

**REPUBLIC OF TURKEY  
HACETTEPE UNIVERSITY  
INSTITUTE OF HEALTH SCIENCES**

**THE EFFECT OF SEGMENTAL WEIGHT OF PROSTHESIS ON  
HEMODYNAMIC RESPONSES OF LOWER EXTREMITY  
AMPUTEES**

**Dr. Mohammad Dawood KHAROOTY**

**Physical Therapy and Rehabilitation Program  
MASTER OF SCIENCE THESIS**

**ANKARA**

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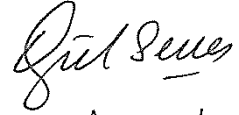
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#### APPROVAL

This thesis has been approved by the committee above in conformity of the regulations and by laws of Hacettepe University Graduate Programs and has been accepted by the Board of Directors of the Institutes of Health Sciences.



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## ABSTRACT

**Dr. Mohammad Dawood Kharooty. The effect of segmental weight of prosthesis on hemodynamic responses of lower extremity amputees. Hacettepe University, Institute of Health Sciences, Physical Therapy and Rehabilitation Program, Master Thesis, Ankara 2014.** The aim of this study was to determine the effect of segmental weight of prosthetic on hemodynamic Responses of lower extremity amputees. Thirteen patients with unilateral transtibial, transfemoral and syme's amputation who were referred to Prosthetics and Orthotics Unit of Physiotherapy and Rehabilitation Department, Hacettepe University were included to the study. The difference between the lightest and the heaviest prosthesis used as the weight and it was 250 gr. All the patients completed the measurements first without weight and then with 250 gr weight on the ankle joint. The blood pressure and pulse rate of the patients were recorded before and after Six Minute Walk Test (6MWT) and 10 Steps up and down stairs test. Paired T- test was used to analyze the comparison of before and after test data. Mean age of the patients were  $44 \pm 15.84$  years (min: 18-max: 65 years), 9 of patients were man and 4 were woman. Paired-samples T tests were used for before and after analysis of the data. No significant difference was found in blood pressure before and after (6MWT) and 10 Steps up and down test with weight and without weight ( $p > 0.05$ ). Although pulse rate increased significantly, it showed statistical significance ( $p < 0.05$ ). Our results indicated that segmental weight of prosthesis does not have significant effect on the blood pressure but have effect on the heart rate of lower extremity amputees in this study. In order to generalize our results to lower limb amputees, more patients are needed to be included.

Key words: Amputation, Prosthesis, Blood pressure, Heart rate, Six minute walk test, Ten steps up and down stairs climb test.

## ÖZET

**Muhammad Dawood Kharooty. Alt ekstremite amputelerde protez segmental ağırlığın hemodinamik yanıtlar üzere etkisi. Hacettepe Üniversitesi, Sağlık Bilimleri Enstitüsü, Fizik Tedavi ve Rehabilitasyon Programı, Yüksek Lisans Tezi, Ankara 2014.** Bu çalışmanın amacı, alt ekstremite amputelerinde protezin segmental ağırlığının hemodinamik cevapları etkileyip etkilemediğini belirlemektir. Çalışmaya, Hacettepe Üniversitesi, Fizyoterapi ve Rehabilitasyon Bölümü, Protez–Ortez Ünitesine başvuran, toplam 13 unilateral transtibial, transfemoral ve syme amputasyonlu hasta dahil edildi. En hafif ve en ağır protezler arasındaki fark 250 gram olarak saptandı. Tüm hastalar, ölçümleri önce ağırlıksız ve daha sonra ayak bileklerine takılan 250 gramlık ağırlıkla tamamladılar. 6 dakika yürüme testi ve 10 merdiven inip çıkma testlerinden önce ve sonra kan basıncı ölçümü ve nabız ölçümleri kayıt edildi. Ölçüm öncesi ve sonrası karşılaştırmaların veri analizi, paired T- test kullanılarak analiz edildi. Hastaların ortalama yaşları  $44 \pm 15.84$  yılı (min: 18-mak: 65 yıl), hastalardan 9’ü erkek, 4’ü kadındı. Ağırlıklı ve ağırlıksız olarak gerçekleştirilen 6 dakika yürüme testi ve 10 merdiven inip çıkma testlerinin öncesi ve sonrasında kan basıncında anlamlı bir fark bulunmadı ( $p > 0.05$ ). Nabız sayısında istatistiksel anlamlı bir fark vardı ( $p < 0.05$ ). Sonuçlarımız, bu çalışmada alt ekstremite amputelerinde protezin segmental ağırlığının kan basıncı üzerinde etkisi olmadığını göstermiştir. Ancak protezin segmental ağırlığı alt ekstremite ampute kalp hızı üzerinde etkisi vardır. Sonuçların alt ekstremite amputelerine genellenebilmesi için daha fazla vakanın dahil edilmesi gereklidir.

Anahtar kelimler: Amputasyon, protez, kanbasıncı, kalp hızı, 6 dakika yürüme testi, 10 merdiven inip çıkma testi.

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## SYMBOLS AND ABBREVIATIONS

%	percent
±	Plus minus
2MWT	Two minute walk test
6MWT	Six minute walk test
ABI	Ankle-brachial index
ACA	Axillary crutches ambulation
BP	Blood pressure
BTFA	Bilateral Transfemoral amputation
BTTA	Bilateral Transtibial amputation
CAD	Computer-aided design
CAM	Computer-aided manufacture
CM	Centimeter
COPD	Congestive Obstructive Pulmonary Disease
DBP	Diastolic blood pressure
EMG	Electromyography
ESR	Energy storing and returning
GRF	Ground reaction force
HR	Heart rate
KG	Kilogram
LLA	Lower limb amputation
m	meter
n	number
NAL	Non amputated limb
OA	Osteoarthritis
PCI	Physiological Cost Index
PL	Prosthetic limb
PTB	Patella tendon bearing
ROM	Range of motion
SACH	Solid ankle cushioned heel foot
SCPT	Stair climb power test
SD	Standard Deviation

SPO	Oxygen saturation
SSWs	Self-selected walking speed
TFA	Transfemoral amputation
TKR	Total knee replacement
TTA	Transtibial amputation
VO2	Volume of Oxygen uptake

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## 1. INTRODUCTION

Amputation is the surgical removal of an external part of the body, most often a limb or part of it, as a form of treatment. The aim of amputation is to save the patient's life and or reduce debility (1). Impact amputation is a commonly performed procedure during natural disasters and mass casualties related to industrial accidents and military conflicts where large civilian populations are subjected to severe musculoskeletal trauma. Crush injuries and crush syndrome, an often-overwhelming number of casualties, delayed presentations, regional cultural and other factors, all can mandate a surgical approach to amputation that is different than that typically used under non-disaster conditions (2). Amputation of the lower extremity can have a major impact on the health and quality of life of the recipient. Amputation is surgery that not only requires additional funds for rehabilitation, but also prosthetic creation, management, and maintenance (3). Most amputations (80%) carried out to treat the complications of vascular peripheral diseases (4). Causes of amputation vary between and within countries, depending on ethnic background and socio-economic status. In sub-Saharan Africa, tumors and trauma are often reported to be the leading causes. With increasing incidence of cardiovascular risk factors, most common causes of amputation (35.7%), followed by congenital defects (20%), dysvascular causes (17.1%), infection (14.3%) and tumors (12.8%). The trauma cases, road traffic accidents (RTA) constituted 29%, burns 24% and falls 22% (5). In estimated 1.5 million Americans are living with a lost limb, 54% as a result of complication due to peripheral vascular diseases, two third had diabetes mellitus, high blood pressure (6). The causes of amputation could be congenital defect, vascular, trauma, infection, tumors and other cases are divided into 3 groups: diabetes, arterial embolism and chronic vascular diseases (7). Approximately 50% of all lower extremity amputations are performed secondary to complications from Diabetes Mellitus (8). Amputees require a prosthetic foot. The prescription criteria for these feet take into consideration the amputation level, residual limb length, subject activity level, cosmetic needs, and the weight of the individual. The physiotherapist and technicians give information about the prosthesis to patients which are suitable for the amputees. The most basic artificial feet are SACH, dynamic foot, classic foot, c-walk and spring lite (9, 10, 11, 12). The aim of prosthesis is to mimic the function of biological system. In case of the human lower limb (13). Most prosthetic

feet are designed to improve amputee gait by storing and releasing elastic energy during stance. However, how prosthetic foot stiffness influences muscle and foot function is unclear. Identifying these relationships would provide quantitative rationale for prosthetic foot prescription that may lead to improve amputee gait (14). The fit between residual lower limb and prosthesis is a key determinant for successful ambulation. A well-fit prosthesis provides a comfortable and functional limb, allowing pursuit of many vocational and recreational interests (15).

Biomedical engineers have also been involved in the development of computer-aided design (CAD) and computer-aided manufacture (CAM) of these limbs. Future opportunities for biomedical engineers include continued development and incorporation of strong, lightweight materials in lower extremity prosthetic limbs, high-technology prosthetic components that improve lower extremity amputee performance and prosthetic sockets and interface materials that minimize risk of dermatological breakdown of residual limb tissues. Additional opportunities involve the enhancement of CAD-CAM systems and technology, assessment of lower extremity prosthetic fit, evaluation of lower extremity amputee function and development of sensors and technology to more reliably produce comfortable sockets and optimally align prostheses (16).

The effects of prosthesis on the hemodynamic responses of the amputees are different. In the patients who have COPD when they use the lower limb prosthesis they need for more oxygen and energy. The energy required for ambulation in trans-tibial amputation is about 40-60% above normal. This energy demand becomes even higher when patients have COPD and additional significant co morbidities (17). Normal walking speed and cadence decreased and oxygen consumption per meter walked increased with more proximal amputation. The ratio of cardiac function and oxygen consumption at normal walking speed as compared with at rest increased with more proximal amputation, and the capacity to increase walking speed and oxygen consumption lessened. Peripheral vascular insufficiency amputees function at a level approaching their maximum functional capacity. At more proximal amputation levels, the capacity to walk short or long distances is greatly impaired (18). Energy expenditure as measured by oxygen consumption rate is important for amputees. The energy cost of ambulation is greater for amputees than for no amputees (19). Exercises

have effect on the heart rate of prosthetic patients. Blood circulation responses to wheelchair ergometry exercise training. A marked increase of heart rate in all groups with disabilities (regardless of the level of amputation) (20).

Amputees expend more energy per unit distance traveled than do their non-amputee counterparts walking at similar speeds. Therefore the burden on the cardio-respiratory system of amputees can be expected to be considerably high (21).

Research in people with non-pathological gait and persons with transtibial amputation has shown curvilinear relationships between energy cost and increasing walking speed. However, the energy cost is higher in persons with transtibial amputation at the same walking speed. People with transtibial amputation spent 33% more energy walking at 50 m/min than people with non-pathological gait (21, 22).

There are many physical factors that regulate prosthetic walking capacity. One of the most important factors is physical fitness in relation to the increased energy consumption when walking with prosthesis. Movement capabilities depend to a large extent on the physical fitness of the subject. Individual physical exercise capacity may be another important factor affecting the physiological responses of transtibial amputee gait. Aerobic exercise training in persons with lower extremity amputation is effective in improving cardiovascular fitness and in decreasing the energy cost of walking (21, 22, 23).

Gait deviations in individuals with TTA can include decreased walking velocity and increased inter limb asymmetries in step length, swing time, stance time, and joint mechanics. According to the different level of amputation showed minimal differences in oxygen consumption (0–5% reduction), heart rate response (0–1% reduction), or gait efficiency (0–5% improvement) across all speeds when compared with Syme's prosthesis (both with SACH foot). However, the SSWV was 6–8% faster for the transtibial SACH foot. Walking with transtibial Flex-Foot required less cardiovascular demand than with transtibial SACH foot at higher speeds (24, 25). The energy cost necessary for the motion (for the thigh muscles) was greater in the case of the amputees. This is a consequence of the higher forces that the muscles in the posterior group are required to generate (26). There is no empirical formula or standardization to decide the weight of prosthesis for an Amputee. Increased energy cost and decreased gait efficiency of walking has been a concern for persons with

lower extremity amputation (27). The consumed energy mean (kilocalorie) in the amputee group throughout the walking time on the treadmill was 6 percent higher than the healthy group. Also in the amputee group, the heart rate mean was 5.5 percent and the PCI mean was 13 percent higher than those of the healthy. Claimed that the oxygen cost that is the consumed oxygen volume per the covered distance in the transfemoral amputees is 28-33 percent higher than that of the normal (28). The relationship between walking speed and oxygen uptake in all cases oxygen uptake increased with increasing walking speed (29).

Knowing that energy consumption increase with speed of gait, we can conclude that walking with a prosthesis is quite energy consuming and that the transfemoral amputees use a higher proportion of their maximal aerobic capacity at a lower speed of gait compared to non-amputees during ordinary walking on a horizontal walking surface (30). Transtibial amputees have a much symmetrical gait pattern and more proficient gait with the added mass to prosthesis. For heart rate, energy expenditure and energy expenditure per minute per velocity showed linear increase as the weight of the prosthesis increased. It was expected that if weight of the transtibial prosthesis change, the gait changes, the step length and stride length would have changed considerably, because it is known to be a sensitive variable for evaluating an amputee's gait (31). When mass is added to prosthetic limb, the metabolic rate is increased. Significant difference in energy expenditure has obtained when steel components were replaced with titanium (32, 33). One of the main reasons for this is that energy consumption during prosthetic walking increases when the amputation level becomes more proximal (34). Gait assessment in lower extremities amputees, the functional assessment of the amputated patient is of great importance, as the main rehabilitation goals in this group of individuals are mobility and independence (35). The efficiency of prosthetic gait can be described in terms of energy cost (also known as metabolic cost or oxygen cost), which describes the metabolic consequences of walking in relation to the distance travelled.

The golden standard for the assessment is to perform direct measurements of the volume of oxygen uptake ( $VO_2$ ) and express the cost as  $VO_2$  per unit of distance walked. In normal walking, the highest efficiency exists when walking at CWS for persons with a TFA socket prosthesis, the energy cost has been shown to increase by



40-67% compared with the normal uptake of VO<sub>2</sub> is a cumbersome method which requires advanced equipment, limiting the assessment to being primarily performed within small groups and in a laboratory setting. Another, simpler method for estimating the energy cost based on the registration of heart rate is the physiological Cost Index (PCI) (36). Human gait is forward progression, which is achieved using the limbs. It can describe many functional movement patterns including swimming and cycling. However, it is generally used for classification of ambulation of which different limb movement patterns define the type of gait used (37).

The effect of different weights of modular prosthetic components (steel and titanium) on the gait of transtibial amputees has different results. When the steel prosthesis is replaced by titanium, no statistically significant change was seen titanium and steel trials in kinematic parameters, likely because differences in weight were not large enough (38). In PCI (physical cost index) the changes are observed in heart rate and speed walking. TTAs with relatively light prostheses (less than or equal to 2.27 kg) showed mean resting heart rate, walking heart rate, speed of walking. It appears that prosthetic weight at the level of approximately 180 g does not systematically influence the kinetics and kinematics of TTA gait over a short time. However, the PCI was shown to be significantly reduced with lighter components within a 5-minute walk (38). The prostheses looked upon in this work are devices which replace body parts after amputation, the severance of a limb, or part of a limb, from the rest of the body. The term transtibial implies that the limb in this case is the lower leg, and that the amputation happened between the knee and the ankle. The tibia is the largest bone in the lower leg, connecting to the thigh bone at the knee joint and to the ankle joint at its other end (39).

The following hypotheses were formed for this research study.

A1: The segmental weight changes of prosthesis have effect on the hemodynamic responses of the lower limb amputees.

B1: When the segmental weight is increased the hemodynamic responses of lower limb amputees are increased.

The alternative null hypotheses were set accordingly:

A0: The segmental weight changes of prosthesis have no effect on the hemodynamic responses of the lower limb amputees.

B0: When the segmental weight increases the hemodynamic responses of lower limb amputees will not increase.

For this study it was decided to select 13 unilateral lower limb (TTA, TFA) subjects from the clients who were visited to Orthotic and Prosthetic Unit in Department of Physiotherapy and Rehabilitation of Hacettepe University. All the subjects were informed and trained about the tests which were related to this study. The duration of the study was between February 2014 to July 2014.

The aim of this study was to determine the effect of segmental weight of prosthesis on hemodynamic responses of lower extremity amputees.

## 2. GENERAL KNOWLEDGE

Prosthesis is an artificial device that replaces a missing body part, which may be lost through trauma, disease or congenital conditions (9, 39).



Figure 2.1. Modular prosthesis a-modular below knee prostheses, b-modular knee disarticulation prostheses, c-modular above knee prosthesis, d-modular hip disarticulation prosthesis (9, 38, 39, 40, 42)

### a. Prosthetic Devices

Prosthetic devices are designed to enable individuals with amputations to successfully return to functional and recreational activities. Many of these devices, particularly those for individuals with transtibial amputations (TTAs), do not fully mimic the physiologic function of unimpaired joints and are associated with gait deviations and functional limitations (39). Prosthetic systems require integration of a number of components. Many parts are available of the shelf, while others need to be custom made for each individual (39).

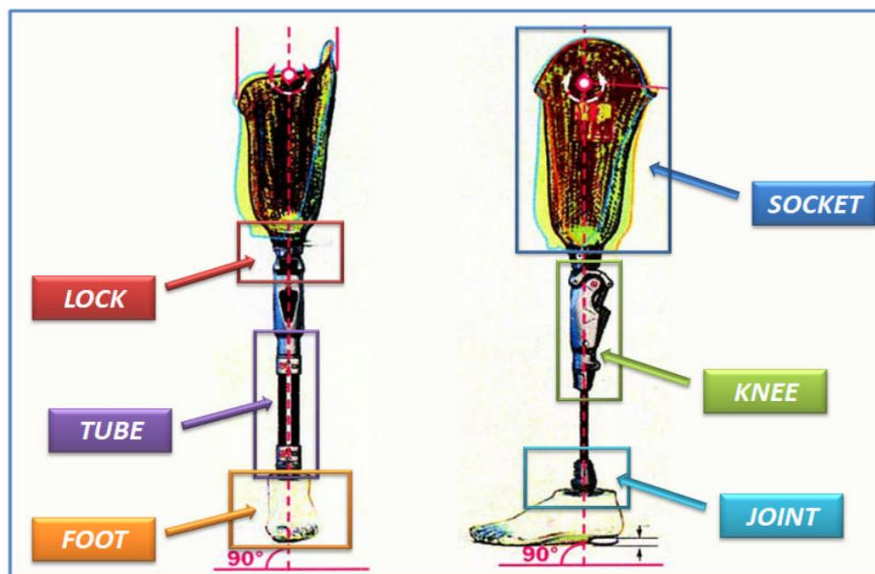


Figure2.2. lower extremity Prostheses (38)



Figure 2.3. Transfemoral prosthesis (40)

### b. Sockets

The socket is the component that contacts the residual limb. A sock is often worn over the residual limb to provide some cushioning and accommodation for fluctuation in its volume. There are two types of sockets, the patellar tendon bearing (PTB) and the total surface bearing (TSB). The principle of the PTB socket is to control pressure distribution between the socket and underlying anatomy. It is designed to load areas such as the patellar tendon, the medial flare, and the anterior side of the tibia, which can tolerate the pressure. Other parts of the limb remain unloaded or minimally

loaded (39). ATSB socket loads the entire surface of the residual limb varying the force distribution according to the different types of tissue rather than the underlying anatomy. In addition, a liner is usually worn over the residual limb. Liners provide an intermediate layer between the limb and socket to improve the pressure distribution and to reduce the tendency of the socket to move with respect to the underlying tissue (39).

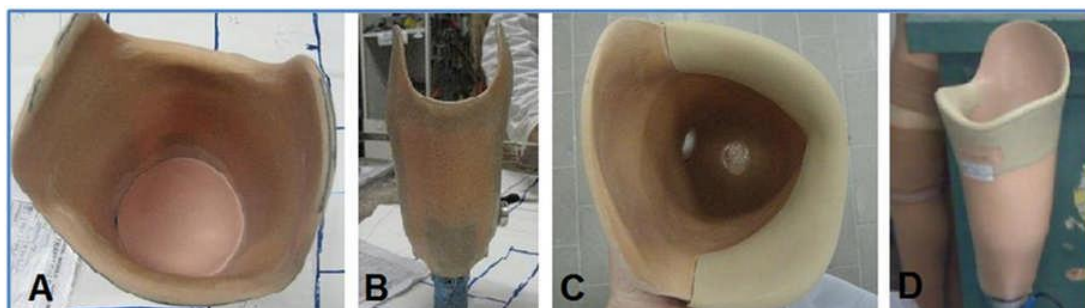


Figure 2.4. Top (A) and frontal (B) view of a definitive TSB socket; top (C) and frontal (D) view of a definitive CAT-CAM socket (38, 42)

### c. Suspension

Suspension systems are designed to keep the socket and, in turn the system securely attached to the residual limb. They are one aspect of the socket-limb interface that can affect an amputee's ability to have a smooth roll over during stance. There is also a strong correlation between the suspension and the overall comfort of the system. If the suspension system is not fitted correctly, it can place the knee in a position of too much flexion or it can lead to the knee being fully extended during heel strike. The latter can lead to skin break down. A number of suspension systems are available (39).

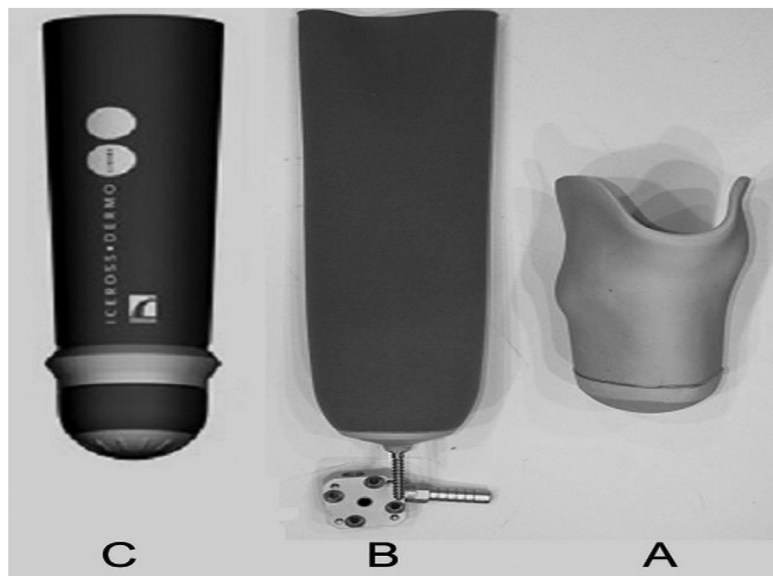


Figure 2.5. Three different suspension systems

- (A) Polyethylene foam liner
- (B) Silicone liner with shuttle lock and seal-in liner
- (C) seal-in liner (38, 42)

#### d. Prosthetic Feet

The stiff, structural part of a prosthetic foot is termed the keel. In single unit designs, the keel is incorporated into the rest of the foot. In other designs, the cover is a separate component into which the keel is inserted; this allows for the cover to be replaced when needed, while continuing to use the same keel. Prosthetic feet can generally be placed into one of four categories: conventional, single-axis, multi-axis and dynamic energy return (39).

#### e. SACH foot

Conventional feet are basic designs that have no moving components. The widely used solid ankle cushioned heel (SACH) foot, shown in Figure. SACH feet have a wooden or rigid plastic keel that extends until the toe section. Dense foam makes up the heel and the remainder of the foot is rubberized foam. Belting is attached to the end of the keel and extends into the toe region.



Figure 2.6. SACH foot (9)

#### f. Single –Axis foot

A single-axis foot has a hinge or other mechanism that allows the foot to plantar flexion and dorsiflexion, as shown in Figure. Single-axis feet were the first prostheses to provide ankle articulations. They typically consist of a keel, with an ankle joint and a molded foot shell. The keel has a plantar flexion bumper located in the heel behind the ankle joint. Some feet have a second dorsiflexion bumper anterior to the ankle. Feet that do not have this second bumper have a dorsiflexion stop. Similar to the SACH foot, belting is attached to the end of the keel and extends into the toes (40, 41).



Figure 2.7. the Niagara foot (single axis foot) (40)

#### g. Multi-axis foot

A typical multi-axis design, has a multi-directional hinge that allows for eversion and inversion as well as plantar and dorsiflexion. The Endolite Multiplex, a newer style of multi-axis foot shown in Figure, has a rubber ball inside the stem of the ankle assembly with an O-ring sitting just below it. This system allows for some rotation of the foot, in addition to eversion, inversion, plantar flexion and dorsiflexion (58, 59).

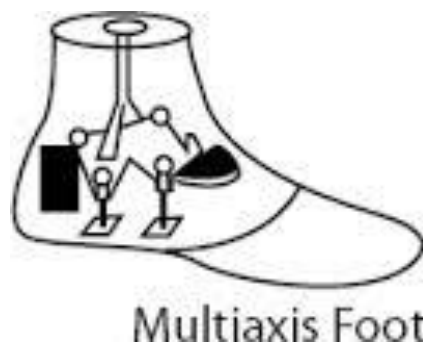


Figure 2.8. multiaxis foot (9, 40)

### **h- Dynamic Energy Return Foot**

There are dozens of different designs of DER feet. Some, like the Impulse shown in Figure, are composed of one unit. In the Impulse design the keel is incorporated in the rest of the foot, and it has a cushioned heel that behaves very similarly to a SACH foot on heel strike. Other feet like the Flex Foot have a keel and a separate cover.

The Niagara foot, is a single-axis DER foot (40, 41). It does not have a hinge or the bumpers normally associated with single-axis feet. Instead, movement of the C-section allows for ankle articulation and aids in propulsion of the limb. During heel loading, the gap between the horns and the top plate increases. Upon toe loading, the horns slide across the underside of the plate, causing the C-section to wind. The College Park Industries TruStep is a multi-axis DER foot. The split toe allows for eversion and inversion. Bumpers on the heel and midsection of the foot help to control dorsiflexion and plantar flexion. As the keel of a DER foot unloads, it provides a push off and helps to start the swing phase (49, 41). Dynamic response feet optimize the energy return during propulsion, but the values achieved are still below those seen among non-amputees (42).





Figure 2.9. Type of Dynamic Energy Return Foot (9, 42)

### **3. MATERIAL AND METHOD**

#### **3.1. Study location**

The study was performed in the Orthotic and Prosthetic Unit in Hacettepe University, Faculty of Health Sciences, Department of Physiotherapy and Rehabilitation.

#### **3.2. Study Design**

To cover all prospects of the research, case control study was selected. The participants of this study were patients who are referred to Prosthetics and Orthotics Unit of Physiotherapy and Rehabilitation Department, Faculty of Health Sciences, Hacettepe University for repairing their prosthesis or for new prosthesis and rehabilitation and lower limb amputees aged older than 18 years, lower than 65years and had cooperation in this study.

The independent variables of the study were age of participants, sex of participants, level of amputation, cause of amputation, age of amputation, time of 6mwt and the number of 10steps up and down stairs climbing test. The dependent variables in this study were the blood pressure, pulse rate (heart rate), walk distance during 6mwt and time stair climbing. The dependent variable blood pressure and pulse rate were recorded before and after six minute walk test and stair climbing test. These variables were recorded in two steps, one without weight and second with weight which was added to the prosthetic foot of amputees. The blood pressure of participants were recorded by sphygmomanometer, the pulse rate is counted by taking the radial pulse method. This method requires access to a clock or watch with the seconds indicated on it. The pulse rate measured by placing the index and middle fingers on the correct spot to feel the pulse, counted the number of beats for a certain number of seconds, then used simple math to calculate the beats per minute. All participants were healthy, they had not any chronic and acute heart disease, and COPD, diabetes, respiratory diseases, their stump and residual limbs were ok and had not any infection and skin problems.

All subjects have been informed about the study and their written consent to participate in the study was taken. Ethical committee of Hacettepe University has approved this study (6014/33.08.01.2014).

### **3.3. Subjects**

A total of 13 amputees with unilateral, transtibial and transfemoral amputation between 18 and 65 years of age who were able to walk and have no need for assessment recruited in this study.

The subjects, who were referred to Prosthetics and Orthotics Unit of Physiotherapy and Rehabilitation Department, Faculty of Health Sciences, Hacettepe University, were included and cooperation problems in this study. All subjects were lower limb amputees had normal blood pressure and heart rate. They had not any cardiac and pulmonary problems. All subjects were using the below knee modular prosthesis and there was no much difference in the weight. Only one patient was using the modular hip disarticulation prosthesis. Therefore, a total of 13 subjects were considered as participants of the study. Among them 9 (69.2%) were male and 4 (30.8%) were female. A number of inclusion and exclusion criteria were applied in selection of the subjects who were suitable for the study.

#### **Inclusion criteria**

Patients who were referred to Prosthetics and Orthotics Unit of Physiotherapy and Rehabilitation Department, Faculty of Health Science, Hacettepe University and lower limb amputees aged older than 18 years to 65years and have cooperation were included.

#### **Exclusion criteria**

Patients with following characteristics were excluded from the study.

Patient under 18years and above 65 years

Patients with hypertension

Bilateral lower limb amputees

Patients who were using the wheelchair and other assess instruments

Patients of COPD, and pulmonary diseases

Patients who have not cooperated

### **3.4 . Methods**

The following outline of methods, evaluations and procedures was appropriate and used for this study:

General information and medical background of the subjects

Observation

Blood pressure

Pulse rate (heart rate)

Functional Performance Tests

- Six minute walk test (6MWT)
- Stair climb test (10 step up and down stair climbing test)

Some devices and measurement tools were required for the purpose of this research study. The following devices were used in this study.

- Sphygmomanometer
- Stethoscope
- Stop watch
- Elastic straps
- Meter strip
- Chair
- External extra added weight
- Camera

#### **3.4.1. General evaluation**

General information and medical background of subjects were collected by means of interview. Personal information such as name, gender, age, height, weight, course and year of education were recorded. The questions were also asked about present medical conditions, and medications as well as present or the rehabilitation of

amputation and about the using of prosthesis. The age of amputation, level of amputation, the use of years of amputation were also obtained from the patients. Some questions were about their daily activities and jobs. Some questions were about their medical history, blood pressure, respiratory system.

### **3.4.2. Observation**

Observation was performed in sitting position, with attention paid to posture and presence of any abnormal signs. General observation is done carefully of all included subjects. The structure of the body, residual limb, the stamp, skin of limb and prostheses were observed. Before starting the study the blood pressure and heart rate of the subjects were obtained. The stair climbing test was applied on the subjects before study to determine that they were able to climb up and down on the stairs.

All of above tests of general evaluation were intended to check the presence of any possible problems and pathologies and to ensure that the subjects were healthy prior to inclusion to the study. In case of any serious complaints, the subject was excluded from the study. Totally one subject was excluded due to sever lower limb pain during walking.

### **3.4.3. Blood pressure**

Blood pressure of every subject was counted before and after 6mwt separately without weight and with weight. It was recorded in the patient follow-up form. The blood pressure of every subject recorded very carefully all the patients had the normal blood pressure. After recording the blood pressure the 6mwt was recommended for the subjects to perform the test. After test the blood pressure of every subject was checked and recorded in patient follow-up form. In the exact form the blood pressure was recorded before 10 steps stairs climb test without weight and with weight before and after. As show in the figure.



Figure 3.4.3. Blood pressure was recorded before and after 6mwt and 10 steps stairs climb test without weight (a).



Figure 3.4.3. Blood pressure was recorded before and after 6mwt and 10 steps stairs climb test (b).

### 3.4.4. Pulse rate

Pulse rate (heart rate) of all subjects were counted before and after 6mwt. The pulse rate is determined without weight and with weight .Normal heart rate is 60-90 beats/minute. The pulse rate was normal of every subject when it was recorded and the record was written in patient fallow up form. The pulse rate was also counted before and after 10 steps stairs climbing test and recorded in patient fallow up form. As shown in the figure.



Figure 3.4.4. Pulse rate was recorded before and after 6mwt and 10 steps stairs climb test without weight

### 3.4.5. Functional Performance Tests

#### 3.4.5.1. Six minute walk test (6MWT)

In this study the procedure for the 6MW test was based on published guidelines (44, 45). A 20 meter section of the indoor corridor was demarcated for this test. Most studies have used a 30-m corridor, but some have used 20- or 50-m corridors. A recent multicenter study found no significant effect of the length of straight courses ranging

from 50 to 164 ft, but patients walked farther on continuous (oval) tracks (mean 92 ft. farther) (61). The turnaround points were marked with a cone (such as an orange traffic cone). A starting line, which marked the beginning and end of each 60-m lap, was marked on the floor using brightly colored tape. The participant was instructed to walk as far as possible for six minutes, straight on demarcated corridor, pivoting to turn at the end of each lap. Timing commenced as the participant stepped over the start line. Standardized encouragement was given to the patient after each minute. The Participant was instructed to stop at six minutes or prior if they were unable to complete six minutes and to maintain their position whilst the assessor measured the final partial lap with a trundle wheel. The use of a walking aid and standing rests were permitted. One test was performed for each participant as we did not want fatigue from completing two 6mwt to undermine performance in the longer test. The patient had been appreciated and encouraged during walking test. If the participants reported that they were unable to continue the distance covered in the walking test, the test was terminated and repeated. At the end of test the patient was sat on the chair near the starting point the blood pressure and pulse rate (heart rate) were measured .The rest time had given to the individual for at least 10 minutes before the test started. After 10 minutes rest, the blood pressure and pulse rate were measured and the 250gram weight was added to the ankle of prosthetic limb of the individual and the test was repeated as like before but with added weight. At the end of 6mwt the distance which was performed by individual was measured by meter and recorded.





Figure 3.4.5.1. 6mwt without weight. Left transfemoral Amputee

### 3.4.5.2 . Stair climb test

Stair climb test is also used for lower limb amputees to improve their muscles, limbs and body function. Some people select 9 steps and some 10 to 12. We have selected ten steps stairs ascend and descend flights for the subjects. Blood pressure and pulse rate were counted before starting the test. All of 13 included subjects of our study have performed the ten steps up and down stairs climb test. Timing began on the signal to start and terminated when the participant returned with both feet to the ground level. First we asked the subjects to climb up on the stairs and come down without weight. When the subject has started to climb on the stairs we have started the stop watch and when the subject completed the ascend and descend trail we have stopped the timer and counted the time, blood pressure and heart rate were recorded. Ten minutes rest time was given to subjects, after ten minutes we have added 250gram weight to their prosthetic limb ankle joint. The blood pressure and heart rate of every subject were counted before starting the test we have started the stopwatch when the subject has started climbing on the stair. At the end of test the stop watch was closed and the time was collected.

The blood pressure and heart rate were counted and recorded in the patient follow-up form .There was a little difference in the time between without weight condition and with weight condition but statistically no difference was found.



Figure 3.4.5.2. Ten steps up and down stair climb test with weight, left transfemoral amputee

### 3.5. Statistical Analysis

To analyze the result of this study, SPSS version 18 was used. All demographic as well as dependent variables are presented by” mean value, “standard deviation – SD”, as “minimal” and “maximal values”. Demographical factors of subjects were compared. The dependent variables of this study 6mwt distance without weight and with weight, time of ten step stair test without weight and with weight, blood pressure of subjects and pulse rate of the subjects 6mwt and ten step stair up and down test without weight and with weight before and after were measured .The distance of 6mwt and time of ten step up and down stair test was compared without weight and with weight data collection. The same comparison was performed for the blood pressure and pulse rate (heart rate) before and after 6mwt and ten steps up and down stair climb test without weight and weight.

For statistical analysis of this study the” Paired-T test “was applied. Paired –T test is a parametrical test, showing t and p values. The homogeneity of all variables showed by Kolmogorov -Smirnov test which is non parametric test. The paired –T test was used because of homogeneity of parameters.

Analysis within depends variables was also performed for showing differences in variables without weight and with weight before and after 6mwt and ten step up and down stair climb test. Similarly the” paired –T test “was used for normal distributed data.

The significance level was set at level  $p= 0.05$ , with  $p= 0.01$  showing strong significance level.

## 4. RESULTS

### 4.1. Demographical data

A total of 13 subjects were considered as participants of the study. Among them 9 (69.2%) were male and 4 (30.8%) were female. 5 participants of this study were right transtibial amputees (38.5%). 6 participants were left transtibial amputees (46.2%) one participant was left transfemoral amputee (7.7%) and one participant was left syme's amputee (7.7%).

Table 4.1. Demographic characteristics of the patients

no	age	sex	diagnosis	causes	Amputation age (years)	Year of Prosthetic use
1	57	m	Right TTA	trauma	47	42
2	45	m	Right TTA	trauma	1	1
3	55	f	Left TTA	trauma	33	22
4	65	f	Right TTA	trauma	38	38
5	18	m	Right TTA	congenital	11	7
6	65	m	Left TTA	trauma	28	25
7	48	m	Right TTA	trauma	4	1
8	52	f	Left TTA	trauma	26	22
9	20	m	Left TFA	cancer	3	1
10	40	m	Left Syme's A	trauma	21	19
11	44	f	Left TTA	gong rain	7	6
12	22	m	Left TTA	congenital	19	18
13	41	m	Left TTA	trauma	1	1

The table has shown the number, age, sex, diagnosis causes, age of amputation and years of prosthetic use of participants.

The following graph shows the age of participants

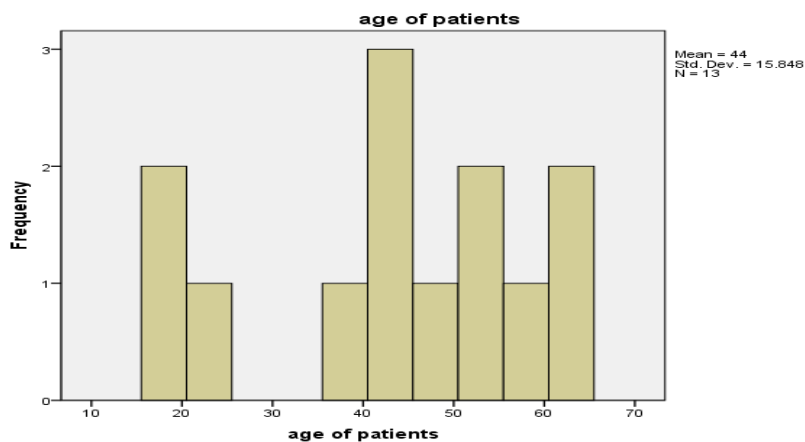


Figure 4.1.2. Age of patients

This graph has shown the patient's age. Minimum age was 18y and maximum was 65years. Mean age was 44y and standard division was 15.84.

The following graph has shown the age of amputation

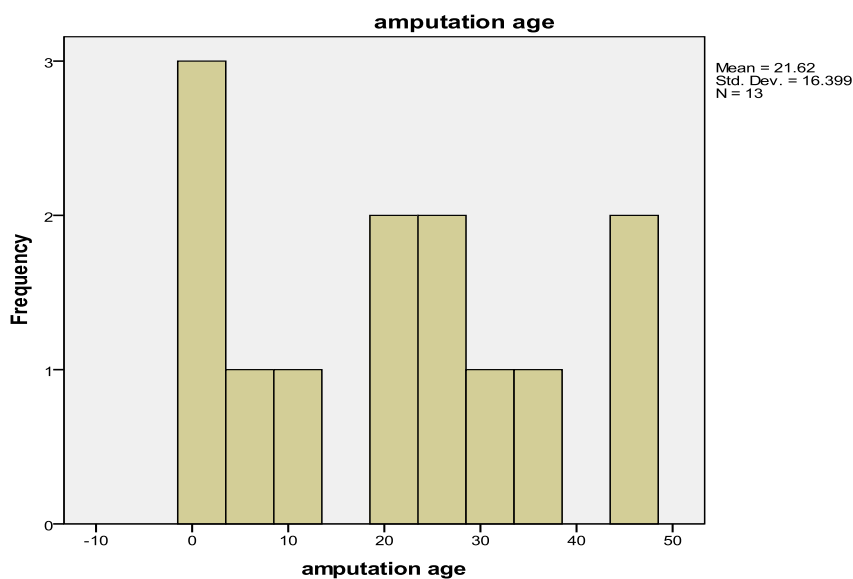


Figure 4.1.3. Amputation age.

This graph has shown the age of amputation. The minimum age of amputation was 1y and maximum was 47years. The mean age was 21.62 and standard division was 16.39.

The following graph has shown the years of prosthetic use.

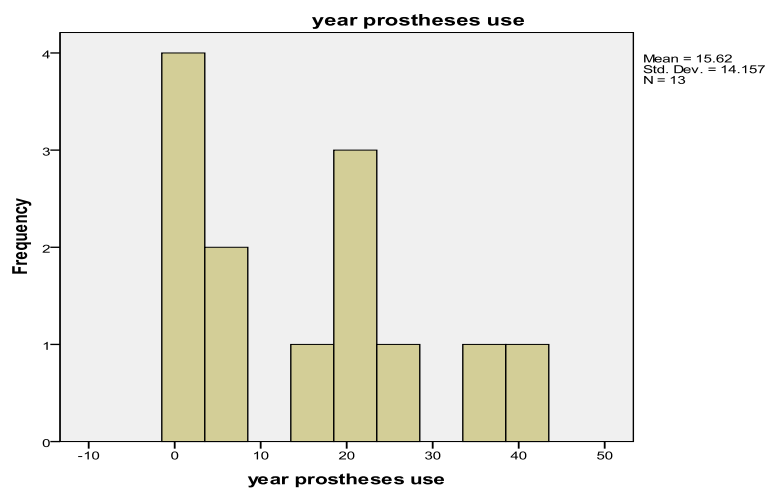


Figure 4.1.4. This graph has shown the years of prosthetic use. Minimum age was 1 year and maximum was 42y. Mean age was 15.62 and Std.Dev was 14.15.

Level of amputation

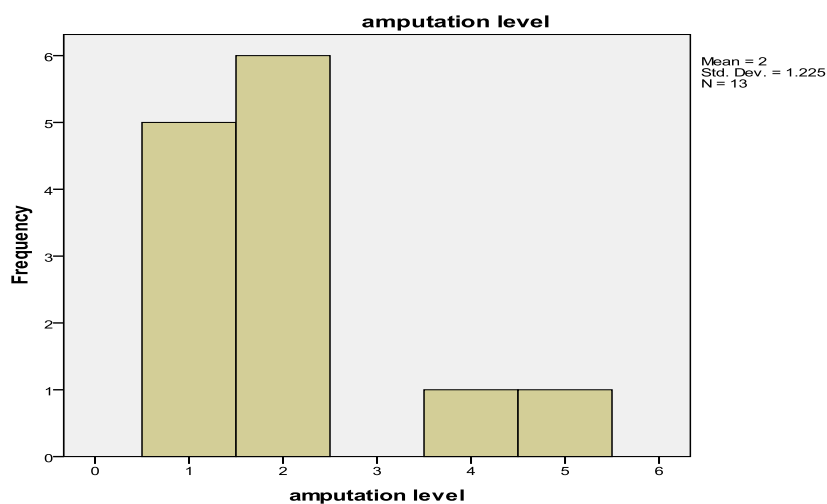


Figure 4.1.5. The graph has shown that there were 5 right transtibial amputations, 6 left transtibial amputations, 1 left transfemoral amputation and 1 was left syme's amputation. Standard division was 1.22.

Causes of amputation were shown in the following figure

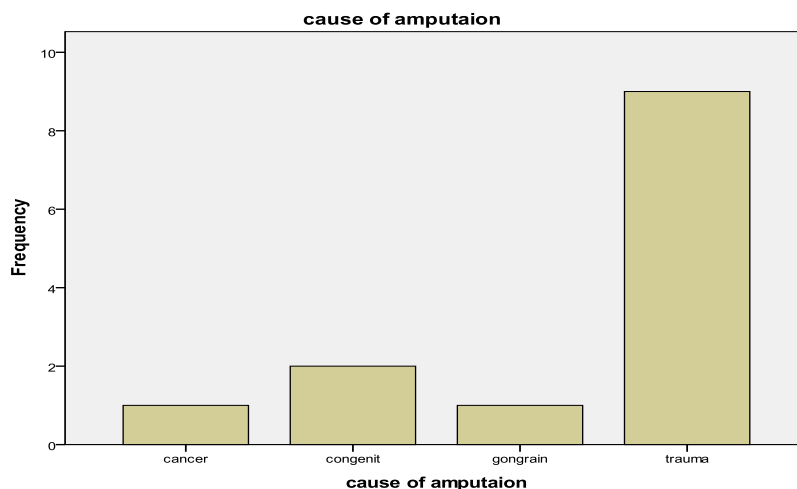


Figure 4.1.6. This graph shows the causes of amputation. Cancer-1, gangrene-1 congenital-2 and 9 were trauma.

#### 4.2. The comparison of distance performed by subjects during 6mwt with weight and without.

Significant difference was found between the distances which were performed by subjects without weight and with weight during six minute walk test. The p value is significance and  $p < 0.05$ .

Table 4.2. The comparison of distance performed in 6mwt without weight and with weight.

n=13	Mean± SD	Min-Max	Mean diff	SD	t	p
6mwt without weight(m)	380.02 ± 79.80	219.0-542.5	14.962	16.2	3,346	0,006
6mwt with weight(m)	365.06 ± 82.30	218.0-533.3				

The table has shown that there was significant difference between the distance covered by subjects without weight and with weight  $< 0.05 (0,006)$ .

#### 4.3. Comparison of systolic blood pressure, diastolic BP and heart rate before and after the test without weight.

The following table has shown the difference between systolic blood pressure Diastolic blood pressure and heart rate before and after 6mwt without weight and with weight.

Table 4.3. Difference between systolic BP, diastolic BP and heart rate before and after 6mwt without weight

n=13	Mean $\pm$ SD	Min-Max	Mean diff	SD	t	p
Systolic BP before 6mwt without weight (mmHg)	116.54 $\pm$ 11.97	100-130	0.76	4.494	0.617	0.549
Systolic BP after 6mwt test without weight(mmHg)	115.77 $\pm$ 11.15	100-130				
Diastolic BP before 6mwt without weight(mmHg)	76.54 $\pm$ 8.75	60-90	1.92	5.22	1.328	0.209
Diastolic BP after 6mwt without weight(mmHg)	75.54 $\pm$ 9.10	60-90				
Pulse rate before 6mwt without weight(bpm)	73.46 $\pm$ 7.75	60-88	-7.38	5.485	-4.85	<0.001
Pulse rate after 6mwt without weight(bpm)	80.85 $\pm$ 9.00	62-96				

As shown in the table, there is no significant difference between the values of systolic blood pressure which was counted before 6mwt and after the test .the p value is not significant and  $p>0.05$ .The table has shown that there is no significant difference in diastolic blood pressure. According to this table, there was significant difference between heart rate before and after 6mwt. The p value is smaller than 0.05,  $p<0,001$ .



#### 4.4. Systolic blood pressure ,diastolic blood pressure and heart rate with weight

The following table has described the difference between systolic, diastolic blood pressure and heart rate of subjects before and after the six minute walking test with weight.

Table 4.4. Systolic, diastolic blood pressure and heart rate with weight before and after 6mwt.

<b>n=13</b>	<b>Mean ±SD</b>	<b>Min- Max</b>	<b>Mean diff</b>	<b>SD</b>	<b>t</b>	<b>p</b>
Systolic BP before 6mwt with weight(mmHg)	116.5± 11.93	100- 130	-1.53	3,15	- 1.780	0.104
Systolic BP after 6mwt with weight(mmHg)	117.69± 12.35	100- 140				
Diastolic BP before 6mwt with weight(mmHg)	75± 8.66	60-90	0.38	1.38	1.000	0.337
Diastolic BP after 6mwt with weight(mmHg)	74.62± 9.00	60-90				
Heart rate before 6mwt with weight(bpm)	77.63± 10.04	56-90	-6.23	1.45	- 4.295	0.001
Heart rate after 6mwt with weigh(bpm)	83.92± 8.89	74-98				

The table has shown that there was no significant difference between systolic blood pressure before and after the 6mwt. Diastolic BP has not shown any difference, the p value is not significance .The table has shown that there was significant difference between the ratio of heart rate before and after 6mwt with weight.  $p=0.001$  and  $p<0.05$ .

#### 4.5. The comparison of systolic, diastolic blood pressure and heart rate without weight and with weight after 6mwt.

The following tables show the comparison of systolic, diastolic blood pressure and heart rate after 6mwt without weight and with weight.

Table 4.5. Systolic blood pressure, diastolic blood pressure and heart rate after 6mwt test without weight and with weight.

n=13	Mean $\pm$ SD	Min- Max	Mean diff	SD	t	p
Systolic blood pressure after 6mwt without weight(mmHg)	115.77 $\pm$ 10.04	100-130	-192	0.90	-2123	0.054
Systolic blood pressure after 6mwt with weight(mmHg)	117.69 $\pm$ 8.9	100-140				
Diastolic blood pressure after 6mwt without weight(mmHg)	74.62 $\pm$ 8.71	60-90	-192	0.90	-2123	0.054
Diastolic blood pressure after 6mwt with weight(mmHg)	74.62 $\pm$ 9.00	60-90				
Heart rate after 6mwt without weight(bpm)	80.85 $\pm$ 9.00	62-96	-3.07	4.53	-2.446	0.031
Heart rate after 6mwt with weight(bpm)	83.92 $\pm$ 8.9	74-98				

The table has shown that there was no significant difference between systolic blood pressure, diastolic blood pressure after 6mwt without weight and with weight. The table has shown the significant difference between the ratios of heart rate after 6minute walking test without weight and with weight the  $p < 0.05$ .

#### 4.6. Systolic BP, diastolic BP and heart rate without weight and with weight

The following table has shown the comparison of systolic blood pressure, diastolic blood pressure and heart rate before 6minute walking test without weight and weight.

Table 4.6. Comparison between systolic BP, diastolic BP and heart rate before 6mwt without weight and with weight.

<b>n=13</b>	<b>Mean ± SD</b>	<b>Min-Max</b>	<b>Mean diff</b>	<b>SD</b>	<b>t</b>	<b>p</b>
Systolic blood pressure before 6mwt without weight(mmHg)	116.54± 11.97	100-130	0.385	3.78 9	0.365	0.72 1
Systolic blood pressure before 6mwt with weight(mmHg)	116.15± 11.927	100-130				
Diastolic blood pressure before 6mwt without weight(mmHg)	74.54± 8.752	60-90	1.538	5.54 7	1.000	0.33 7
Diastolic blood pressure before 6mwt with weight(mmHg)	75.00± 8.660	60-90				
Heart rate before 6mwt without weight(bpm)	73.46±7.75	60-88	-4.23	5.9 1	- 2.57	.02 4
Heart rate before 6mwt with weight(bpm)	77.69±10.04	56-90				

As shown in the table there was no significant difference between systolic blood pressure after 6 minute walking test without weight and with weight, diastolic BP was also not significant .The heart rate has shown significant difference (p<.024).

#### 4.7. Comparison of Ten step up and down stair climbing test

The following table has shown the difference of time between ten steps up and down stair climbing test which was recorded during walking without weight and with weight.

Table 4.7. Comparison of 10steps up and down test with weight and without weight.

<b>n=13</b>	<b>Mean ± SD</b>	<b>Min -Max</b>	<b>Mean diff</b>	<b>SD</b>	<b>t</b>	<b>p</b>
Ten step up and down stair climbing test without weight(sec)	17.61 ± 6.80	10.00- 31.00	-23462	-35006	-670	0.515
Ten step up and down stair climbing test with weight(sec)	17.85 ± 6.78	9.00-30.00				

The test has shown no significant difference between the time of ten step up and down stair climbing test without weight and with weight the  $p > 0.05$  ( $p = 0.515$ ).

#### 4.8. Systolic BP, diastolic BP and heart rate before and after 10step stair test without weight and with weight.

This table shows the comparison of systolic blood pressure, diastolic blood pressure and heart rate of the subjects before ten steps up and down stair climb test without weight and with weight.

Table 4.8. Comparison of systolic PB, diastolic BP and heart rate before 10 steps stairs test without weight and with weight.

n=13	Mean $\pm$ SD	Min-Max	Mean diff	SD	t	P
Systolic BP before 10step stair test without weight(mmHg)	115.38 $\pm$ 12.15	100-140	-769	12.15	-617	0.549
Systolic BP after 10 step stair test without weight(mmHg)	115.38 $\pm$ 12.15	100-140		12.15		
diastolic blood pressure before10step stair test without weight(mmHg)	76.54 $\pm$ 9.43	60-90	1.00	2.317	1.43	0.177
diastolic blood pressure after ten step stairs test without weight(mmHg)	75.54 $\pm$ 9.10	60-90				
Heart rate before ten step stairs test without weight(bpm)	69.08 $\pm$ 15.40	23-86	-11.80	16.80	-2.52	0.027
Heart rate after ten step stairs test without weight(bpm)	80.85 $\pm$ 8.77	62-95				

As shown in the tables there was no significant difference between systolic blood pressure, diastolic BP has not shown any difference before and after the test with weight. The table has shown a significant difference between the ratios of heart rate before and after the ten step up and down climb test without weight  $p=0.027$  ( $p<0.05$ ).

#### 4.9. Systolic BP, diastolic BP and heart rate before and after ten steps stairs test with weight.

The following table shows the difference between systolic blood pressure, diastolic blood pressure and heart rate before and after ten step up and down stairs climbing test with weight.

Table 4.9. Comparison of Systolic BP, diastolic and heart rate before and after 10steps up and down stairs test with weight

<b>n=13</b>	<b>Mean ±SD</b>	<b>Min - Max</b>	<b>Mean diff</b>	<b>SD</b>	<b>t</b>	<b>p</b>
Systolic blood pressure before 10step stair test with weight(mmHg)	116.54± 13.13	100-140	-1.92	3.25	-213	0.054
Systolic blood pressure after ten step stairs test with weight(mmHg)	118.46± 13.44	100-140				
diastolic blood pressure before 10step stair test with weight(mmHg)	76.15± 9.82	60-90	1.00	2.31	1.43	0.177
diastolic blood pressure after ten step stairs test with weight(mmHg)	76.15± 9.82	60-90				
Heart rate before ten step stairs test with weight (bpm)	77.38± 9.49	58-92	-7.077	5.01	-5.09	0.000
Heart rate after ten step stairs test with weight (bpm)	86.44± 8.743	74-98				

The table has shown that there is no significant difference between systolic blood pressure and the diastolic blood pressure also has not shown significant difference before the ten steps stair up and down climbing test with weight. The table has shown that there was significant difference between the heart rate before and after the ten steps up and down stairs climbing test .the heart rate increased after test than before. P=0.000 (p<0.5).

#### 4.10. Systolic PB, diastolic BP and heart rate after ten steps up and down stair test without weight and weight.

This table describes the comparison between systolic blood pressure, diastolic blood pressure and heart rate which was recorded after ten steps up and down stairs climbing test without weight and with weight.

Table 4.10. Comparison of Systolic BP, diastolic BP and heart rate after ten steps up and down stairs test without weight and with weight

<b>n=13</b>	<b>Mean ± SD</b>	<b>Min- Max</b>	<b>Mean diff</b>	<b>SD</b>	<b>t</b>	<b>p</b>
Systolic BP after 10step stair test without weight(mmHg)	115.38± 12.15	100-140	-3.07	5.60	-198	0.071
Systolic BP after ten step stairs test with weight(mmHg)	118.46± 13.44	100-140				
diastolic BP after10step stair test without weight(mmHg)	75.54± 9.10	60-90	-6.15	2.20	- 1.00	0.337
diastolic BP after ten step stairs test with weight(mmHg)	76.15± 9.82	60-90				
Heart rate after stair climb test without weight(bpm)	80.85± 8.77	62-95	-3.61	4.15	- 3.13	0009
Heart rate after stair climb test with weight(bpm)	84.46± 8.74	74-98				

The table has shown that there was no significant difference between systolic blood pressure, diastolic blood pressure after ten steps stairs up and down climb test without weight and with weight ( $p>0.05$ ). As shown in the table there was significant difference between heart rate recorded at ten steps up and down stairs climb test without weight and with weight.  $p=0009$  ( $p<0.05$ ).

## 5. DISCUSSION

It must be acknowledge that in this study the systolic blood pressure, diastolic blood pressure, time of ten steps up and down stairs climb test of the subjects which were divided before test, after test, with weight and without weight. There were no statistically significant differences found but clinically some differences were found in these parameters. This study has shown to say that the prosthetic weight has not significant effect on the blood pressure of lower limb amputees. But it has effect on heart rate and there were significant differences between the heart rate during 6mwt and 10step stairs up and down climb test.

### 5.1. Subjects

A total of 13 subjects have completed the study bases on the hypothesis that the prosthetic mass has effect on the hemodynamic responses of the lower limb amputees. The similar studies(22,23,24,25,26,27,28,29,30,31,32,33,34,35,36,37,38) have studied , most of them have discussed on the effect of added mass of prosthesis on the kinematic and kinetic of gait cycle, and oxygen and energy consumption, some of these studies have also discussed the effect of weight and exercises on the heart rate and stride and steps lengths of the lower limb amputees but about the systolic and diastolic pressure there were no information in these studies. Although we have comparison our study and result with some previous studies. According to the previous studies 13 lower limb unilateral subjects were enough for this study. Similar studies have involved 10-35 subjects. Subjects of our study were recruited from the lower limb amputee patients who have visited to the orthotic prosthetic unit of physiotherapy and rehabilitation department of health sciences of Hacettepe University.

It was fortunate that all subjects have not any cardio pulmonary, skin, limb, stump, wound problems. They have shown interest in study and performed well. We have compared the variables before the tests and after the tests. Likewise without weight and with weight the variables were compared with each other. It has been assumed, that the healthy amputee subjects can be appropriate to perform the 6minute walk test and ten steps up and down stairs climb test with the weight and without weight. It was intended to minimize any influence of underling pathologies or



problems in the lower limbs (prosthetic and intact limb) that could have led to distorted results.

Similarly it was decided to exclude the patients who have cardio pulmonary diseases, hypertension, children below 18 years and older above 65 years. Most of lower limbs had included the subjects from 18-65 years old. Our study has also recruited the same age of subjects like previous studies. In this study 10 minutes rest time was given to the subjects after every test. The total time for every subject assessment and investigation was from 40-50 minutes.

It was not possible to keep the patients for long time, so we have measured every variable very carefully and recorded.

## **5.2. General assessment**

The clinical assessments were performed by researcher to ensure that the subjects had no underlying pathologies.

Posture and the prosthetic limb, stump and prostheses were checked of the subjects and the subjects performed gait before the tests. The six minute walk test was performed on the subjects before to start the study. It evaluates the global and integrated responses of all the systems involved during exercise, including the pulmonary and cardiovascular systems, systemic circulation, peripheral circulation, blood, neuromuscular units, and muscle metabolism and similarly ten steps up and down stairs climb test to improve the flexion, extension of joints, push off, swing and stance phase. The stairs climbing test assesses the ability to ascend and descend a flight of stairs, as well as lower extremity strength, power, and balance. (43, 48, 49, 50).

## **5.3. The effect of added mass of lower prosthetic limb on the distance of six minute walk test.**

13 lower limb amputees have taken part in the six minute walk test with zero added weight and with 250 gm. added weight to their ankle prosthesis. 9 male and 4 female, 11 of them were transtibial amputees, one was transfemoral and one was left syme's amputee. First the subject performed the six minute walk test with no added weight and after ten minute rest, they have performed the six minute test and 250 gram

weight was added to their prosthetic limb with ankle area. The subject covered the different distance with zero added weight and with 250gm added weight, which is shown in the table.

3 of 13 subjects performed the same 6mwt distance without added weight and with added weight to their prosthetic limb. 9 of them had the limitation of walking distance when the weight was added to their prosthetic limb. There was clear and significant difference between the distance of 6mwt without weight and with weight, and one subject performed more distance when the weight was added to her prosthetic limb. The result of our study was clear and it was shown that there was significant difference between the walking distances when the weight was added to the prosthetic limb of the subjects. When the weight was added, the walking distance and walking speed were decreased.

According to the previous studies, there were no significant changes found between the stride lengths, step lengths, stepping speeds, gait cycle duration, and stance and swing phase durations of both the prosthetic and intact limbs with alteration of the prosthetic mass condition. However, the spatiotemporal symmetry of the gait was effected significantly when the COM location of the prosthetic leg was changed (50). When the mass has added to prosthetic ankle the step and stride lengths of the prosthetic limbs were significantly higher than those of the intact limb. The stepping speed of prosthetic limb was higher than that of the intact limb for all prosthetic mass conditions except for the mass added to the prosthetic knee (50). The swing and stance durations of prosthetic limb were significantly longer and shorter than of the intact limb in all prosthetic mass condition (50). In 2 minute walk test the distance was decreased when the weight was added to the ankle of prosthetic limb. Walking distance with no added mass to prosthetic limb is 11.8m and when mass was added the walking distance was decreased and it was 10.8 m. Mass was added to knee the walking distance was 11.6m (50). So there is clear difference in walking distance when the mass was added to ankle of prosthetic limb. Our study has given the result that when the mass was added to the ankle of prosthetic limb the significant changes accord in the walking distance, walking speed, strides and step lengths.

Suh-Jen Lin-Chan, has used 3 different mass prosthesis condition, 100%, 80% and 60%. The prosthetic mass did not significantly alter oxygen consumption or gait

efficiency but the 60% to the 100% prosthetic mass conditions, relative exercise intensity significantly increased and stride frequency significantly decreased (51). Gailey and colleagues studied that SSWS in 39 TFA patients wearing prosthesis with different mass that the SSWS of amputee patients with heavier prosthesis (2.7kg average) was 8% higher than the SSWS of patients with a lightweight prosthesis(2.0kg average) however, this difference was not statistically significant (52). Hillery and colleagues assessed gait kinematics of male TFA patient while masses up to 1.460kg were added to the distal foot portion of the prosthesis. They found small increased. Stride frequency showed a small decrease with increasing mass (53).

Karla H.C.Vilaça and colleagues have applied the 6-minute walk test on elderly women to determine the distance covered in the 6mwt. He determined that the elderly women who covered a shorter distance in the 6mwt also had a higher body mass index (BMI). A greater quantity of fat mass and worse muscle performance, the result of Karla's study demonstrated that in terms of body composition, excess body fat can increase body overload and limit movement due to the stress between joints and muscles. Thus increasing risk of disabilities. Obesity was found to be an important cause of physical dysfunction among the elderly. Although the study suggested that the increase of fat mass may also be associated with this decline, as elderly women with a larger amount of fat performed more poorly on tests of muscles strength and functional capacity (54). Alison and his colleagues performed the six-minute walk test on active duty soldiers and service members with and without traumatic lower limb loss. The statistically significant differences in mean 6MWT performance were noted among the groups with limb and without limb loss. Posthoc testing demonstrated significant difference in mean performances in 6MWT between the group without limb loss and TTA group and both the participants without limb loss and the TTA subjects were significantly different from all other groups.

There was also significant difference in 6MWT performance between BTTA and BTFA participants. Although differences existed in group mean distance, there was substantial overlap among all groups in the range of 6MWT performance (55).

Jos H Meuleman has described the effect of directional inertias added to pelvis and ankle on gait. He obtained that adding inertia to the ankle causes more effect that

adding the same inertia to the pelvis. The double stance time decreased significantly, whereas the swing time increased and has an interaction effect with speed. The stride length decreased significantly, but pair wise comparison showed not significant changes (56).

Prasanna Lenka and her colleagues have written in their study result that when they measured Step length, stride length, cadence and velocity in each subject with five different weights prosthesis, on affected side, where as a significant difference was noted on sound side. Further post hoc analysis was done using Bonferroni test which revealed a significant difference between prosthesis and prosthesis200, prosthesis400, prosthesis600 and prosthesis800, but no significant differences found between different weight prosthesis. The variation of step lengths in effected and normal were found to be similar in prosthesis 200 & Prosthesis 600 (31).

Comparison of stride length between groups was found to be statistically significant on affected side as well as sound side. Further post hoc analysis revealed a significant difference between prosthesis versus prosthesis 600 on affected side where as a significant difference was noted between prosthesis versus prosthesis 400 and prosthesis versus prosthesis 600 (31).

There are a lot of studies which have described that the prosthetic mass has no effect on the distances of walking speed of lower limb amputees.

Studying the effect of adding masses of .68 and 1.34kg to the center of mass of the prosthesis of 10 TFA subjects, Gitter and associates found no statistically significant differences in stride length or stride frequency between the different mass additions (57).

Lehmann studied the effect of changing the prosthetic mass on SSWS in 15 TTA subjects using prostheses weighting 2.3kg and 3.5 kg. No significant differences in SSWS were found between the mass conditions (58).

Andrew and his assistants studied the effect of adding weight to the torso on roll over characteristics of walking. They determined that adding of weight symmetrically about the torso does not significantly affect the roll over shapes of ankle foot and knee foot systems. It does not significantly change between slow and normal walking speed (59). Czerniecki and colleagues studied the effect of systematically varying prosthetic mass in eight TFA patients at four different walking speeds. Load

of.68 and 1.34kg was attached to the center of mass of the prosthetic shank. No significant differences in economy were found between mass conditions in any of the four different walking speeds (60). The results of study showed no consistent differences in the kinematic and kinetic factors of the amputee gait when the steel prosthetic components were replaced by titanium. Hamid Bateni, and his assistant investigated the effect of weight of prosthetic components on transtibial amputees and found suggest that small changes in the weight of a prosthetic limb do not affect the stance time of the affected side. It was expected that a lighter prosthesis would cause changes in the pattern of the knee relative angles during the swing phase of the affected side. It was hypothesized that a heavier prosthesis demands more muscle activity to decelerate during the last part of swing. However, their results did not support any statistically significant difference between steel and titanium trials regarding knee relative angles (33).

Thomas Schmalz and colleagues have described the influences of prosthetic alignment and different prosthetic components. They used five different prosthetic alignments and different prosthetic feet and determined that the mean walking speeds and stride lengths during level walking varied in small ranges between 5.2 and 5.3 km/h and 0.74 and 0.76m without significant differences between five prosthetic feet (61). Although our result has shown that when the mass was added to prosthetic leg attached to ankle joint the speed of walking, step length and the cover distance was decreased.

### **5.3.1. Blood pressure**

Blood pressure was measured and recorded before and after the tests in sitting position on the chair. The systolic and diastolic blood pressure was recorded without weight before and after the tests and later 250gm weight was added to the ankle of prosthetic limb and the systolic and diastolic blood pressure was measured before and after the tests. Our study result has not shown any significant statistical difference in systolic and diastolic blood pressures of the subjects in all conditions. There was a little difference in the blood pressures of some subjects but statistically were not significant. So this study has given us information that the prosthetic mass has not effect on the blood pressure of lower limb amputees. There are just few studies which

have described the effect of exercises and prosthetic weight on the hemodynamic responses of the lower amputees. Comparison with other studies, Suh-Jen Lin and colleagues obtained that there were no differences in the blood pressure of subjects before and after 6minute walk test. Our study has given the same result (62). The following is the result of Suh-jen

Results of the 3Trials of the 6mwt. Peak heart rate, diastolic pressure and systolic pressure. Paired T- test showed significant differences between trial 3 and trial1 and between trial 3 and trial 2. Pair wise comparisons showed significant differences between trial 1 and trial 2 and between trial 1 and trial 3.

Results showed a significant main effect for peak heart rate. Results of mean arterial blood pressure did not show a significant main effect.

Indicating that mean arterial pressure did not significantly change among the 3 trials. Results of RPE also did not show a significant main effect, indicating that RPE did not significantly change among the 3 trials (62).

Catherine A Hinton and Karen E Cullen investigated the hemodynamic responses of subject to the effect of ortho crutches and axillary crutches and obtained that there was no significant difference between mean systolic blood pressure for OCA and ACA. The mean systolic blood pressures of UA were less than OCA and ACA. No significant differences in mean diastolic blood pressure were found among the three modes of ambulation (83).

E. Jakubseviciene and his colleagues have investigated the effect of exercises base rehabilitation on hemodynamic responses after lower limb Arterial Blood Flow Surgery and obtained that before and after 6minute walk test there were no significant differences between the groups in baseline ABI, HR and blood pressure levels. But the peripheral hemodynamic measurements of the rehabilitation and control groups after 6 months a statistically significant difference in ABI was observed in both groups. However, the mean resting HR, SBP and DBP level was significant improved after 6 months in the rehabilitation group as compared to the control group (79). The first part of this study is similar to our study and the second part 6months are long times when they repeated the test on the subjects and found changes in hemodynamic responses. According to our hypothesis the result of our study statistically hasn't supported. We suggested that the blood pressure of amputees will be increased with the added

prosthetic mass but statistically it was not significant. Although the heart rate was increased with adding prosthetic weight.

### 5.3.2. Heart rate

The heart rate was increased in all tests .Our result described that exercise and addition of weight has effect on the heart rate and heart rate was increased. We have compared the heart rate after 6mwt without weight and with weigh and also compared the heart rate without weight and with weight after 10 step up and down stairs climb test and obtained that heart rate was increased with weight .

S. Provencher and colleagues obtained from their research that 6mwt has increased the heart rate of the patients (64). Myrthe M. Vestering and colleagues have proven that the Combined arm–leg ergo meter test has effect on the heart rate of lower limb amputees. It increased the heart rate of subjects when they performed this exercise (65).

We have compared the heart rate after 6mwt without weight and with weight there was a significant difference between these two variables. So the result obtained that the prosthetic weight has effect on the heart rate of amputees. The result of this study with comparison with other studies, Suh-Jen Lin-Chan has described in his study that the weight has effect on heart rate he used three different mass conditions on the transtibial subjects and obtained that the 100%condition increased the heart rate of the subject (51).

PrasannaLenka and his colleagues had added four different weights to the lower limb amputee’s prosthetic ankles and obtained that when the prosthetic weigh was added to the prosthetic limb the heart rate was increased. He added 200gm, 400gm, 600gm and 800gm and the heart rate was increased.

This result is similar to our result and both have shown that prosthetic mass has effect on the heart rate when the mass was increased the heart rate was also increased during walking and exercises (39). Yahya Sokhangoei1 and colleagues compared the heart rate of amputee group and in control group and explained that the energy consumption amount and the heart activity in any speed, is higher in the amputee group. He noted the heart rate of amputees at different speed and determined that when the speed was fast heart rate was also increased.

They have obtained that heart rate of amputees in three trails. Slow, medium and fast. There was a difference between the beats of heart rate (28).

R S Gaily and his colleagues determined that the HR values for TTAs were higher than those of control subjects when masses were added of 0, 454g and 907g respectively (66). Catherine A Hinton and Karen E Cullen investigated the hemodynamic responses of subject to the effect of ortho crutches and axillary crutches and obtained that Results of the analysis of heart rate Comparison of the three modes of ambulation during each collection period showed that mean heart rates during OCA and ACA were significantly greater than during UA for all four periods. Additionally, significant differences in mean heart rates were found between OCA and ACA during Periods 1 and 4. During Period 1 of ACA, the mean heart rate was significantly greater than the mean heart rate during OCA. During period 4 of ACA, the mean heart rate was 142 bpm, which was significantly greater than the mean heart rate during OCA (63).

Sergey F. Has determined that tests of cardiac and respiratory functions were performed at rest as well as in balanced wheelchair ergometer testing, increased the heart rate of lower limb subjects (67). Although our study has proven that mass addition has increased the heart rate during exercises tests because muscles use more oxygen and glucose from the blood with increased movement. This product wastes that decrease blood pH below the normal range causing an increase in heart rate. The heart rate increase delivers blood to the lungs and kidneys more quickly so these organs can remove the wastes from the body. The faster the muscles use energy and create waste. The faster the heart must pump the blood.

### **5.3.3. Stairs up and down climb test**

All of 13 included subjects of our study have performed the ten steps up and down stairs climb test. Timing began on the signal to start and terminated when the participant returned with both feet to the ground level (47, 48, 68). The subjects have performed this test two times. Once without weight and secondly the 250gm weight was added to their prosthetic ankle limb. There was a little difference in the time between without weight condition and with weight condition but statistically no



difference was found. Gustav and colleagues determined that there was no significant difference in the time of stairs climb test (69).

The blood pressure and heart rate were measured before and after the test there was no significant difference in the blood pressure, but the heart rate was higher after test and significant. Shiomitaizo performed the stair climb test on five healthy men and determined that the heart rate was increased after ascend and descend stairs climb test and the difference was statistically significant (70). We have compared the heart rate before and after the test without adding weight there was significant difference in beats of heart rate per minutes. When the test was repeated on the subjects with weight the difference was found again and it was significant. We have also compared the heart rate after ten step stair up and down climb test without weight and weight and obtained that there was significant difference on heart rate without weight and weight which has improved that weight has effect on the heart rate of amputees during walking and exercise.

#### **5.3.4. Limitations of the study**

In this study 13 subjects have participated. A sample of 13 subjects were minimally required, possibly larger sample would have been more informative. One limitation of the study, there was a need to group the amputees according to their level of amputation. Because their energy expenditure will be different. Upper levels need more energy. More patients should be included.

The sex and age were also having effect on the result of study. In this study the subject's age was from 18 years to 65 years. Male and female subjects were participated in the study. These factors have also effect on the result of the study.

We have added 250 gm weight to the individual's prosthesis. We have used the same weight for every test and every individual and did not change the mass for every test and for every individual during the study.

The hypothesis of the study was when the segmental weight is increased the hemodynamic responses of lower limb amputees are increased. Our result has shown that particularly heart rate of subjects was increased with additional weight, but no changes were observed in the blood pressure.

## 6. CONCLUSION

The purpose of this study was to determine the effect of prosthetic mass on the hemodynamic responses of the lower limb amputees especially on blood pressure and heart rate. To achieve our goals we have selected six minute walk test and ten steps up and down stairs climb test for the subjects. Blood pressure and pulse rate (heart rate) of every subject was measured before and after the tests, with weight and without weight and recorded. A total of 13 subjects were recruited in this study. The primary dependent variables were the blood pressure before and after the tests without weight, heart rate, 6minute walking distance without weight and ten steps up and down stair climbing time without weight. The secondary dependent variables were the blood pressure, heart rate before and after the tests with weight, six minute walking distance with weight and the time of stairs up and down climbing test with weight. These variables were statistically compared with each other.

Following conclusions can be drawn from the study.

- \_ The weight of prosthesis should be considered in the rehabilitation of amputees.

- \_ The results have shown that heart rate was increased with additional weight, so we have to fabricate low weight prosthesis.

- \_ The segmental weight of prosthetic limb has effect on the walking speed and cover distance of subjects. The cover distances were decreased when the weight was added to the ankle joint of prosthetic limb during six minute walk test.

- \_ No differences were observed in the blood pressure of subjects during six minute walk test without weight and with weight. Numerically there were some differences seen, but statistically were not significant.

- \_As expected the heart rate was increased during six minute walk test when the weight was added to the prosthetic limb of the subjects, we have recorded the heart rate before 6MWT with weight and after 6MWT with weight the significant differences were found. We have done the comparison of heart rate after 6MWT without weight and with added weight, statistically significant differences were observed. This has shown that prosthetic weight has effect on the heart rate of lower limb amputees.

\_ No differences were observed between blood pressure during ten steps up and down stair climb test when the weight was added and attached to the ankle joint of prosthetic limbs of the subjects. The systolic blood pressure and diastolic blood pressure did not change statistically, so no significant differences were found between blood pressure.

\_ No differences were found between time of ten steps up and down stair climb test without weight and with weight. There was a numerical difference between the time of ten step stair climb test with weight and without weight and this difference was not statistically significant.

\_ Significant differences were observed during ten steps up and down stair climb test with zero weight and with 250gm added weight. The heart rate was significantly increased when the mass was added to prosthetic limb of the subjects.

We have done the comparison of our study with previous studies and have shown almost the same result some studies have different result. We have obtained that the prosthetic mass has effect on the heart rate of lower limb amputees, but statistically has no effect on the systolic and diastolic blood pressure of the lower limb amputees. In order to generalize our results to lower limb amputees, more patients are needed to be included.

### **6.1. Suggestions for future studies**

There are very few studies which have described the effect of prosthetic mass on the hemodynamic responses of lower limb amputees, so it will be beneficial to work on more studies in the future.

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ANNEX

Annex 1. Ethical Permission of the Research Project



T.C.  
**HACETTEPE ÜNİVERSİTESİ**  
Girişimsel Olmayan Klinik Araştırmalar Etik Kurulu

Sayı : 16969557 - 89

4 Ocak 2014

**ARAŞTIRMA PROJESİ DEĞERLENDİRME RAPORU**

**Toplantı Tarihi** : 22.01.2014 ÇARŞAMBA  
**Toplantı No** : 2014/02  
**Proje No** : GO 14/33 (Değerlendirme Tarihi 08.01.2014)  
**Karar No** : GO 14/33 - 11

Üniversitemiz Sağlık Bilimleri Fakültesi Fizyoterapi ve Rehabilitasyon Bölümü öğretim üyelerinden Doç.Dr.Akmer MUTLU'nun sorumlu araştırmacı olduğu Mohammad Dawood KHAROOTY'nin tezi olan GO 14/33 kayıt numaralı ve "Alt Ekstremité Amputasyonu Olan Bireylerde Protez Segmental Ağırlık Değişiminin Hemodinamik Yanıtlara Etkisi" başlıklı proje önerisi araştırmının gerekçe, amaç, yaklaşım ve yöntemleri dikkate alınarak incelenmiş olup, etik açıdan uygun bulunmuştur.

- |   |  |
|---|--|
| 1.Prof. Dr. Nurten Akarsu (Başkan)      | 9 Prof. Dr. Melahat Görduysus (Üye)        |
| İZİNLİ                                  |  |
| 2. Prof. Dr. Nüket Örnek Buken (Üye)    | 10. Prof. Dr. Cansın Saçkesen (Üye)        |
| 3. Prof. Dr. M. Yıldırım Sara (Üye)     | 11. Prof. Dr. R. Köksal Özgül (Üye)        |
| 4. Prof. Dr. Sevda F. Müftüoğlu (Üye)   | 12. Prof. Dr. Ayşe Lale Doğan (Üye)        |
| 5. Prof. Dr. Cenk Sökimensüer (Üye)     | 13 Doç. Dr. S. Kutay Demirkan (Üye)        |
| İZİNLİ                                  |  |
| 6. Prof. Dr. Volga Bayrakçı Tunay (Üye) | 14. Prof. Dr Leyla Dinç (Üye)              |
| 7. Prof. Dr. Songül Vaizoğlu (Üye)      | 15. Yrd. Doç. Dr. H. Hüsrev Turnagöl (Üye) |
| İZİNLİ                                  |  |
| 8. Prof. Dr. Yılmaz Selim Erdal (Üye)   | 16. Av. Meltem Onurlu (Üye)                |

## Annex 2. Patient Follow-up Form

Hasta Takip Formu									
Adı:					Amputasyon yaşı:				
Soyadı:					Amputasyon seviyesi:				
Yaş:					Amputasyon nedenleri:				
Cinsiyet:					Kaç yıldır protez kullanıyor?:				
Teşhis:					Mesleği:				
Adresi:					Tel:				
Değerlendirme									
Ağırlık takmadan					Ağırlık takarak				
6dk. yürüme testi	Yürüme Mesafesi	Önce		Sonra		Önce		Sonra	
		Kan basıncı (S/D)	Nabız	Kan basıncı (S/D)	Nabız	Kan basıncı (S/D)	Nabız	Kan basıncı (S/D)	Nabız
10 basamak merdiven inip çıkma	Süresi	Önce		Sonra		Önce		Sonra	
		Kan basıncı (S/D)	Nabız	Kan basıncı (S/D)	Nabız	Kan basıncı (S/D)	Nabız	Kan basıncı (S/D)	Nabız

S: Sistolik Basınç

D: Diastolik Basınç

Hangi durumdan memnun kaldınız?

 Ağırlıksız Ağırlıklı

## ARAŞTIRMA AMAÇLI ÇALIŞMA İÇİN AYDINLATILMIŞ ONAM FORMU

### (Hasta Grubu)

Bacak protezi kullanan hastaların protez ağırlıkları ile ilgili yeni bir araştırma yapmaktayız. Araştırmanın ismi “Alt ekstremite amputasyonu olan bireylerde protez segmental ağırlık değişiminin hemodinamik yanıtlara etkisi”dir.

Sizin de bu araştırmaya katılmasını öneriyoruz. Ancak hemen söyleyelim ki bu araştırmaya katılıp katılmamakta serbestsiniz. Çalışmaya katılım gönüllülük esasına dayalıdır. Kararınızdan önce araştırma hakkında sizi bilgilendirmek istiyoruz. Bu bilgileri okuyup anladıktan sonra araştırmaya katılmak isterseniz formu imzalayınız.

Bu araştırmayı yapmak istememizin nedeni, bacak protezi kullanan hastalarda protez ağırlığının aktivite sırasında, kan basıncı nabız üzerinde etkisi olup olmadığını saptayabilmektir. Çalışma, Hacettepe Üniversitesi Sağlık Bilimleri Fakültesi Fizyoterapi ve Rehabilitasyon Bölümü, Protez-Ortez Bölümünde gerçekleştirilecektir ve bu çalışmaya katılımınız araştırmanın başarısı için önemlidir.

Eğer araştırmaya katılmayı kabul ederseniz Dr. Mohammad Dawood Kharooty sizi değerlendirecek ve bulgular kaydedilecektir. Bu değerlendirme sonucunda uygun görülürse bu çalışmaya alınacaksınız. İzniniz doğrultusunda bu çalışmayı yapabilmek için sizin yürüyüşünüz ve merdiven inme çıkma aktivitelerinde kan basıncınız ve nabızınız ölçülecektir. Proteziniz ağır ağırlıkta ise ağırlık takmadan, hafif ağırlıkta ise önce ağırlık takmadan sonrasında ise 250 gramlık ağırlık takarak yürümeniz ve merdiven inip çıkmanız istenecektir.

Bu çalışmaya katılmanız için sizden herhangi bir ücret istenmeyecektir. Çalışmaya katıldığınız için size ek bir ödeme de yapılmayacaktır.

Siz ile ilgili tıbbi bilgiler gizli tutulacak, ancak çalışmanın kalitesini denetleyen görevliler, etik kurullar ya da resmi makamlarca gereği halinde incelenebilecektir.

Bu çalışmaya katılmayı reddedebilirsiniz. Bu araştırmaya katılmak tamamen isteğe bağlıdır ve reddettiğiniz takdirde size uygulanan tedavide herhangi bir değişiklik olmayacaktır. Yine çalışmanın herhangi bir aşamasında onayınızı çekmek hakkına da sahipsiniz.

***(Katılımcının/Hastanın Beyanı)***

Sayın Dr. Mohammad Dawood Kharooty tarafından Hacettepe Üniversitesi Sağlık Bilimleri Fakültesi Fizyoterapi ve Rehabilitasyon Bölümünde tıbbi bir araştırma yapılacağı belirtilerek bu araştırma ile ilgili yukarıdaki bilgiler bana aktarıldı. Bu bilgilerden sonra böyle bir araştırmaya “katılımcı” olarak davet edildim.

Eğer bu araştırmaya katılırsam doktor/fizyoterapist ile aramda kalması gereken kendime ait bilgilerin gizliliğine bu araştırma sırasında da büyük özen ve saygı ile yaklaşılacağına inanıyorum. Araştırma sonuçlarının eğitim ve bilimsel amaçlarla kullanımı sırasında kişisel bilgilerimin ihtimamla korunacağı konusunda bana yeterli güven verildi.

Projenin yürütülmesi sırasında herhangi bir sebep göstermeden araştırmadan çekilebilirim. *(Ancak araştırmacıları zor durumda bırakmamak için araştırmadan çekileceğimizi önceden bildirmemim uygun olacağını bilincindeyim)* Ayrıca tıbbi durumuma herhangi bir zarar verilmemesi koşuluyla araştırmacı tarafından araştırma dışı tutulabiliriz.

Araştırma için yapılacak harcamalarla ilgili herhangi bir parasal sorumluluk altına girmiyoruz. Bize de bir ödeme yapılmayacaktır.

İster doğrudan, ister dolaylı olsun araştırma uygulamasından kaynaklanan nedenlerle meydana gelebilecek herhangi bir sağlık sorunumun ortaya çıkması halinde, her türlü tıbbi müdahalenin sağlanacağı konusunda gerekli güvence verildi. (Bu tıbbi müdahalelerle ilgili olarak da parasal bir yük altına girmeyeceğim).

Araştırma sırasında fiziksel bir sağlık sorunu ile karşılaştığımda; herhangi bir saatte, Dr. Mohammad Dawood Kharooty’ı 03123052525-139 (iş) veya 05384265486 (cep) no’lu telefonlardan ve HÜ Sağlık Bilimleri Fakültesi Fizik Tedavi ve Rehabilitasyon Bölümü adresinden arayabileceğimi biliyorum.

Bu araştırmaya katılmak zorunda değiliz ve katılmayabiliriz. Araştırmaya katılmak konusunda zorlayıcı bir davranışla karşılaşmış değiliz. Eğer katılmayı reddedersek, bu durumun benim tıbbi bakımına ve doktor/fizyoterapist ile olan ilişkiye herhangi bir zarar getirmeyeceğini de biliyorum.



Bana yapılan tüm açıklamaları ayrıntılarıyla anlamış bulunmaktayım. Kendi başıma belli bir düşünme süresi sonunda adı geçen bu araştırma projesinde “katılımcı” olarak yer alma kararı aldım. Bu konuda yapılan daveti büyük bir memnuniyet ve gönüllülük içerisinde kabul ediyorum.

İmzalı bu form kağıdının bir kopyası bana verilecektir.

***(Katılımcının/Hastanın Beyanı)***

**Katılımcı**

Adı,

soyadı:

Adres:

Tel.

İmza:

**Görüşme tanığı**

Adı,

soyadı:

Adres:

Tel.

İmza:

**Katılımcı ile görüşen hekim**

**Adı:** Mohammad Dawood

**Soyadı:** Kharooty

**Unvanı:** Doktor

**Adres:** Gültepe Toki Binaları, mevlana sitesi Blok 7-3L, Daire No: 54 Altındağ/  
Ankara

**Tel:** 05384265486

**İmza :**

## ARAŐTIRMA BÜTÇESİ

AraŐtırma dahilinde kullanılacak olan kronometre, kan basıncını ölçmek için kullanılacak sfigmomanometre ve kırtasiye masrafları araŐtırmacılar tarafından karşılanacaktır. AraŐtırma dahilinde ek bir bütçeye ihtiyaç yoktur.

Sorumlu AraŐtırmacı: Akmer Mutlu

İmza

## İYİ KLİNİK UYGULAMALAR TAAHHÜTNAMESİ

### *Çalışmanın Adı:*

T.C. Sağlık Bakanlığı'nca; 51748 sayılı genelge eki olarak 29 Aralık 1995 tarihinde yürürlüğe konulan İyi Klinik Uygulamaları (İKU) Kılavuzu' nu okudum. Yukarıda adı geçen çalışmanın bu kılavuz prensiplerine uygun yapılacağını taahhüt ederim.

Sorumlu AraŐtırmacı : Akmer Mutlu

İmza:

Yardımcı AraŐtırmacı(lar) : Mohammad Dawood Kharooty

İmza