



MARMARA UNIVERSITY
INSTITUTE FOR GRADUATE STUDIES
IN PURE AND APPLIED SCIENCES



DESIGN, ANALYSIS and CONTROL of a HYDRAULIC-AIDED STANCE CONTROL KNEE-ANKLE-FOOT ORTHOSIS

SERMET DEMİR

Ph.D. THESIS

Department of Mechanical Engineering

Thesis Supervisor

Prof. Dr. ERTURUL TAÇGIN

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Sermet DEMİR, a Doctor of Philosophy student of Marmara University Institute for Graduate Studies in Pure and Applied Sciences, defended his thesis entitled “**Design, Analysis and Control of a Hydraulic-Aided Stance Control Knee-Ankle-Foot Orthosis**”, on 30 May 2018 and has been found to be satisfactory by the jury members.

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ACKNOWLEDGMENT

I would first like to thank and express my sincere gratitude to Professor Erturul TAÇGIN for his invaluable guidance and help during the preparation of this dissertation. I would like to mention his patience, giving me inspiration and hope when I was stuck at dead-ends. Also I would like to thank to Professor Abdul Kerim KAR, Assistant Professor Vahan KALENDEROĞLU, Assist. Prof. Dr. Kıvanç Onan and Can GAVRİLİDİS for his support.

I must express my gratitude to Hatice Kübra, my wife, for her continued support and encouragement. I am also especially thankful to my son Ahmed Emin. I have very much benefited from the discussions with my dear friends Sinan Dönmez, among whom I would like to mention especially Ercan Kara, Berat Gürcan Şentürk, Kübra Tural, Ömer Çelepçikay and Caner Okutkan. I thank them all.

Sermet Demir
May 2018

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ABSTRACT

DESIGN, ANALYSIS and CONTROL of a HYDRAULIC-AIDED STANCE CONTROL KNEE-ANKLE-FOOT ORTHOSIS

The starting point of this study was the emerging interest on Knee-Ankle-Foot orthosis (KAFO). KAFO is prescribed many diseases such as polio, muscle weakness, spinal injury and multiple sclerosis. There are commercial examples and numerous attempts in literature, but functional KAFO still is a challenging issue. Users reject to use orthosis because of functional, comfortable and cosmetic problems. Beside this, the knee joint has to allow for a certain range of motion. Otherwise, it causes circumduction or hip hiking and more energy expenditure. A sophisticated and reliable system is desired.

This dissertation proposed a framework for designing both functional and comfortable KAFO. This framework includes a wide literature review, an engineering design approach, manufacturing of the designed system, two different control systems and operating the orthosis. Especially phase detection system and smart control system have abilities to adapt different gait profile. On the basis of this framework, it integrates design, functionality and control system of an orthosis for solving rejection problems as users desired. Furthermore, a risk analysis was implemented to advance the design. Researcher interested in this topic can refer this study.

The prototype knee joint mechanism has advantages such as smooth lock, inhibits knee flexion at the same time allowing knee extension during weight acceptance phase, light weight and low number of parts. Future works will be made to improve a new valve mechanism and dimension optimization on parts.

ÖZET

HİDROLİK DESTEKLİ DURUŞ KONTROLLÜ UZUN YÜRÜME CİHAZININ DİZAYNI, ANALİZİ ve KONTROLÜ

Bu çalışmanın başlama noktası uzun yürüme cihazları hakkında ki yükselmekte olan ilgidir. Uzun yürüme cihazları çocuk felci, yetersiz kas gücü, omurilik zedelenmesi ve multiple skleroz (MS) gibi rahatsızlıkların tedavisinde kullanılmaktadır. Uzun yürüme cihazının ticari örnekleri ve literatürde birçok araştırma olmasına rağmen, uzun yürüme cihazı hala ilgi çekici bir konudur. Kullanıcılar ortez kullanımını fonksiyonel, konfor ve kozmetik problemler sebebiyle reddetmektedir. Bunun yanında kilit mekanizması hareket kabiliyetine sahip bir yapıda olmak zorundadır. Aksi takdirde, bu durum kullanıcıların kalça kaldırmalarına ya da ayaklarını dışarıdan savurmalarına böylelikle daha çok enerji harcamalarına sebep olmaktadır. Bir gelişmiş ve güvenilir bir sistem arzu edilmektedir.

Bu tezte fonksiyonel ve konforlu bir uzun yürüme cihazının dizayn çerçevesi sunulmuştur. Bu çerçeve geniş bir lüteratür ve pazar araştırmasını, bir mühendislik yaklaşımıyla dizayn çalışmasını, dizayn edilen sistemin üretimini, iki farklı kontrol sistemini ve bunların uygulanmasını içermektedir. Özellikle faz belirleme sistemi ve akıllı kontrol mekanizması değişik yürüme durumlarına uyum sağlayabilmektedir. Bu çerçeve neticesinde, dizayn, fonksiyonellik ve kontrol sistemi birleştirilerek kullanıcıların arzu ettiği yönde problemlere çözüm üretilmiştir. Ayrıca, risk analiz sistemi uygulanarak, dizaynın daha da gelişmesi sağlanmıştır. Konu ile ilgili araştırmacılar bu çalışmayı bir kaynak olarak kullanabilir.

Prototip diz kilit mekanizması yumuşak kilit, diz bükülmesine ve yük durumunda diz iletmesine izin verme, hafif olma ve az sayıda parça içirme gibi özelliklere sahiptir. Gelecekte ki çalışamalar yeni bir valf sistemine ve mekanizmanın parçalarının optimizasyonuna odaklanabilir.

CLAIM OF ORIGINALITY

This dissertation presents a framework for a new KAFO design which allow knee flexion and extension with the integration and cooperation of a smart control system. The simple (low number of parts) and reliable mechanism makes the orthosis attractive for cosmetic issues.

The proposed study in this thesis is a whole work starts with a wide literature research and market example analysis integrated with Quality Function Deployment design system. This part of the thesis can be used for another design to determine design parameters. The mechanism of the lock system consists of two parts; piston and four-bar mechanism. There are examples of hydraulic system in the literature but this design has very low number of parts that is light in weight.

The challenging part of the study is control system of the orthosis. Phase detection and control of the lock system were worked in many studies usually individually. Two different control algorithm were implemented. The first method is a unique rule based method and another method is fuzzy logic system. The implementation of fuzzy system in phase detection and control of an orthosis is the first ones to applied a lock system.

Failure mode and effect analysis for an orthosis, through the proposed study is another contribution to the field. Risk analysis will lead the way for new studies and guide to determine design parameters of orthosis.

SYMBOLS and ABBREVIATIONS

BME	: Biomedical Engineering
KAFO	: Knee-Ankle-Foot Orthosis
SCKAFO	: Stance Control Knee-Ankle-Foot Orthosis
AFO	: Ankle Foot Orthosis
FS	: Foot Strike
FO or TO	: Foot Off
FF	: Flat Foot
HO	: Heel Off
SW	: Swing
HS	: Heel Strike
COG	: Center of Gravity
QFD	: Quality Function Deployment
FMEA	: Failure Mode and Effect Analysis
AI	: Artificial Intelligence
RPN	: Risk Priority Number
CSCM	: Compliant Stance Control Module
CCM	: Compliance Control Module
CSCO	: Compliant Stance Control Orthosis
SCI	: Spinal Cord Injury
HKAFO	: Hip Knee Ankle Foot Orthosis

DKBS : Dynamic Knee Brace System

OA : Osteoarthritis

TA : Thigh Angle

TAV : Thigh Angle Velocity

SA : Shank Angle

SAV : Shank Angle Velocity

TL : Turkish Lira



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1. INTRODUCTION

Engineering is designing things or another way to say engineers are trying to apply science i.e., taking scientific information to make something new. That things are not just new but also they are useful and improves the quality of human life.

Our experience show that world has changed and shaped a lot by engineering and technology. With this changes, we can move easily from place to place, communicate with others at distant sites, live and work in buildings that are safe and smart. At this point we can say medical technology is the most visible aspect aspects of the modern world. People from all walks of life are eager to hear about new machines, new medicines, and devices that will uncover hidden disease, treat previously untreatable ailments, and mend weary or broken organs [1].

Biomedical engineering (BME) is the field which has many different disciplines with a focus on the human body. It applies engineering principles to design and develop new equipment, methods and even medicine to improve the quality of human health. Today's clinicians work very closely to patients, scientists and engineers to solve real life problems. A concept solution is advised to problem and project starts by combining creativity and innovation with the latest technology to produce products that would help patients and improve their ability. Thus, in this field researcher try to adapt engineering and medicine, involving the design and problem solving skills of engineering with medical and biological sciences to advance health care treatment, including diagnosis, monitoring, and therapy.

The term biomedical engineering appears to have the most comprehensive meaning. Biomedical engineers apply electrical, chemical, optical, mechanical, and other engineering principles to understand, modify, or to control biological (i.e., human and animal) systems. For example, one of the challenging topic is making artificial limbs which are for people who have either lost a limb or maybe need to have to compensate disabilities. This design has to be similar to a normal human limb with a weight as similar amount. If it is not, it may cause strain other parts of the person's body. The quality of person life is maintained with proper mechanical structure design. This aspect generally about the mechanical engineering.

KAFO (Knee-Ankle-Foot Orthoses) is also an example of biomedical engineering. Over the last 100 years, engineers have found and learned a lot about the mechanics of human organism and how it works, how it obeys physical. The gravitational force has effects on our body as well as walking. If a person has a polio, knee pain or diseased in some way, he cannot stand up or walk against that gravitational field. It limits motion and sometimes causes severe accidents like falling. So engineers have been working for many years to design a device for joints which behaves like the knee. The KAFO is the most well developed device of it and also the developments continue in nowadays.

1.1 Literature Survey

Approximately 1.8% of the population of the world requires some form of orthotic treatment [2]. The need in Turkey can be assumed to be of the same order [3]. Knee Ankle Foot Orthosis (KAFO) is one of the lower extremity orthosis. They are prescribed for patients who have hip and quadriceps muscle weakness due to polio, degenerative muscle disease, stroke, partial spinal injury, congenital defects or aging with or without foot pathology. While bearing their own weight, these people cannot walk safely without collapsing. A KAFO is a full-length leg brace designed to stabilize and lock the knee, ankle and foot in a profile while supporting the leg muscles (Fig. 1.1).

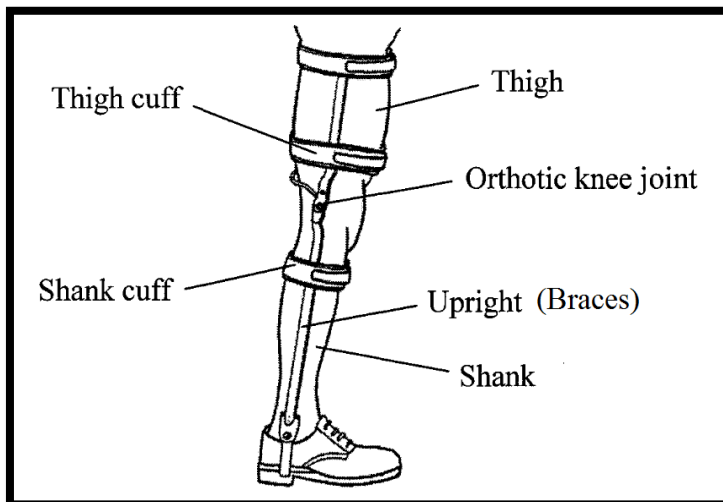


Figure 1.1. A conventional KAFO.

For a patient experiencing this type of illnesses, the best option associated with the use of the knee is to wear a KAFO with a locked knee joint. However, there are many problems

about conventional KAFO; limited mobility and pain and loss of motion at the hip and lower back with increased energy expenditure in gait, cosmetic problems [4]. The major problem for KAFO users is that they cannot flex their knee while swinging leg forward during walking. The stage from toe off to foot strike is named to be swing. The swing phase approximately occurs during 35-40% of the gait cycle. A swing consists of three phases which are initial swing, mid-swing and terminal swing. If a person cannot flex his knee, he should throw his leg and the upper body forward, around the side of his body. Another possibility is to lift the hip during swing phase and then bring the leg towards to initial contact. This type of KAFO also limits stairs or walking over inclined surfaces.

Within the past few years, a new design of a knee joint that can automatically lock and unlock at the appropriate phases of the gait cycle to allow a more fluidic walking style has been developed. These knee joints can be used to design a KAFO that is appropriate for certain patients with knee weakness. These types of KAFO have been known as Stance Control Knee-Ankle-Foot Orthosis (SCKAFO). There are many commercial SCKAFO in the market. Unfortunately, these designs either provide no support while walking stairs or inclines, nor in stumbling and they are too heavy and bulky for many patients. Also many patients cannot afford this type of KAFO.

Each KAFO is custom-made in accordance with the specific requirements of the individual. There are numerous design options available that makes use of orthosis both functional and comfortable.

Abnormal gait patterns can cause to soft tissue and joint dysfunction of the hip and lower back which lead to pain and loss of motion [5]. Beside this, walking with a fixed knee decrease gait efficiency by 24 percent [6] and increase lateral displacement of the center of mass of the body by up to 65 percent [7]. This increase in muscle can lead to higher energy expenditure [8] and early fatigue for the KAFO user during ambulation [6]. Increased energy need with KAFO contributes significant increase of KAFO rejection rates (between 60% and %100) [9].

The lack of the knowledge for orthotic design is the main problem. Orthotic design must be based on a complete engineering approach. Data should be collected from users, practitioners and manufacturers to find all objective criteria which customize the general

shape and provide design route for study. Researches, design study, simulation studies and implementation of new methods, technics and materials will increase the comfort and functionality of the device while minimizing rejection rate.

At this point the literature review provides a fundamental approach about recent limitations with searching all the relevant technologies and studies. Thus possible improvements about these problems can be provided. In this section compulsory knowledge about KAFO which are elements of human gaits, the function of KAFO, their limitations, attempts to design a better KAFO, the studies for optimization KAFO design will be examined.

1.2 Principles of Walking / Gait

Gait is the medical term and refers to human locomotion or the way that we walk. Walking (also known as ambulation) is one of the main gait of locomotion. Also it is defined by an inverted pendulum gait in which the body vaults. The figure 1.2 shows the stages of walking and corresponding forces according to the right foot.

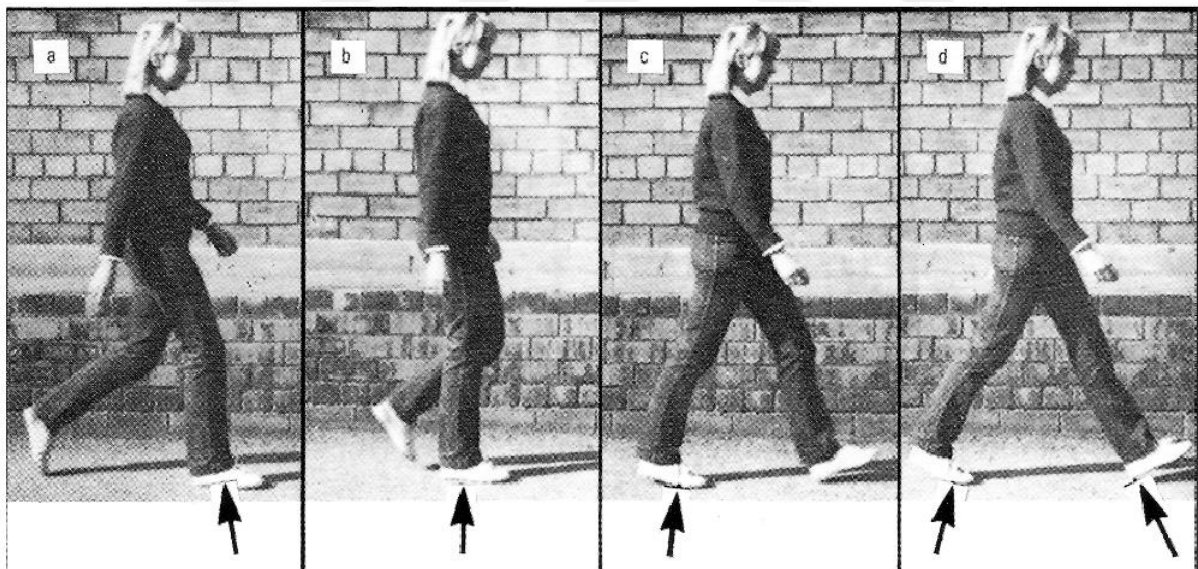


Figure 1.2. A typical walking sequence. Arrows show force directions on the feet [10].

Human gait refers to locomotion achieved through the movement of human limbs. It is composed of two distinct phases – stance and swing [10]. The stages and sub stages of human gait are shown in a diagram in Figure 1.3.

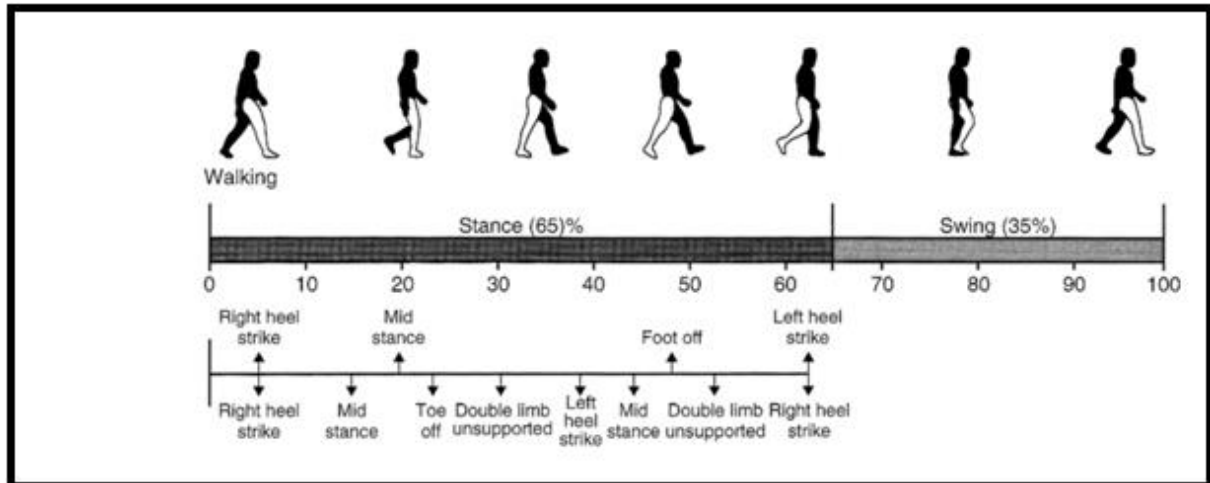


Figure 1.3. Walking gait sequences [10].

The hip, knee and ankle sagittal (in the direction of vertical plane which passes from anterior to posterior, dividing the body into right and left halves) plane angles are usually referred to the time the foot touches the ground that is foot strike FS or heel strike/contact and when the toe leaves the ground that is toe off, TO or foot off (see fig 1.4). The stance phase is beginning from foot strike and ends at toe off. In other words, it is the period which foot is contact with the ground. Second stage swing is beginning when the foot leaves the ground, travels to the front of the body and finally contact the ground again (from toe off to foot strike). The swing consists of three sub-stages which are initial swing, mid-swing and terminal swing respectively.

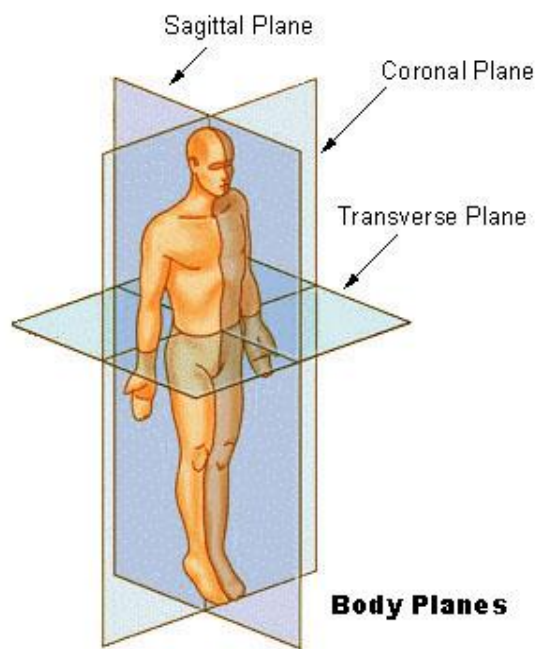


Figure 1.4. Human body planes. Sagittal, coronal and transverse planes. [11].

The stance phase covers 60% of the gait cycle for each leg and swing lasts 40 % of the gait cycle. Two feet are in contact with the ground for the first and last 10 % of the stance phase. First one is occurred after foot stroke and second one is just before toe off. These two stages are called as double limb support and it is absent in running. The middle part which covers the 40% of the stance phase, limb is sole support and it is named as single support. Swing phase begins for the last 40% duration of the gait cycle just after the stance phase for the right foot is concluded. In this phase left leg is on single support. Right leg accelerates to mid-swing and decelerates to foot stroke. As described here both feet are never off the ground at the same time. The evaluation of sagittal plane angle during gait is shown in figure 1.5.

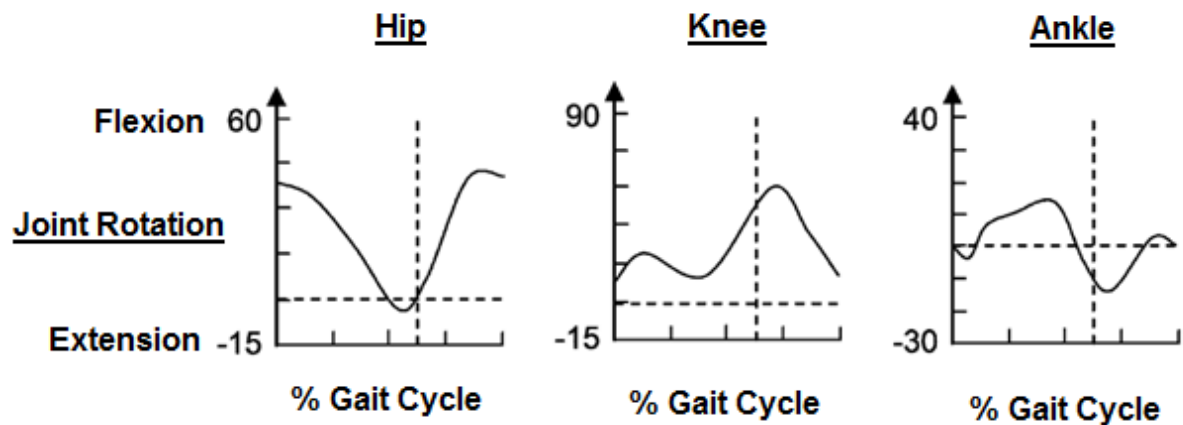


Figure 1.5. Sagittal plane joint rotation for the hip, knee and ankle in one step.

As described above a gait cycle is composed of two periods. Three tasks are carried out in these periods (Fig. 1.6). They are weight acceptance, single limb support and limb advancement respectively. Single limb support is common for stance and swing. Weight acceptance is the most demanding task in the gait cycle. It has three main functions; shock absorbance of initial foot contact, providing initial limb stability and preserving forward progression. In this phase forward limb resists to body weight and the knee is flexed for shock absorption. The main task as well as problem is to withstand the body weight that acts on the limb suddenly. The initial contact lasts only 2 % of the gait cycle. In this time the limb is positioned to start stance with using heel as a rocker. The loading response lasts 0-10 % of the gait cycle and covers the initial contact. This phase continues until the other foot is lifted.

	Period	Task	Phase
Stride (Gait Cycle)	Stance	Weight Acceptance	Initial Contact Load Response
		Single Limb Support	Mid stance Terminal Stance
			Pre-swing
	Swing	Limb Advancement	Initial Swing Mid swing Terminal Swing

Figure 1.6. Gait cycle divisions [12].

N.P. Single limb support begins when the contra lateral (back) foot is lifted. It continues until the contra lateral foot completes its swing phase and contacts the floor again. In this phase one limb resists to total body weight in both sagittal and coronal planes while progression continuing. This phase has two sub phases which are mid-stance and terminal stance.

Mid-stance covers 10-30% of gait cycle. It begins with the single limb support and continues until body weight is aligned over the forefoot. Principal functions of this phase are progression over stance foot and stabilizing weight acceptance.

Terminal stance covers 30-50% of gait cycle. Single limb support is completed in this phase. In the stance limb the heel begins to rise with keeping contact with floor until the other foot hits the ground. Only objective is providing forward progression to continue [13].

The double stance interval is concluded with the final phase of stance. Weight transfer to one foot to another is happened. The unloaded limb begins to swing which is called as

pre-swing phase. Per-swing time interval is between 50 - 60 % of gait cycle and limb takes its position for swing.

The interval between 60 – 73 % of gait cycle is named as initial swing. It begins with the toe off of the stance foot and continues until the swing foot aligned with the stance foot. The swing foot is cleared from ground and limb is advanced its trailing position.

Swing phase also has two sub phases, mid swing and terminal swing respectively. This two phases duration are approximately equal. Mid swing is 73 - 87 % of gait cycle and terminal swing is 87 - 100 % of gait cycle. The phase end when the swinging limb is forward and the tibia is vertical according to the ground. Foot clearance and limb advancement are continuing in this phase. Terminal swing ends when the foot strikes the floor. Limb advancement is completed as the shank moves ahead of the high.

1.3 Functional Features and Center of Displacement of a Locomotion Pattern

Locomotion is the act of self-propulsion including jumping, running, and swimming. Human locomotion can be categorized as running and walking. Locomotion requires energy to overcome friction, drag, inertia and gravity, though in many circumstances some of these factors are negligible. Animal living on the ground must overcome the gravity rather than drag of air or water. This difference of forces that have to be overcome in gait occurred due to the way of locomotion. In other word it is the locomotion pattern that used to move. At this point the functional features of a locomotion pattern come into prominence.

The main tasks of locomotion patterns are providing stability, propulsion and efficiency of system. Stability is the most important one that provide balancing by resisting gravitational forces acting on the body and body inertial forces. In the propulsion phase energy needed to provide movement is added to the system. Efficiency means minimizing the energy expenditure of locomotion. This can be provided by two ways by minimizing kinetic energy or by minimizing potential energy. A fine or suitable shock absorption and prevention of repetitive injury decreases the kinetic energy. Potential energy can be minimized by smaller change of center of body or decreasing body pattern mass. If a device is used to provide locomotion, decreasing device weight also minimizes potential energy.

Knee provides connection between two lower limbs, thigh and shanks. It plays an important role both stability and mobility of the lower limb throughout the gait cycle [4]. It makes a rotational movement both in sagittal and coronal planes, and small amount of rotation result in a larger amount of foot movement. It has ability to flex 60° in sagittal plane and also makes 8° movements in the coronal plane as shown in fig 1.7. During stance the knee major figure is supplying limb stability. Also during swing phase, the knee gives flexibility to the limb to advance cycle. Thus the knee makes flexing and extending movement, which has very important significance during gait cycle.

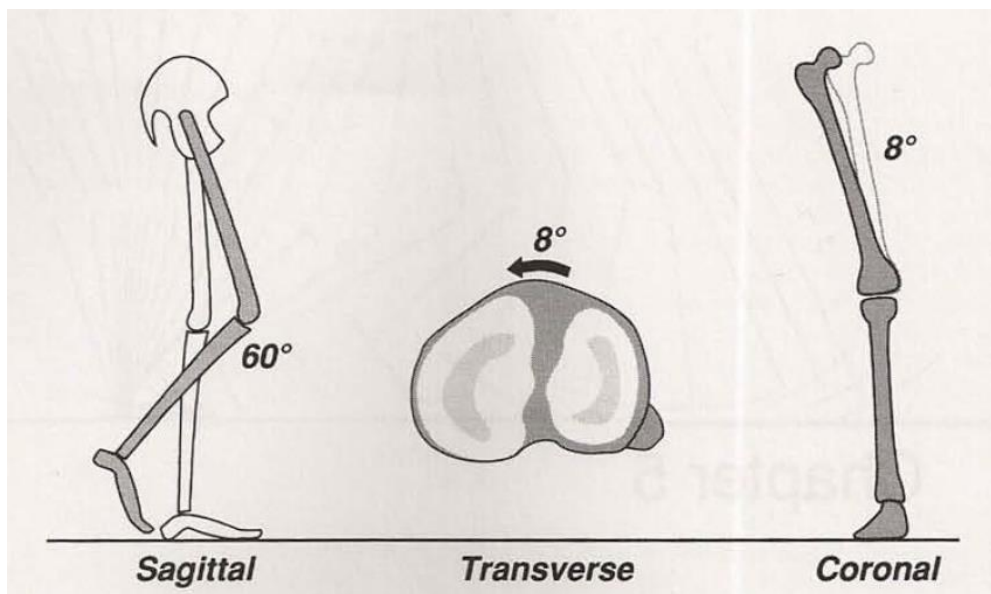


Figure 1.7. Three dimensional knee motion and arcs used in free walking: sagittal, transverse and coronal plane [12]

Hip has different function in several ways according to other joints. It makes the connection between locomotor units and upper body. Different from other joint, it has ability to provide three dimensional motions. Sagittal plane is the one which make largest arc. Hip has two functions in the gait cycle. Primary role is providing stabilization of trunk. During swing phase, limb control is the primary function.

The hip extends during stance and flex in swing. The exchange of motion from one direction to other is gradual [12].

During ambulation, the body's center of gravity is propelled forward. However, it also moves vertically and laterally as indicated in the figure 1.8. Vertical and lateral displacement of the center of gravity (COG) of the body examines in different part.

Vertical displacement of COG: Especially appeared in sagittal plane, the vertical displacement of the center of gravity follows a smooth sinusoidal curve. This curve up and down distance in the normal adult male is approximately 5 cm. The center of body moves vertically through two steps of a gait cycle, so that the curve has two peaks and two low points.

The low point of the sinusoidal pathway indicates double limb support periods of the gait cycle. These are loading response and pre-swing. The amplitude is depending on pelvic rotation and knee-ankle-foot interactions. During gait, pelvis makes a forward rotation movement on lateral plane. This rotation on the swing side compensates excessive displacement of the Body's center of mass. Initial contacts of the both foot pelvis is perpendicular to forward direction. It rotates during periods of double limb support.

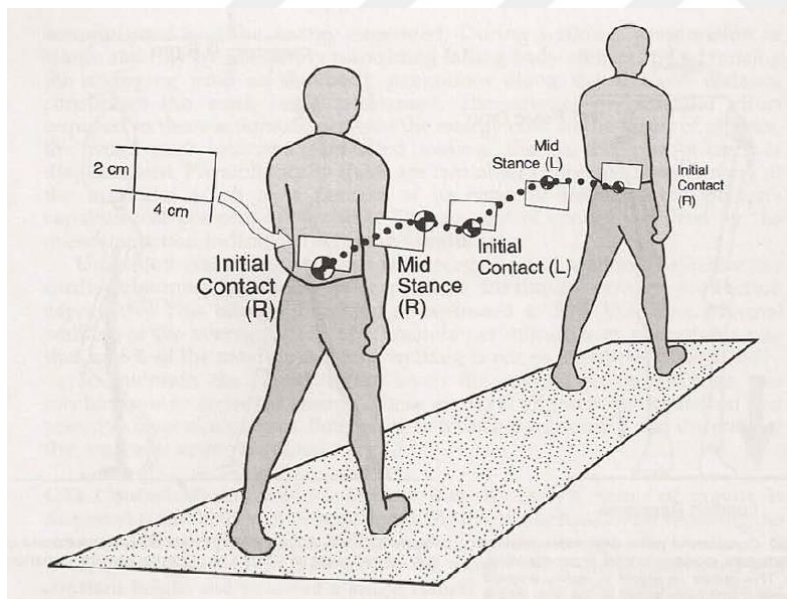


Figure 1.8. The normal path of the body center of gravity (black/white circle) illustrated by a stride [12].

If the pelvis does not rotate, the vertical amplitude of the center of the body will be much more than ordinary gaits. The pelvis rotates forward on the swing side, and then rotates relatively backward during stance. The high points of the sinusoidal pathway indicate

mid-stance and mid-swing of the gait cycle. The amplitude is depending on lateral pelvic drop and knee flexion in stance. Pelvis dropping on the unsupported side provides a reasonable rise in the body center during mid-stance. Like pelvic rotation, if pelvis does not drop, the vertical amplitude of the center of the body will be much more than ordinary.

Lateral displacement of body center: The center of the body also oscillates laterally by tracing a sinusoidal curve during ambulation. The total displacement is approximately 6 centimeters. The peak point is reached at the end of the mid stance. Therefore, only one lateral oscillation occurs during a gait cycle. Mid stance knee flexion prevents an excessive rise in the body's center during that period of the gait cycle (see fig 1.9).

	%	EVENTS	LOWER LIMB	KNEE JOINT	ANKLE JOINT	SUBTALAR JOINT	MIDTARSAL JOINT
STANCE		I.C. → foot flat →	medial rotation	flexion	plantar flexion	pronation	free motion
	20	midstance	lateral rotation	extension	dorsi-flexion	supination	restricted
	40	heel rise →		flexion	plantar flexion		
	60	toe-off →	medial rotation	extension	dorsi-flexion		
SWING	80						
	100	I.C. →					

Figure 1.9. Physiological genuvalgus is a structural feature of the human knee joint that limits lateral movements in the body's center during gait cycle [13].

1.4 Knee Ankle Foot Orthosis (KAFO)

Orthotics is a medical field that is concerned with the design, manufacture and application of orthoses. It combines anatomy physiology, pathophysiology, biomechanics and engineering interdisciplinary. Orthosis is an orthopedic appliance or apparatus that is specially designed to support, align, prevent, correct or compensate deformities or to

improve function of movable parts of the body. The difference between the prosthesis and orthosis is prosthesis used for non-existent limb or body part but orthosis used for improving or correcting existing limb.

KAFO is a lower limb orthosis that is externally applied to span the knee, the ankle and the foot. It stabilizes the lower limb joints and helps the muscle of leg [13].

The term KAFO is an acronym and describes the part of the body that this device encompasses [14].

In the case of weak deformed muscle, the knee cannot resist knee flexion and then the knee will collapse under knee flexion moment. Common indications for such an orthosis can be due to, paralysis, muscular weakness, arthritic joints, knock knee, poliomyelitis, muscular dystrophy, multiple sclerosis, spinal cord injury. The best option for a patient that suffers from these indications is to wear a KAFO. Thus patient can control the knee and stabilize leg. However, this situation causes other problems such as muscle atrophy and increased energy expenditure in gait. Although the person can walk with a KAFO, the gait is in an abnormal manner. Minimal knee extension strength is needed to use a KAFO. Total absence of knee extensor muscle activity makes walking impossible [15].

People who suffer from weak or absent knee extension force can maintain knee stability in stance by changing ground reaction force from back of the knee axis to anterior. To do this people flex their trunk forward, thus their body's center of mass relocates to anterior to the knee joint axis. As a result, body's center of mass force pushes backward the knee and provides stability.

Persons afflicted with moderate quadriceps weakness can be prescribed to use a floor reaction Ankle foot orthosis to inhibit instability of the knee [16]. A typical example is shown in figure 1.10.

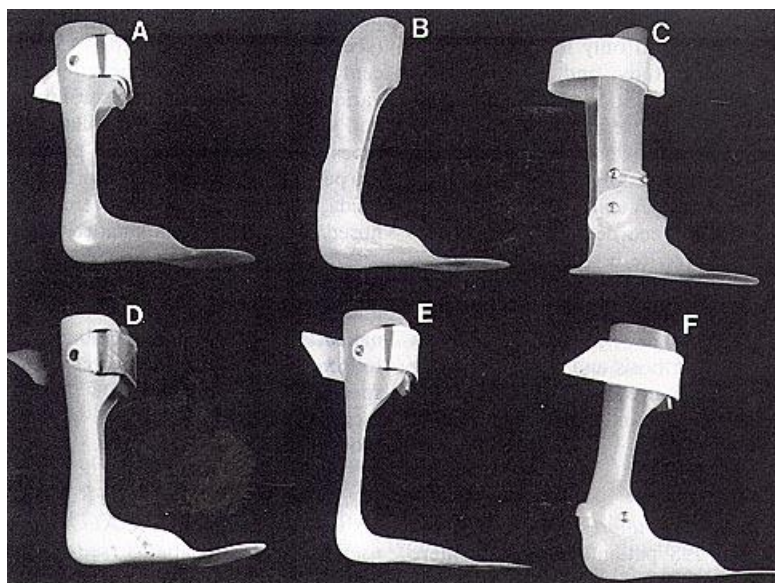


Figure 1.10. Thermoplastic AFOs. Note: A = solid ankle, B = floor-reaction, C = articulated floor-reaction, D = thermoplastic elastomer, E = dorsiflexion-assist, F = articulated [16].

An ankle-foot orthoses (AFO) is an orthosis or brace that surrounds ankle and part of the foot. It is used to control instabilities or compensate for weakness in the lower limb by maintaining proper alignment and controlling motion. AFO also is prescribed in the presence of arthritis and to correct foot drop. There AFO is also named as a foot-drop brace. The AFO keeps the angle in neutral position. Thus the track of the ground reaction force is in front of the knee axis. As a result, the involved leg is not to be lifted excessively in order to clear foot from ground.

Dorsiflexion is inhibited by AFO. Dorsiflexion is the act of bending backward or flexion in the dorsal direction. In gait, dorsiflexion refers to foot rotation about ankle pointing the toes upward or towards the body [15]. Plantar flexion is the movement which increases the approximate 90-degree angle between the front part of the foot and the shin, as when depressing an automobile pedal.

Knee-ankle-foot orthosis is the extension of the AFO proximally knee motion and alignment. Typically, KAFO are mechanically simple and often have several moving parts. They are durable but functional abilities are very low. KAFO may be in form eccentric (free knee-joints) or locked knee-joints with a variety of locked, fixed, limited range of motion or assistive ankle joints [16]. Free-knee joints KAFO position the orthotic

knee joints axis posterior to the natural knee joint axis. Individuals with this type of orthosis can flex their knee at all phase. Orthotic knee joint axis remains posterior to the ground reaction force in stance phase. Thus individual can be ensured a state of constant knee stability. However, these types of KAFO are only applicable for a very low percent of individuals.

1.5 Drawback in KAFO and Stance Control Orthosis

Unlike conventional KAFO, an orthosis should provide a knee support in stance and free knee motion in swing. There are several attempts about this topic. In these studies, a new term is used for this type of functional orthosis that is Stance Control Knee-ankle-foot orthoses (SCKAFO). In SCKAFO individuals have the ability to flex their knee in stance and manually or automatically can lock the mechanism. At least individuals should have minimum muscle strength to preserve forward progression in walking. Some newer version sometimes called skeleton system (exoskeleton) also has facility to use for individuals who have very low or absent muscle strength.

Conventional KAFO only locks in full extension to provide lower limb stability. However, it causes patients to ambulate with gait deviations that may lead to other problems over time [17,18]. According to the clinical orthotics, generally individuals prefer fixed knee KAFO although they have sufficient muscle strength to use a SCKAFO.

Yokimovich made a worthy study about stance control KAFO [3]. In his article, various SCKAFO are examined by engineering design review. The existing design limitations are observed and possible design challenges are showed. An ideal SCKAFO should have main functions such as a) allows free knee extension but resist flexion and b) extension knee in the case when no force on foot in swing and allows free knee movement when flex. These functions could not be covered by none of the reviewed designs. Only a few of them satisfy while some have additional features. These additional functional features are;

- 1) Locking the knee at any angle rather than at full knee angle on wide range
- 2) Locking the knee at any angle of knee or ankle
- 3) Allowing knee locking when the braced limb unloaded

- 4) Allowing controlled knee flexion in stance
- 5) Smooth transition between phases
- 6) Assisting knee extension during stance

It is concluded that size, weight and noise are the other most important factors for KAFO. In the summary of characteristics of commercial KAFO design it is denoted that designs that meet main functions of KAFO have disadvantages of being heavy and bulky commonly. The minimal dimensions of whole orthosis importance are emphasized, because these devices are commonly worn under clothing.

1.6 Stance Control KAFO

Objective design criteria for orthotic device design are lacking. This paucity of data results in prescription guidelines based on assumptions or practitioners' past experience and the potential for incorrectly designed components. Up to 80 % of KAFO users reject to use their device and 40 % declare their dissatisfaction and discomfort about their orthotic device. The general reasons for rejection of an orthotic device are weight, size, noise and bulky shape. Since there are no general objective design standards for orthotic devices, they are not optimal for different conditions. As a result, commonly over designed devices prescribed to users because of safety problems and this causes unnecessary bulkiness on device.

As mentioned before designing a functional SCKAFO is a trend topic of interest in recent years. One of these studies, Shamaei designed a quasi-passive compliant SCKAFO [19]. The mechanical design, control algorithm and functional algorithm were presented in the study. The orthosis is consisting of a compliant stance control module (CSCM) integrated into a regular KAFO that has no lateral knee joint. The control module is responsible for activate and deactivate the support spring that is placed parallel with the knee joint.

In the experimentation phase, firstly the gait phase is identified by a specially designed insole which instrumented by force resistive sensors. At the same time, a rotary potentiometer was used to measure the knee angle. According to the collected data, a program embedded to the microcontroller which determine the phase of gait according to the signal and activate or deactivate the lock system. Three able bodied subjects were

participated to mechanical tests. Pre-clinic static loading test was carried out. The maximum moment that can orthosis resist was determined. After that reliability and the latency of CSCM were measured by a mechanical knee simulator that specially designed. The prototype successfully underwent 300 000 gait cycles without any failure. The test mechanism is shown in figure 1.11.

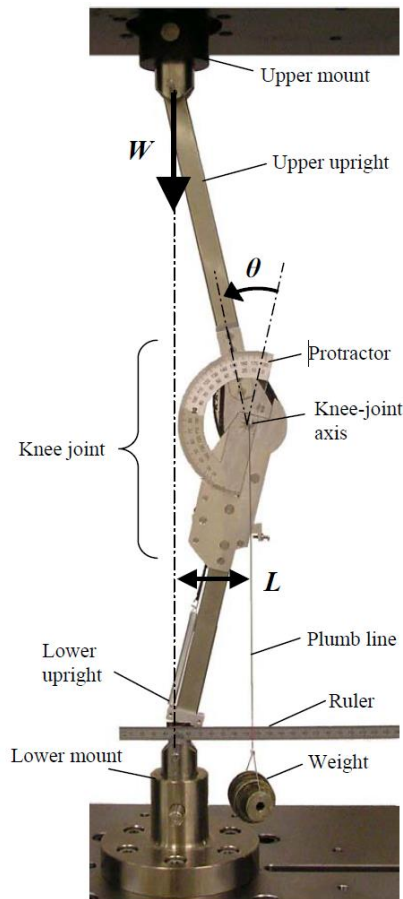


Figure 1.11. Photograph of the mechanical test apparatus [28].

The latency of the Compliance Control Module (CCM) for both engagement and disengagement were reported as approximately 30 ms. After the dynamic and static experiment successfully concluded, human subject test was carried out. Experiment results showed that Compliant Stance Control Orthosis (CSCO) could provide biomechanical benefits to healthy subjects. CSCO was compared with commercial SCKAFO (sensor walk Ottobock) and it is found that the performance is very close. However, the orthosis should be tested on subjects with a variety of neuromuscular impairments for a better comparison.

Since the conventional KAFO limit users to walk efficiently and does not allow knee flexion, walking on incline ground and different weather conditions such as snow and rain, research and development about effective SCKAFO is trend topic for recent years. Academical researches about this topic has tried many systems like hydraulic [20], friction [21], elastic [22], clutches [23-25] and brake [26,27] for orthotic knee joint (see fig 1.12). Unfortunately, many of these designs are not valuable to propose clinical and commercial applications. Four different model of SCKAFO come to the market at 2005. Patient wearing this type of SCKAFO have to be fully extend their leg to engage lock mechanism. This shows that these orthoses are nor suitable for stairs and uneven surfaces. Also they are too heavy and bulky. Cosmetically they do not have a beautiful appearance. The cost of the lock system and orthoses (including material and labor) are very high to afford for the most people.

Yakimovich has many studies about KAFO's design, construction and control. One of these study, he made a new type electromechanical KAFO beginning form its design to construction and evaluation [28]. The manufactured prototype was mechanically tested to determine the moment at failure, loading behavior and device safety.

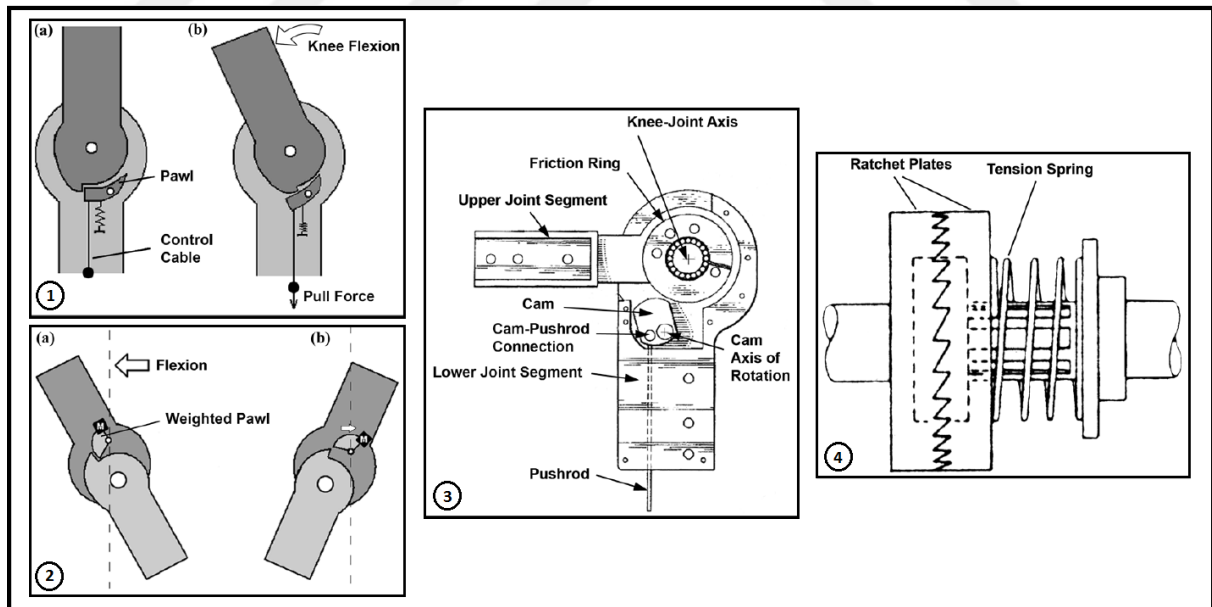


Figure 1.12. Examples prototype and design of KAFO and SCKAFO

Yakimovich aimed to design a SCKAFO that is light in weight and has slim structure, allowing knee flexion and lock at any angle and more affordable. Preventing excessive

knee flexion, cosmetics, compactness, withstanding to heavier patients (up to 90 kg) were other design considerations. These design parameters tried to be gained while safety factors still remain in the safe area. The main components were aluminum to provide lightweight structure and connection parts were hardened steel (see fig. 1.13).

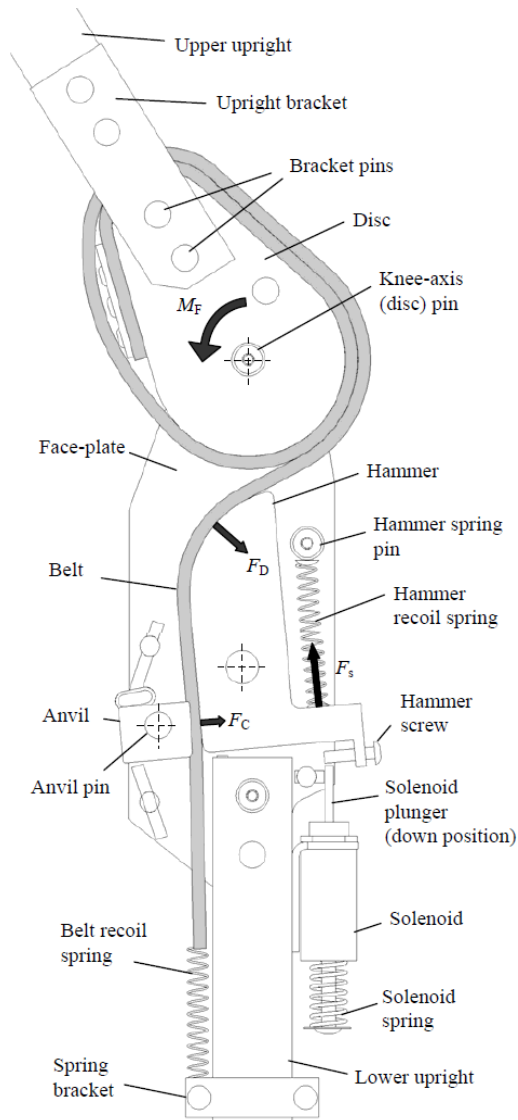


Figure 1.13. The structure of the designed SCKAFO [28]

Three able bodied subjects were participated to the walking experiments. According to the results, the effect of the SCKAFO while walking for an able bodied subject has minimal effect with respect to normal walking. The SCKAFO also increase the knee range of motion and reduction in pelvic obliquity. Control system worked properly. The

SCKAFO resist the applied flexion moment at mechanical test. All components except belt showed no failure or yielding. Yakimovich advised reducing the size and weight of the joint for the future work. At this point the optimization of dimensions of the SCKAFO components should be carried out. A sophisticated control system also is an attractive project.

Another study Yakimovich applied mechanical tests on designed knee joint [29]. According to the results knee joint is sufficient and give enough performance for a 90 kg subject at normal walking. A friction based belt clamping mechanism was used to lock the joint when it is necessary. This mechanism consists of a disc, belt, hammer and anvil. The belt wraps around the disc. The hammer is activated by a solenoid motor and this allows squeezing the belt between hammer and anvil in the weight bearing phase. An electronic control mechanism is used for activating and deactivating solenoid. A series of force-sensing-resistor placed to the foot plate of the orthosis measures the bearing weight continuously. When the signal indicates that the pressure reaches the predetermined threshold, solenoid is activated by a microcontroller system and joint locked.

The designed SCKAFO knee joint is 30% slimmer and 7% lighter than commercial joints. Yakimovich advised the researcher to focus mainly to increase the cycle life and factor of safety for the joint belt.

At a newer study Yakimovich performed gait analysis on three KAFO subjects with knee extensor weakness [30]. They have completed three walking trials with both conventional and new designed SCKAFO. The main objective of this study was providing free knee flexion in swing and locking knee at weight bearing. It is observed that all subjects exhibited more knee flex than former KAFO. Also knee range of motion was increased. Yakimovich indicated that providing thinner and less bulky profile and light weight structure also has to be considered. These factors have effects on benefits mentioned above.

1.7 Investigations on Loading SCKAFO

The KAFO design has not been changed for a relatively very long time. Although the new highly sophisticated production system and stronger & lighter material come out, the main form and material type of KAFO is not changed. Thus KAFO are still manufactured

as overdesigned. The unchanged rejection rate of KAFO usage supports this consideration. The optimization of KAFO or weight reduction is a trend topic research. The optimization of KAFO, making weight reduction still providing same structural integrity and comfort, can be gained by exactly realization of loads during gait. Also this information can be very useful to develop selection guidelines for practitioners. However, there is no exact measurement way to know whether a patient is using an optimally designed orthosis. The satisfaction and pleasure level of user may indicate some valuable information.

Little effort has been performed to measure loads on an orthosis. The relation between the load on orthosis and user weight can show the optimality level. The piston forces in orthotic knee joints was studied by Micheal [9]. On the other hand, an older study, considers forces in a prophylactic knee braces as a measure of brace-knee motion [31]. A recent study load sensor was preferred at the KAFO joint to directly measure the loads on the joint, and repeated the need of much effort to improve orthotic component design [32] (see fig. 1.14). Kaufman shows the importance of considering patient's entire clinical condition when prescribing an orthosis. In his study, he advised to further focus on loads imparted on KAFO by different patient group or brace forms [33].

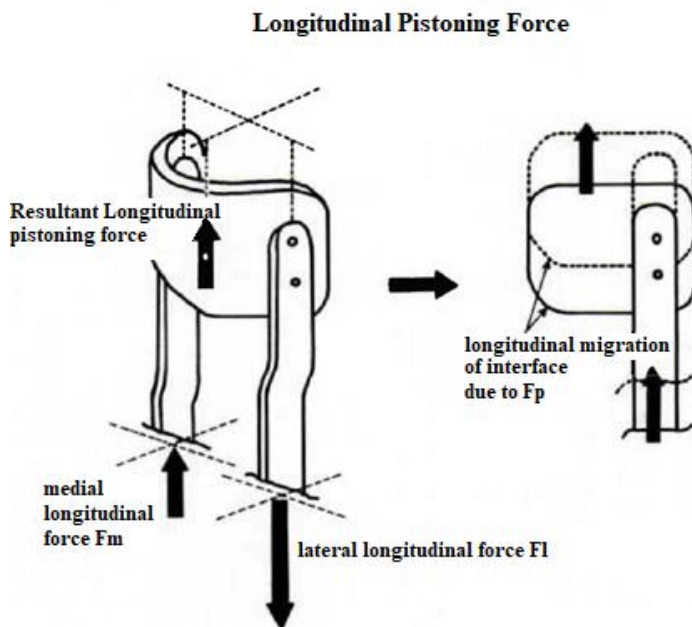


Figure 1.14. The difference between lateral longitudinal force and medial longitudinal force (left) is the resultant longitudinal pistoning force [31].

Objective design criteria for orthotic components especially for braces and locking system are lacking. There is only very low number of design standards and test methods. This lack knowledge was filled by practitioner's past experience or assumptions. This results in incorporate an uncomfortable devices and lead to some other ailment.

Kaufman measured the loads on the orthosis braces [27]. He was aimed to directly measure loads on the knee joint of a KAFO. This information can be used to guide orthotic component design and to form a prescription guideline. Also knowledge of load effect on orthosis provides to get more optimal devices for patients and increased comfort. KAFO is a general term that is prescribed several common indications for such a muscle weakness, paralysis etc. as described before. However, general treatment may not be suitable for all these conditions. Load sharing is an important factor for an orthosis especially for user comfort. Since the limb can accomplish some part of its task (weight bearing), the orthosis bear only the remainder part of the body weight. At this point, the weight sharing issue comes into prominence. The patients may have different degree of illnesses; therefore, individual prescribing is compulsory. When the orthosis is selected by practitioners past experience based on patient weight, height, strength and limb alignment, the over designed or under designed components are inevitable. This condition causes adverse effect on patients such as decreasing walking efficiency, imperative motions.

Three subjects have quadriceps weakness and use a KAFO were participated for gait analysis and orthotic data collection. A load sensor is placed on the knee joint. All load measured in a locked KAFO. Three forces and three moments were measured while subjects walking in three knee flexion positions which are 0, 10 and 20 degrees.

According to the results the forces observed highest for compression and lowest for lateral direction. Moments were highest in the sagittal plane and smallest in the transverse plane. Maximum moment is less than calculated from software. All force and moment magnitudes increases as the knee flex. On the contrary to the common prediction, there is no direct relationship between the body weight and the loads on the upright. The lightest subject in the experiments shows highest compression forces and higher sagittal and transverse moments than others.

This study is one of the leading projects in measurement of load on KAFO bracing. In this paper, it is tried to emphasize the importance of taking account a patient's entire clinical situation when prescribing an orthosis. Body weight alone is not sufficient to prescribe orthosis. Kaufman encourage researcher to obtain a greater knowledge about this so that it will be possible to design an orthotic device that is neither too flexible and liable to fail, nor too stiff and likely to be abandoned. Also the loads on different brace configuration can be an interesting topic for further investigations. Load measurement on single brace system is another advice for future project.

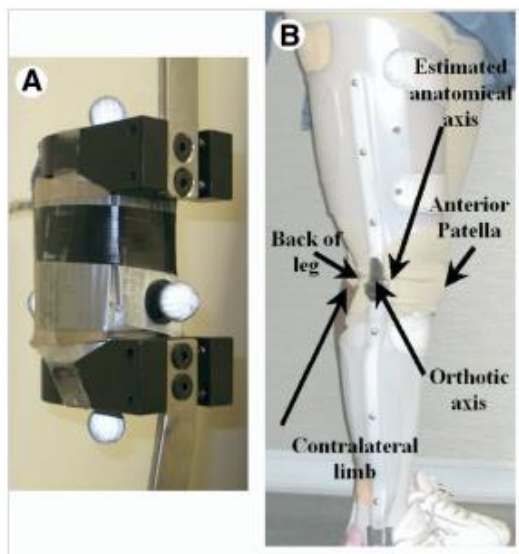


Figure 1.15. The placement of the load cell on KAFO. (A) The load cell (B) The KAFO prototype [33].

The accuracy of the conventional gait analysis was studied by Andrysek [34]. He was aimed to examine and investigate the forces and moments on KAFO during gait and also finding a way to compare the results of these two ways This information will help the orthotics when prescribing and also designing a better SCKAFO.

Andrysek emphasized that orthotic weight reductions are an important factor in overall usability and ultimately user acceptance of a KAFO. Overdesigned orthosis can be safer but this makes it heavy, bulky and uncomfortable to use. Structural optimization of orthosis yields comfortable and efficient KAFO while reducing the probability of failures [33]. Andrysek tried to find a more convenient way to find orthotic load data (see fig.

1.15). Thus the required information that is needed in designing specific orthosis have the structural integrity can be gained.

Earlier studies about load and moment measurement were usually used outdated technologies and small numbers of subjects were participated. Johnson examined on a large number of subjects but conventional gait analysis was used to measure knee, ankle and hip joint moments [35]. Conventional gait analysis has some assumptions such as assuming that limb and orthosis act as a uniform structure and internally generated loads imposed on the orthosis by the limb are inconsistent. Thereby these assumptions make some points of the measurements unclear.

A conventional KAFO was instrumented with load cell that capable of measuring 6 degrees of freedom (3 forces and 3 moments). Data were collected via an amplifier and a data acquisition system. Knee extension moment was measured in a human movement laboratory with a load cell mounted KAFO. Also conventional gait analysis was carried out. Four subjects with poliomyelitis were participated. Test was performed as locked and unlocked knee joint.

As expected, axial force and sagittal plane moment are the highest loads. Also these two loads were higher for the unlocked knee condition compared to locked knee. The main finding of the study, substantial underestimates of KAFO joint moments when using conventional gait analysis techniques is a deficiency of that method. These differences can be decreased by several modifications. Knee joint moments can be gained more accurately by tracking the anatomic knee joint dynamically instead of measurement with load cell.

A simulation study about estimation muscle forces and orthosis actuation in powered assisted walking of spinal cord injured subjects has been studied by Alonso [36]. Analytical and computational simulation of walking of individuals suffer from spinal cord injury (SCI) is an interesting problem. Since the nervous system is cut at these patients, an active orthosis is needed (see fig. 1.16). These types of orthoses have an actuation mechanism to provide gait. However, the interaction between musculoskeletal actuation and assistance device should be clearly known to provide a suitable gait. In this study the contributions of muscles and joint moment measurement was aimed. Biomechanical

model of the body is constructed using rigid bodies. Moving way constrained only in the sagittal plane. Since the muscle forces cannot be directly computed from joint moments, an optimization approach was used to solve the problem. Static and physiological static optimizations were used. The results for the two optimization systems are similar.



Figure 1.16. Quasi-passive compliant stance control orthosis lateral and frontal of prototype [19].

Andrysek searched the effect of clinically relevant biomechanical conditions relating to the setup and alignment of KAFO's on knee extension moments [37]. As mentioned, stance control KAFO is new type orthoses that provide flexion during the swing phase. However, in addition to drawbacks of SCKAFO such as bulkiness, heavy and cost, they generally need an external knee extension moment to unlock the knee joint. As mentioned previous study, in conventional gait laboratory measurement knee extension moment is either very low or entirely absent. The inherent lock system of the SCKAFO needs to clear information about patient knee extension moment condition. This cannot be ensured via conventional gait analysis. The second aim of the study is to find the effect of dorsiflexion stop on knee extension moment.

The knee moment was measured by an embedded load transducer has 6 degrees of freedom on knee joint. It is specially designed at gait laboratory. The custom made attachment has enable flexion 0 to 20 degree. Four subjects with poliomyelitis were participated to the experiment. According to the results only one subject produced an external knee extension moment in stance phase. Participants were not able to produce extension moment continuously. Adding a dorsiflexion stop at the orthotic ankle significantly increased the knee flexion moments in late stance phase, while slightly decreasing flexing the knee in stance phase. Thus persons who have problems to initiate swing phase flexion with stance control orthoses; it can be suggested to adding a dorsi-flexion stop provides functionality. Walking speeds were not changed. This shows that dorsi-flexion stop has only a partial effect on knee extension moment. Andrysek suggested that SCKAFO that do not need any knee extension moment should be studied. Apart from his aim, Andrysek found that increasing hip extensor strength has a positive effect on knee extensor moment.

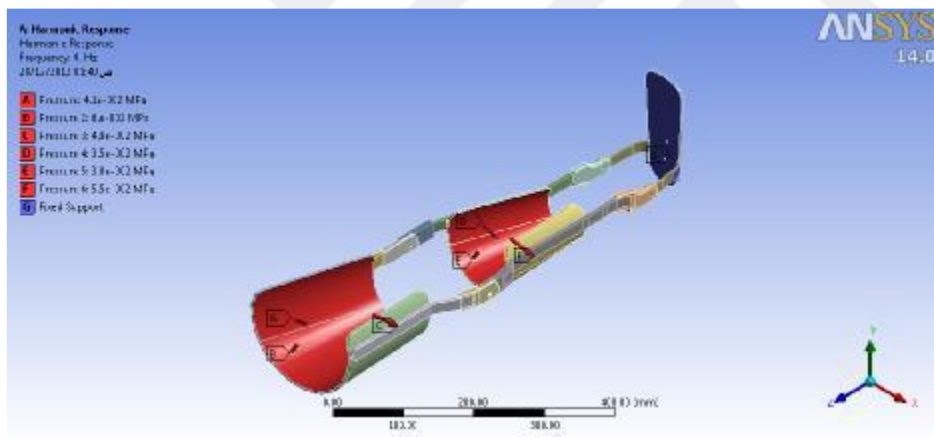


Figure 1.17. The model subjected to maximum pressure load [14]

1.8 Comparison of Energy Expenditures Between KAFO and SCKAFO

There are not enough but valuable studies about SCKAFO. On the whole, they showed that unnatural gait with conventional KAFO causes lower efficiency in gait and more energy expenditure. Mc million analyzed the effectiveness of commercial SCKAFO in his study [4]. He is aimed to find whether individuals with lower limb weakness walk more efficiently when using SCKAFO than using a conventional KAFO with the locked knee. Three client suffer from limb weakness are subjected in a series of experiment

including gait analysis, obstacle course and treadmill walking. He is reported all the subjects exhibited increased walking speed, stride and step length and lower compensatory movements at hip. They also exhibited more symmetric walking gait than walking with a conventional KAFO. Additionally, Mc million said that improved symmetry and decreased compensatory movements may decrease the energy expenditure for walking.

Davis researched the effectiveness of SCKAFO used for patients with lower limb pathology [38]. Energy expenditure and walking velocity of 10 subjects who use a commercial SC-Horton Stance Control Knee Joint were measured and evaluated (see fig. 1.18). Two cases were compared; walking with a locked KAFO and walking with Stance Control Orthosis. Significant increase in walking velocity was reported. This is because of increased step length on the non-affected limb and decreased swing phase duration on the affected limb. However, in a distinctive manner there was no difference in energy expenditure during walking.

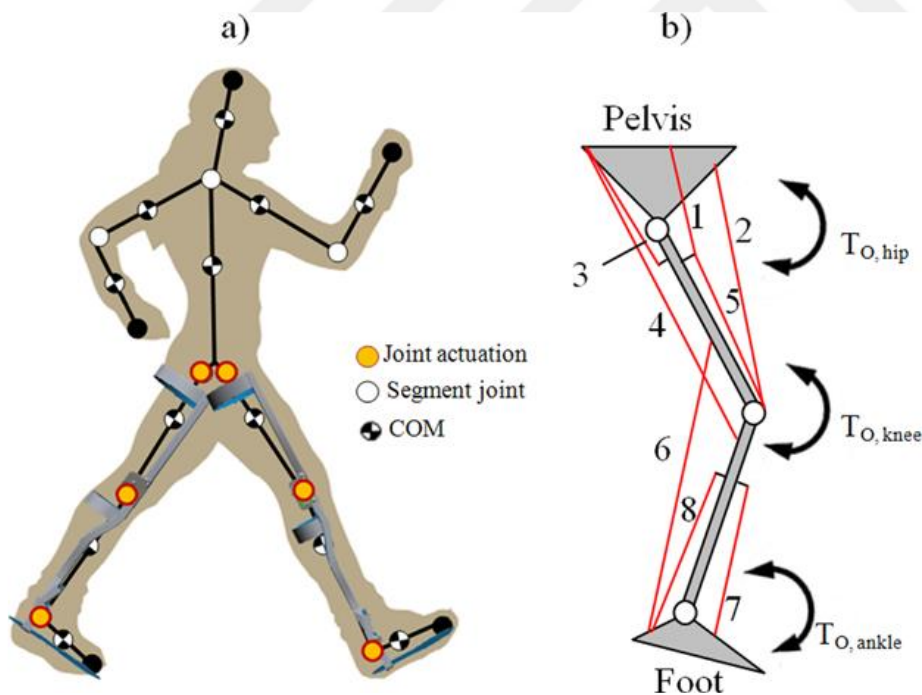


Figure 1.18. (a) Planar bio-mechanical model of the human-orthosis system. **(b)** Muscle groups for the shank and thigh [38]

Lehman studied two able bodied subjects and two patients with spinal cord lesions [39]. It is reported that energy savings with the stance control gait is only significant for able bodied subjects at higher ambulation rate (73m/min normal walking speed). Since disabled subjects did not have enough hip flexor strength to attain normal gait speed, they showed little improvement in energy expenditure [15].

Kaufman made a comparison between standard locked knee KAFO and free knee KAFO [5]. Post-polio subjects' oxygen rate and energy cost are found to be significantly lower during free knee gait.

As mentioned before Mcmillian searched effectiveness of a SCKAFO and during five minutes of tread mill walking in a comfortable speed two of three subjects exhibited a lower heart rate but for the third subject heart rate was increased [5].

1.9 Investigations on Actuating KAFO Systems

A pneumatically powered KAFO with myo-electric activation was studied by Sawicki [40]. In this study artificial pneumatic muscle powered KAFO mechanical performance was observed. Artificial muscles were used to power ankle plantar flexion / dorsi-flexion and knee extension/flexion movements. Three able bodied persons participated to the experiments. Subjects walked over ground at constant speed and four scenarios were implemented. They were walking without wearing orthosis, wearing the orthosis while artificial muscles turned off, wearing the orthosis activated under direct proportional myo-electric control and wearing the orthosis activated under direct proportional myo-electric control with flexor inhibition produced. Joint kinematics, ground reaction forces, electromyography and orthoses kinetic data were collected. It was emphasized that myo-electric control of orthoses has some advantages as well as disadvantages. These are stated in the paper as follows; 1) 1) it provides an effective way to scale the magnitude of the orthosis mechanical assistance due to its physiological nature [41,42], 2) it appears to lead to a greater reduction in biological muscle recruitment compared to kinematic based control algorithms [43], and 3) it easily allows the nervous system to adapt orthosis control for novel motor tasks. The disadvantages are: 1) it can be difficult to obtain a reliable and consistent myo-electric signal due to the surface electrode interface [42], 2) choosing the appropriate threshold and gain requires tuning [44], and 3) the complexity

of the musculoskeletal system includes many synergistic muscles that are not all easily accessible with surface electromyography [45]. Although, the disadvantages may indicate the complexity and difficulty of using myo-electric sensor, motor learning can remove these disadvantages.

The knee underwent approximately two times displacements of the ankle during gait. Because of the artificial pneumatic muscles nature, the proposed design supply knee torques smaller than the ankle torque. Mechanical system or components like cams, gears or different actuators to gain more torque at the knee should be added.

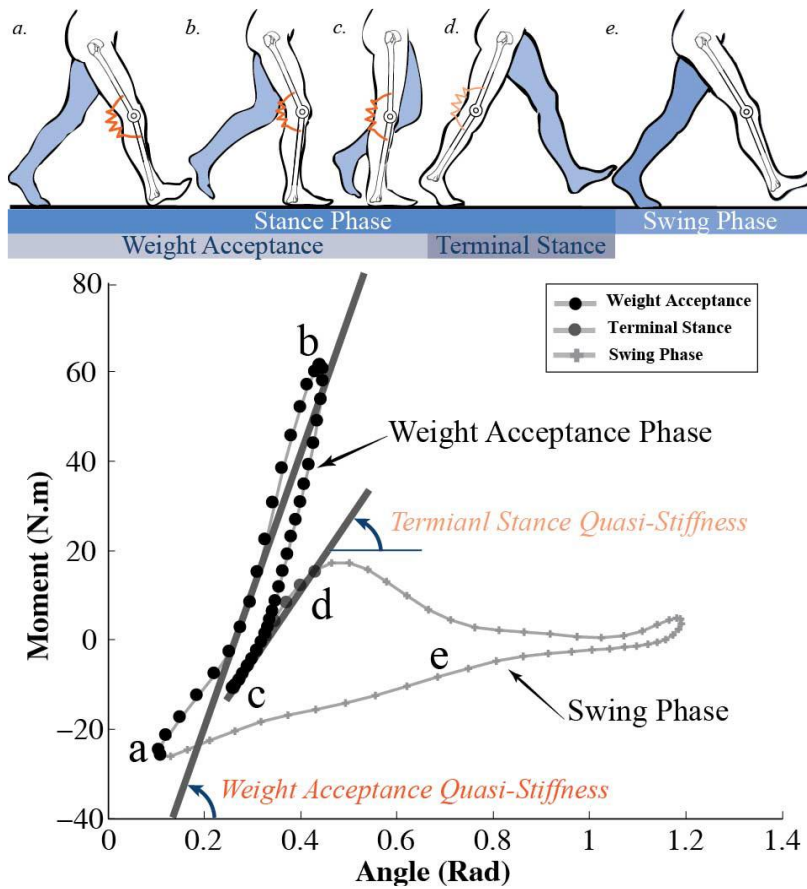


Figure 1.19. Top: Schematic view of the limbs for a gait cycle. Bottom: Moment angle diagram for gait [46].

At the figure 1.19, it can be observed that knee behaves like a torsional spring in the stance phase of the gait as indicated. Bottom: the knee moment angle diagram of a subject walking at 1.25 m/s^{-1} [47]. Slope of the linear fit to the graph in the weight acceptance

phase is termed as the knee quasi-stiffness in this phase. Knee function can be replaced by a linear torsional spring with spring constant equal to the knee quasi-stiffness.

Powered lower limb orthosis is a type of wearable mechanical devices that can serve a wide variety of important biomedical purposes. However, the movement of the orthosis or the lock system is designed either passive or tethered to external power sources. Therefore, these disadvantages limit the orthosis functionality. Wu designed a fully mobile powered lower limb orthosis by using pneumatic actuators [47]. Walking with conventional KAFO is very different from the normal gait as described before. SCKAFO that has an active joint has some significant disadvantages such as bulky structure and power source problem. Especially such systems are not different from conventional KAFO when the battery is flat. This energy constraint can be solved by integrity the KAFO with impedance based control. The proposed orthosis was constructed on a standard KAFO. The pneumatic actuators were attached to the knee and ankle to help the wearer's locomotion. In the commercial orthosis on market and literature the control system of the orthosis follows predetermined functions and trajectory. Sometimes the orthosis cannot perform their task properly such as in an unexpected situation. Thus in this design impedance control was selected. The system combined with a finite-state machine to a better assistance. This finite state machine consists of four distinct states which are weight acceptance, push off (maximum flexion), early swing and late swing respectively.

The functionality of the orthosis was tested on a healthy subject. Participant conducted to on a commercial tread mill system the knee angle trajectory showed that the test result is very similar to the natural gait. Also the calculated joint power trajectory reached to 30% of the locomotive power.

In a similar study, angular velocity based control knee joint combined with linear hydraulic piston was mechanically and biomechanically analyzed [48]. As it stated above, predetermined methods, trajectory and detection of phases make orthosis complexity bulky and costly. If this complex electronic system does not apply, most mechanical system only locks at full knee extension. As distinct from, the angular velocity based controls do not need any mechanical or electronic sensor to maintain safe gait.

Linear piston attached to the upper upright. The hydraulic knee joint act as a slider crank mechanism and was mounted between the braces. The working principle of the orthosis is when the knee flexes the piston pushes fluid through a spring-biased valve. The drag force occurred in the piston forces the brace towards to the opposite way. This drag force is directly related to the speed of the movement. As the speed increases, the magnitude of the drag force also increases. Thus the resulting pressure stops the knee flexion. Dynamic loading and cyclic loading tests were carried out on the prototype. During tests, the resisting moment of the joint reached about 150 Nm. In the cyclic loading test, joint completed 400,000 cycles for the load 50 Nm which is a typical walking moment of a 90 kg person. Biomechanics tests were performed on five able bodied participants. Knee angle pattern were similar to normal gait for below-threshold walking. Fast walking speed that caused the knee flexion resistance to engage reduced the peak knee-flexion angle during initial swing but did not produce an unsafe condition.

Hwang developed an ideal electromechanical KAFO that allows knee flexion in the swing phase and stability in the weight bearing [49]. The complexity of the gait stated before. The current orthoses are not capable to meet these all requirements (support body weight, rotation of the joints, flexing the knee and to further smooth the trajectory COG). In the presented paper a commercially available wrap spring clutch was used for the knee joint. A servo motor was also mounted on the clutch to engage or disengage the stop collar of the wrap spring clutch. A foot switch (force sensing resistors) was used to determine the phase of gait. A control unit was placed to the top of the orthosis. The manufactured prototype was tested by four poliomyelitis patients. Gait analysis of each subject was performed by using a three dimensional motion analysis system (see fig. 1.20). Also the energy expenditure of subjects was measured by using a respiratory gas analyzer. Gait analysis results showed that developed KAFO is more effective than locked knee gait. All subjects achieved increased knee flexion in the swing phase. In the controlled knee gait, subjects achieved took approximately 5 % less oxygen and 30 % less oxygen were burned when compared to the locked KAFO. There were no differences for the heart rate and ventilation. It is concluded that controlled knee gait is more efficient and functional.

Cullel [50] developed a KAFO actuator based on biomechanical data. The function of the real muscles of the leg and its behavior were adopted at designing actuator. The skeletal

system of the human lower limb was simulated as mechanical system to establish its action in the joints and their functions. Single sided frame with two joints at knee and ankle was used in the structure. A four bar mechanism was used at the knee joint. This type of joint allows the knee to follow more natural trajectory in the lateral side. Two spring mechanism was used in the knee actuator. One is spring is responsible to control stance phase and the other one is for weight bearing. According to the phase of gait these springs are activated or deactivated by an electromagnetic solenoid switch. In the experimental evaluation stage potentiometer attached to the joint and two gyroscopes one for angular velocity of the shank and another for measuring angular velocity of the foot added to the orthosis. Despite some minor differences, the gait pattern quite constant during the experiment. Switching mechanism works properly both weight acceptance and stance phase. Knee flexion in stance phase was not noted. Observing velocities, it was realized that foot and shank velocities were not equal when the foot is not contact with the ground. This indicates the relative displacements between them. The author advised that the proposed actuator should be revised. Actuators may work not only in extension but also in flexion.

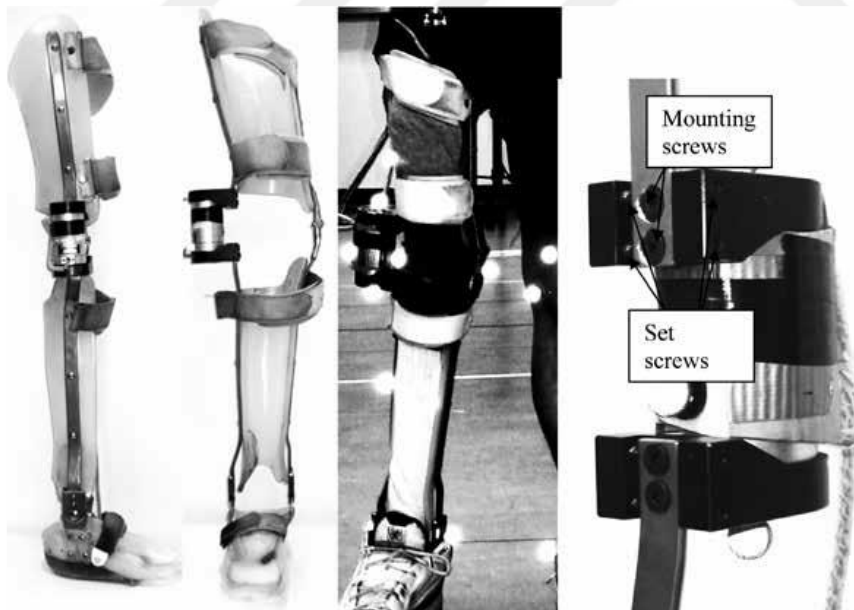


Figure 1.20 Sagittal (left) and frontal (middle) view of a KAFO instrumented with the load transducer [2].

The high rejection rate of KAFO and its causes was mentioned before. Ackermann emphasized this issue in his study (According to the Association for the Assistance of handicapped Children this rate is approximately %95) [51]. Users generally prefer wheelchair for its safety and lower energy requirement with respect to KAFO. A light and compact device with low energy requirement with was proposed in the study. This orthosis has better performance and increase gait aesthetic of the KAFO.

The swing phase was simulated as two-degree freedom model (only lower limb). Two different tests were performed on prototype. The spring was tested first and then the control mechanism functionality tested. After the natural dynamic of gait deeply examined, a spring based system was added to a standard KAFO. A control system that consists of sensors, electric motor and microprocessor was constructed to control the orthosis.

The patient was able to control the walking velocity by controlling the initiation of the swing phase in the first test. All the functions of the control system worked properly.

The proposed solution seems to restore normal gait especially in swing phase. The foot clearance simplified by adding knee flexion. Also this gave an extra aesthetics to the gait. These improvements may reduce the rejection rate. Another conclusion can be extracted from the fact that, simultaneous flexion of ankle and knee during the swing phase would further improve the performance of orthosis.

An older study automatic control designs for a dynamic KAFO was proposed [52]. The functionality of the orthosis and energy expenditure was tested with able bodied subject. The orthosis consists of wrap spring clutch, foot switch, a linear solenoid, battery and control unit. There components were mounted on a conventional KAFO. To control the system, the finite state approach was used because of its simplicity. The phase of the gait was determined by foot floor contact sensors. Cardiovascular energy assessment was used to measure energy expenditure. Two scenarios were carried out in experimental protocols. First one was walking with locked knee and second one was with active joint. The energy measurement results showed that, tidal volume, ventilation rate and oxygen consumption rate were increased when treadmill speed increased. Oxygen cost was increased for immobilized knee.

1.10 Literature Review for Design of SCKAFO

A general review to give brief information was made in previous sections. However, in this section a deeply analysis was carried out. Keywords about SCKAFO such as SCKAFO, Stance Control KAFO, Stance Control, Stance Control Knee Ankle Foot Orthosis were searched in most used databases. Papers about AFO and Hip Knee Ankle Foot Orthosis (HKAFO) were discarded. Especially papers including design study, survey and parameter research were examined. Some authors made recommendation for further studies. These advices were taken as the parameters that need to be improved.

The summary of the results from KAFO conference were reviewed by Micheal [53]. He indicates the lack of scientific studies about the use of KAFO for ambulation. Instead of substantive evidence, participants stated that there are many fundamental assumptions provided by expert opinion and examined publications. Consequently, they tried to answer these questions which are; 1) what do we have? 2) what is accepted to be true? and 3) what have to be studied and determined to optimize the application of orthoses. In a similar study, Fatone reviewed a large number of studies (240 Articles) about KAFO and HKAFO for ambulation [54]. After applied an extensive selection, he tried to find out answers similar questions which Micheal search. The results of the review indicate that while a reasonable amount of literature has been written regarding KAFO, the level of evidence regarding the use of KAFO for ambulation is generally low. Also small sample size and inadequate study design stated as the main limitation. Especially an engineering approach for the design was recommended for the future studies. The distribution of the articles by decade of publication showed that most of the articles were published in the 1990s %47,9 over the last five decades.

Hurley examined usage of KAFO for patients with Cerebral Vascular Accident, Spinal Cord Injury and Traumatic Brain Injury [55]. The features of the KAFO that makes uncomfortable to use were stated as too heavy weight and cumbersome, difficulties of donning on and off and cost of higher energy requirement for gait. Additionally, locked knee KAFO (Conventional KAFO) have higher fall of risk with respect to SCKAFO. She indicated that due to the disadvantages of KAFO mentioned above and limited time usage during one day, patients generally prefer wheelchair. Hurley claims that SCKAFO may be an alternative to delay or decrease the use of wheelchair. To do this she pointed out

the gap in the literature. Also he made a recommendation for future research to find a standard comparison method to measure the result of different study.

Kaufman searched energy cost difference of locked KAFO and SCKAFO [8]. The designed KAFO which allows free-knee motion during swing and locked conventional KAFO were tested for normal gait on an even ground and on an incline plane with a %5 in a post-polio subject. According to the result free knee motion decreases the oxygen consumption rate and energy expenditure.

A more sophisticated KAFO called intelligent orthosis was designed by Suga using microcomputer [56]. The observed gait with the intelligent orthosis is smooth and close to normal gait.

In 1999, Irby published two papers about dynamic KAFO [51,56]. In the first one he applied a wrap-spring clutch to knee joint and tests on a normal subject showed that knee flexion during swing is very close to normal gait. In the second study an automatic control design was applied. Cardiovascular energy measurements indicate that dynamic KAFO use allowed a more energy efficient gait.

Harrison examined 3 different SCKAFO [23]. He showed the effectiveness, functionality and disadvantages of each design. In roller-clutch bearing design lock releasing force was observed very high. Lever-lock design is expensive and joint sliding motion is not smooth. Wedge-joint type lock requires small extension moment.

Mcmillian showed effectiveness of a SCKAFO [5]. He compared SCKAFO with respect to conventional KAFO. Three male subject participated to the study each have at least one lower limb weakness. According to the results participants showed increased speed and cadence, stride and step length while decreasing compensatory movements. Also in the thread mill walking lower heart response observed in two subjects.

In a newer study Irby designed a new orthosis, named as the dynamic knee brace system [58]. It has an automatic lock system that uses an electro-mechanical wrap spring clutch. The lock mechanism is initiated according to the data that are collected from sensors placed at the knee and footplate. 21 subjects were participated to study (13 subjects were KAFO users and 8 subjects were novice users). According to the results novice users

demonstrated increased velocity and cadence with Dynamic Knee Brace System (DKBS) over conventional KAFO. Knee range of motion was high at novice group while peak knee extension moment was greater for experienced group. Irby said that familiarity of the experienced group to the conventional KAFO may suppress adaption to new DKBS orthosis. Therefore, he recommended that longer term studies are needed to clarify benefits.

Bernhardt published a survey paper about SCKAFO to quantify the users' opinions of a SCKAFO and to find important factor for orthosis [57]. In this study, 20 subjects participated to the experiments. 9 subjects used a locked KAFO and 5 subjects used free KAFO while 6 choose to ambulate without an orthosis. Users clearly specified that effectiveness, operability and dependability are well features of DKBS. However, weight, cosmetic and ease of donning and doffing were indicated as features need to be improved.

Terris Yakimovich is a Canadian researcher who has many studies about KAFO. He designed a SCKAFO which provides knee stability during stance and also knee extension in stance while free knee motion in swing phase. In 2005, an electromechanical SCKAFO was projected for people with knee-extensor weakness [28]. Orthosis provides knee flexion at any angle while allowing knee extension during stance. Experiments were performed on able-bodied subjects and KAFO users. He found that SCKAFO had a very low effect on able-bodied subjects. Also increase in sagittal motion, decrease in pelvic obliquity and hip abduction were observed.

In his 2006 paper, some mechanisms (friction-based, belt-clamping) were used to show functional evaluation of orthosis [29]. The prototype was mechanically tested and he concluded that strength and performance were sufficient to use on 90 kg subject.

In the same year, Yakimovich started to design a new orthosis to reduce the limitations such as bulky weight, bulkiness and price [30]. Thus new orthosis is 33% thinner and 7% lighter than commercial one. 3 KAFO users with knee extensor weakness were participated tests. The results showed improved gait kinematics and more natural gait. At the end of the study, two subjects preferred using this new orthosis instead of conventional KAFO. Nevertheless, Yakimovich indicates that performance, safety, lifetime and cosmetic should be improved in the further studies. In this connection he presented

another study about the refinement of that orthosis. He changed the solenoid by a simple pushrod mechanical system. Sensors located on the foot plate measure the pressure and control mechanism activates or deactivates solenoid according to the information gathered from these sensors. Users should

In 2007, Irby proposed a long term study including 14 SCKAFO users [58,60]. The designed SCKAFO in the previous study was fitted to subjects who had been prescribed but did not use KAFO. Results showed that the new SCKAFO increased gait velocity, stride length, knee flexion and more balanced over 3-month tests. They concluded the study as subjects had significant changes in temporal-distance changes, but longer observation should be made to observe changes in joint kinematics.

A commercially available knee joint, Horton Stance Control orthotic knee joint performance was examined by Zissimopoulos [61]. 9 able bodied subject were fitted with KAFO that incorporated with this joint. It has different mode options which are locked, unlocked and auto (knee stability at weight bearing and free motion in swing phase). He observed biomechanical and energetic effects. A more natural gait pattern was observed especially in the auto mode.

Rasmussen et.al. reported effect of combination bilateral SCKAFO and a reciprocating gait orthosis in subject with spinal cord injury [62]. He compared the effect of two phases; locked knee during the entire gait and free knee which allows flexion during stance. 3 dimensional gait analyses showed that subject ambulated with a faster, more natural gait with addition SCKAFO and free knee feature activated.

An electromechanical KAFO which uses wrap spring clutch knee joint was developed by Hwang et.al. [50]. They performed biomechanical test on four patients with poliomyelitis. Subjects flexed their knee during swing phase and consumed %33 less energy with respect locked-knee gait. This design was helpful for patients having partial or complete paralysis.

Horton stance control knee joint was used in another study to observe the effect on gait characteristics and energy expenditure [39]. 10 subjects joined Davis study. Two phases were tested like previous studies (locked knee, stance control). Walking speed was significantly increased in the stance control condition ($p < 0.001$). However, no difference

was observed in the energy cost of walking or physiological cost index. This study supports previous studies about increasing walking speed with stance control KAFO.

Yakimovich is another researcher that used Horton Stance Control in his study [4]. In 2009, he examined and discussed commercially available orthosis. In addition to Horton, he included other commercially available orthosis (Otto Bock Free Walk, Becker UTX, Fillauer Phase Lock, Becker 9001 E-knee, Dynamic Knee Brace System, Ottowalk Belt-Clamping Knee Joint, Dual Stiffness Knee Joint). Specific joint angle and need of high knee moment specified as functional limitations. Controlled knee flexion in stance phase, knee-extension in every phase and soft switching between stance and swing phases were common deficiency of orthosis.

In the same year, Lemaire designed a new controlled SCKAFO that do not require external control unit [63]. A rotary-hydraulic device was used as the lock mechanism the lock mechanism is activated when the angular velocity reaches a pre-determined value. The hydraulic mechanism improved safety and security for people with lower extremity weakness.

A newer scientific literature review was published by Zacharias in 2012 [64]. The study covers the entire literature of pre-published review study by Yakimovich, in 2009. Despite limited methodological quality (generally individual case descriptions of few subjects included), the majority of the studies point out advantage of SCKAFO with respect to knee flexion in the swing phase, a reduction of compensatory movements and energy cost, and improved functionality with a more natural gait. Consequently, benefits of the SCKAFO were indicated various studies, but high number of patients should be involved to get significant statistical information.

1.11 Scope of This Study

Attempts have to be made to design new orthosis that would improve gait as compared to conventional locked-knee KAFOs. Design considerations and multi body dynamics of gait as well as gait with KAFO should thus be studied first. Simulation results will provide additional information for orthotic device design. The control of the orthosis is a very crucial aspect. The control of an orthosis has two parts; first part phase detection and then defining valve clearance (stiffness) of the lock. A risk analysis to enhance the proposed

design will be implemented. It is expected to that this study covers the design, manufacturing and control of a functional SCKAFO from engineering perspective thus rejection problems of users can be diminished and solved.



2. MATERIAL AND METHOD

A detailed literature searches about KAFO and its new type SCKAFO are given in the previous section. This search can be gathered around two main topics. They are design and control of the orthoses. There are numerous design types and besides different control systems in the literature. However, that designs are generally bulky, as well as impractical and inapplicable to real life. Furthermore, control of the KAFO is still a challenging problem. Consequently, this project focus on the design of a controllable KAFO (SCKAFO). Study starts with design of a KAFO with engineering approach, manufacturing a prototype, operating and then its control.

There are lots of technological developments in recent decades, but the voice of the orthosis's users is still very loud. Technological improvements such as sensors, servo motor and other actuators and also new materials were implemented to the orthoses in many studies that mentioned before. However, surveys conducted about user preferences and comfort about KAFO show that these new commercial products were only accepted by a very low number of users.

A very small group of KAFO design has actuation ability. Generally, KAFO are prescribed to person who has disability that means has no enough strength to withstand at the stance phase. Generally, orthosis has no any actuator, there is only a mechanical or electronical lock mechanism. It activates at the stance phase and help user in weight bearing by restricting motion. Leg has motion in every part of the gait, but if lock mechanism restricts the motion for a while it directly affects the way of walking.

Flexion mostly observed at the swing phase but a small amount also occurs at the stance. Therefore, lock mechanism desired to has a range of motion also in the stance phase to provide that flexion. The commercial examples usually have rigid lock.

Comfort, reliability, functionality and adaptability are still main problems. At this point an engineering design approach has to be implemented. Studies shows that user problems were clarified and examined deeply but a hierarchical approach did not conduct until yet.

Design is an interplay between what we want to achieve and how we want to achieve it. [65]. Therefore, an engineering design approach should start with a detailed explanation of what is desired and mapping them with a clear description of how it will have achieved. The ultimate goal of an engineering design is to find a scientific basis for design and to improve design activities. Since there are many user demands and most of these conflict with engineering parameters in designing orthoses, Quality Function Deployment (QFD) method seems to be a very useful way to bring out a new SCKAFO design.

2.1 Quality Function Deployment

QFD is a method which focusses on characteristics of a new or existing product or service from the separate viewpoints of customer market segments, company or technology developments. Generally, this customer demands named as voice of customer. For this reason, customer requirements first determined and translated to design requirements. Thus, a matrix which correlates the design requirements with the customer requirements can be obtained. This matrix is very useful in analyzing trade-offs among the design requirements. A typical structure of an QFD is given in fig. 2.1.

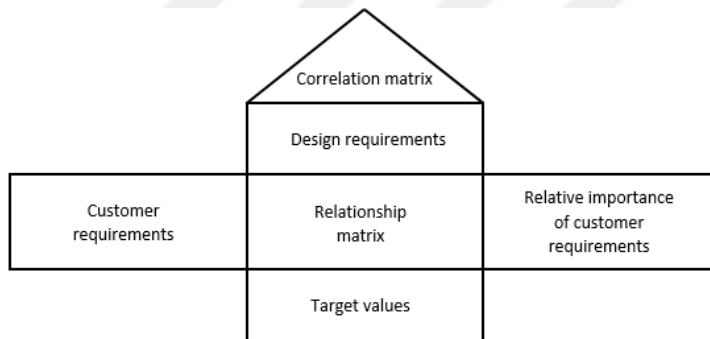


Figure 2.1. The fundamental representation of house of quality chart, a very useful tool for quality function deployment (QFD).

The voice of the customer is defined as the identification and prioritization of customer's perceptions. Orthosis's user needs are determined by asking questions directly users and practitioners about what they are desiring in a SCKAFO. These design parameters are categorized into five groups; performance requirements, usability, structural requirements, electro mechanical desires, servicing and miscellaneous. 47 design requirements determined and relative importance of each parameter tabulated next to

them. Commercially available SCKAFO and our design were compared by their satisfying degree of design requirements at the right side of the table 2.1. The relationship between design requirements, available and desired design were represented by factors which they are starting from 1 (weak) and the highest value is 5 (strong). This QFD study is very helpful to find the limitations and weakness of the exist products and also show how an ideal SCKAFO should be.

Ottobock[®], Fillauer[®] and Becker[®] are commercially available products for SCKAFO. Myo and Compliant mechanism orthosis are research studies which are ready to use and functionally completed products. Motor is an option to use directly for lock system and also for actuation. The final section is desired products in this study. The last two columns are expected values because currently they are not available.

All the commercial examples have no any actuation capability. Only the have locking mechanism. The reason is orthosis add extra weight on the disabled leg, any actuation needs some energy source. This means more extra weight. Since the leg could not fulfill its function, excess weight causes abnormal gait. Details can be found at the appendix (see Appendix A).

Table 2.1. Quality function deployment chart for the design of KAFO. The values for our design are expected values.

QFD analysis for SCKAFO			Relative Importance	Ottobock	Fillauer	Becker	Myo	Compliant	Motor	Our design
1 Weak 2 Slight 3 Moderate 4 Strong 5 Complete ↗ Larger the better ↘ Smaller the better ○ Nominal the better										
Direction of improvement										
WHATs (Design Requirements)	Performance / Functional Requirements	1 Capable to resist excessive flexion moments	10	4	3	3	3	4	5	5
		2 In stance free to extent	10	5	5	5	5	5	5	5
		3 Controlled flexion in stance	10	3	3	3	5	4	5	5
		4 Resists flexion at any knee angle in stance	10	3	3	4	4	5	5	5
		5 Allow free knee movement in swing	10	5	5	5	5	5	5	5
		6 Easy sit and stand	8	5	5	5	5	5	5	4
		7 Can be used on uneven terrain or ascendin/descandng	9	3	3	3	4	5	5	4
		8 Reduction of compensatory movements	8	3	3	3	5	5	5	5
		9 No specific joint angle to switch between phases	9	5	3	5	5	5	5	4
		10 Shock absorption	8	1	1	1	2	5	4	3
		11 No rigid lock	8	2	2	2	3	5	5	5
		12 Compatible with any KAFO	7	2	4	3	0	1	2	3
		13 No accidental release	10	5	4	3	4	4	0	5
		14 Optional control modes (Automatic, manual lock&unlock)	9	5	5	5	5	5	5	2
		15 Rapid swithch between phases	9	3	3	3	2	3	5	4
		16 Allow faster gait speed	7	2	4	4	3	5	5	3
		17 Will support ligament instability	7	4	4	4	4	4	4	1
	Usability & Human Factors	18 Easy to dress on / dress off	9	4	4	4	0	0	0	3
		19 Manual Control Capability	7	4	4	4	0	2	0	2
		20 Attractive and have aligent shape	9	4	4	4	0	2	1	4
		21 Easy control	8	3	3	3	3	4	5	5
		22 Flexion contracture (up to 15 degree)	8	5	5	5	5	5	5	3
		23 No need dorsiflexion stop	7	5	5	5	3	3	3	5
	Structural Requirements	24 Light weight	10	3	3	3	1	2	1	4
		25 Stability	9	3	3	3	4	5	5	5
		26 Unobtrusive form	8	3	3	3	1	2	2	5
		27 Noise free	9	2	2	2	1	3	4	4
		28 Wear bumper	10	2	2	2	2	4	2	2
		29 No sharp edges on joint	8	4	4	4	4	3	3	5
	Electro-mechanical	30 Extensive charged state	10	3	3	3	1	2	1	5
		31 Small battery (Removable universal battery)	9	4	4	4	1	2	1	5
		32 Antiflexion in case of failure	10	2	2	2	3	3	4	5
		33 Continuous use time	8	4	4	4	2	3	4	5
	Miscellaneous	34 Competitive price	9	2	2	2	1	1	1	3
		35 Dynamic stability	9	2	2	2	3	4	4	4
		36 Decreased gait anomalies (vaulting, circumduction)	8	3	3	3	4	5	5	5
		37 Resist to weather conditions / Wheather Proof	7	5	5	5	5	5	5	4
		38 Paintable	8	3	3	3	1	2	2	4
		39 New technology	9	3	3	3	4	5	5	3
	Servicing	40 Ease of integration into a KAFO	9	3	3	3	0	1	1	3
		41 Correct adjustment / attachment availability	10	2	2	2	1	1	1	1
		42 Long time between services	8	3	3	3	2	2	4	4
		43 No maintenance in between services	9	4	4	4	4	4	4	4
		44 Easy to service / replace parts	8	3	3	3	1	1	4	4
		45 Sold as joint	6	1	1	1	0	2	3	5
		46 Low service / replacement part cost	8	3	3	3	1	2	4	5
		47 Easily adjustable trim settings	7	3	3	3	1	3	4	4
			Weighted Importance							
			1334	1324	1335	1070	1360	1389	1618	

2.2 Design Criteria for an Ideal KAFO

The most important goal of QFD is to prioritize resources to work on the areas with the biggest impact on customer. The house of quality chart is a very useful way to translate customer needs into development goals and technical capabilities. The house of quality chart of the design can be found at the appendix A. The relations and important factors are discussed in the further part.

Conventional KAFO affects the way of walking. Functions of the gait cannot be completed because of the restriction of the KAFO. People use that orthosis by hip hiking or circumduction. An orthosis should be adaptive on all conditions such as even and uneven ground, up and down stairs, inclines and declines. This mentioned conditions have different functions and mechanisms but the free knee flexion in swing is common. Beside this, safety standards must be provided. These all requirements require a phase detection system and also mechanism allows extension and flexion in the stance phase.

A rigid lock mechanism and rapid change between sub-phases of gait also affect the way of walking. Rigid lock mechanism causes an uncomfortable walking while rapid change of phases causes stumbling. A lock mechanism which resists high moments while a precise step lock or soft lock system is desired.

A SCKAFO is desired to design to hold excessive flexion moments. Generally, it is manufactured to resist approximately 90 kg person's dynamic movements. The weight limit directly affects the size, dimension and weight of the orthosis. The maximum user weight was determined 100 kg as commercial samples.

The most important factor of an orthosis is its functionality. At the same time the cosmetic issues are very important. One of the general reason for rejection of the use of orthosis is cosmetic. Cosmetic problems are not directly about visual view of orthosis. Users are fastening their orthosis under clothes and they desire to hide it. Bulky and excess size are noticeable; this makes user unpleasant. The width of the orthosis has to be approximately same with knee width in the sagittal direction. Also the thickness of the lock system maximum value has to be 50 mm. The height is another important parameter but if it is in the direction of orthosis brace and do not exceed brace thickness, the height can be as long as the bar length. Although the orthosis is worn under clothes, it has to be resist

weather conditions. Stainless steel, aluminum and sometimes titanium are generally preferred materials. Other materials can be used by covering or providing these specifications.

Noise is another important factor for comfortable use of KAFO. Lock system and mechanic parts should be noise free. In the case of any need warning system can be designed as a vibrating mechanism. Noise alert can be preferred only for emergency situations.

Safety of an orthosis is about endurance of the system when using and the locking mechanism in the case of any emergency. The strength of the orthosis parts has to be simulated on computer programs according to the maximum weight. Safety factor should be between 2 or 3. This part is about the safety of the mechanical system, but stumbling, limping and any failure of the orthosis may also cause falling. In the swing phase lock is free and lock mechanism allows knee flexion in the stance phase. It is possible to occur impact loading because of uncontrolled motion or falling at this conditions. The lock mechanism and mechanic parts must resist that excessive forces. Beside this sensing elements of the orthosis must detect these situations and must lock the system. A sudden locking probably affects the posture or cause stumbling but it is more preferable than uncontrolled falling.

The orthosis nowadays is generally an electro-mechanical system. The battery should provide at least one day or 6000 steps usage per charge. Standard batteries or cells with standard socket increase the attraction of the orthosis. Structural part of the KAFO is prescribed specific to user. The weight, height, posture, degree of disability and other factors are different for all users. The lock system should be compatible for all types of KAFO.

Accuracy of the sensors and the durability of the mechanic parts are very important for an orthosis. When the first time, the device is used, the sensors and the mechanical parts may need some calibration procedure. A manual adjustment or self-calibration system may be added. Service provides preventative maintenance to full calibration, cleaning and repair if necessary. However, the time interval between services should be at least 6 months.

People perform different activities such as walking, stairs up and down or exercise. Mode options or temporary unlocking-locking mechanism give opportunity to use orthosis in every part of life. For example, free swing mode is very suitable to use it when cycling, or temporary lock when standing.

Orthosis are complex and advanced devices and these cause high cost. Maximum sale price for entire system for an accessible and reasonable SCKAFO should be less than 7000 TL (Turkish Lira).

2.3 Mechanical Design of Orthosis

An orthosis is an externally applied mechanic device. Generally, springs, rods, pulley, ratchets, band clutch, roller clutch, shape memory alloys and hydraulic-pneumatic systems were studied [14]. Each system has advantages or disadvantages over other systems. Spring system has opportunity to allow different stiffness, but a very high stiff spring is needed to compensate peak load at the stance phase. Recovering and releasing this high stiff spring is very difficult to control and need high energy. Rods are generally used to transfer forces from one point to another point. Pulley with ropes and angular spring were used to lock and to control KAFO in a study [66]. Test results show that high knee flexion speed, high sensitivity to friction and high stiffness are the main problems of this system.

The ratchet lock is the most common prescribed knee lock mechanism. Ottobock[®], Fillauer[®] and Becker[®] have commercial examples of ratchet-like mechanisms. Ratchet mechanisms generally have two disadvantages. First, they have limited number of positions. Simple ratchet system has only one lock position. Locking system activates only a specific angle which makes the orthosis position dependent. There is no flexion capability in the stance phase. Ratchet can have more than one teeth, thereby allow more angle settlements. However, finite number of knee flexion interval may not be comfortable for users. Second main problem for the ratchet is noise. Switching and locking of the mechanism teeth between angles creates an annoying noise. The function of an orthosis is very important for a user but also the comfort and the cosmetic are desired. The other drawback of this type of mechanism is its size and weight. Ratchet makes the orthosis bulky and heavy.

Clutch are generally used for transmitting torque between two concentric shafts. It allows silent engagement at any position and low disengagement force. However, the disadvantages are; they need substantial engagement force, low torque capability, abrasion cause service maintenance in a short period. Also friction between the surfaces cause wear in a short time and the belt generates heat.

New technology and materials tried to adapt orthotic device. Shape memory alloys belong to a class of shape memory materials, which have the ability to memorize or retain their previous form when subjected to certain stimulus such as thermomechanical or magnetic variations. [66] The important feature of this material is capability to endure very high plastic strain and retain its original shape when load is removed or the material is heated. At first it seems to be very practical to use this alloys for SCKAFO joint. However, Efsahani proposed the disadvantages of using shape memory alloy in orthotic devices as follows; slow response, low energy efficiency due to conversion of heat to mechanical energy and motion control difficulties due to hysteresis, nonlinearities and parameter uncertainties [67].

Hydraulic and pneumatic systems have been used especially prosthetic and sometimes orthotic devices [68]. The piston and rod act as a femur bone. The piston rod connected to the knee and the bottom part of the cylinder attached to the lower part of the shank. Piston-cylinder device can provide a variable stiffness and has very high moment resistance. Double-acting cylinders transmit hydraulic power in two different directions, with both pulling and pushing force. They have precise adjustment in push and pull direction, continuous adjustment over the entire stroke and deceleration characteristic. A typical example is shown below. Low working temperature range, load capacity, very low noise and reliability of the piston is very suitable to use in orthosis. In the event that there is a falling situation, even if piston valve would be in fully opening situation, the high flow of fluid restrains the speed of falling and help to straight oneself up.

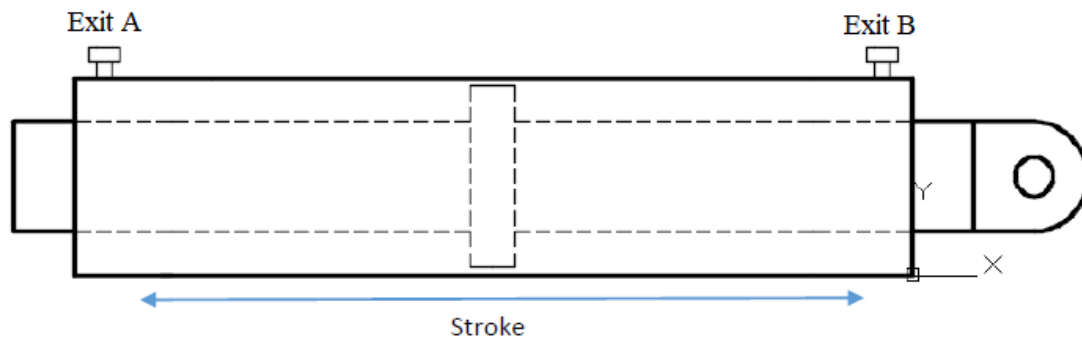


Figure 2.2. A typical double-acting piston representation.

A double acting cylinder permits more control over the movement by acting pressurized fluids to both sides. A closed system was constructed by connecting to exits of the piston and adding a valve on this connection (see fig. 2.2). When the valve is fully closed, it blocks the movement and when starting to open, it slowly starts to allow movement. In the stance phase, the weight of the user slowly is borne by orthosis and transferred to piston. The piston rod force the bottom part of the cylinder and fluid escape from lower exits. At this stage, this movement can be controlled by the valve. The clearance of the orifice directly affects the fluid flow. In the stance phase, only a lower range of flexion is desired. Thus, if the clearance is opened only a bit, it restricts the motion even if there is a very high load. In the swing phase, the foot does not contact with the floor. Therefore, the valve is fully opened and fluid easily flow inside the closed-system.

A hydraulic piston system combined with linkage system was selected. The hydraulic piston can resist high load and subjects load can be transferred to piston with a simple linkage system. Thus, the number of parts can be minimized.

One of the first concern in the design of a mechanism is the number of freedom of the device. The number of degrees of freedom of a mechanism is called the mobility of the device. The mobility is the number of input parameters that must be independently controlled in order to bring the device into a particular position [69]. The control of the mechanism is only possible when independent input motions is equal to the number of degrees of freedom. The Kutzbach criterion is used to calculate the degree of freedom of a kinematic system and determine mobility. The mobility can be determined by the number of links and the number of joints that device have.

The Kutzbach criterion formula is given by as follows:

$$M = 3(n - 1) - 2J_1 - J_2$$

where n is the number of the link, J_1 and J_2 are used to denote the number of single and two degree of freedom pairs.

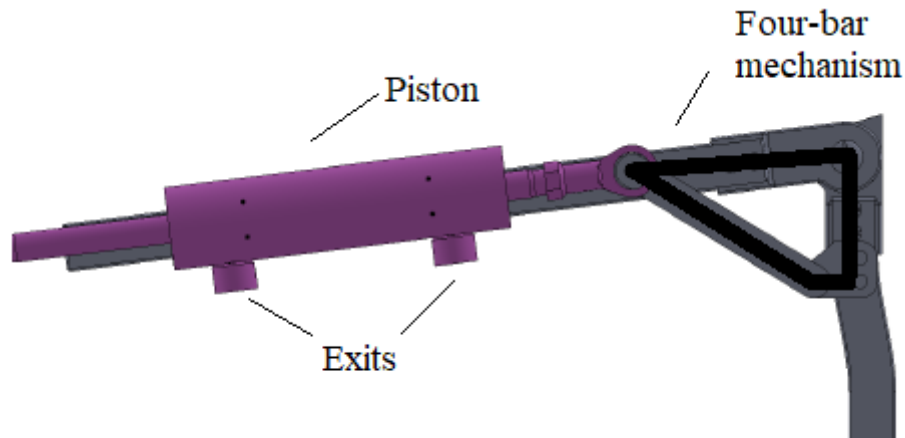


Figure 2.3. The schematic view of the mechanism.

If $m=1$ than mechanism can be controlled by a single input, if it is zero impossible to form a structure and if it is negative this means mechanism is redundant. According to the QFD results mechanism has to have low number of parts and dimension has to be small. A pair of rod which one is small and other one is long were selected. The preliminary design of the mechanism is shown in figure 2.3.

2.4 Valve and Valve Control System

EPV 10 is a uni-directional proportionally controlled, normally closed poppet valve. It is ideal for lowering circuits controlling the speed of movement with low leakage when closed. Our system is a bi-directional but there is no small bi-directional valve in the market. The size and the weight are inapplicable to this study. The application pressure of valve is 350 bar and flow rate is 30 L/min. The total fluid in the closed-system is under 300 ml which means the rate of the valve is reasonably high. Since the control of the valve is very easy and the aim of this study is not the design of a valve the smallest option was selected.

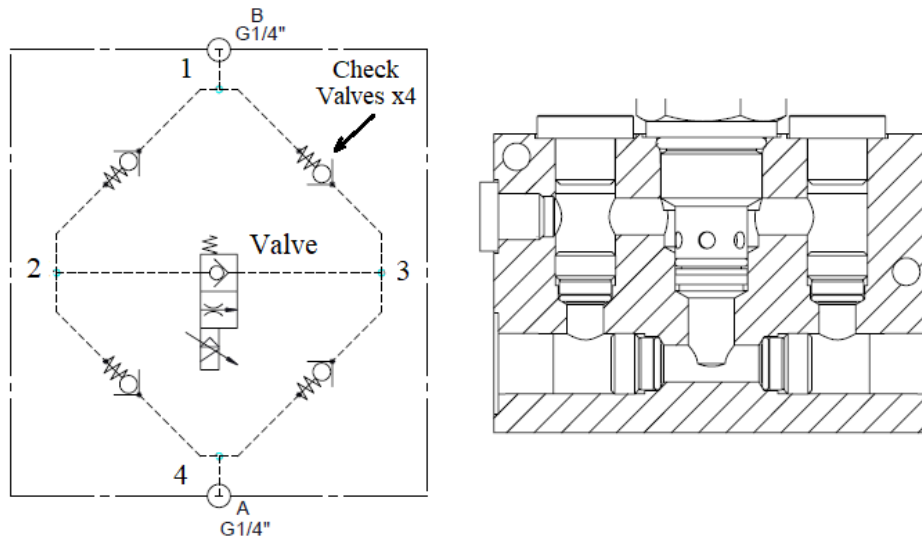


Figure 2.4. The schematic and technical representation of the direction changing system for valve.

There is no actuator at this study and the motion is bi-directional. Fluid flow is from bottom exit to top exit and vice versa. A by-pass system which converts a uni-directional flow to bi-directional was added to the valve. The schematic representation of this system is shown above. The valve is positioned in middle of the block. If liquid enters the block from point B, it follows direction to the point 3 and pass the midpoint (bridge) then turns to the direction 4 and exits at A. If the liquid enters from point A, it follows direction to 3 and pass through the midpoint then turns to the point 1 and exits at B (see fig. 2.4 and 2.5).

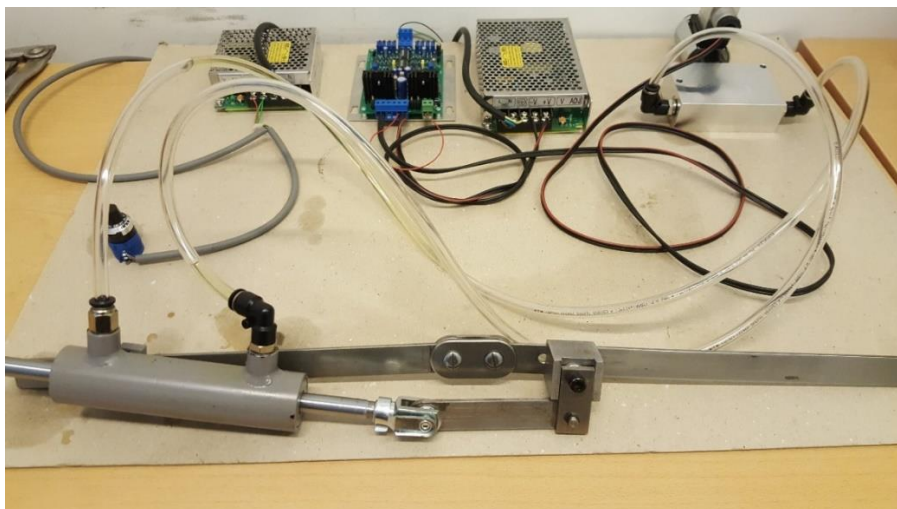


Figure 2.5. The manufactured prototype.

2.5 Phase Detection

Gait cycle phase detection provides useful information to diagnose possible problems on walking [70]. Walking is a complex mechanism and one of the most common activity in our daily life. People can do it without any thinking. Therefore, it seems to be a very simple task but it requires an advance balance and coordination of the limbs. At first, the gait can be thinking as two phases; stance and swing. However, there are more sub-phases that means more sub-functions especially in the stance phase as it was mentioned deeply in the introduction part. A detailed representation is shown in figure 2.6.

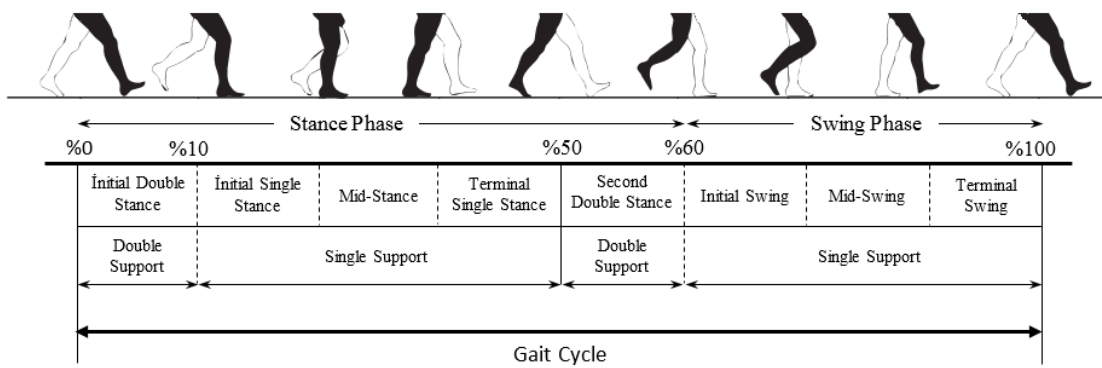


Figure 2.6. Phase, tasks and intervals in gait.

Every sub-phase has different task. For example, mid-stance is the point which the body weight advances over stationary foot and the center of mass of the body is above the supporting foot and also it is single-leg support period. These tasks make necessary to divide the gait into some sub-intervals. One gait cycle was divided into 10 equal sub-intervals.

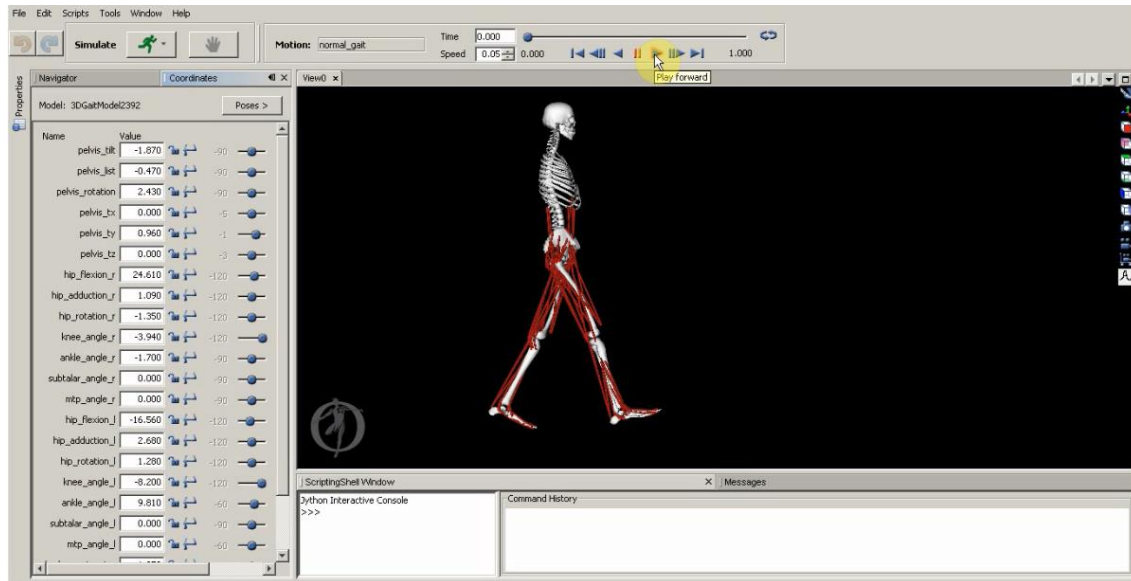


Figure 2.7. OpenSim menu. All angle values were gained for thigh and shank.

The sensor has ability to get angle and velocity information. The control mechanism will use that and make a decision to adjust valve clearance. A gait pattern for a healthy person is gained from a software (OpenSim). OpenSim is a powerful and freely available tool for modeling and simulation of movement (see fig. 2.7). A normal gait motion for only one step gait was selected. The gait starts at the double limb contact and finish at the next same situation. One step is accepted to take 1 second. The angle of thigh and shank were taken every millisecond. Angular velocities were calculated according to these angle values and time. Values for every phase are tabulated in table 3.1. The valve clearance actually indicates the stiffness of the lock mechanism. The higher number means higher stiffness and lower number means full flow. With the help of the ground force and other information the valve clearance values were calculated for each phase.

2.6 Operation of the System

The position (angle and velocity information) of the thigh and shank have to be specified to detect the gait phase. Arduino MEGA and sensors MPU 6050 (for both thigh and shank) were used in this project. MPU 6050 contains a three axis accelerometer, a three axis gyroscope also a temperature sensor and digital motion processor inside. Thus the sensor has 6 degrees of freedom. Accelerometer measures non-gravitational acceleration whereas gyroscope scraps gravity to determine orientation. The digital motion processor was used to process complex algorithms directly on the board. It provides motion data

like roll, pitch, yaw angles which can be converted to useful information. The temperature sensors are disabled in our project. Placement of sensor on orthosis is shown in figure 2.8.

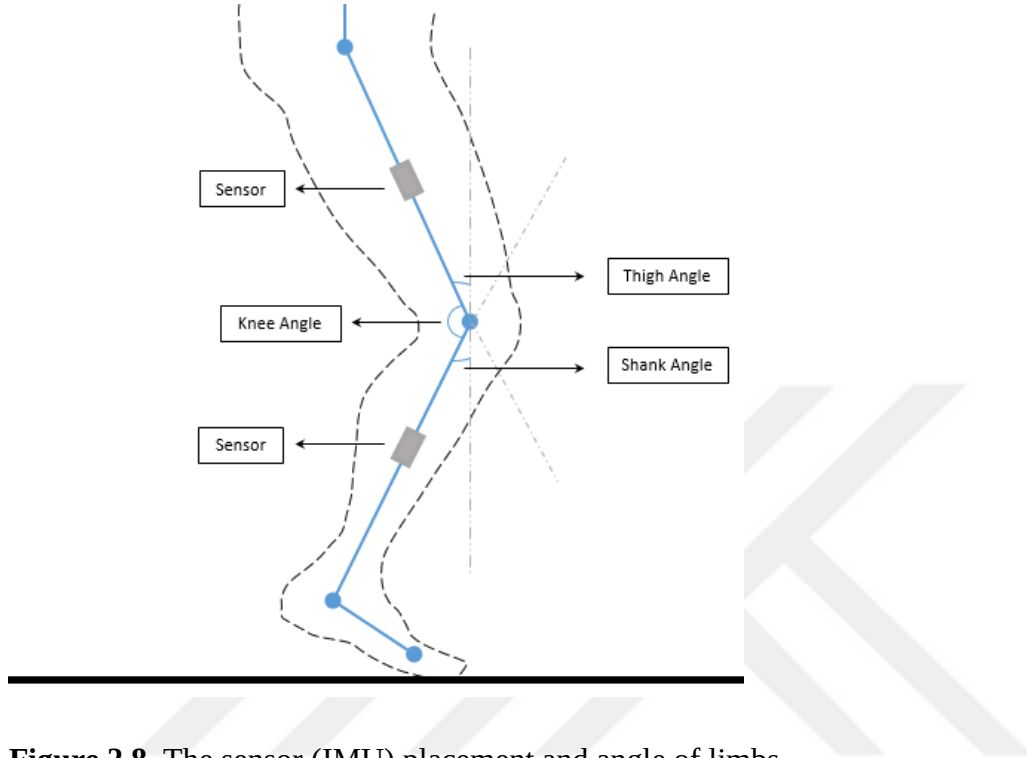


Figure 2.8. The sensor (IMU) placement and angle of limbs.

The gyroscope and accelerometer have features as follows; the gyroscope sends digital output X, Y and Z-axis angular rate sensor with a user-programmable full-scale range of ± 250 , ± 500 , ± 1000 and ± 2000 $^{\circ}/\text{sec}$. There is a wide range of scale for gyroscope but also it has a trade-off. The sensitivity will decrease as the full-scale range increases. In our project it is expected to be instantaneous movement such as falling or rapid change of acceleration in the swing phase. Therefore, a high full-scale range is necessary as well as a high sensitivity to determine the gait phase exactly. Optimal full-scale range of gyroscope was selected as ± 1000 $^{\circ}/\text{sec}$. The accelerometer also has a full-scale range starting from $\pm 2g$ and up to $\pm 16g$. The sensitivity of the accelerometer decreases as the full-scale range increases like the gyroscope. Therefore $\pm 4g$ is selected as the optimal full-scale range.

The sensors and devices communicates with I²C protocol. The sensor sends raw values to Arduino, and these data were converted. The connection of the one sensor is shown in figure 2.9.

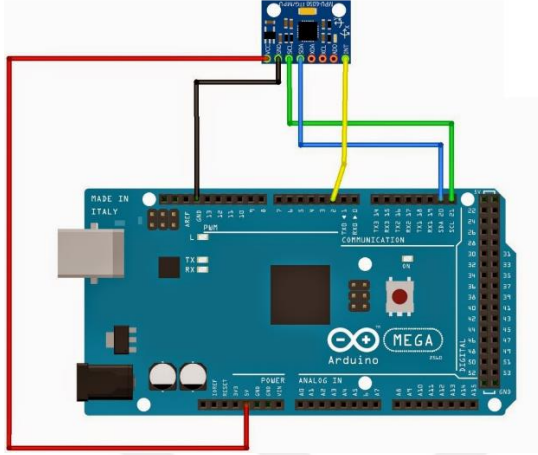


Figure 2.9. Connection circuit of a MPU 6050 sensor.

A common method to determine body movement is by integrating angular velocity data gained by accelerometer and gyroscope. However, here there are small error in the angular velocity data and then these errors accumulate with integration. Thus the result has calculation error.

2.7 Flow Control Algorithm Approach

Control of an orthosis has two steps. The first one is gait phase detection and the second step is generating an output signal to actuate mechanism. The second step may differ from design to design according to the mechanism type. For example, this signal can be a motor control, hydraulic control or other types mentioned at the literature review. However, the first step is common for all control algorithm, because according to the gait phase, that subject being in, system generates a respond.

In this project there are two different control strategies. The first one is a new proposed control mechanism. It is designed uniquely for this project. It follows if-not rules that determined at first and according to the results, it applies them for every different steps. Particularly, this strategy focuses on using the angle information of the thigh and shank with velocities of lower limb to detect the current phases of a subject's gait cycle. Then it calculates the valve clearance value which controls the valve and restricts the motion

of the orthosis. The second method is fuzzy logic control. As the first method, the fuzzy control system adjusts the valve clearance according to the gait phase. These two methods have advantages and disadvantages each other. In the following part detailed explanation of these methods are given. The brief flowchart of the first proposed algorithm is shown in figure 2.10.

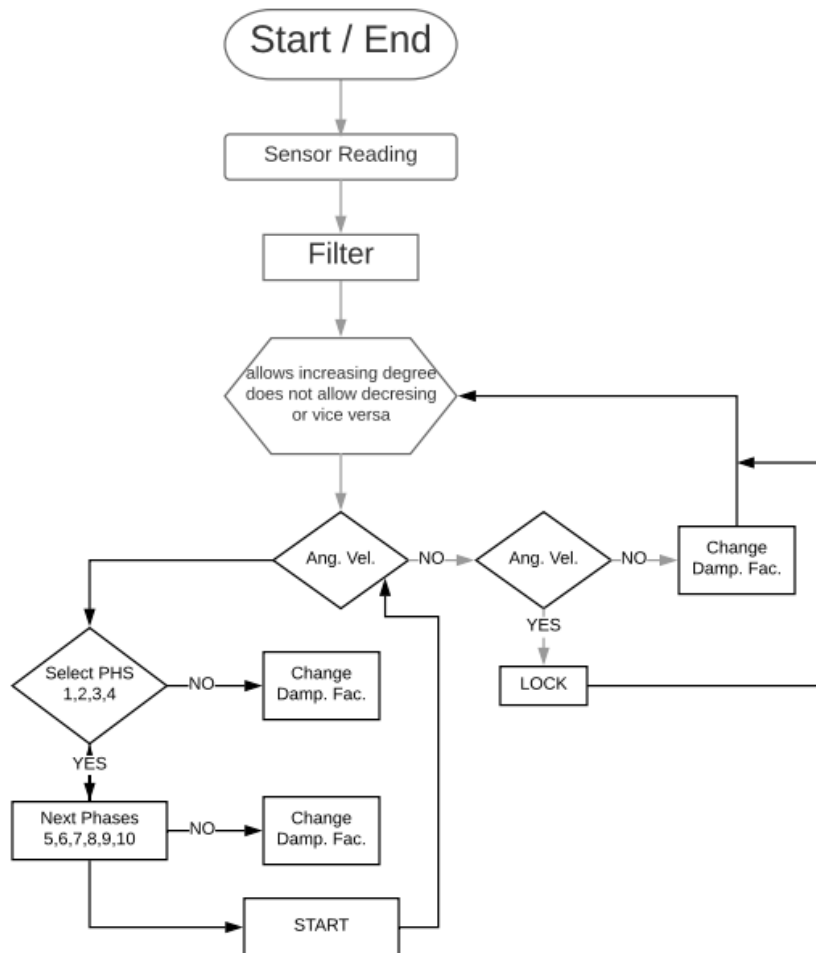


Figure 2.10. The proposed algorithm of flowchart. A more detailed one can be seen at appendix C.

The first proposed method is a rule based method. At the beginning it has two options; start and end. The algorithm accepts two starting postures. They are sitting to stand and vice versa. If you push start button for the first time, it allows only for decreasing degree movement to make the posture upright in position. Control system only starts algorithm when user reach that upright posture. If you press it second time, algorithm allow only

for increasing degree movement stage by stage because this means user wants to sit any place.

Walking with this assistance starts when user reach the knee angle which between 85 - 90-degree and then algorithm continues to next stages. Algorithm checks thigh and shank angular velocity separately for both safety reason and detection gait phase at every stage. At this part, the angular velocity should be up to 100 °/sec for both thigh and shank. If it is in the interval, algorithm determine the phase, if it is not there is a new if question which states that the angular velocity is higher than 500 °/sec or not Figure 2.11. The angular velocity higher than 500 °/sec means user tend to falling or this velocity cause falling. Therefore, algorithm locks the valve and turn to the first step to stand up user to the upright position. Other option is the angular velocity between 100 and 500 °/sec. If the angular velocity is in this range, this means the fluid flow in the piston should be restricted more according to this difference. Here, valve clearance factor is multiplied by constant numbers that determined for every 50-degree difference. Then algorithm goes back to first step as the previous case (see fig. 2.11).

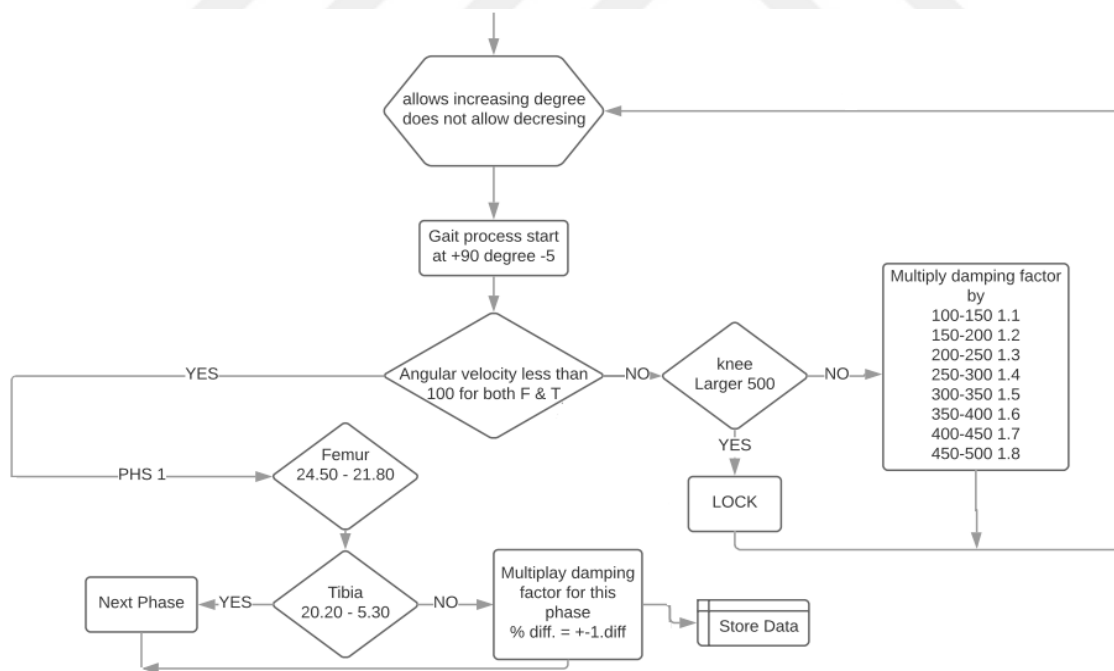


Figure 2.11. A part from the flow chart approach control.

Algorithm now reach the phase detection part. The angles for both thigh (femur) and shank (tibia) and also angular velocities must be in the range to phase detection. In this

stage, first thigh angle is checked. According to the angle the gait phase is determined. These phases can be first 4 phases. Then shank angle checked. Here there are two options. The first option is the angle is in the range for that phase then algorithm go to next phase. The second option is shank angle out of the range for that phase. Here there are two options according to the angle value. If the angle value is under the range, this means user could not provide enough force to reach that angle. The valve clearance should be decreased for only this phase. If the angle value is over the range, this means user applied much force and pass the range. The valve clearance should be increased for only this phase.

Algorithm calculates a multiplying (correction) factor to stabilize the gait. First the sign of the multiplying factor is calculated according to the shank position. It is negative for under the range and positive for above the range. Then a simple sub-algorithm calculates the multiplying factor according to the difference from the range. The bigger difference means the bigger multiplying factor. After this implementation the old valve clearance is omitted but restored and the new one is accepted. Then algorithm continues to the next phase.

At the next phase the same procedures are applied. First the angular velocities of both thigh and shank are checked. Then angles are checked. If any of these values are out of the range a correction multiplying factor is determined by sub-algorithms according to the values. Walking continues phase by phase and thus step by step like mentioned procedure.

The gait speed has an important effect on gait values such as knee angle and angular velocities. As a result of this angle interval for both thigh and shank can be changed dramatically. Same situation is also valid for angular velocities of thigh and shank. Oberg published a study about joint angle parameters for a wide range of ages. [71] The result of the study can be summarized as follows; minor changes were observed with age for knee angle in sagittal plane, there was no difference for left and right leg, significant differences were observed while walking at different sex and also it was determined that there was significant change with increasing gait speed. These are the results for healthy subjects. Oberg stated that characteristic change can be observed in disease but it is difficult to quantify.

Astephen searched the biomechanical changes at the hip, knee and ankle joints during gait are associated with knee osteoarthritis severity [72]. Three subjects group that have different level of osteoarthritis were observed. According to the result, changes observed nearly all mechanical factors such as knee flexion moments, angles and velocities. The below graph (figure 2.12) shows stance phase knee flexion angles for this study.

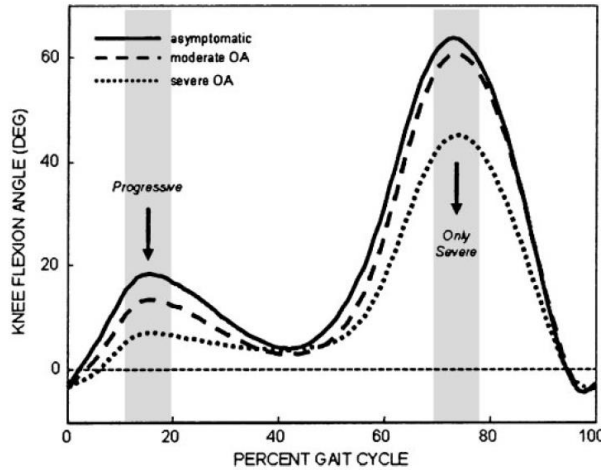


Figure 2.12. Knee flexion angle for OA subject group. [72]

Algorithm uses the angles information that gained from a healthy subject. According to the studies and information given above the angle-step graph of the algorithm has to change. It is stated above that sex difference and different gait speed as well as subject health situation have effects on angles. Therefore, this changing operation should be implemented continuously over gait phase. The algorithm should update valve clearance at every step.

Second control system is an implementation of a known mechanism to our project.

2.8 Fuzzy Control Algorithm Approach

Fuzzy logic is the of reasoning that processes uncertainty. It takes the input and transform it into a degree of memberships and then these memberships make up a fuzzy set. This fuzzy set is used to evaluate a number of rules which are combined and then use the formal conclusion. This conclusion makes up another fuzzy set which then has to be defuzzify in order to be understandable. The purpose of the fuzzy logic which carried out

in this work is to determine the gait phases for a given gait cycle and then calculating the damping ratio (valve clearance).

Human gaits are complicated, and the gait phases cannot be exactly distinguished. A gait step is composed of many sub-phases. These sub-phases are results of many factors. Knee moment, knee angle, ground reaction force were used to determine the gait phases in previous studies [73]. Knee moment especially used in prosthesis for gait phase determination. Ground reaction force is also mostly used factor to determine gait phase. Most studies [73-77] used knee angle combined with other information such as feet angular rate, foot pressure, hip and ankle angles, velocities and accelerations of locomotors.

In medical practice, there is no appropriate widely used application or a system based on fuzzy logic for identifying the lower limb movement type or type of walking [78]. The most widely used method for analyzing gait behavior is gait phase analysis by gait time phase cycles [79]. Gait phases diagrams have been implemented to detect gait with the help of artificial intelligence (AI) methods [80-83]. One of the AI method fuzzy logic have been used to analyze gait recognition systems. Hip, knee, foot angle, knee velocity and ground reaction force (GRF) were used to as an input variables of fuzzy logic system. Because of the its adaptability, speed and accuracy, fuzzy logic was implemented in this study.

The most used data to define gait phase are ground reaction force and angles of locomotor limb members such as knee, hip, ankle, thigh and shank. The angle data are very useful but in this study if the angle information of thigh and shank would use solely, it causes some problems to detect gait phase. First, there are many different gait scenarios for every different gait disease. The condition of the thigh and shank but also the condition of the ankle and the trunk can affect the angles and velocities of the limbs. Secondly, different phases can have same angle during gait. For example, a gait graph for a normal subject is shown in figure 1.5. The angle values are same for starting and ending sections of the gait. The same situation is valid for angular velocity. However, the rule that is the action for the first decision and for the end section are different. The input values are same but the rules are different for that two conditions. As a result, it can be said the gait phase cannot be clarified with only angle and angular velocity information of thigh and shank

when using fuzzy. Also Kutilek advised to modify fuzzy logic system by taking into account appropriate parameter such as angular velocity of knee and acceleration.

The MPU 6050 and same type of sensors can also detect linear acceleration. However, there is no such a detectable linear acceleration change during gait. The linear acceleration is almost same at all phase.

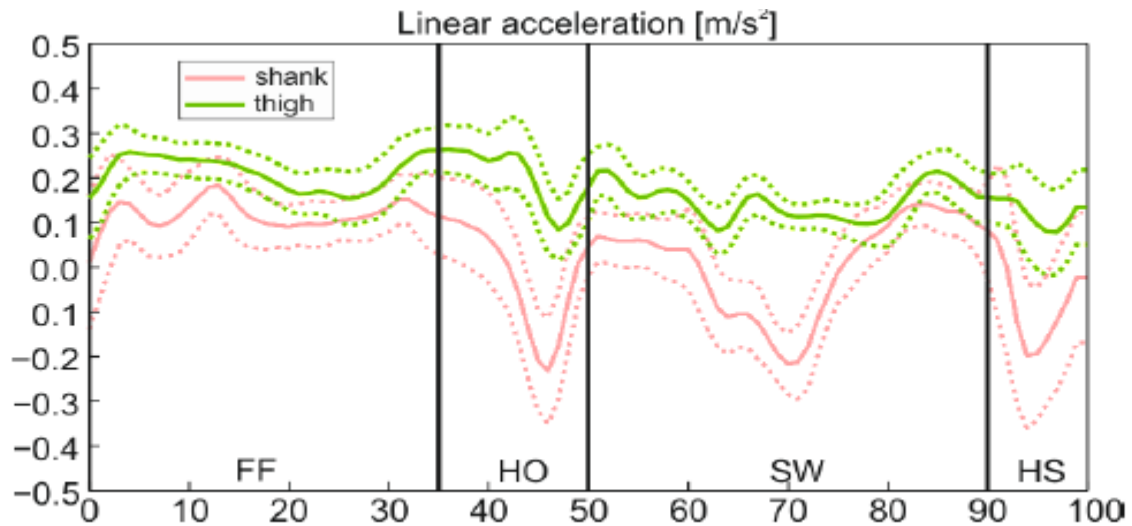


Figure 2.13. The linear acceleration of thigh and shank. Bold line shows different phases. (FF: Flat foot, HO: Hell off, SW: Swing, HS: Heel strike). [84]

GRF is very useful to find gait phase. The stance and the swing phase can easily be detected by this method (see fig. 2.14). If there is no force, this means subject is at the swing phase. If there is any ground reaction force, this means it is the stance phase. Thus the gait first can be easily divided into two parts. Magnitude of the ground reaction force also can be useful. As the below figure indicates, beginning and ending sections of the stance phase reaction force increases and decreases respectively. Also it reaches and exceeds body weight two times at the mid-stance phase. A normal person ground reaction force is a single valued function. This means, determination of the phases with only ground reaction is not a useful way.

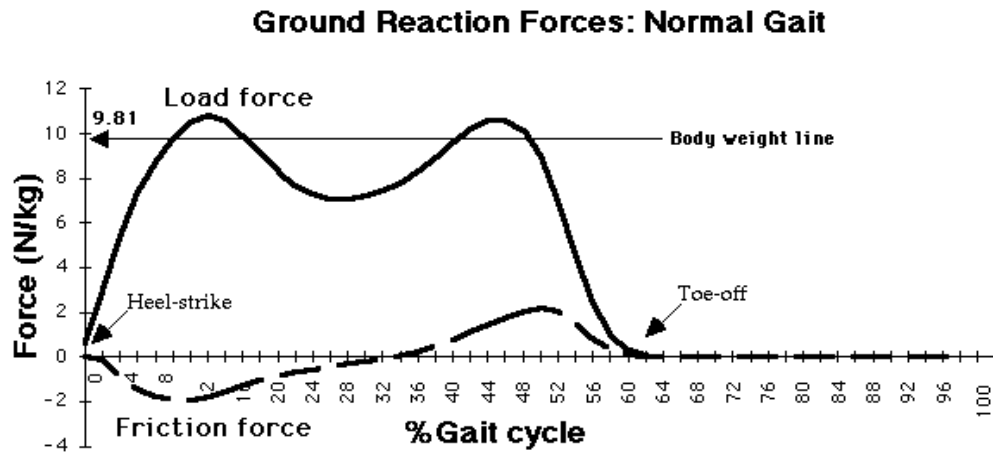


Figure 2.14. Vertical ground reaction forces during normal gait. [85]

These problems were solved by accepted that gait starts at an upright posture in the first sub-phases in the flow chart method. Thus the algorithm easily detects the phase in the first 4 phases and then continues a constant sequence. The efficiency of this method only observed on a continues gait.

Fuzzy logic is very useful when there are no precise definitions and boundaries. A fuzzy logic system is desired to control KAFO that is to determine the appropriate valve clearance for piston according to the angle, velocity and ground reaction force. The components of a fuzzy set can be shown in figure 2.15.

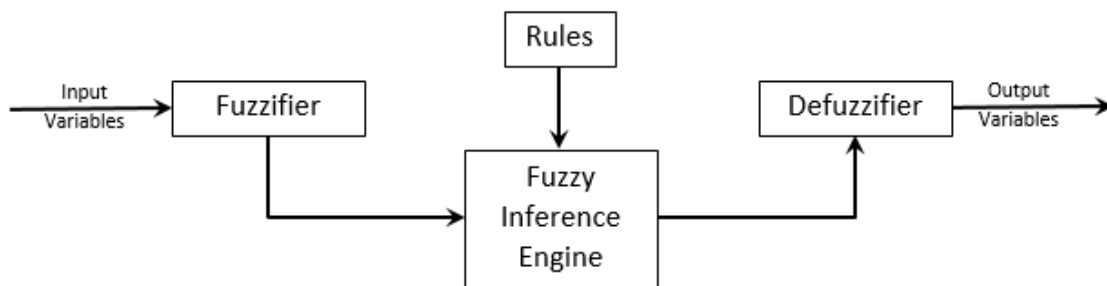


Figure 2.15. The typical Fuzzy logic system.

The advantages of fuzzy logic indicated as (1) decreasing the massive gait data, (2) easy to understand and state the results, (3) ability to adapt non-linear gait variables, (4) has opportunity to comprise input and output variables, (5) easy and simple interface and less processing time, and therefore, suitable for real time applications [86-87].

There is no such an admission at the fuzzy method, therefore a new information is essential. As it emphasized in the previous section, the GRF is useful. It is adapted in the fuzzy set. Thus thigh and shank angles and angular speeds with ground reaction force are combined at the fuzzy section for the input variables. The combinations of these values can be found in figure 2.16 with their intervals.



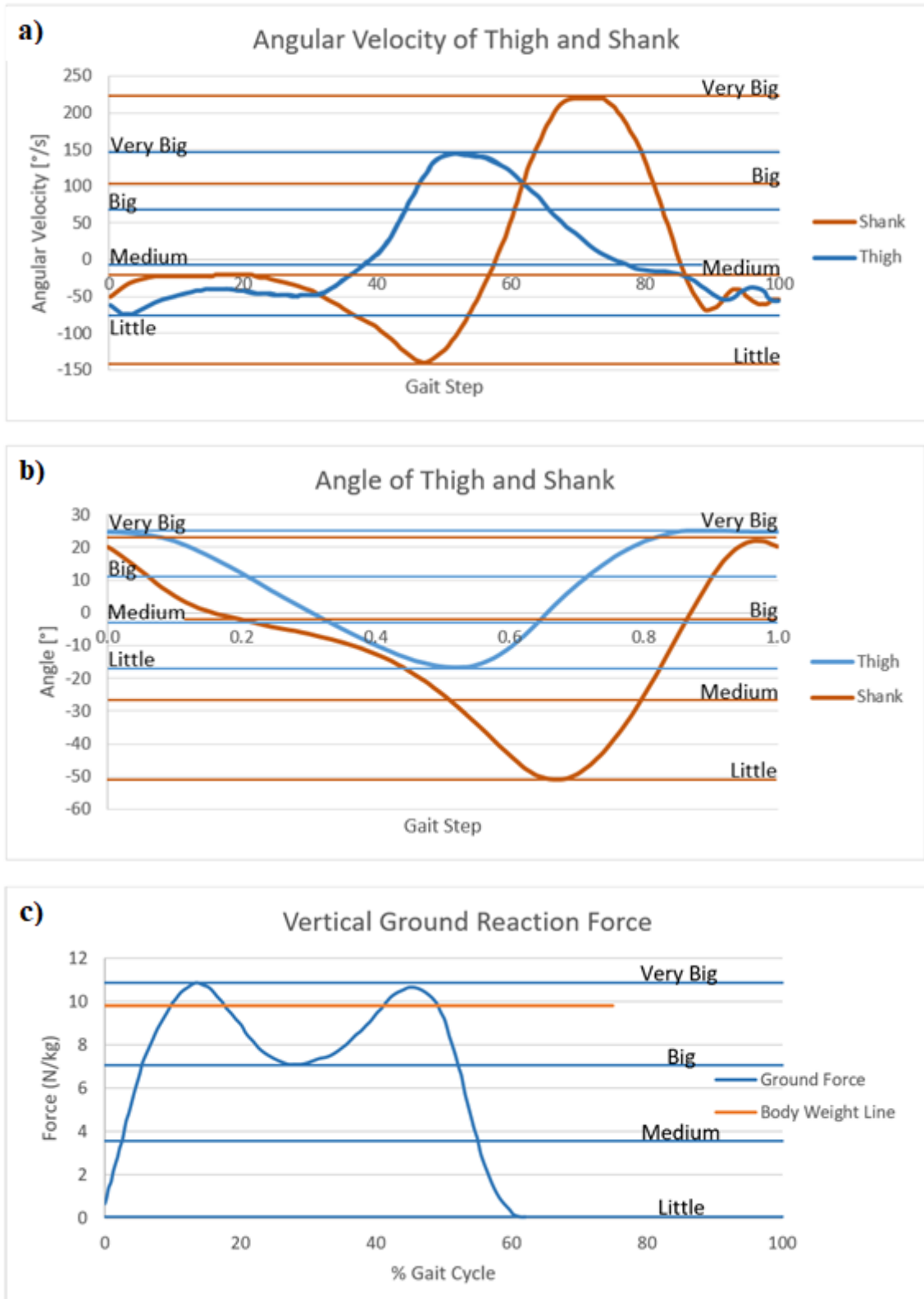


Figure 2.16. The angle (b) and angular velocity (a) of the thigh and shank with ground reaction force (c). The fuzzy interval are shown on the graphs.

The inputs for this fuzzy set are thigh angle and velocity, shank angle and velocity and vertical GRF. The output is valve clearance. The valve clearance should be high when there is no force that exerting the food. In the case of acting force, the valve clearance should be arranged according to the gait phase, velocity and ground reaction force. The valve clearance is very low when the force exceeds the body.

The MatLab toolbox is very useful to apply fuzzy system. There are four basic steps of building and simulating a fuzzy logic system. First the inputs and outputs should be defined. The second step is creating membership function. Then the rules have to be created. Finally, results can be simulated.

The first stage of the fuzzy process is to fuzzify each of the input variables using the linguistic variables showed in figure 2.18. Four membership functions are defined for every variable. They are Little (L), Medium (M), Big (B) and Very big (VB). Same abbreviation is used for output membership functions which correspond to valve clearance value. The time information of the given angle is included in the input parameter. Therefore, there is no need any time value for the output variables. This is because the uniform sizing of the membership function was used. [88]. There are 5 different variable and every variable has 4 membership function (see fig. 2.17).

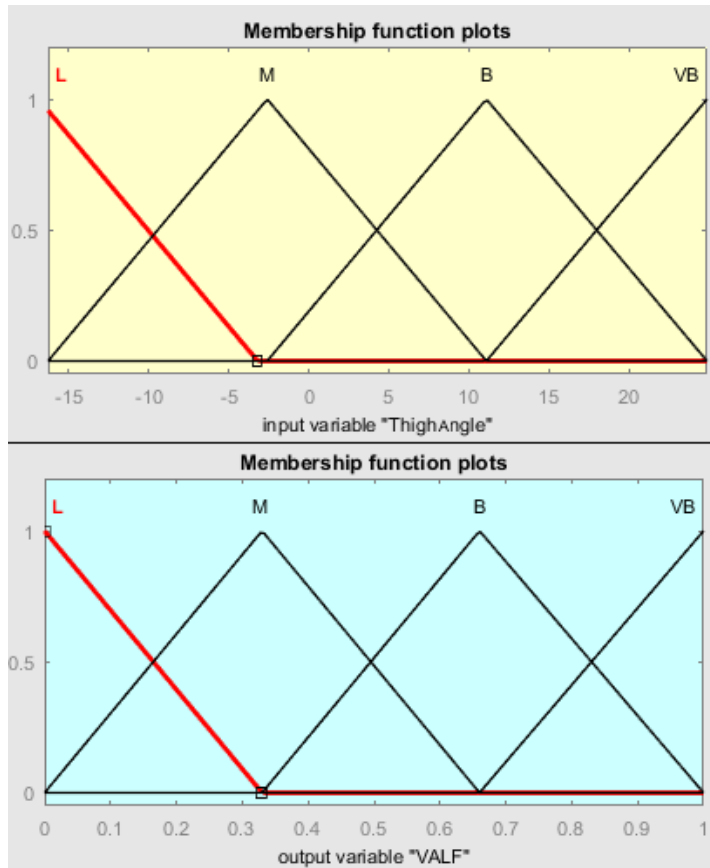


Figure 2.17. Membership functions. Top: Membership functions for L, M, B and VB input values. Bottom: Output membership functions correspond to each of the valve clearance range.

The range of the membership functions are determined according to the maximum and minimum value of the input variables. The membership function is a right triangle. The range is divided equally into three intervals and parameters of the functions are selected by starting at the right corner point as the peak point of the triangle.

Gait is a continuous process and calculation time should be low to accurately control the system. Therefore, the simplest type is selected as membership function type which is triangular membership function (see fig.2.18).

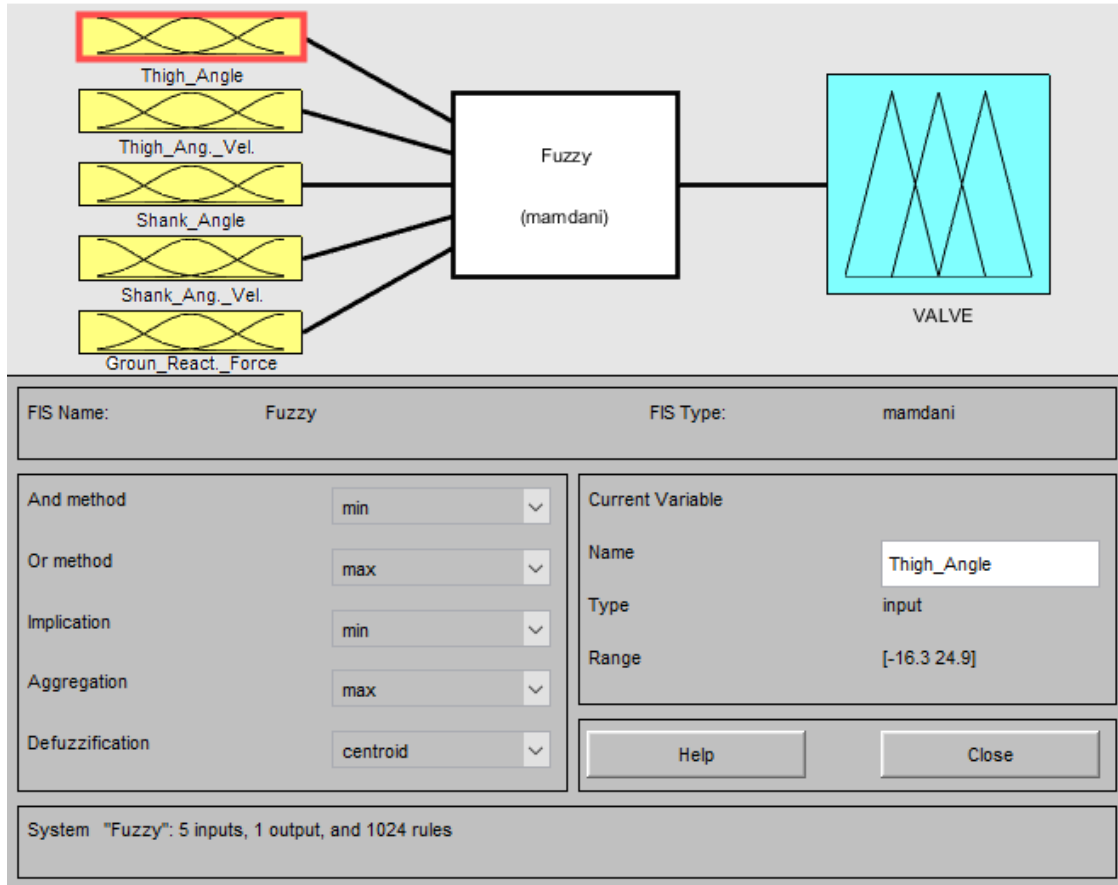


Figure 2.18. The fuzzy inference system editor. The input and output membership functions, the rule base and the fuzzy operators are set.

Next point is selected as the right point of the triangle. Thus the first membership function is defined. The second membership function starts at the rightmost point but this point is the right corner of the isosceles triangle. The next point which is the first internal of the range is the peak point of the triangle and second next point is left corner of the triangle. Other two input membership functions and output membership function are also created by following this procedure. The triangular shaped membership function described as follow;

$$f(x, a, b, c) = \begin{cases} 0, & x \leq a \\ \frac{x-a}{b-a}, & a \leq x \leq b \\ \frac{c-x}{c-b}, & b \leq x \leq c \\ 0, & c \leq x \end{cases}$$

In this equation a and c are the bottom corner and b is the peak point.

The next step of the fuzzy logic system is defining rules. Rule statements are constructed at this stage. Every input membership function has a probability of different result. Since there are 5 input with 4 options, there could be potentially 4^5 (1024) rules for the fuzzy system. All these rule statements were defined one by one and entered to the program. The Mamdani fuzzy model was used and the rules are in the form:

IF thigh angle is ... AND thigh angle velocity is ... AND shank angle is ... AND shank angle velocity is ... and ground reaction force is ... THEN valve clearance is

The rules were determined by referred input variables in table 2.2. Five inputs and one output Mamdani fuzzy model rule base is shown below. (Other rules can be found at the appendix B.)

Table 2.2. Some examples for rule statements.

Some examples for Rule Statements						
Memb. Func. Number	Thigh Angle	Thigh Ang. Vel.	Shank Angle	Shank Ang. Vel.	Ground Reaction Force	Valve Cle.
1	L	L	L	L	L	VB
32	L	M	VB	VB	L	M
722	VB	M	L	M	B	B

2.9 Failure Mode and Effects Analysis

Failure mode and effects analysis (FMEA) is a design tool for examining risk associated with the different ways (modes) in which a system can fail. It identifies the effect of this risks and provides solution for redesigning the system to decrease risk where necessary. This tool can be implemented on different things. The failures can be simple or catastrophic. The advantages of the tool are clarifying different risks and consequences of those failures, providing a method for quantitative analysis of risk, very helpful to compare design concepts and refining design.

The first step of FMEA process is defining modes of failure. Basically, two potential failure modes were recognized for a KAFO. These are stumbling and falling. Stumbling is a potential risk created by the control system or mechanism and cause an uncomfortable gait but user can continue to use for a short time. On the other hand, falling is a serious

issue for gait safety and reasons that causes falling makes the orthosis inoperable and also cause injury.

The next step is to identify potential root causes for each failure mode and quantify those risks. Six roots for stumbling and five roots for falling were determined. A 10-point scale was used to assign severity to potential effects. In this scale high numbers are bad. After this it is time to another quantification that is probability of occurrence. A 10-point scale was also used in this quantification and high number shows occurrence level is very high. Finally, one last quantification was made for detectability. It is going to use to determine how detectable is this problem. In this assigning 1 means it is almost certain of detecting this well in advance where 10 is absolutely uncertain. The rating values and their meaning is tabulated in figure 2.19.

Severity		Occurrence		Detection	
1	No effect - no danger	1	No documented failures	1	Fault is certain to be caught by testing
2	very minor - usually noticed by only very observant user	2 3	Low - relatively few failures	2	Fault almost certain to be caught by testing
3	minor - only minor part of the system affected	4 6	Moderate - some occasional failures	3	High probability that tests will catch fault
4 6	moderate - most users are inconvenienced	7 8	High - repeated failures	4 6	Moderate probability that tests will catch fault
7 8	high - loss of primary function	9 10	Very high - failure is almost certain	7 8	Low probability that tests will catch fault
9 10	very high - hazardous			9 10	Fault will be passed undetected

Figure 2.19. The rating value for severity, occurrence, detection and their meanings.

3. RESULTS and DISCUSSIONS

There are numerous design attempts to make a SCKAFO which allows flexion in the swing and the stance phase. However, they are infeasible to use because of bulky shape, weight, energy need and cosmetic. This problem requires a complete engineering design approach for orthosis which starts from its mechanism to control system. QFD approach is a very efficient way to implement voice of the customer to a product. Demands of users and practitioners were collected as functional requirements to define main problems. Results showed that main drawbacks of an orthosis are number of parts and determining user positions. Other influential parameters are maximum client weight, flexion resistance and main frame material. These parameters can be collected in two main topics; orthosis weight and controllable system. After these parameters clarified, mechanism model and lock system model were studied. A very simple mechanism with combined piston were selected. The control mechanism has two steps; first is phase detection and then clarifying damping ratio. Phase detection requires data to detect gait sequences. Inertial measurement sensors were used to collect data. According to that information, an algorithm calculates the damping factor and microprocessor send signals to valve. A light in weight and controllable KAFO (SCKAFO) design achieved. In the following parts the procedure and results of all these steps are given.

3.1 Mechanism

The mechanism has major effect on orthosis weight. A simple but functional design which provide all duty of an orthosis was aimed. There are conflicts between some parameters such as maximum client weight and flexion resistance. Increase in client's weight also causes increase in flexion resistance. At the same time, orthosis weight also increases. Because of the safety problems and this conflicts maximum client weight has to be limited. It was determined as 100 kg which is a general acceptance like other examples. Different lock mechanisms were examined. Many of them have noise problem, others cosmetically not preferred and some are infeasible to apply (they are deeply mentioned in section 2). The selected system must have a very low number of parts, high flexion resistance, noise free lock system and have a cosmetic fashion. Hydraulic system has advantages like high flexion resistance, precise movement control and noise free moving

capability. Besides this hydraulic allows a smooth lock system which is another design demand. Piston device can be mounted on orthosis bar and dimensions can be minimized thus cosmetic problems may be solved.

McCormack indicates in his studies, piston have disadvantages such as heavy in weight and expensive system [68]. Yakimovich specifies in his thesis that the major drawback of a hydraulic or pneumatic systems are their size. Development of both material and new technology can help to decrease the size of the piston. There is no need to change the length but cylinder diameter must be decreased under 30 mm. By this way the weight of the piston cylinder system would be between 400 – 500 gr.

The dimensions of the rods have direct influence on the working angle of the orthosis. The relative difference between thigh and shank is up to 110 degrees in normal gait. However, the difference between the maximum and minimum value of knee angle is approximately 60 degrees. The difference at the sitting position is approximately 100 degrees. Orthosis users do not have enough muscle force to get down and up. Therefore, the range of motion for the device was determined as maximum 100 degrees. The larger the range of motion, the bigger the size of the device thus it increases the weight.

The width and thickness of the piston, rod and linkage system were calculated according to the 100 kg person. The safety factor is 3. Simulation studies about this calculation are shown in figure 3.1.

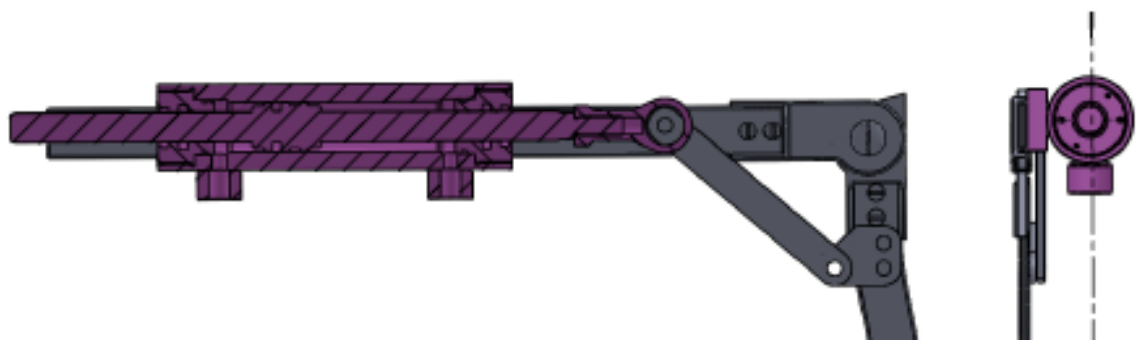


Figure 3.1. Front sectional and side view of the piston.

The mechanism type was determined according to the design parameters. Piston and rod can be accepted as one part and piston moves parallel with the direction of the upper bar. In order to minimize weight and maximize movement interval the simplest way is four-

bar linkage. A four-bar linkage were constructed from four links connected in a loop by one-degree-of-freedom joints upper and lower bars are the two bars of the mechanism. It has to be connected to the lower bar and also has to allow flexion. The other two parts dimensions were determined as small as possible because of weight issue. The movement range of the mechanism was achieved (100°) by this system which is enough to walk and sit in any manner.

The designed mechanism was manufactured. The piston and bars are simulated in a computer program. The piston can be named as double acting linear mechanism. However, since there is no actuator in the system and users have disabilities, the actuation force to need to start moving piston, has to be very low. With the help of the precise machining and grinding and advanced material at the contact face a very low actuation force was achieved. Seal rings and materials were selected according to this issue. The manufactured piston only needs 20 N to start moving. This means user can easily flex and extent orthosis. Piston and four-bar mechanism were attached to the orthosis bar and user can hide it under clothe.

The speed and movement are controlled by adjusting valve clearance between two exits. There are two exits at the two ends of the piston and they are connected each other over a valve. Variable stiffness provides a smooth lock When the valve is closed, piston lock the knee and as the clearance is increased it allows flexion or extension. The valve is controlled by voltage signals. The relationship between voltage value and valve clearance is nearly linear.

The maximum diameter of the piston is 38 mm which means there is approximately 8 mm difference with the orthosis bars. The weight of the piston and two bars that connects the piston to the new SCKAFO in nearly 0.7 kg. If it would be possible to find a very tiny servo valve the remaining part of the orthosis which are valve, circuit and battery weight could be 0.5 kg. Thus the total weight would be nearly 1.2 kg. However, valve weight is 1.1 kg in our study because of the over range one-way valve and direction chancing system.

Inertial measurement sensors were used to measure angle and velocity of the thigh and shank. The sensors have ability to detect every changes in gait for 200 times in a second.

Their dimension is very small, weight can be ignored and performance is very suitable to use in this project. (The capabilities of sensor mentioned in section 2)

After manufacturing and assembly of parts the system was operated. The orthosis range of motion was nearly 100 degrees. The valve was first controlled by a potentiometer to operate the system. When the control mechanism will be implemented on the mechanism, valve control signal will be sent by microprocessor. This part will be discussed in the next section. It is observed that piston mechanism was very flowing and by controlling the valve voltage the motion can be restricted.

3.2 Flow Control Approach

Gait have different tasks through walking as mentioned at the introduction. Valve clearance of the piston has to be arranged according to these tasks. To do this gait phase first must be detected simultaneously. Gait phase detection is challenging problem in the literature. Potentiometers, inertial measurement sensors and force sensors were used with different systems such as neural network. In this study, two different methods were implemented and their efficiencies were compared. They are flow chart approach and fuzzy logic system. Both system use same fundamental information which are collected in section 2. These data are associated with valve clearance value in table 3.1 to use them in control mechanism.

Table 3.1. The angle and angular velocity information for each phase and valve clearance values for algorithms

Thigh			Shank		Valve
Step Duration	Angle (Degree)	Angular Velocity (degree/second)	Angle (Degree)	Angular Velocity (degree/second)	Clearance
0,0-0,1	24.50 - 21.80	0-100	20.20 - 5.30	200-100	4
0,1-0,2	21.80 - 12.10	50-150	5.30 - -1.90	100-0	4.5
0,2-0,3	12.10 - 0.70	150-150	-1.90 - -6.20	100-0	6
0,3-0,4	0.70 - -9.60	150-50	-6.20 - -12.30	0-100	5
0,4-0,5	-9.60 - -16.30	50-0	-12.30 - -24.20	100-200	5
0,5-0,6	-16.30 - -11.50	0-200	-24.20 - -42.50	150-250	5.5
0,6-0,7	-11.50 - 7.20	200-150	-42.50 - -50.00	250-0	6
0,7-0,8	7.20 - 20.80	150-50	-50.00 - -27.80	0-400	4
0,8-0,9	20.80 - 24.90	50-0	-27.80 - 7.50	400-100	2.5
0,9-1,0	24.90 - 24.60	0	7.50 - 20.30	100-0	3

The flow chart approach is a straight forward but efficient method (all steps can be found in Appendix C). It needs only two angle values and works in a continuous walking. Also it can update their gait pattern values according to the deflection of the desired and measured values. Fuzzy needs one more input information that is ground reaction force. However, it is very rapid and creates nearly the same values for desired path. These two methods are compared in the following section.

Flow chart approach tries to adapt orthosis user into a healthy person gait pattern. The scope of this implementation is forcing disabled person to approach normal gait pattern. Even if user could not reach desired path, the closer to normal gait pattern means the more natural walking. However, because of the injured parts user may cannot achieve normal pattern. This requires an update for gait pattern. Flow chart approach has a sub algorithm which compares the determined point and reached point. If there is a difference, it calculates a multiplication factor for valve clearance value and changes it. The procedure is described in the following part.

Angle-step graph is different nearly for all subject according to the disability factors. That sub-algorithm first searches the angle value location with respect to the desired value. If it fit with the desired value, then continues. If it is under the pre-determined value or above the pre-determined value, there are different scenarios. The location is important because if it smaller than desired value this means subject could not apply enough force to reach that point and also if it is larger than desired value this means subject applied much more force and passed the point. According to the results sub-algorithm applies different multiplication factor.

When point side is defined (above or under point) algorithm calculates a multiplication factor that will be multiplied with valve clearance factor. First the difference between the desired value and achieved value is calculated and divided into the phase interval. The interval for every phase is different, therefore a constant number for every phase is determined as correction number. Then this correction number and the first calculated one are multiplied. Finally valve clearance factor is multiplied with this gained number.

According to the being side, that value is divided or added to the pre-determined value. An example of this calculation can be seen in figure 3.2.

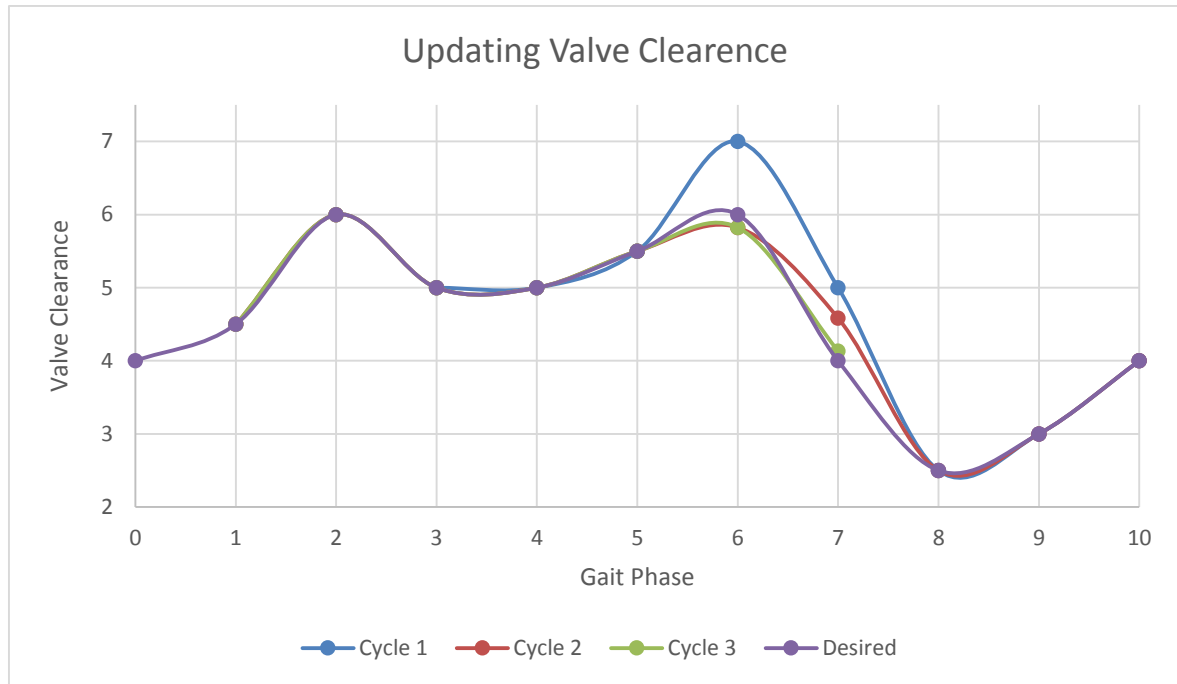


Figure 3.2. Updating operation for valve clearance according to the subject inputs.

On the above figure, 4 gait steps are represented for an updating operation. The first cycle is above the desired values at the end section of stance and pre-swing parts (between % 50 – 80 of gait cycle). This indicates the stiffness of the orthosis could not compensate user weight or more force applied by user. The valve clearance has to be decreased. The sub-algorithm calculates a factor number and multiply with desired value. This new number will be used for the next cycle. As the figure indicates, gait pattern gets slowly fit with the desired value. Sometimes this could not be possible because user have no enough muscle strength to accomplish that gait pattern. In this case, algorithm uses stored data (all generated values were stored) and creates a new gait pattern. This new gait pattern is only updated when there is a difference more than %10 between the desired and measured value.

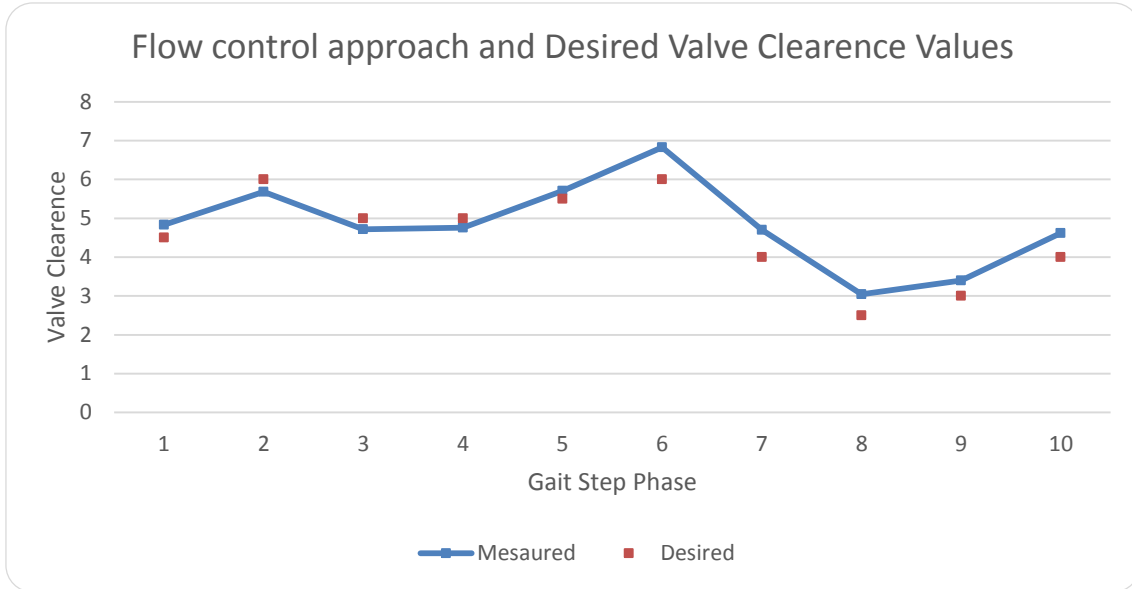


Figure 3.3. The comparison of the flow control approach and desired values.

A typical example of a designated pattern is shown in figure 3.3. The sensors collect data continuously, but desired values determined for only phase interval start point. Therefore, measured values showed by a continuous line and desired valued showed as a point.

3.3 Fuzzy Control Approach

After the application of the fuzzy rules, fuzzy logic system is ready to simulate result. Based on the input variables, the fuzzy expert system selects the output. Results can be seen by graphical user interface of MatLab[®] fuzzy toolbox. In the figure 3.4, each column shows the sets of membership functions for a particular input. Each membership function in this set is associated with a particular rule and maps variable values thigh angle and velocity, shank angle and velocity and ground reaction force to rule input values. In other words, the number of rows in rule viewer is the number of rules that system have. The rules were determined by the help of the input values graph (a typical example is shown in figure 2.1). The input values were labeled on that graph and according to condition of that points required stiffness or the other words valve clearance value was selected.

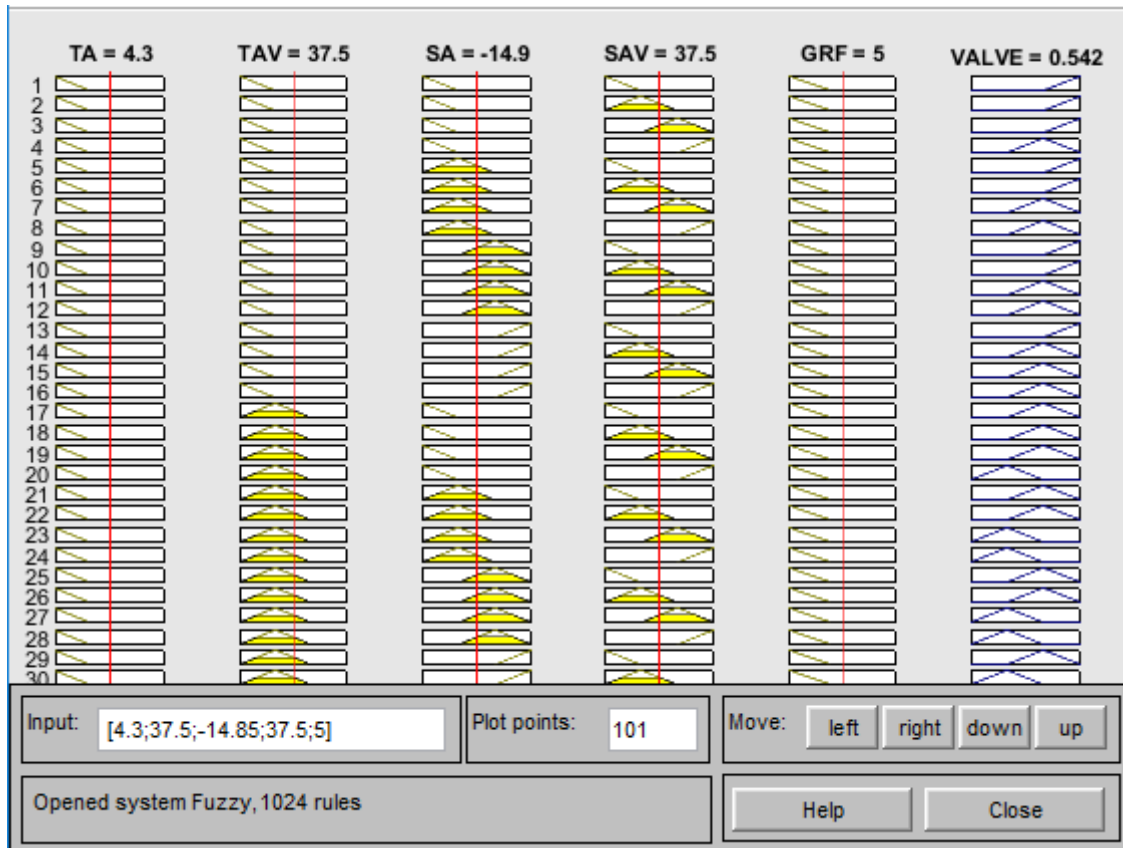


Figure 3.4. The graphical user interface to see the result of the fuzzy system. (TA: Thigh angle, TAV: Thigh angular velocity, SA: Shank angle, SAV: Shank angular velocity, GRF: Ground reaction force, VALVE: Valve clearance). Other examples can be found at appendix D.

The input values are the first 5 columns as shown in figure 3.4. The last column is the generated result. The input values can be changed in the input box and this generates new output response.

The fuzzy result can be compared with desired values. The desired values of a normal gait were given in the first control mechanism which is flow control approach. Now that values were entered to the fuzzy logic system and outputs were gained. Also the maximum and minimum values of the fuzzy calculation for each phase represented by error bars. The result is shown in figure 3.5.

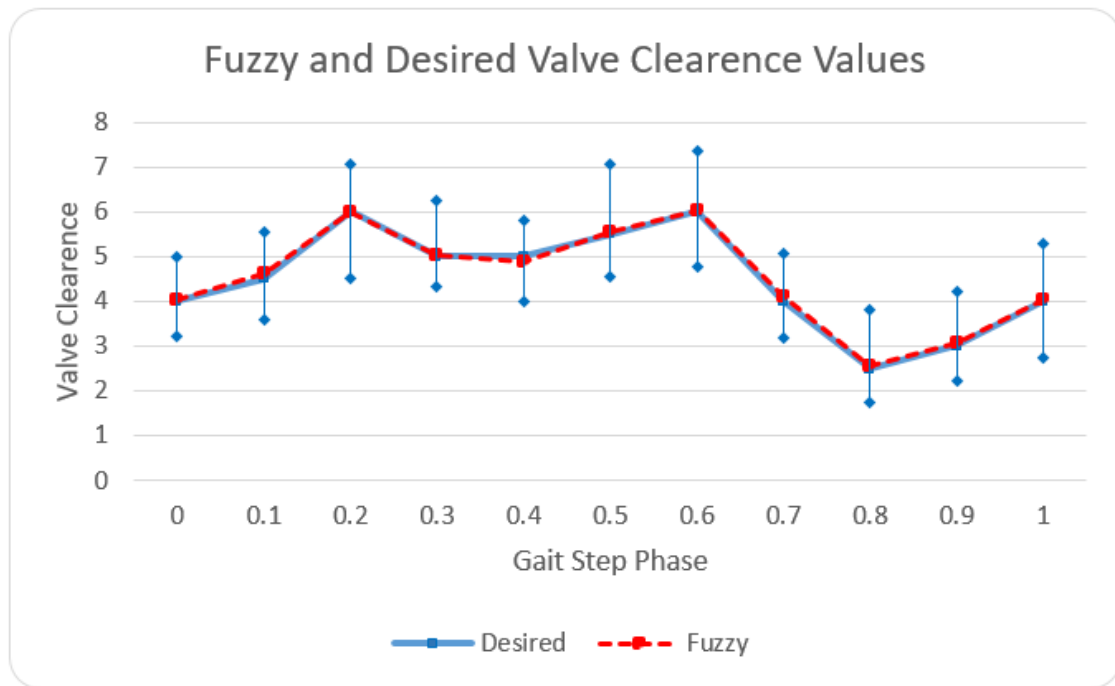


Figure 3.5. The comparison of the fuzzy logic system and desired values.

The fuzzy results and desired values are closely fit. This shows the power of the fuzzy method. The gait phase is divided into 10 sub-phases at the beginning section of this study. However, this number of interval is not possible in fuzzy logic system. Even though the fuzzy set is only divided into 4 part, it gives very good results.

Gait is a very rapid process. The optimal motion for one step, beginning at a given state and ending at another given state is under 0.4 second. Besides this the angular velocity sometimes is higher than 200 %/s. According to these values, the maximum effect for 10 percent error yields only 2.5 degree for a given fuzzy set participation. The maximum difference of fuzzy calculation in our study is under 3%. This value can be accepted as negligible.

Table 3.2. Percentage difference between fuzzy logic and desired values.

Phase	Fuzzy Result	Phase max.	Phase min.	Desired Valve Clea.	Difference
0	4.04	5.01	3.21	4	1.00
0.1	4.61	5.54	3.58	4.5	2.44
0.2	5.98	7.07	4.51	6	-0.33
0.3	5.02	6.24	4.32	5	0.40
0.4	4.87	5.8	3.98	5	-2.60
0.5	5.55	7.07	4.56	5.5	0.91
0.6	6.04	7.35	4.77	6	0.67
0.7	4.11	5.08	3.18	4	2.75
0.8	2.57	3.81	1.76	2.5	2.80
0.9	3.09	4.21	2.22	3	3.00
1	4.02	5.01	3.21	4	0.50

In this study, the effectiveness and speed of fuzzy is also showed (see table 3.2). Fuzzy is very adaptable to different scenarios. At the first experiments, fuzzy sets were arranged for only two and three intervals. That results had very high error according to the final trials. The increased interval numbers as well as increased rule statements advance the consistence of the algorithm and desired values. However, after a point it is not possible to enter very high number of rules.

There is another way to see the results of the fuzzy logic system; surface viewer. The surface viewer displays the result on a surface graph that represents the mapping between input variables and output result. Any two inputs and output can be selected for plotting. The relation and effect of the input variables on the output result can be examined by this representation. The relation between the output result with respect to thigh angle and thigh angular velocity can be seen at the figure 3.6. As the figure indicates, the low values of the thigh angle which means subject is nearly at mid-stance and the high angular velocity cause higher valve clearance. This is because, at this phase leg is under nearly highest pressure but the velocity and exerted force on the leg is in decreasing trend. The relationship between input parameters and output parameter were observed on these graphs.

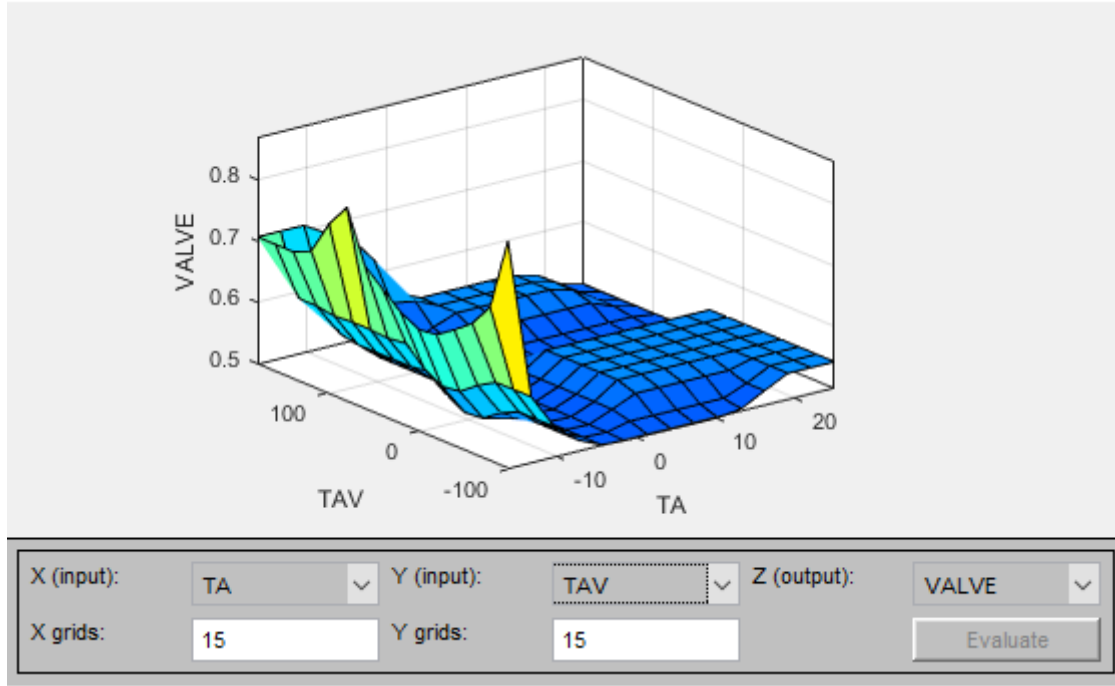


Figure 3.6. The surface diagram for Thigh angle, Thigh angular velocity with respect to valve clearance. Other examples can be found at appendix E.

3.4 Comparison of the control methods

There are two different control method in this study. The first method is a flow chart approach system. The gait phase specified and then the rule based system generates a respond according to the that phase. Since this method divides a gait phase 10 sub-phases, the algorithm controls that entire sub-phase with only one valve clearance factor. For example, there are approximately 7 and 12-degree change for thigh and shank angle for phase 5. However, the algorithm generates same valve clearance for all values through this phase. This condition is also valid for angular velocity intervals. This also cause rapid change for valve clearance.

The flow chart approach starts with an assumption that is algorithm begins at vertical posture. This is because, the knee angle vs the gait is a single valued function. Algorithm first decreases interval for only 4 sub-phases by forcing user to be in vertical posture. Then gait phase detected between these phases. Besides this, control system follows sub-phases sequentially. If there are any interruption or skipping any sub-phases it turns to original posture and then continues.

The mentioned topics up to this point are disadvantages of proposed algorithm. However, system has an updating part. The effect of the gait speed and other factor on joint angle parameters were given previous parts. As showed in the flow chart, flow control mechanism update valve clearance values if there is a difference between the measured value and the desired value for that interval. In this case, a correction is applied to the valve clearance factor according to the difference between the values and the phase being in. This process is implemented in every phase.

In this study, the second implemented method is the artificial fuzzy logic system based on the expert knowledge. Computerized gait analysis using fuzzy logic has become an integral part of the treatment in decision-making process [89-90]. Nowadays, fuzzy becomes very popular to use it in phase detection system [91]. Fuzzy logic is a powerful problem-solving methodology with a myriad of applications in embedded control and information processing. The control of the SCKAFO has two main parts; phase detection and determining lock stiffness. Therefore, the control system requires a fast respond performance. This is a real-time control and fuzzy is very suitable to real-time control of applications.

The fuzzy membership functions and rule statements were determined by gait pattern graph and previous studies. The thigh and shank angle and velocities with GRF were used to provide a very delicate phase detection thus an optimum lock stiffness (In our study it corresponds to valve clearance). According to the result, the fuzzy performance was proved. The typical gait pattern and fuzzy calculation difference was under %3. This difference can be ignored.

The performance of the fuzzy control of an orthosis has been showed in many studies. Beside this, a SCKAFO design with has a very low number of parts thus less in weight and dimensions were introduced in this study. The main rejection problems that are cosmetic, weight, flexion have meaningful solutions in this design.

3.5 Risk Analysis

FMEA chart is created according to information given materials and method section. The risk priority number (RPN) is the multiplication of severity ranking, occurrence ranking and detection ranking. Since all quantification up to this point is between 1 to 10, RPN

ranges from 1 to 1000. The best case scenario is 1. 1000 is the highest risk score and shows the most dangerous thing that it could injure user and it is very likely to occur and it is not possible to see it until occur. The chart is shown in table 3.3.

Table 3.3. The two possible failure mode for orthosis (a) stumbling and (b) Falling.

(a) Failure mode 1 : Stumbling					
Possible Effect	Root Cause	Severity (S)	Probability of Occurrence (O)	Detectability (D)	RPN
Uncomfortable gait, Can be used for a short time	Blockage in piston	5	8	5	200
	Blockage in mechanism	7	5	8	280
	Sensor broken	6	2	10	120
	Fluid leakage	4	8	3	96
	Algorithm crash	10	5	6	300
	Calibration deviation	6	8	2	96

(b) Failure mode 2 : Falling					
Possible Effect	Root Cause	Severity (S)	Probability of Occurrence (O)	Detectability (D)	RPN
Injury, Inoperable until service	Broken wire	6	2	10	120
	Battery dead	10	5	6	300
	Broken parts	10	3	8	240
	Joint corroded	8	5	3	120
	Circuit Shortcut	10	2	10	200

According to the results the highest ranked risks are algorithm crash and blockage in mechanism for stumbling, battery dead and broken parts for falling. Algorithm crash can easily be solved by adding a line about locking system in the case of any crash. The mechanic part of the orthosis can buckle, turn and twist after a while. Thus mechanism can lock in any position. Also user's cloth can get in jam in mechanism. Rounded edges on bar and wedges at necessary parts would be solution for this problem.

Other remaining and important risks are battery dead and broken parts. A high safety factor and deep simulation studies can solve this problem. It may cause some increase in weight but falling is a very serious risk therefore it is essential. The circuit can measure remaining battery. At the low level a sound alert can be used to warn the user that left only a particular battery level.



4. CONCLUSIONS

This study is about the design, prototype production, operation and smart control of a KAFO. The study starts with a very comprehensive literature search about KAFO. Gait and walking terminology, parameters and functions were deeply analyzed to understand every aspect of the gait mechanism. Literature search topic first divided into two main parts. They are conventional KAFO and SCKAFO. Conventional KAFO have basic and primitive design. They are generally mechanical and do not allow flexion while walking. Thus subject only walk by hip hiking or circumduction. The improved design of the conventional KAFO is Stance Control KAFO. This type of orthosis has controllable lock mechanism this means it allows flexion in the swing phase. There is numerous different type of SCKAFO in the literature such as spring loaded system, hydraulic system and motor controlled system. These studies were grouped under the topic of the SCKAFO by their system type.

All related studies were observed according to their advantages, disadvantages, advancement over other designs and used technologies. There are many manufactured prototypes but it is observed that much of them are not feasible. Every different design system solves a problem and also bring other problem. Therefore, it is concluded that an engineering design approach has to be applied to determine the most desired problems to solve.

4.1 Contribution to the Field

Quality function deployment method is used to identify user attributes and a link between user attributes and design parameters created. It was preferred some previous medical device studies [92,93]. The design parameters were determined asking questions to KAFO users and personal conversations with practitioners. After this 47 design parameter were concluded. On the other hand, 24 engineering parameters were set to map that design parameters. The interrelationships between engineering parameters and design parameters were associated each other. All the associations with their weight were multiplied by importance of the design parameters percent. Results show that the most important parameters are number of parts and phase detection system.

These two outcomes indicate two different desires. The parameter, number of parts has a broad meaning. The higher number of parts means the more complex, bulky and heavy orthosis. Especially bulky shape and heavy orthosis are the main rejection problems. Heavy orthosis causes abnormal gait because of excess weight on the disabled leg. Bulky shape has an esthetic problem. Users want to hide their appliance under clothes. Complex mechanism sometimes may difficult to use. An adaptable and easy to use orthosis the most preferred models. Other important outcome parameter determining user's position is actually phase detection system that is detecting user position and calculating their gait phase. This shows that users desire an automatically controllable system. Thus a user can easily flex their leg in the swing phase. The important parameters were collected into two main topics by contributing other effective parameters. They are orthosis weight and controllable KAFO system.

The hydraulic system generally preferred at prosthetic devices, because it also acts like a tibia bone. Some researcher indicated disadvantages of this system on orthosis as follows; high weight, high price and large dimension. However, if the piston moves along the orthosis' rod and the width does not exceed the bar width, it will be very useful. Unlike mentioned issues, the piston system has some advantages like high flexion resistance, precise motion control capability, soft lock and reliability. A piston device lock system was selected according to the aim of low number of parts. The piston attached to upper bar and connected to lower part by rods. This system forms a four-bar mechanism. It has only one degree of freedom thus the motion can be controlled by valve control. The two ends of the piston connected each other and a controllable valve attached between them. A microprocessor gathers the information from sensors and sends determined current to coil of valve.

The piston was manufactured and prototype was assembled on orthosis. It was operated before adding any control system. The another challenging part of an orthosis design is its control. Two different control scenario were implemented and compared. First one is a rule-based flow chart approach. It follows a gait pattern and if it detects any deviation from that pattern apply a new valve clearance and try to force user to turn back that desired route. The first gait pattern was gained from a normal person walking way. It is expected to every person has different gait pattern. Therefore, if user could not achieve that first

determined pattern then algorithm draw a new line and accepts this as users' new gait pattern. This system has some disadvantages mentioned before but it works well in a normal continuous gait.

The gait is not only walking on an even surface. It also covers hill and down walking as well as stair up and down. The algorithm must adapt these all different gait scenarios. Kutilek advised in his study that new method based on soft computing not only fuzzy logic but also other AI methods such as neural networks and genetic algorithm can be applied in practice for characteristics in the motion function of the human body. He also emphasized that the method can be used in advanced control systems to control orthosis and prosthesis of the lower limb extremities. Fuzzy system was selected as an AI system because ability to adapt different situation is high. The membership functions were divided into four interval and 5 input parameters were selected. 1024 different case were entered. Capacity of algorithm for different case thus was increased. The results and the comparison of the method to known gait pattern showed that there is only a negligible difference between desired and measured values. This method also showed the relationship between input and output parameters individually.

4.2 Future Works

Gait analysis is very important assessment tool in clinics and hospitals. The most used way of analyzing gait is the optical system using high-speed cameras to record subjects in 3-D motion [94]. However, as the Alaqtash expressed this technic of system requires expensive equipment and a relatively large amount of space; it requires data processing times that preclude clinical application in real time, pre-calibration experiments, off-line analysis of recorded pictures and limb movements cause obscuration of the reflective markers, requiring reliance on extrapolation by auto-tracking paradigms [95]. Moreover, the human body is composed of many highly flexible segments, and the upper-body motion of human is especially complicated in terms of accuracy calculations [96]. This study covers the research, design, manufacturing, operation and control of the orthosis. Therefore, the effectiveness of the system on normal and abnormal subjects via gait analysis was postponed to future studies.

This thesis is a very extensive study starts from investigations of literature and market then an engineering design, manufacturing, detection system, control system and operating of the system. Review and design study can be used for the future design as an essential guide. Future studies should include a clinical research for effect of the designed orthosis on subjects. The safety factor of the mechanism was determined very high, a new study about optimization on dimension of the orthosis will be very valuable. Control system of the orthosis is a unique study, clinical research can show the effectiveness and adaptability of the proposed control algorithm.

The control circuit and sensor energy expenditure are very low, therefore there is no need any improvement on this issue. However, a remote communication system between the sensor and the processor can increase comfortability, safety and functionality of the orthosis.

A one-way valve was used in the study. This makes necessary to use another system to convert it to bi-directional flow. Even though the lowest capacity valve in the market was used, the lock system which are valve, direction changing system and connections brought out excess weight and volume. A tiny lock system like servo valve that has two directional flow capability and very low volume and weight is very worthy to future study.

The control design for the orthosis to provide flexion in swing was developed by using Fuzzy logic. Custom-made orthosis based on an individual's gait pattern can be adapted by adaptive learning of the fuzzy rules in real-time. With further development of this method, it may be possible to develop a system for quantification of gait and disabilities. It is advised that the combination of sensors and the fuzzy algorithm are worthy of further exploration as a potential basis for more flexible, efficient and cost effective technologies for gait assessment [95].

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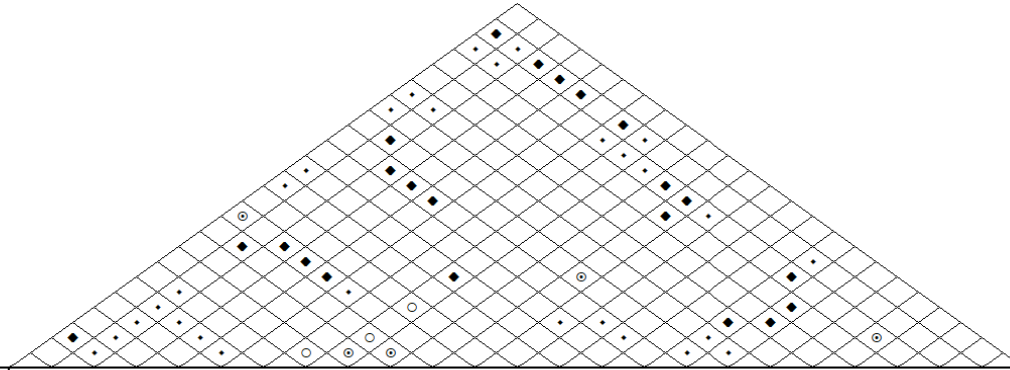
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APPENDIX A

⊕	Strong Positive Relationship
○	Positive Relationship
⊖	Strong Negative Relationship
•	Negative Relationship



QFD analysis for SCKAFO			Relative Importance	HOWs (Engineering Parameters)																								Otto	Fillauer	Becker	Myo	Compliant	Motor	Our design
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24							
				Flexion resistance (Nm)	Number of parts (#)	Joint Thickness (mm)	Joint Width (mm)	Joint Length (mm)	Combined Weight of knee joints	Compliant mechanism	Microprocessor Control	Remote control	Operating modes (Free motion, automatic lock/unlock, Manual lock/unlock)	Main frame material	Determining user's position (gyroscope & Accelerometer)	Minimum Resistance Angle	Power Consumption (days/charge)	Reaction Time (ms)	Max. Client weight (kg)	Product Life	Wear Resistance	Mean time between servicing (months)	Ease of manufacture	Casing form & colour & Surface	Sale Price	KAFO Weight (kg)	Sophistication of mechanism							
Direction of improvement				↑	↓	↓	↓	↓	↓	○	○	○	↑	↑	○	↓	↓	↓	↑	↑	○	↑	○	○	↓	↓								
Performance / Functional Requirements	1	Capable to resist excessive flexion moments	10	5		3	3	3	3	1				5		5	2		1	5	5	3	1		4			4	3	3	3	4	5	5
	2	In stance free to extent	10		5				3	2			1		5		1						4		1			5	5	5	5	5	5	5
	3	Controlled flexion in stance	10	5	5					5	5		1		5													3	3	3	5	4	5	5
	4	Resists flexion at any knee angle in stance	10	5	5	2	2	2	1					3	5	5	2	5	3	5	5	5	3		2	1		3	3	4	4	5	5	5
	5	Allow free knee movement in swing	10		5						3				5		1						1					5	5	5	5	5	5	5
	6	Easy sit and stand	8	3	3	1	1	1				2	2		3								2		1			5	5	5	5	5	5	5
	7	Can be used on uneven terrain or ascendin/descending	9		4	1	1	1															1					3	3	3	4	5	5	5
	8	Reduction of compensatory movements	8		5				1	3	2		1		5	2		5							3			3	3	3	5	5	5	5
	9	No specific joint angle to switch between phases	9	2	3				1	3	1				5	5		2	1				2		1			5	3	5	5	5	5	5
	10	Shock absorption	8		3		1		1	5				1	3			1	3	3	1		1		1			1	1	1	2	5	4	5
	11	No rigid lock	8	2	2				1	5				1	2	3			1			2	1		3			2	2	2	3	5	5	5
	12	Compatible with any KAFO	7	2	3		5	4		2				1					2				2		1			2	4	3	0	1	2	4
	13	No accidental release	10	2					1	2	2		2		3	2			1				1					5	4	3	4	4	0	5
	14	Optional control modes (Automatic, manual lock&unlock)	9		2				1		5		5		1		3						2		1			5	5	5	5	5	5	5

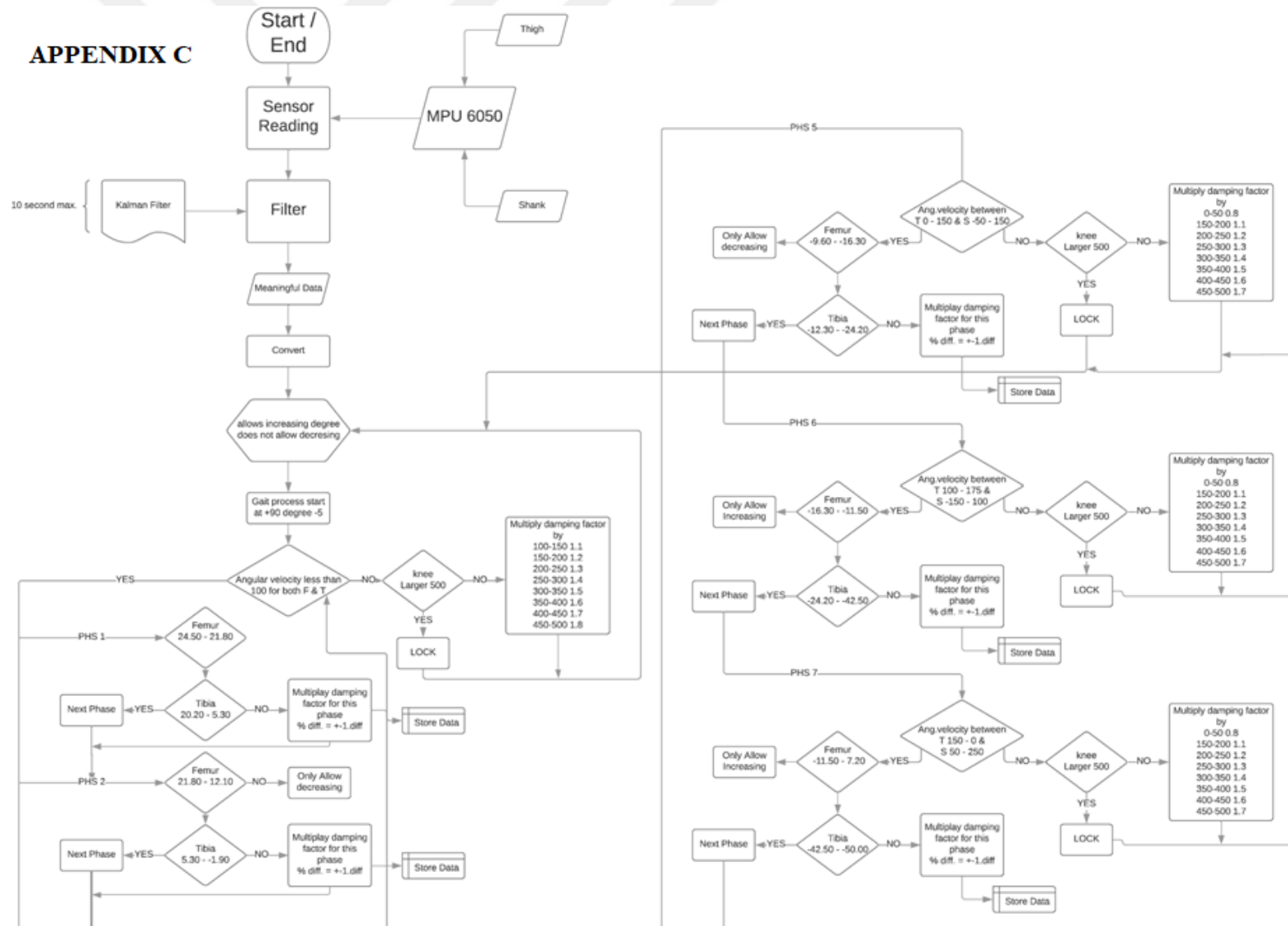
WHATs (Design Requirements)	Usability & Human Factors	15	Rapid swithch between phases	9	3	2					2		1		2			3							1					3	3	3	2	3	5	5		
		16	Allow faster gait speed	7		2				3	2		3		1	3		2	1												2	4	4	3	5	5	5	
		17	Will support ligament instability	7	1		2			5				1				5									3				4	4	4	4	4	4	1	
		18	Easy to dress on / dress off	9		2		2	4	3				2				4									5				4	4	4	0	0	0	5	
		19	Manual Control Capability	7																							4				4	4	4	0	2	0	5	
		20	Attractive and have aligent shape	9	2			2	2	2	1			4											5	2					4	4	4	0	2	1	5	
		21	Easy control	8		2					2	5	5		3											1					3	3	3	3	4	5	5	
		22	Flexion contracture (up to 15 degree)	8	2						3					2								1		1					5	5	5	5	5	5	5	
		23	No need dorsiflexion stop	7							2					1															5	5	5	3	3	3	5	
	Structural Requirements	24	Light weight	10	2		4	3	3				5				3					3								3	3	3	1	2	1	5		
		25	Stability	9	2	3					2	3		1		4		1													3	3	3	4	5	5	5	
		26	Unobtrusive form	8	3	2	5	5	5	1	3			3		2		3					5	3						3	3	3	1	2	2	5		
		27	Noise free	9	1	2					2	2																			2	2	2	1	3	4	5	
		28	Wear bumper	10	2	3					1			2	1	4			3		5		2				2				2	2	2	2	4	2	5	
		29	No sharp edges on joint	8			2				1				3																4	4	4	4	3	3	5	
	Electro-mechanical	30	Extensive charged state	10	3						2	1	1	1		1		5		2					3						3	3	3	1	2	1	5	
		31	Small battery (Removable universal battery)	9			2	4	2	3		2		1		1		5		3											4	4	4	1	2	1	5	
		32	Antiflexion in case of failure	10	4	3					1					5			5	2		3				1					2	2	2	3	3	4	5	
		33	Continuous use time	8	1									3	5		1	2		3	4	3				2					4	4	4	2	3	4	5	
	Miscellaneous	34	Competitive price	9		3				1	4	3	2	1	3	2	5	1	2	5	2	1		3		3					2	2	2	1	1	1	5	
		35	Dynamic stability	9		3						3				5			2	2											2	2	2	3	4	4	5	
		36	Decreased gait anomalies (vaulting, circumduction)	8							5	3				3	2		1												3	3	3	4	5	5	5	
		37	Resist to weather conditions / Wheather Proof	7											5										3						5	5	5	5	5	5	5	
		38	Paintable	8											5										5						3	3	3	1	2	2	5	
		39	New technology	9	1	1					2	5	5	2		2	5		1	3		1	1		1						3	3	3	4	5	5	5	
	Servicing	40	Ease of integration into a KAFO	9		2	5	5	4	1	4				3				2	2											3	3	3	0	1	1	5	
		41	Correct adjustment / attachment availability	10	2	2			3		4				4				3			1	2								2	2	2	1	1	1	5	
		42	Long time between services	8		3					2				2		3			3	5		3								3	3	3	2	2	4	5	
		43	No maintenance in between services	9		1					1			1	2																	4	4	4	4	4	4	5
		44	Easy to service / replace parts	8		2									3						2										3	3	3	1	1	4	5	
		45	Sold as joint	6	1				2		2				1											3					1	1	1	0	2	3	5	
		46	Low service / replacement part cost	8		2					2	3	3		5		2				1										3	3	3	1	2	4	5	
		47	Easily adjustable trim settings	7	3		1				1					5																3	3	3	1	3	4	5
	Weighted Importance			535	759	247	297	315	294	687	448	126	237	611	757	350	216	278	502	249	246	130	305	146	327	124	0	1334	1324	1335	1070	1360	1389	1980				
	Relative Importance																																					

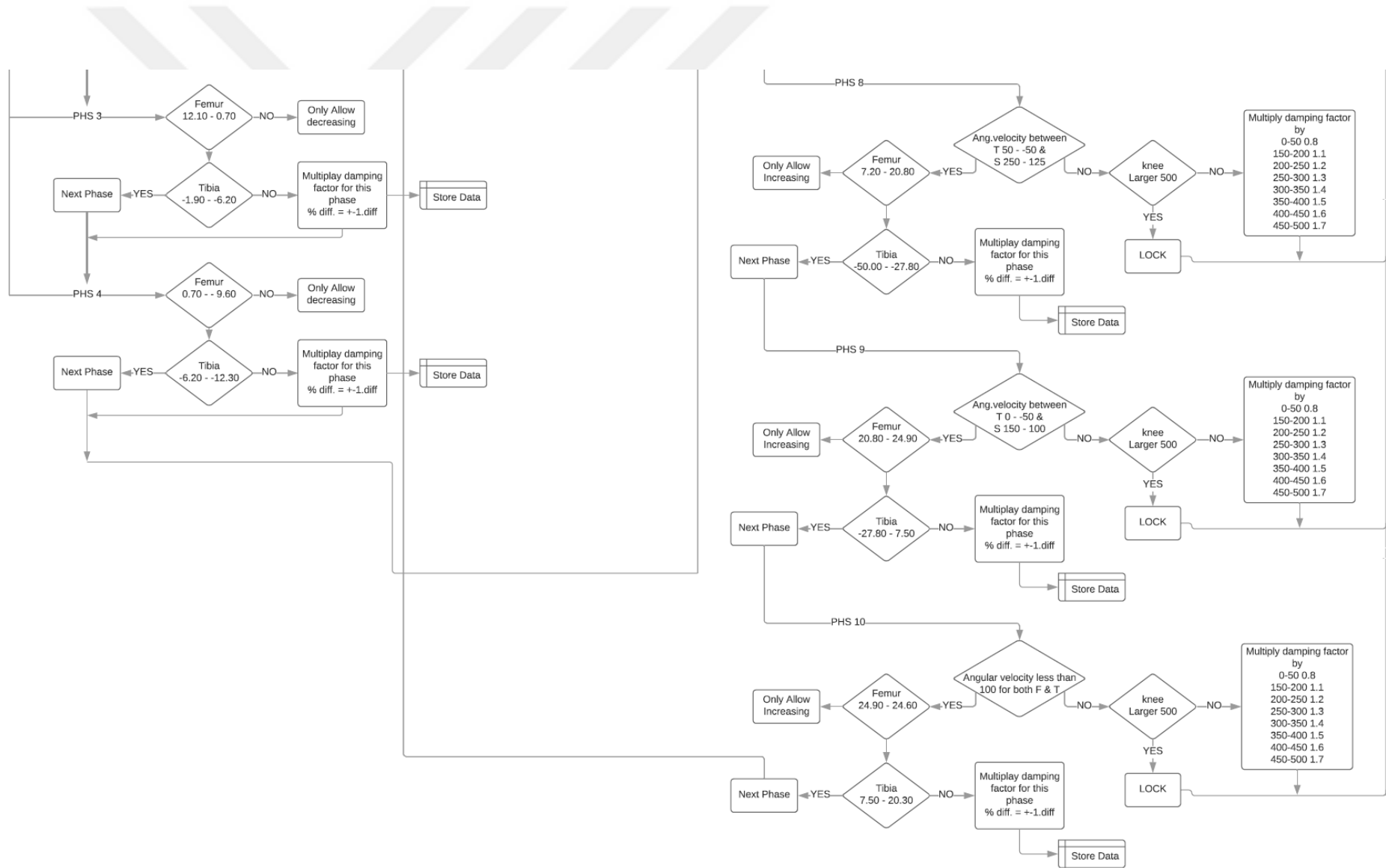
APPENDIX B

	A	high A	high V	Shank A	Shank V	Ground	Wall		A	high A	high V	Shank A	Shank V	Ground	Wall		A	high A	high V	Shank A	Shank V	Ground	Wall
1	L	L	L	L	L	L	VB	65	M	L	M	M	M	L	M	129	B	B	B	B	B	L	VB
2	L	L	L	L	L	L	VB	66	M	L	L	L	L	L	M	130	B	B	B	B	B	L	VB
3	L	L	L	L	L	L	VB	67	M	L	L	L	L	L	M	131	B	B	B	B	B	L	VB
4	L	L	L	L	L	L	B	68	M	L	L	L	L	L	B	132	B	B	B	B	B	L	B
5	L	L	L	M	L	L	VB	69	M	L	M	M	M	L	M	133	B	B	M	M	M	L	VB
6	L	L	L	M	B	L	VB	70	M	M	M	M	M	L	M	134	B	L	M	M	M	L	VB
7	L	L	L	M	B	L	B	71	M	M	M	M	M	L	L	135	B	L	M	M	M	L	B
8	L	L	L	M	VB	L	B	72	M	L	M	M	VB	L	L	136	B	L	M	VB	L	L	B
9	L	L	L	L	L	L	VB	73	M	L	B	B	L	L	M	137	B	L	B	L	L	L	VB
10	L	L	L	B	B	L	VB	74	M	L	B	B	M	L	M	138	B	L	B	M	L	L	VB
11	L	L	L	B	B	L	B	75	M	L	B	B	M	L	L	139	B	L	B	M	L	L	B
12	L	L	L	M	VB	L	B	76	M	L	B	B	VB	L	M	140	B	L	B	VB	L	L	B
13	L	L	L	VB	L	L	VB	77	M	L	VB	L	L	L	M	141	B	L	VB	L	L	L	VB
14	L	L	L	VB	M	L	B	78	M	L	VB	M	M	L	M	142	B	L	VB	M	L	L	VB
15	L	L	L	VB	M	L	B	79	M	L	VB	M	B	L	M	143	B	L	VB	M	L	L	VB
16	L	L	L	VB	VB	L	B	80	M	L	VB	VB	VB	L	L	144	B	L	VB	VB	L	L	VB
17	L	M	L	L	L	L	B	81	M	M	L	L	L	L	M	145	B	M	L	L	L	L	B
18	L	M	L	L	L	L	B	82	M	M	L	L	M	L	M	146	B	M	L	L	M	L	B
19	L	M	L	L	B	L	B	83	M	M	L	M	B	L	M	147	B	M	L	B	L	M	B
20	L	M	L	L	VB	L	M	84	M	M	L	VB	L	M	M	148	B	M	L	VB	L	L	B
21	L	M	M	M	L	L	B	85	M	M	M	M	L	L	M	149	B	M	M	L	L	L	B
22	L	M	M	M	L	L	B	86	M	M	M	M	L	L	M	150	B	M	M	M	L	L	B
23	L	M	M	M	B	L	B	87	M	M	M	M	B	L	M	151	B	M	M	M	B	L	B
24	L	M	M	M	VB	L	M	88	M	M	M	VB	L	M	M	152	B	M	M	VB	L	L	B
25	L	M	B	L	L	L	B	89	M	M	B	L	L	L	M	153	B	M	B	L	L	L	B
26	L	M	B	B	M	L	B	90	M	M	B	L	L	L	M	154	B	M	B	M	L	L	B
27	L	M	B	B	B	L	B	91	M	M	B	B	L	L	M	155	B	M	B	B	L	L	B
28	L	M	B	B	VB	L	M	92	M	M	B	VB	L	L	M	156	B	M	B	VB	L	L	B
29	L	M	VB	L	L	L	B	93	M	M	VB	L	L	L	M	157	B	M	VB	L	L	L	B
30	L	M	VB	M	L	L	M	94	M	M	VB	B	L	L	M	158	B	M	VB	M	L	L	B
31	L	M	VB	B	L	L	M	95	M	M	VB	B	L	L	M	159	B	M	VB	B	L	L	B
32	L	M	M	VB	VB	L	M	96	M	M	M	VB	L	L	M	160	B	M	M	VB	L	L	B
33	L	B	L	L	L	L	B	97	M	B	L	L	L	L	VB	161	B	B	L	L	L	L	B
34	L	B	L	L	M	L	B	98	M	B	L	L	M	L	M	162	B	B	L	L	L	L	B
35	L	B	L	L	B	L	B	99	M	B	L	M	B	L	M	163	B	B	L	B	L	L	B
36	L	B	L	L	VB	L	VB	100	M	B	L	VB	L	L	M	164	B	B	L	VB	L	L	B
37	L	B	M	L	L	L	B	101	M	B	M	L	L	L	B	165	B	B	M	L	L	L	B
38	L	B	M	M	L	L	B	102	M	B	M	M	L	L	M	166	B	B	M	M	L	L	B
39	L	B	M	M	B	L	VB	103	M	B	M	M	B	L	M	167	B	B	M	M	L	L	B
40	L	B	M	M	VB	L	VB	104	M	B	M	VB	L	L	M	168	B	B	M	VB	L	L	B
41	L	B	B	L	L	L	VB	105	M	B	B	L	L	L	B	169	B	B	B	L	L	L	B
42	L	B	B	B	L	L	VB	106	M	B	B	L	M	L	M	170	B	B	B	M	L	L	B
43	L	B	B	B	B	L	VB	107	M	B	B	B	VB	L	L	171	B	B	B	B	L	L	B
44	L	B	B	B	VB	L	VB	108	M	B	B	VB	L	L	M	172	B	B	B	VB	L	L	B
45	L	B	VB	L	L	L	VB	109	M	B	VB	L	L	L	M	173	B	B	VB	L	L	L	B
46	L	B	VB	M	L	L	VB	110	M	B	VB	M	L	L	M	174	B	B	VB	M	L	L	B
47	L	B	VB	B	L	L	VB	111	M	B	VB	B	L	L	M	175	B	B	VB	B	L	L	B
48	L	B	VB	VB	VB	L	VB	112	M	B	VB	VB	L	L	M	176	B	B	VB	VB	L	L	B
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51	L	VB	L	B	L	L	VB	115	M	VB	L	B	L	L	M	179	B	VB	L	B	L	VB	B
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55	L	VB	B	L	B	L	B	119	M	VB	M	B	L	L	M	183	B	VB	M	B	L	L	B
56	L	VB	M	VB	L	L	B	120	M	VB	M	VB	L	L	M	184	B	VB	M	VB	L	L	B
57	L	VB	B	L	L	L	VB	121	M	VB	B	L	L	L	M	185	B	VB	B	L	L	L	B
58	L	VB	B	M	L	L	B	122	M	VB	B	M	L	L	M	186	B	VB	B	M	L	L	B
59	L	VB	B	B	L	L	B	123	M	VB	B	M	L	L	M	187	B	VB	B	M	L	L	B
60	L	VB	B	VB	L	L	B	124	M	VB	B	VB	L	L	M	188	B	VB	B	VB	L	L	B
61	L	VB	VB	L	L	L	VB	125	M	VB	VB	M	L	L	M	189	B	VB	VB	L	L	L	B
62	L	VB	VB	B	L	L	B	126	M	VB	VB	M	L	L	M	190	B	VB	VB	B	L	L	B
63	L	VB	VB	VB	L	L	B	127	M	VB	VB	M	B	L	M	191	B	VB	VB	B	L	L	B
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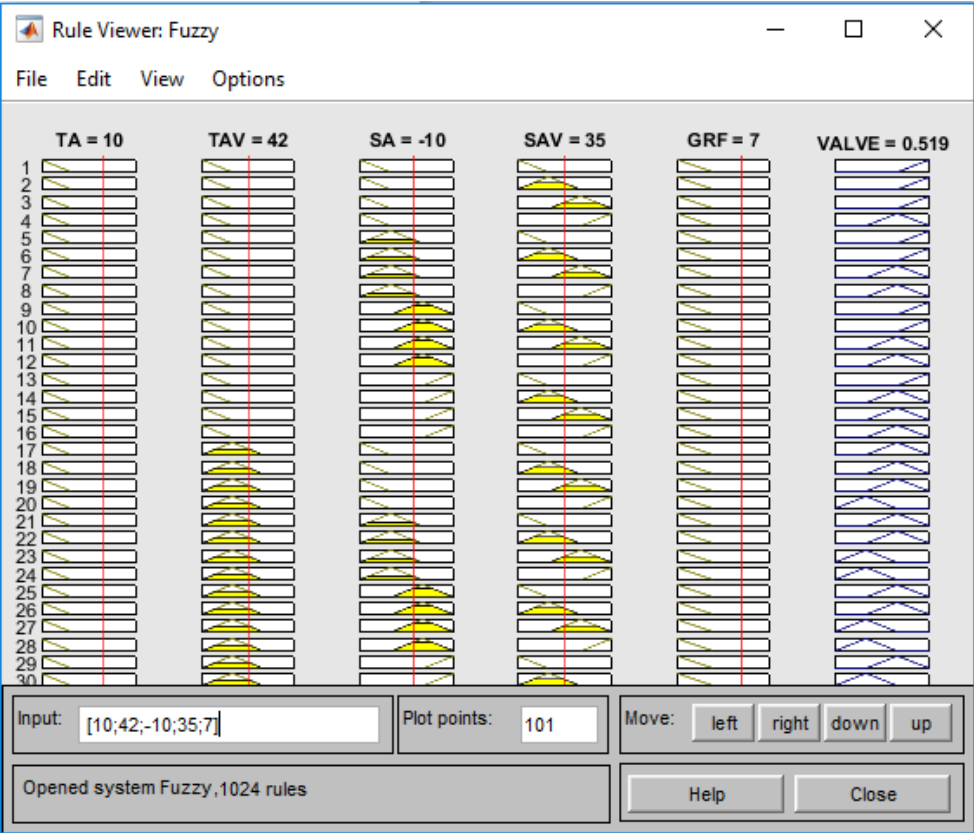
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257	L	L	L	L	M	VB	321	M	L	M	M	VB	385	B	L	L	M	VB
258	L	L	L	L	M	VB	322	M	L	M	M	VB	386	B	L	L	M	VB
259	L	L	L	L	M	VB	323	M	L	M	M	VB	387	B	L	L	M	VB
260	L	L	L	VB	M	B	324	M	L	VB	M	B	388	B	L	VB	M	B
261	L	L	M	L	M	VB	325	M	L	M	M	B	389	B	L	M	M	B
262	L	L	M	M	M	VB	326	M	L	M	M	B	390	B	L	M	M	B
263	L	L	M	B	M	VB	327	M	L	M	B	B	391	B	L	M	B	B
264	L	L	M	VB	M	B	328	M	L	M	VB	M	392	B	L	M	VB	M
265	L	L	B	L	M	VB	329	M	L	B	L	M	393	B	L	B	L	M
266	L	L	B	B	M	VB	330	M	L	B	M	B	394	B	L	B	B	B
267	L	L	B	B	M	VB	331	M	L	B	B	M	395	B	L	B	B	M
268	L	L	B	VB	M	B	332	M	L	B	VB	M	396	B	L	B	VB	M
269	L	L	VB	L	M	VB	333	M	L	VB	L	M	397	B	L	VB	L	M
270	L	L	VB	B	M	VB	334	M	L	VB	M	B	398	B	L	VB	M	B
271	L	L	VB	VB	M	B	335	M	L	VB	M	M	399	B	L	VB	M	B
272	L	L	VB	VB	M	B	336	M	L	VB	VB	M	400	B	L	VB	VB	M
273	L	M	L	L	M	VB	337	M	M	L	L	M	401	B	M	L	L	M
274	L	M	L	B	M	B	338	M	M	L	B	M	402	B	M	L	B	M
275	L	M	L	B	M	B	339	M	M	L	B	M	403	B	M	L	B	M
276	L	M	L	VB	M	B	340	M	M	L	VB	M	404	B	M	L	VB	M
277	L	M	M	L	M	VB	341	M	M	M	L	M	405	B	M	M	L	M
278	L	M	M	M	M	B	342	M	M	M	M	B	406	B	M	M	M	M
279	L	M	M	M	M	B	343	M	M	M	M	B	407	B	M	M	M	M
280	L	M	M	VB	M	B	344	M	M	M	VB	M	408	B	M	M	VB	M
281	L	M	B	L	M	VB	345	M	M	B	L	M	409	B	M	B	L	M
282	L	M	B	M	M	B	346	M	M	B	M	B	410	B	M	B	M	M
283	L	M	B	B	M	B	347	M	M	B	B	B	411	B	M	B	B	M
284	L	M	B	VB	M	B	348	M	M	B	VB	M	412	B	M	B	VB	M
285	L	M	M	VB	L	M	349	M	M	VB	L	M	413	B	M	VB	L	M
286	L	M	M	VB	M	B	350	M	M	VB	M	M	414	B	M	VB	M	M
287	L	M	M	VB	B	B	351	M	M	VB	B	M	415	B	M	VB	B	M
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290	L	B	L	L	M	VB	354	M	B	L	M	M	418	B	B	L	M	M
291	L	B	L	B	M	VB	355	M	B	L	B	M	419	B	B	L	B	M
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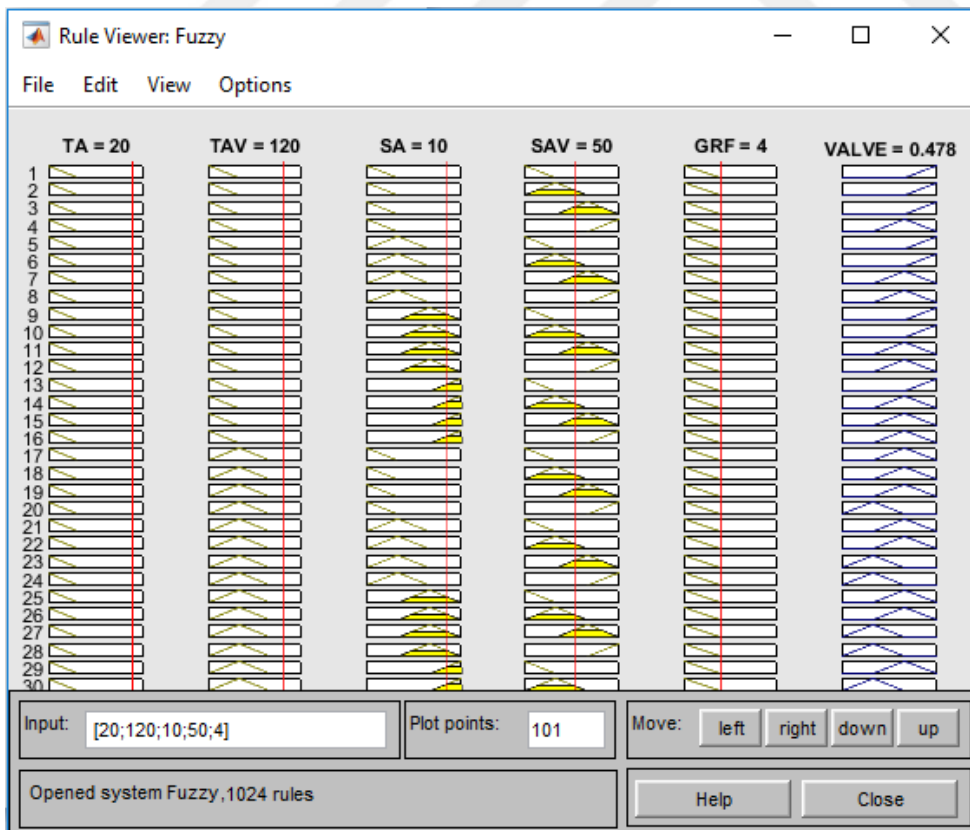
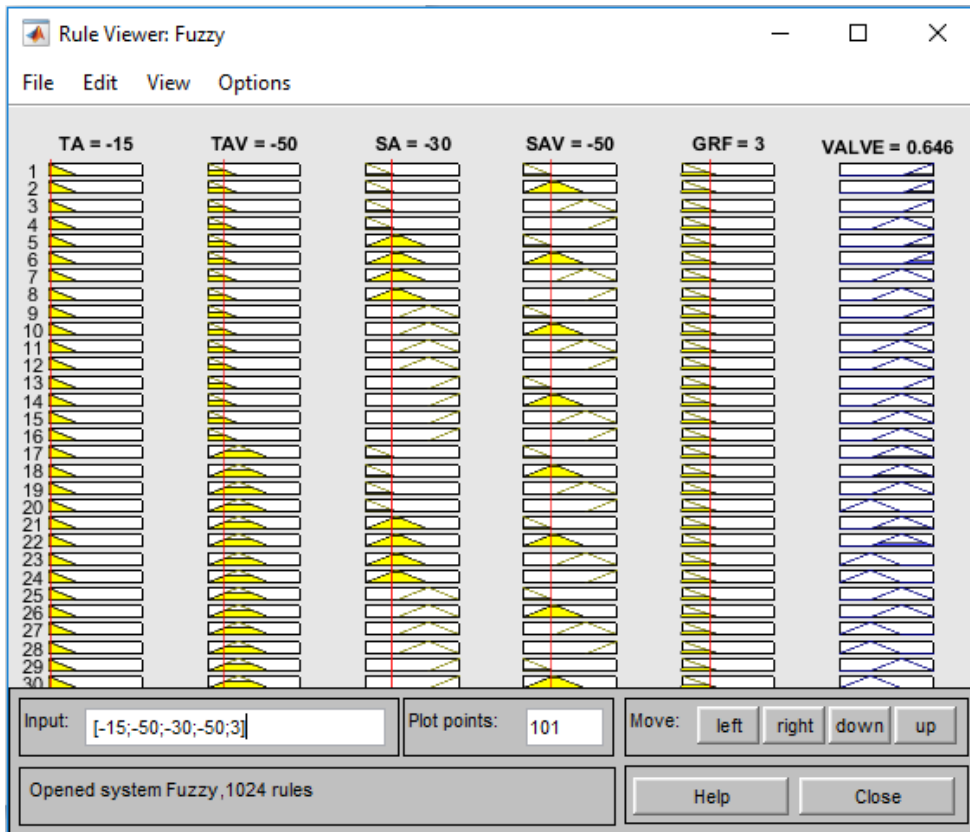
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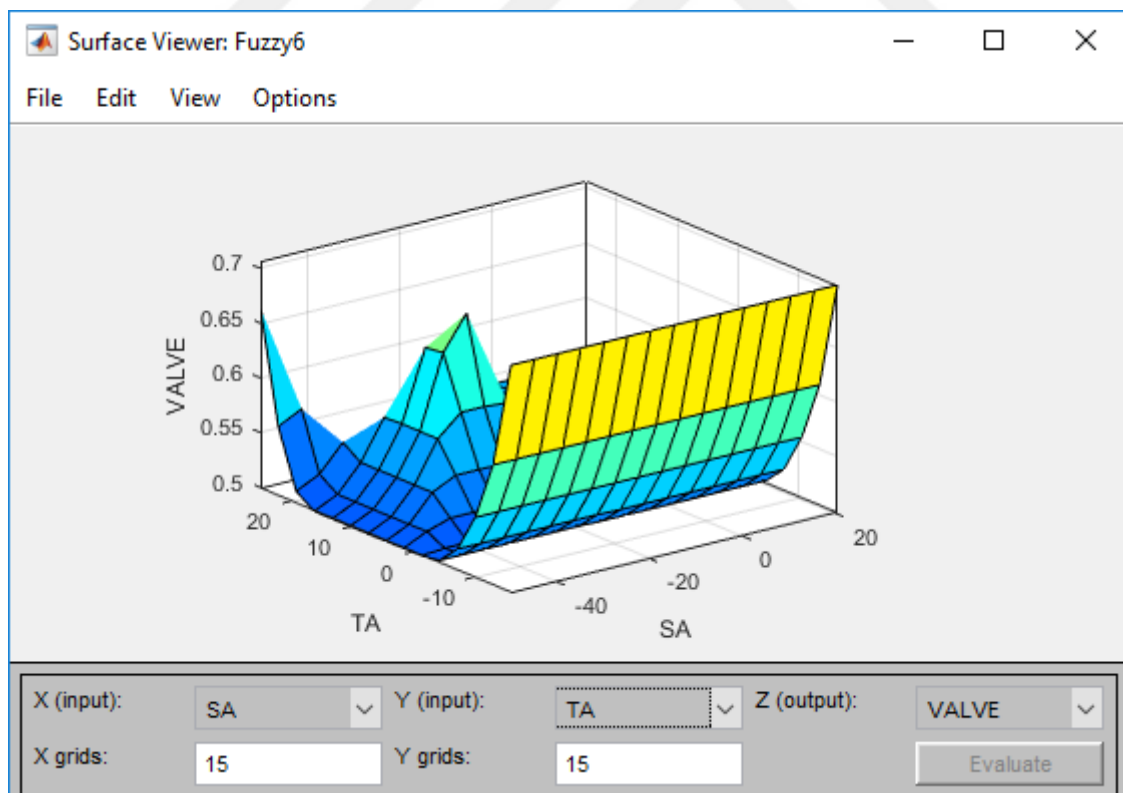
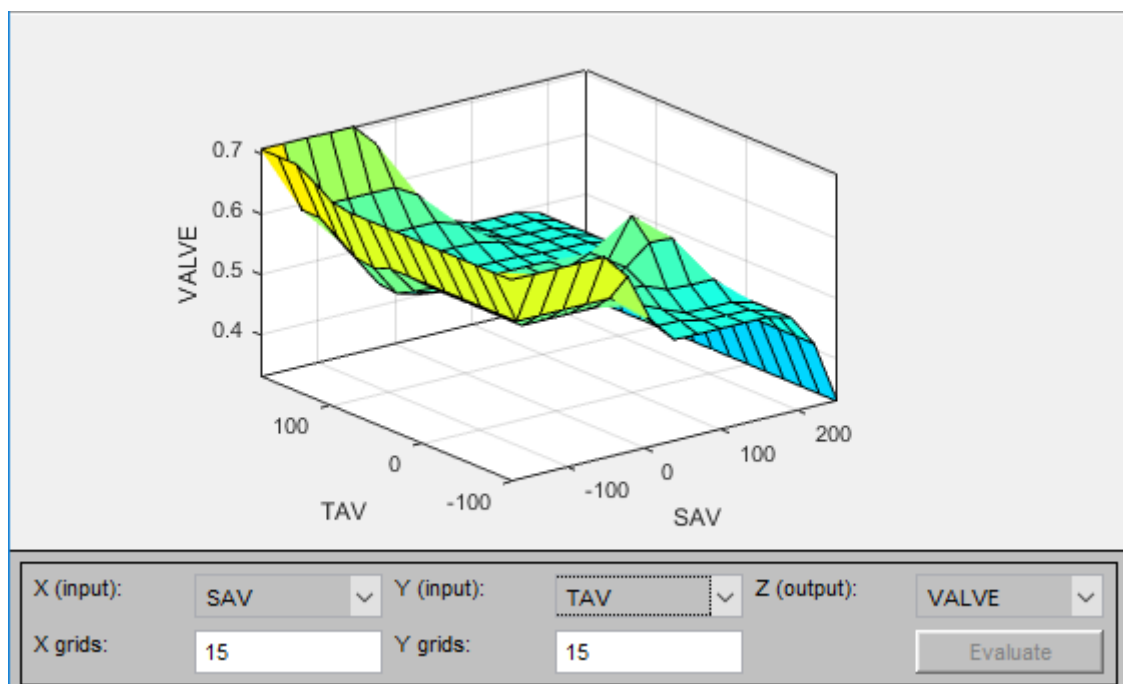


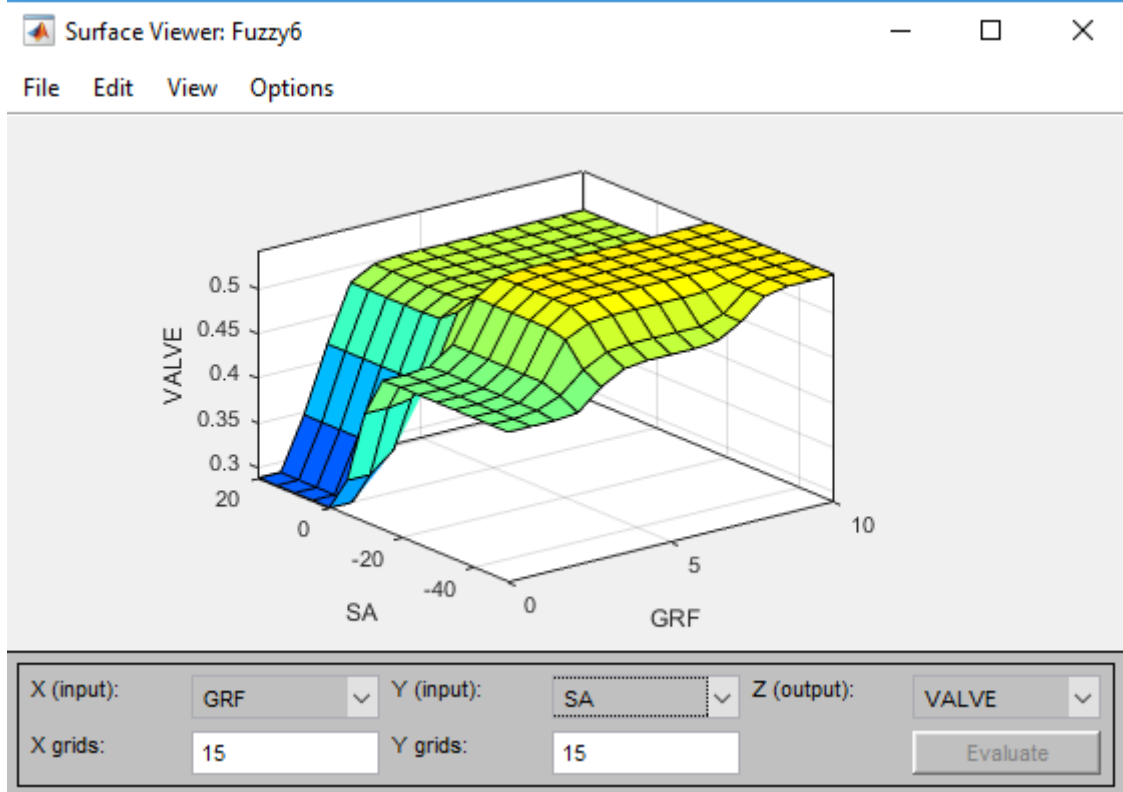
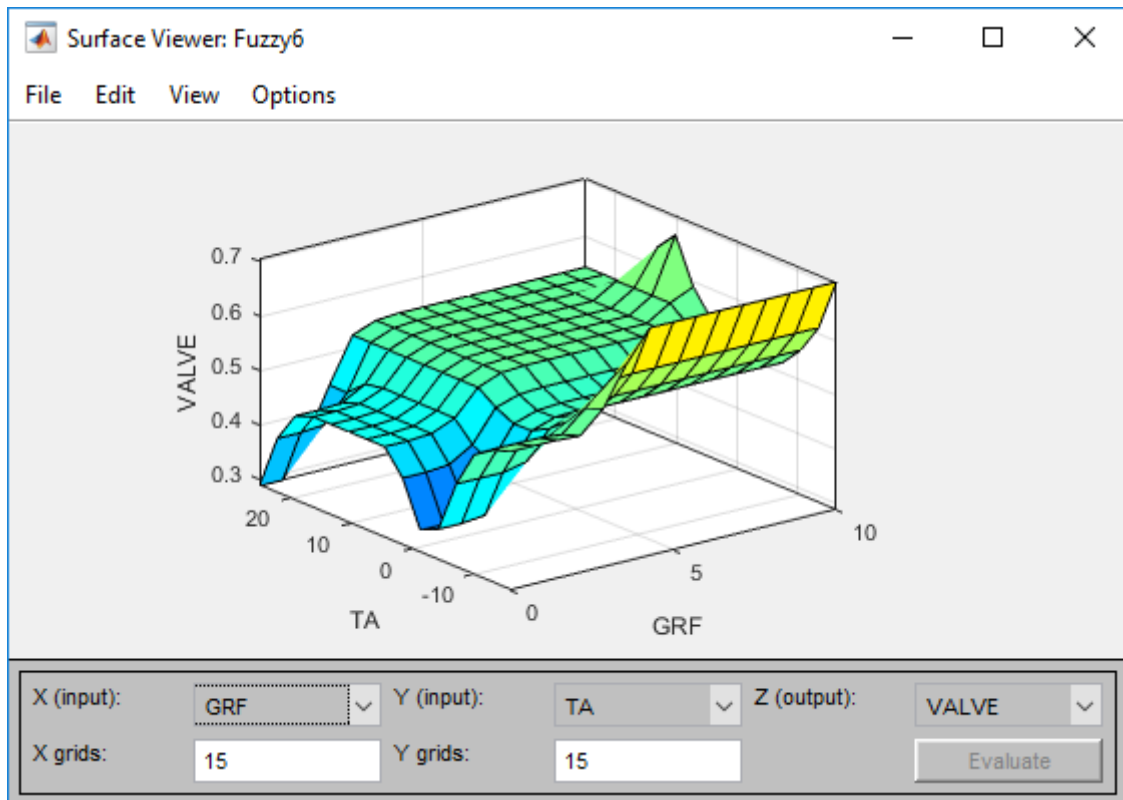
APPENDIX D





APPENDIX E





CURRICULUM VITAE

1. **Name** : SERMET DEMİR
2. **Date of Birth** : 18 04 1987
3. **Academic Title** : Instructor
4. **Education** : Phd (Cont.)
5. **Institution** : DOĞUŞ UNIVERSITY

Degree	Program	University	Date
BA / BS	Mechanical Engineering	Marmara University	2009
MA/MS/MBA	Mechanical Engineering	Marmara University	2012
Ph.D.	Mechanical Engineering	Marmara University	Cont.

5. **Academic Titles**

Assistant Professor	:	
Associate Professor	:	
Full Professor	:	
6. **Theses Supervised**
 - 6.1. M.A. /MBA/MS Theses
 - 6.2. Ph.D. Theses
7. **Publications**
 - 7.1. Articles published in SCI, SSCI, AHCI journals
S. Demir, B. Ekici, Optimization of design parameters for Turkish Tirkeş (war) bow, November 2014 Composites Part B Engineering 66:147–155
 - 7.2. Articles published in other international indexed journals
 - 7.3. Proceedings (International)
A. Kentli, S. Demir, B. Ekici, Design and shape optimization of a Turkish Tirkeş bow, September 2011 Conference: BALCOR 2011, International Symposium and Balkan Conference on Operational ResearchAt: Thessaloniki, Greece Volume: 2
S. Demir, B. Ekici, An Efficient Path Planning Strategy for a Snake Robot, IMS 2010 Bosna.
 - 7.4. Books or chapters in books (International)
 - 7.5. Articles published in national refereed journals
 - 7.6. Proceedings (national)
 - 7.7. Other publications
8. **Projects**
Sanayi Bakanlığı Tekno Girişim Sermayesi / Duyarlı Uzun Yürüme Cihazı
9. **Administrative Responsibilities**
Summer practice and graduation commission
10. **Membership for academic or professional organizations**
11. **Awards**
12. **Undergraduate and graduate courses taught in the last two years (including the summer school program)**

Academic Year	Semester	Course Title	Teaching Hours (Weekly)		Number of Students	
			Theory	Practice		
2017 - 2018	Fall	ME 103 Computer Aided Engineering Graphics / 2 sections	2	2	120	
		MM 103 Bilgisayar Destekli Mühendislik Çizimi	2	2	60	
	Spring	MM 103 Bilgisayar Destekli Mühendislik Çizimi	2	2	85	
		EM 222 İmalat Teknolojisi	3	0	60	
		IE 222 Manufacturing Technology	3	0	70	
2016 - 2017	Fall	ME 103 Computer Aided Engineering Graphics / 3 sections	2	2	180	
		MM 103 Bilgisayar Destekli Mühendislik Çizimi	2	2	60	
	Spring	EM 222 İmalat Teknolojisi	3	0	100	
		IE 222 Manufacturing Technology	3	0	70	
		MM 103 Bilgisayar Destekli Mühendislik Çizimi	2	2	60	
		ME 103 Computer Aided Engineering Graphics	2	2	60	
		ME 264 Termodinamik	3	1	70	
	Summer	MM 351 Akışkanlar Mekaniği	3	1	20	
		MM 352 Isı İletimi	3	1	25	