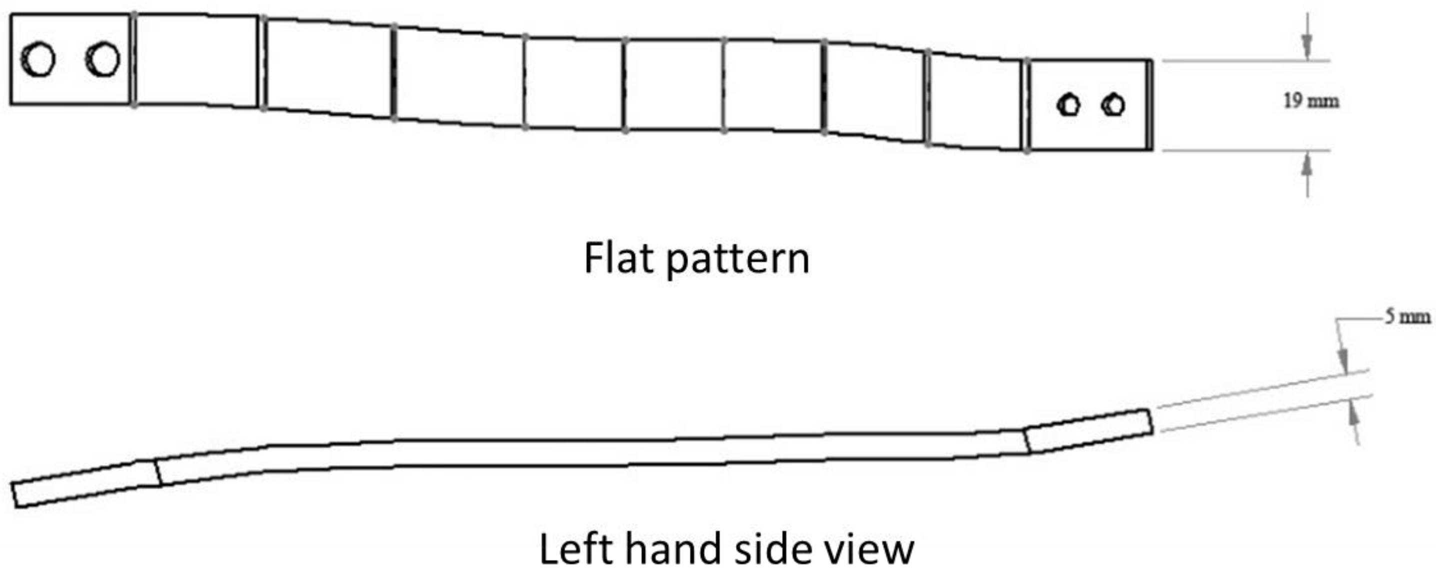
CAD drawing of KAFO lateral thigh sidebar



Flat pattern

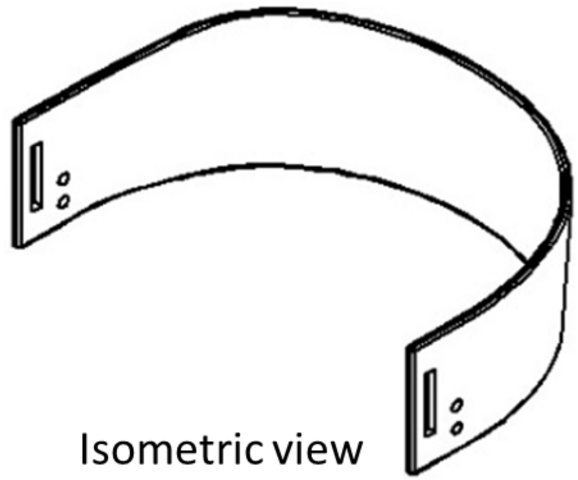
Righ hand side view

CAD drawing of KAFO lateral thigh sidebar



CAD drawing of KAFO thigh support

Top view



Isometric view

Right hand side view

APPENDIX B

FUNCTIONAL STATUS MEASURE AND USER EVALUATION OF SATISFACTION FORM

Functional Status Measure and User Evaluation of Satisfaction

Technology device: Custom made ankle foot orthosis

Date of assessment: 05/07/2014

The purpose of this questionnaire is to evaluate how easy this device is for you and how satisfied you are. The questionnaire consists of 13 satisfaction and functional items.

- For each of 13 items, rate your satisfaction with your assistive device by using following scale of 1 to 3.

1	2	3
Not satisfied	More or less satisfied	Satisfied

- Please circle or mark one number that best describes your degree of satisfaction with each 13 items.
- Do not leave any question unmarked.

Thank you for completing the questionnaire.

How satisfied are you with,	
1. the dimensions (size, height, length, width)?	1 2 3
2. the weight?	1 2 3
3. the ease in adjusting (fixing, fastening) the parts?	1 2 3
4 how safe and secure your device is?	1 2 3
5. the durability?	1 2 3
6. how comfortable your device is?	1 2 3
7. how easy to dress your lower body?	1 2 3
8. how easy is it for you to get up from the floor?	1 2 3
9. how easy is it for you to walk around?	1 2 3
10. how easy is it for you to walk outside on uneven ground?	1 2 3
11. how easy is it for you to walk up to two hours?	1 2 3
12. how easy is it for you to walk up a steep ramp?	1 2 3
13. how easy is it for you to put on and take off the orthotic?	1 2 3

Functional Status Measure and User Evaluation of Satisfaction

Technology device: Custom made knee ankle foot orthosis

Date of assessment: 08/07/2014

The purpose of this questionnaire is to evaluate how easy this device is for you and how satisfied you are. The questionnaire consists of 13 satisfaction and functional items.

- For each of 13 items, rate your satisfaction with your assistive device by using following scale of 1 to 3.

1	2	3
Not satisfied	More or less satisfied	Satisfied

- Please circle or mark one number that best describes your degree of satisfaction with each 13 items.
- Do not leave any question unmarked.

Thank you for completing the questionnaire.

How satisfied are you with,	
1. the dimensions (size, height, length, width)?	1 2 3
2. the weight?	1 2 3
3. the ease in adjusting (fixing, fastening) the parts?	1 2 3
4. how safe and secure your device is?	1 2 3
5. the durability?	1 2 3
6. how comfortable your device is?	1 2 3
7. how easy to dress your lower body?	1 2 3
8. how easy is it for you to get up from the floor?	1 2 3
9. how easy is it for you to walk around?	1 2 3
10. how easy is it for you to walk outside on uneven ground?	1 2 3
11. how easy is it for you to walk up to two hours?	1 2 3
12. how easy is it for you to walk up a steep ramp?	1 2 3
13. how easy is it for you to put on and take off the orthotic?	1 2 3