T.C.
DOKUZ EYLUL UNIVERSITY
HEALTH SCIENCES INSTITUTE

THE INFLUENCE OF REDUCED VISION, REDUCED PLANTAR SENSATION AND SIMULATED MUSCLE WEAKNESS ON PLANTAR PRESSURE DISTRIBUTION

Ebru KAYA MUTLU, PT

PHYSICAL THERAPY AND REHABILITATION
MASTER THESIS

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Socrates-Erasmus Exchange Program 2007

University of Maastricht
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ABBREVIATIONS

DM	Diabetes Mellitus
DN	Diabetic Neuropathy
DPN	Diabetic Peripheral Neuropathy
IDDM	Insulin Dependent Diabetes Mellitus
NIDDM	Non-insulin Dependent Diabetes Mellitus
QOL	Quality of life
DCCT	Diabetes Control and Complications Trial
BMI	Body maas index
Kg	Kilogram
M	Meter
ºC	Degree Celsius
PPP	Peak Plantar Pressure
MTH	Metatarsal Head

ABSTRACT

‘‘The Influence of Reduced Vision, Reduced Plantar Sensation and Muscle Weakness on Plantar Pressure Distrubition ’’

Ebru Kaya, PT

Purpose: To examine the influence of reduced vision, reduced plantar sensation and muscle weakness on plantar pressure distribution. These factors were seperately simulated on disease-free cases.

Material and Methods: The study group consisted of 20 healthy subjects (12M- 8F) ranged in age from 20 to 44 years. Subjects walked in five different conditions with their preferred walking speed. First was normal condition walking in normal gait pattern. Second was simulated muscle weakness walking by wearing waistcoat contains 40% of subject’s body weight. Third was reduced plantar sensation walking after 12 minutes ice immersion approach. Fourth was reduced vision by a pair of plane eyeglasess covered by black dots. Fifth walking condition was combination of iced feet, weight vest, and glasses. Plantar surface of the foot divided into ten different areas as two areas for hindfoot, two areas for midfoot, three areas for MTHs (1, 2, 3-4-5) and three areas for toes (1, 2, 3-4-5).

Results: The peak pressure under the first, second and third metatarsal head were significantly increased under reduced plantar sensibility. The peak pressures increased significantly under the second and the third to fifth toes under blured vision ($p \leq 0.05$). The peak pressure under the medial and lateral heel, second, and third to fifth toes were significantly increased under simulated muscle weakness. The peak pressure under medial, lateral midfoot, first, second, and third to fifth metatarsal heads were significantly increased under combined condition.

Conclusion: Reduced plantar sensation simulation results in high pressure under all metatarsal heads, reduced vision simulation results in high pressure under the second and the third to fifth toes, muscle weakness simulation results in high pressure under heel. However, combined condition simulation increase the pressure under all metarsal heads, lateral and medial midfoot.

Key words: Reduced plantar sensation, reduced vision, simulated muscle weakness, diabetic foot, plantar pressure

ÖZET

‘‘Azalmış Görme, Azalmış Plantar Duyu ve Kas Zayıflığının Plantar Basınç Dağılımı Üzerine Etkisi”

Ebru Kaya, FT

Amaç: Azalmış görme, azalmış plantar duyu ve kas zayıflığının plantar basınç dağılımı üzerindeki etkisini incelemektir. Bu faktörler sağlıklı olgularda ayrı olarak simüle edilmiştir.

Gereç ve Yöntem: Çalışma grubu 12’si erkek 8’i kadın olan, 20 ila 44 yaş aralığındaki 20 sağlıklı olgudan oluşmuştur. Olgular tercih ettikleri yürüme hızlarıyla beş farklı koşulda yürümüştür. İlk koşul, normal yürüyüş paterniyle yürüme idi. İkincisi her olgunun, kilosunun %40’ına eşit ağırlık içeren bir yelek giymesiyle gerçekleştirilen simüle edilmiş kas zayıflığı yürümesiydi. Üçüncü koşul, ayakların 12 dakika buza batırılmalarından sonraki azalmış plantar duyu yürümesiydi. Dördüncüsü, üstünde siyah alanlar bulunan düz camlı bir gözlük ile sağlanan azalmış görme idi. Beşinci yürüme koşulu ise buz, ağırlık yeleği ve gözlüğün kombinasyonuydu. Ayağın plantar yüzü arka ayak iki, orta ayak iki, metatarsal başlar üç (1, 2, 3-4-5) ve parmaklar üç (1, 2, 3-4-5) olmak üzere on farklı alana bölünmüştür.

Bulgular: Azalmış plantar duyu koşulunda pik ilk, ikinci ve üçüncü metatarsal başların altında anlamlı olarak arttı. Bulanık görme koşulunda pik basınç ikinci, üçüncü, dördüncü ve beşinci ayak parmaklarının altında anlamlı olarak arttı ($p \leq 0,05$). Simüle edilmiş kas zayıflığı koşulunda pik basınç, medial ve lateral topuk, ikinci, üçüncü, dördüncü ve beşinci ayak parmaklarının altında ise anlamlı olarak arttı. Kombine koşulda pik basınç medial ve lateral orta ayak, ilk, ikinci, üçüncü, dördüncü ve beşinci metatarsal başların altında anlamlı olarak arttı.

Sonuç: Azalmış plantar duyu simülasyonu tüm metatarsal başlarda; azalmış görme simülasyonu ikinci, üçüncü, dördüncü ve beşinci ayak parmaklarında; kas zayıflığı simülasyonu ise topukta yüksek basınca yol açarken kombine koşul simülasyonu tüm metatarsal başlarda, lateral ve medial orta ayakta basıncı artırır.

Anahtar kelimeler: Azalmış plantar duyu, azalmış görme, simüle edilmiş kas zayıflığı, diyabetik ayak, plantar basınç

PREFACE AND PURPOSE

Diabetes is a major health care problem in the world affecting millions of people every year. Diabetes can also cause many acute and long-term complications (1). Foot ulceration is a major complication of diabetes. Some studies show that foot ulceration occurs in 15% of diabetic patients. Diabetic foot ulceration is a significant cause of morbidity and can lead to larger hospital stays, which is evidenced by the fact that approximately 20% of hospitalizations related to diabetes involve diabetic foot ulceration (2,3,4).

The reason for foot ulceration to be such a major health issue is the coexistence of several aggravating factors (5). Some studies stated that high plantar pressure is a significant risk factor for foot complications (6,7,8). Yet, high plantar pressure may develop depending on several factors, and the determination of such factors is of great importance for the prevention and the treatment of pressure lesions.

Diabetic neuropathies are a family of nerve disorders caused by diabetes. Symptoms may involve the sensory or motor nervous system, as well as the autonomic nervous system (9). Diabetic neuropathy (DN) may affect both afferent and efferent pathways of the lower extremity. Therefore patients with DN have different walking patterns, such as a lower walking velocity, shorter stride length or cadence, longer loading time and less movement in the ankle joint. These changes on gait may lead to a differentiation of plantar pressures distribution (10,11,12).

Patients with DM and DPN are at risk of distal motor impairments as well as sensory impairments. Andersen et al. reported loss of muscle tissue and muscle strength of up to 40% for ankle dorsal and plantar flexor (13). Moreover, it has been reported that motor neuropathy leads to atrophic changes in the foot musculature which end up with foot deformity and decreased joint mobility (14).

The possibility that alterations in plantar pressure distribution may lead to plantar pressure lesions have been shown through several researches conducted on patients with diabetic peripheral neuropathy (15,16). Furthermore, studies have shown that neuropathy, peripheral vascular diseases, generalized limitations of joint mobility, overweight, structural foot deformities, and soft tissue damages are among the factors that cause plantar pressure lesions (16,17,18,19). Despite findings concerning patients with lower mean visual acuity being at greater risk of foot ulceration, there is lack of studies and information in the literature about the influence of a visual impairment such as reduced vision on plantar pressure distribution (20,21).

The importance of measuring plantar pressure distribution in determining foot ulceration risks is widely known (22). Researches have evaluated the heel, the medial and lateral arch, the first head of the metatarsal, the metatarsal heads of the other toes, toes and hallux; as well as peak pressure, pressure time integral, center of pressure fore- and hind-foot peak pressure ratio parameters (6,16,18,23,24). Trough the literature, our investigation evaluated medial and lateral hint food, medial and lateral mid food, hallux and 2-3-4-5 toes and heel parts respect to peak pressure, contact time and pressure time integral parameters.

In order for proper rehabilitation approaches to be determined, reduced vision, reduced plantar sensation and muscle weakness, which may lead to alterations in plantar pressure distribution, need to be examined in isolation. Yet, there are several factors within the scope of diabetic cases that affect plantar pressure distribution, hence the need for simulations in disease-free cases (23,24). Simulatory studies of the influences of reduced plantar sensation on plantar pressure have been documented in the literature (23,24,25,26), however there is lack of studies about the influence of reduced vision and muscle weakness by means of simulated patients. Therefore, this study is the first of its kind.

The results of this simulatory study on disease-free participants [simulated patients] will pave the way for studies on foot ulceration of diabetic patients as well as provide a scientific groundwork for optimal treatment programs used in cases of diabetic foot ulceration.

Given these facts, the aim of this study was to examine the influence of reduced vision, reduced plantar sensation and muscle weakness on plantar pressure distribution. To do so, these factors were separately simulated on disease-free cases. To simulate reduced plantar sensation, feet were submerging in ice water, to simulate muscle weakness, subjects weared a weight waist, and to simulate reduced vision, subjects were put eyeglasses. It was expected that these factors contribute to changes in the plantar pressure, which could results in the development of foot ulceration. It was hypothesized that the reduction in the muscle strength, plantar sensation, and visual acuity would lead to increase in the plantar pressure distribution.

INTRODUCTION

Diabetes Mellitus

1.1 Epidemiological data

Diabetes is a major health care problem in the world affecting millions of people every year (1). The World Health Organization estimates that 175 million people in the world (> 3% of total world population) have diabetes and predicts a rise to approximately 330 million by the year 2025 (28, 29). This increase will occur particularly in developing countries and will partly be due to population growth, aging, unhealthy diets, obesity, and sedentary lifestyles (30). The prevalence of Diabetes patients in Turkey was 2.9 million in 2003 and is expected to rise to approximately 5.4 million in 2025. In 2000, 426.000 people in the Netherlands were diagnosed with diabetes and in 2030, these figures may rise to 720.000. In the United States, about 17.7 million people were diagnosed with diabetes in 2000, and this number is estimated to increase to 30.3 million in 2030 (1,30,31). These numbers give an indication about the growing epidemic of diabetes in the world.

1.2 Diabetes

Defined as early as in 1500 BC by the Egyptians, Diabetes Mellitus is a chronic disease. The name Diabetes Mellitus is a combination of the Greek word for διαβαινειν meaning draining, and the Latin word mellitus, meaning sweet or honey (32). Diabetes Mellitus is a syndrome characterized by chronic hyperglycemia and disturbances of the carbohydrate, fat, and protein metabolism (33). Normally blood glucose concentration is tightly regulated by the coordinated action of insulin and counterregulatory hormones. During fasting a balance is maintained between glucose production by the liver and glucose clearance into peripheral tissues, primarily muscles. Insulin secretion from ß-cells of the pancreatic islets is constantly adjusted so that normoglycaemia is maintained. However, in patients with diabetes mellitus, the regulation of blood glucose levels is impaired and the blood glucose concentrations are elevated (hyperglycemia). Diabetic patients are not able to maintain normal blood glucose levels due to a defect in insulin release or an ineffective utilization of insulin, both of which result in hyperglycemia (28,29,34,35).

Two types of Diabetes can be identified: namely type 1, or insulin dependent Diabetes Mellitus (IDDM) and type 2, or non-insulin dependent diabetes mellitus (NIDDM) (36).

Type 1 diabetes is characterized by the autoimmune destruction of the insulin producing ß-cells of the islets of Langerhans in pancreas. Patients with type 1 diabetes do not produce any insulin and have to be treated with insulin injections (36, 37).

Characterization of type 2 diabetic patients is more complicated due to a complex disease process. The process starts with insulin resistance, resulting in compensatory hyperinsulinemia by increased pancreatic insulin production in order to keep blood glucose levels within normal limits. When pancreas is no longer able to produce enough insulin, postprandial and, afterwards, fasting blood glucose levels start to increase to maintain blood glucose levels within the normal range, leading to diagnosis of type 2 diabetes (37,38,39).

Initially, this will result in increased insulin production by the pancreas and will eventually lead to exhaustion of the ß-cells. Because there is either little or no insulin in the bloodstream (type 1) or the target cells do not respond to the insulin (type 2), the glucose cannot be cleared from the blood in the desired rate, which leads to chronically elevated blood glucose levels in patients with diabetes. An elevated glucose level in the blood can have serious consequences (28,36,38). In time, diabetes has an increased risk of developing macrovascular complications such as coronary, cerebrovascular, and peripheral vascular diseases, and so called “microvascular complications” such as retinopathy (eye disease), nephropathy (kidney disease), and neuropathy (peripheral nerve damage). These complications of diabetes are all highly associated in retrospective studies with poor diabetes control (34,36).

1.3 Diabetic Neuropathies

Neuropathies are the most common complication of diabetes mellitus (DM). Neuropathies related to DM affect up to 50% of patients both with type 1 and type 2 DM. Neuropathies also cause great morbidity because the symptoms severely decrease patients' quality of life (QOL) (40,41).

The main risk factor for diabetic neuropathy is hyperglycemia. It is important to note that people with diabetes are more likely to develop symptoms relating to peripheral neuropathy as the excess glucose in the blood results in a condition known as Glucojasinogen (42). In the DCCT (Diabetes Control and Complications Trial, 1995) study, the annual incidence of neuropathy was 2% per year, but dropped to 0.56% with intensive treatment of type 1 diabetics. The progression of neuropathy is dependent on the degree of glycemic control in both type 1 and type 2 diabetes. Duration of diabetes, age, cigarette smoking, hypertension, height and hyperlipidemia are also risk factors for diabetic neuropathy(12,36,43).

Diabetic neuropathies are heterogeneous in type; thus, several classifications of diabetic neuropathy were created and recognized. Diabetic neuropathies can be classified as peripheral, autonomic, proximal, and focal. Each affects different parts of the body in different ways (9,40).

Peripheral neuropathy damages the peripheral nervous system. Symptoms may include numbness or insensitivity to pain or temperature; a tingling, burning, or prickling sensation; sharp pains or cramps; extreme sensitivity to touch, even a light touch; loss of balance and coordination. Peripheral neuropathy may also cause muscle weakness and loss of reflexes, especially at the ankle, leading to changes in gait. Nerve damage in the feet can result in a loss of foot sensation, increasing the risk of foot problems such as ulcers, infections, and bone and joint deformities (16,44,45,46).

Autonomic neuropathy damages the autonomic nervous system. The autonomic nervous system is composed of nerves serving the heart, gastrointestinal system, and urinary-genital system. These nerves control the involuntary functions such as heartbeat, blood pressure, sweating, digestion, urination, and some aspects of sexual function. This is also a common form of diabetic neuropathy (9,43).

Proximal neuropathy, also known as lumbosacral plexus neuropathy, primarily affects the hips, thighs, and buttocks. The nerve damage may cause pain or muscle weakness that may increase as the condition worsens. The condition particularly interferes with an individual's ability to stand from a sitting position. Proximal neuropathy is usually asymmetrical, causing problems on only one side of the body. The pain and weakness

associated with this condition is often accompanied by unexplained weight loss. The type, severity and duration of the symptoms from proximal neuropathy vary according to the specific nerve damage (43,47).

Focal neuropathy can also appear suddenly and affect specific nerves, most often in the head, torso, or leg, causing muscle weakness or pain. Symptoms may include inability to focus the eye, double vision, aching behind one eye, paralysis on one side of the face (Bell's palsy), severe pain in the lower back or pelvis, pain in the front of a thigh, pain in the chest, stomach, or flank, pain on the outside of the shin or inside the foot, chest or abdominal pain that is sometimes mistaken for another condition such as heart attack (9,48).

1.4 Loss of Sensation

Many people with long-standing diabetes have significant deficits in tactile sensitivity, vibration sense, lower-limb proprioception, and kinesthesia (44,49). The loss of sensation associated with diabetic peripheral neuropathy (DPN) is thought to contribute to impaired balance, altered gait patterns, and increased risk of falling (25,50). People with DPN exhibit greater postural sway when standing, and numerous gait studies have revealed characteristic changes in walking patterns associated with DPN, including decreased power generation at the ankle, decreased knee joint flexion, and decreased ground reaction forces (24,44,49).

Hyperglycemia is one of the severe consequences of diabetes mellitus and is responsible for sensory deficiencies of hands and feet (41,51). The motor control of gait is compromised by the diminished feedback from the somatosensory system, and nerve degeneration may also compromise the performance of gait (24,44,47).

The complications of diabetes most relevant to the lower extremity are distal peripheral neuropathy and, to a lesser extent, peripheral vascular disease. The most feared lower extremity problem among patients with diabetes is amputation, and the sequence of events leading to amputation is usually initiated by skin ulceration. This occurs most frequently due to loss of sensation (5,8,19,20,21,48,52).

Due to the somatosensory threshold reduction in peripheral neuropathy, diabetic patients may develop changes in the foot contact phase during gait in order to reduce pressure

in the injured areas, overloading other plantar areas (5,20,49,52). Researches have demonstrated close relationships between peak plantar pressure during gait and ulcer regions in diabetic neuropathic patients (8,10,16,51). Some longitudinal studies have also demonstrated close relationships among peak plantar pressure, ulcer regions and plantar areas of diminished sensibility (12,19,21,46,44).

1.5 Muscle Weakness

Sensory symptoms and deficits are frequent in distal diabetic polyneuropathy (44). Motor symptoms are less dramatic and motor deficits are more difficult to recognize (13,53,54). Motor nerve damage, dysfunctions and atrophy are the results of the motor component of neuropathy. Muscle weakness is related to neurogenic atrophy, which is caused by axonal degeneration of motor fibers (14,53,54).

Motor neuropathy is commonly believed to lead to weakness in the intrinsic muscles of the foot, thus upsetting the delicate balance between flexors and extensors of the toes. Strength losses of 16-21% in the plantar and dorsal flexors of the ankle had been reported (14). Atrophy of the small muscles responsible for metatarsophalangeal plantar flexion is thought to lead to the development of hammer toes, claw toes, prominent metatarsal heads, and pes cavus. Unfortunately, structural deformities are common sites of abnormally high pressure, and repetitive pressure at these sites could result in tissue breakdown. Likewise, callosities may develop at these high-pressure sites; in the absence of protective sensation, continued activity can cause the callosities to thicken, hemorrhage underneath, and eventually ulcerate. Thus, foot deformities can cause alteration in pressure distribution, predisposing the skin to traumatic ulceration. This is confirmed by evidence that ulcers develop at sites of maximum pressure (55,56,57,58).

The sensory and motor diabetic neuropathies modify the amount and the quality of the sensorial information necessary to motor control. Consequently, there is an increase in instabilities during gait and static posture, which were previously considered to be due to muscular weakness (10,11,57,59).

While significant strength loss because of diabetic neuropathy that limits motor function is rare, many studies have shown that decrements in strength are common in neuropathic patients for whom the sensory symptoms often dominate clinical care and attention (13,53,54,60).

1.6 Reduced Vision

Diabetes causes a problem with the blood vessels in the body. The blood vessels begin to leak fluid, blood, and protein. In the eye, the retinovascular complications associated with diabetes mellitus are currently the major cause of blindness in adults. They are probably the result of several factors impairing blood supply and oxygen delivery to the retina. These factors include an increase in glycosylated hemoglobin (HbA1c) and thickening of the retina's basal membrane. This can lead to a progressive deterioration of the blood-retina barrier, causing leakage through the vessel wall, and focal retinal ischemia. Both of these occurrences lead to a progressive deterioration of the functional capacity of the retina resulting in decreased vision, reduced visual acuity, scattered central scotomas, peripheral and mid peripheral scotomas, and macular edema which is shown in figure 1 (61,62).

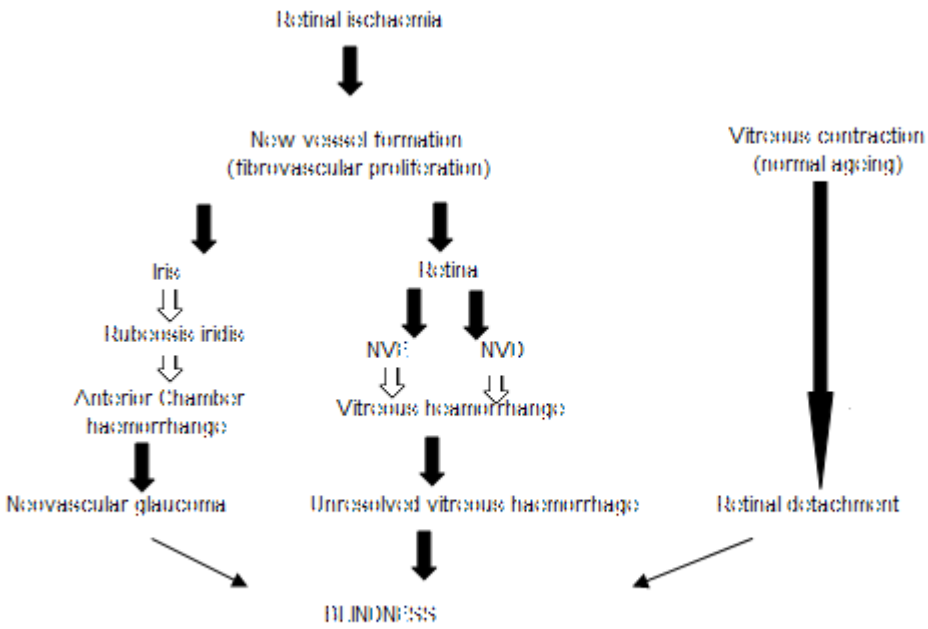

Figure 1: Blinding complications of diabetic eye are neovascular glaucoma, unresolved viterous haemorrhage and retinal detachment.

The central and peripheral components of the nervous system constantly interact to control body alignment. The peripheral component includes the somatosensory, visual and vestibular systems. The control nervous system incorparates the peripheral inputs from these systems and selects the most appropriate muscular responses to control body position (63,64). Consequently, these two systems cooperate in walking and create a balanced gait.

Visual loss in diabetic patients is often a late symptom; therefore, severe retinal damage caused by DM may remain undiagnosed. It has been estimated that about 10% of people after 15 years of DM will develop severe visual handicap. Examples are difficulty with tasks requiring visual detail such as reading, distorted central vision, fluctuating vision, loss of color perception, mobility and balance problems resulting from loss of depth and contrast cues (63,65,66,67).

1.7 Diabetic foot ulceration

Diabetic foot ulceration represents a major medical, social and economic problem all over the world. The lifetime risk for a person with diabetes of developing a foot ulcer could be as high as 25%, and it is believed that in approximately 30% under go of foot ulcers, a lower limb is amputating surgery (21,34,68,69).

Diabetic neuropathy and peripheral vascular disease are the main etiologic factors in foot ulceration; they act together and in combination with other factors such as unrecognized trauma, biomechanical abnormalities, limited joint mobility and increased susceptibility to infection (19,20,48), which is shown in Pecoraro's diagram (Figure 2).

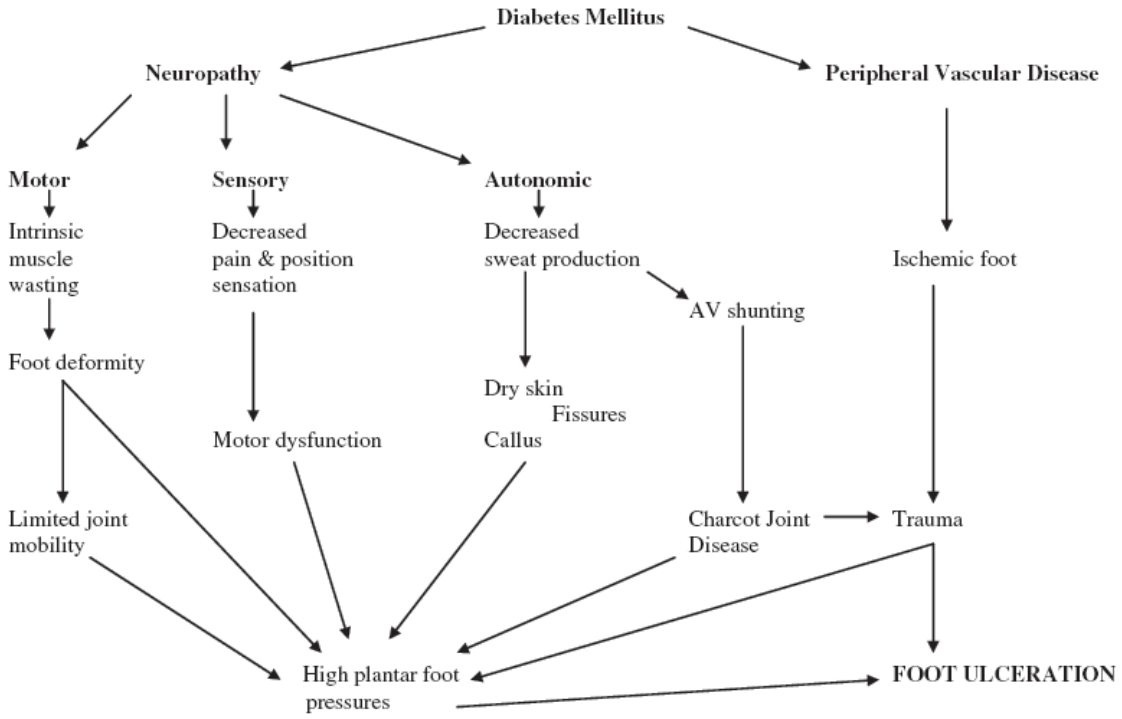

Figure 2: Clinical pathways leading to foot ulceration

The areas under the metatarsal heads are the most vulnerable areas for plantar ulcerations. These areas have been identified as areas having high focal pressures in patients with diabetes. These high pressures, which lead to foot ulceration, are caused by a number of diabetic symptoms (7,34,69).

1.8 Plantar pressure measurement methods

Plantar pressure measurement, in general, and peak plantar pressure (PPP) measurement, in particular, have been investigated extensively in the literature as a surrogate measure of trauma to the plantar foot and are known to be important contributing factors to skin breakdown in people with DM and DPN (6,10,20,51,52,70). Several pieces of equipment exist to measure high plantar pressure, producing static or measurements from in-shoe or force plate systems, with outputs manifest as simple or highly sophisticated quantitative measures (8,17,19,21,69,71).

Repeated loading of high PPP via walking has been associated with the location of skin breakdown (7,69,72). However, there does not appear to be a specific threshold of PPP that predicts ulceration (45,50). Clearly there are many mechanical factors that may contribute to skin breakdown besides the magnitude of pressure, including the duration and repetition of pressures (16,19,20).

One of the principal functions of the foot is its shock-absorbing capability during heel strike and its adaptation to the uneven surface of the ground during gait. In this function, the subtalar joint (allowing motion in 3 planes) plays a basic role. The ankle joint is the major point for controlling sagittal plane movements of the leg relative to the foot, which is essential for bipedal ambulation over flat or uneven terrain. The main motion of the first, and the lesser metatarsophalangeal joints are in the sagittal plane (dorsiflexion and plantarflexion). Normally, heel and forefoot get higher peak pressure than midfoot. During normal gait pattern, the highest peak pressure occurs on the medial metatarsophalangeal area and on the hallux. It shows that areas that have higher pressure may change depending on body weight and walking speed. Normal gait pattern may also have biomechanical alteration because of the morphological nature, physical activity, age and the presence of some disease such as loss of sensation and muscle weakness caused by diabetic peripheral neuropathy (7,8,16,17,19,69,71,73).

1.9 Influences of loss of sensation, muscle weakness and reduced vision on plantar pressure

Diabetes patients demonstrate significant increases in postural sway. Biomechanical gait analyses have shown that diabetic patients walk with slower speeds, shortened stride lengths, greater double support times, decreased ankle movements and powers and decreased vertical and anterior-posterior ground rection forces when compared to matched controls (8,17,59,49).

Gait is acquired as an outcome of a harmonic interrelation between coordinated neural and muscular action, which also requires intact skeletal function (74). Failure in this relationship may result in changes in the locomotor pattern (75,76). Gait is controlled through information received from the vestibular, visual and somatosensory systems with final control mediated through the motor system (64,67,77). Any impairment in any of these systems

would have a negative effect on gait, altering movement in the limbs as well as pressure distribution on the foot (8,16,17,25,26,59,71,78,79).

In our simulation study, we used diabetes mellitus as a model and we focused mainly influences of diabetic complications on the plantar pressure distribution.

MATERIALS AND METHODS

Subjects

Twenty disease-free participants with body mass index values of under 25 kg/m^2 were included into the research for investigating the effects of diabetic complications on plantar pressure by simulating the reduced vision and plantar sensation, muscle weakness, and of the combination of these three conditions on plantar pressure distribution. The research was conducted at the laboratory located in the Department of Movement Sciences of the Faculty of Health, Medicine and Life Sciences at Maastricht University, The Netherlands.

Criteria for inclusion into the Research:

Participants did not have communication- and health-related issues, which may have interfered with participation.

Participants did not seek medical services within the last two years due to neuromuscular or musculoskeletal system disorders.

Participants did not have lower extremity operation.

Participants did not have visual or vestibular dysfunction.

The composition of the participants are shown in Table 1.

Table.1: Participants distribution

Gender (n)		Age (years)		BMI (kg/m^2)	
Male	Female	Mean	SD	Mean	SD
12	8	25.3	6.34	21.8	2.45

Equipment

Plantar pressure measurement procedure was administered using the commercially applicable EMED-AT system (EMED AT-2, type 1377/2, 50 Hz, Novel GmBh; Munich, Germany). The sensor platform accommodates 2736 capacitance transducers with a data acquisition rate of 50 Hz, two sensors per cm^2. The participants were asked to walk on a 12-meter-long wooden platform, which was equipped with EMED-AT system.

The walking velocity was measured using two infrared sensor poles placed two meters apart. The first sensor was positioned in front of the force platform and, if interrupted, triggered a digital timer. The second infrared sensor was positioned behind the platform and stopped the timer if it was interrupted. The sensors were set at shoulder height to minimize interference of moving arms or legs that may have triggered the timer too early as the subjects passed through them.

The temperature of the plantar surface was measured on the heel, forefoot, and hallux using a K-type thermocouple (Testo 901). This device measured the plantar surface temperature instantaneously when the measuring sensor touched the skin (Figure 3).

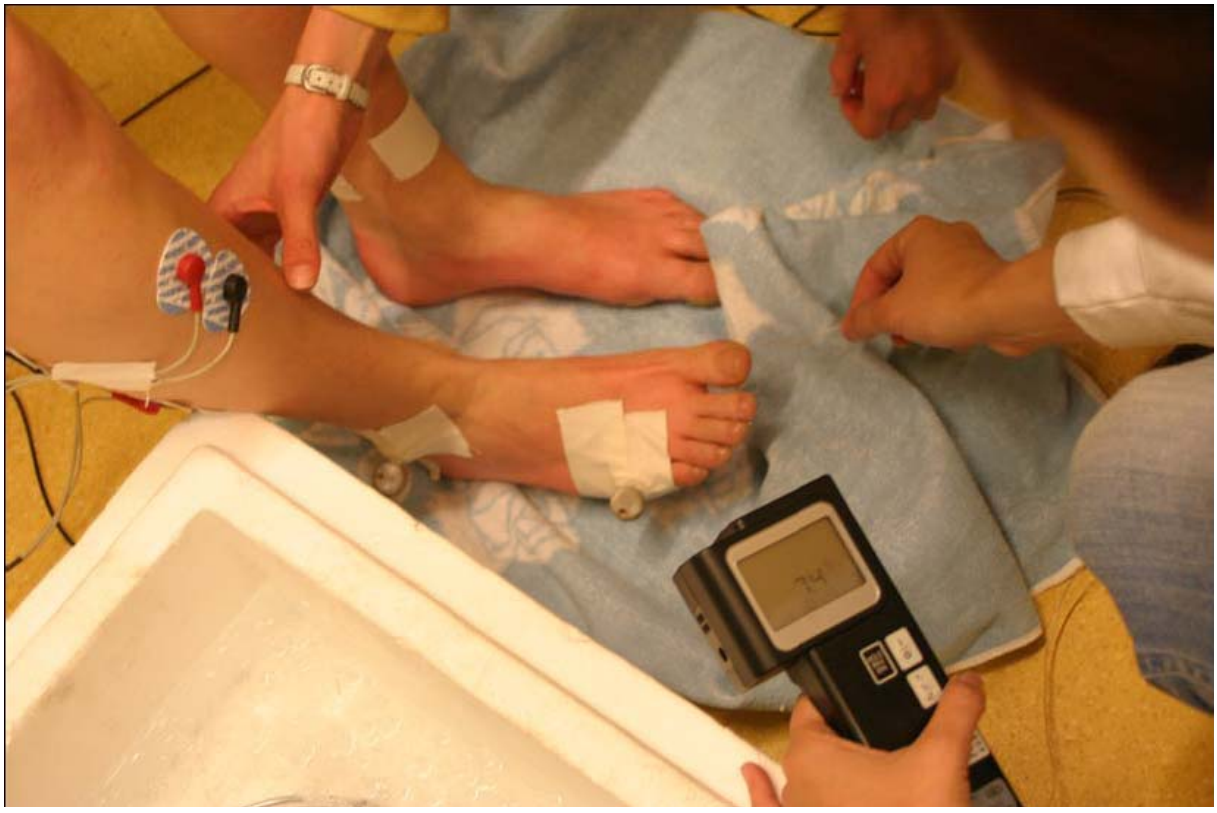

Figure 3: Temperature measurement

Pre-testing Procedure

The tests were performed at the movement analysis laboratory of the Department of Human Movement Sciences at Maastricht University. The study was approved by the Ethics Committee of Maastricht University Hospital, Maastricht, The Netherlands (see Appendix A for report in Dutch and Appendix B for report in English). Prior to inclusion, participants were informed on the objectives of the study and the methods to be used throughout the research. The tests were initiated once participants signed the informed consent form (see Appendix C). The evaluation began by recording the demographics (e.g. name, age, height, weight, gender) of participants. Age was recorded as year of birth only. Participants were weighed in kilograms on a standard scale without their shoes or any other additional weight on. Height was measured in meters using a standard tape measure while the participants stood barefoot by a specified wall. The body compositions of participants were judged by body mass index, which was calculated by dividing body weight (in kilograms) into height square (in meters). All data were recorded on a form (see Appendix D)

The authors of studies on diabetic gait pointed out that the differences between diabetic patients and control groups might be the result of a lower walking velocity of diabetics (25,49,78). In order to eliminate this possible confounder, the subjects in this study walked during all the different conditions at the same velocity. This velocity equalled their preferred walking velocity. A small range of variance ($\pm$ 5%) was allowed to make it feasible for the subjects to perform the test. The preferred walking velocity was determined during this pre-testing period after several practice runs that were done to familiarize the participant with the equipment and to find the right starting point. This is important because the subjects had to land with their right foot on the force platfom without targeting. The subjects walked five times at their normal preferred walking velocity, after which an average value was calculated. A schematic summary of the pre-testing phase is represented in Figure 4.

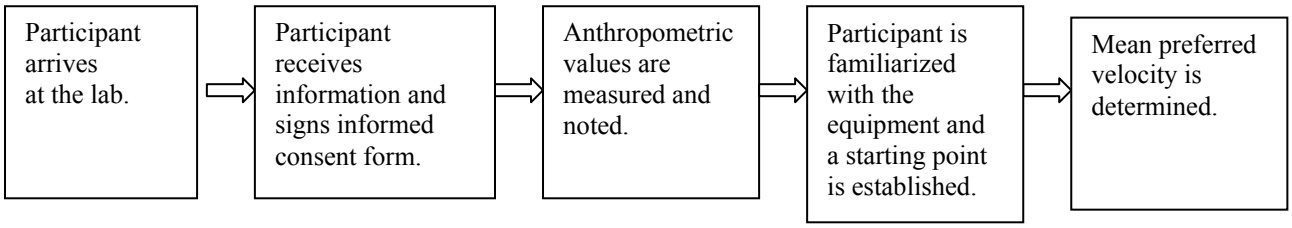

Figure 4: Schematic representation of the pre-testing procedure

Procedure :

This study focused on the effect of reduced vision and plantar sensation, muscle weakness, and of the combination of these three conditions on plantar pressure distribution. These conditions were simulated in the healthy subjects. These are described in the following paragraphs.

The measurements of the right foot were recorded when the velocity was within the determined range and if the foot was placed in the centre of the pressure platform without targeting. Peak pressure, contact time, pressure time integral accompanied by a color-coded pressure pattern were projected onto a computer monitor. These data were recorded and analyzed by the computer.

Reduced Vision

Blurriness (visual acuity) is defined as reduced vision. Therefore, a pair of plane eyeglasess covered by black dots to create a similar reduced vision throughout the entire field of vision was used to simulate reduced vision, *i.e.*retinopathy (Figure 5). Participants were asked to walk on the platform after putting on the glasses. The measurements were taken at the pre-calculated preferred walking velocity, and the data obtained when the right foot hits the center of the platform was recorded.

Figure 5: A pair of plane eyeglasess covered by black dots

Reduced plantar sensation

Plantar sensation was simulated by utilizing the ice immersion technique. Participants' feet were submerged at the medial malleus level in 0-1^{0}C water for 12 minutes (Figure 6). The subject sat on a chair with both feet on a metal grid, which was placed in an expanded polystyrene container. The grid enabled efficient cooling of the bottom of the feet.

The feet dried off at the end of twelve minutes. The temperature of the plantar surface was measured on the heel, the forefoot, and the hallux. Subsequently, the subject trod the walkway. The measurement was successful when the velocity was within the determined range and if the foot was placed in the center of the force platform without targeting. After each measurement the participants placed their feet back into the ice water for one minute to sustain the effect of cooling. Each walking condition was repeated five times.

Figure 6: Ice immersion

Reduced Muscle Strength

A vest that accommodates weight equal to 40% of the body weight was worn by each participant to simulate muscle weakness (Figure 7). Because the added weight was in proximity of participants' bodies, the increase in the body weight of the participants did not affect their center of weight. By changing the relation between load and load capacity, muscle weakness can be simulated. In diabetics, load capacity is normally affected because of the reduction of muscle mass. In the participants of this study the load was changed. It is assumed that increasing the load/load capacity ratio by increasing the load will have a similiar effect on gait as increasing this ratio by decreasing the load capacity, as is the case in diabetics patients. Afterwards, the subjects trod the walkway.

Figure 7: Weight vest (back)

Combinations of Factors

The fourth walking condition was a combination of the above mentioned factors: iced feet, weight vest, and glasses.

Normal Walking

All the effects of the manipulated factors were compared to the normal walking pattern. In other words, the subjects also walked without iced feet, weight vest, or glasses.

Randomization

Due to time constraints and in order to reduce the level of discomfort for the participants, randomization of the conditions was done in two parts. The conditions without ice (normal, glasses, vest) and the conditions involving ice (ice; vest, ice, and glasses) were randomized separately. The conditions not involving ice were always performed first (Figure8).

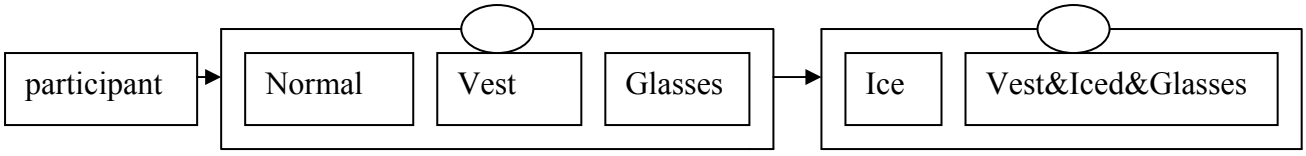

Figure 8: Randomization procedure

This approach may have influenced the results due to—for instance—possible fatigue of the subjects. However, the tests did not consist of physically demanding tasks, and the subjects were all healthy young individuals with good physical fitness. Furthermore, twelve minute intervals were included between the non-iced and iced conditions when the subjects sat with their feet in ice water. Therefore, the chosen randomization procedure is assumed not to seriously interfere with the results. Appendix E contains the complete randomization plan used in this study.

Data analysis:

The collected data was analyzed using Novel Database Pro, version 11.38, a commercial computer software. The parameters were determined in 10 areas after using the PRC mask for subdividing the foot (Figure 9). Peak pressure, contact time, and pressure time integral were calculated using Novel Auto Mask.

1- Medial hindfoot
2- Lateral hindfoot
3- Medial midfoot
4- Lateral midfoot
5- First metatarsal head
6- Second metatarsal head
7- 3rd, 4th, 5th metatarsals heads
8- Hallux
9- Second toe
10- 3rd, 4th, 5th toes

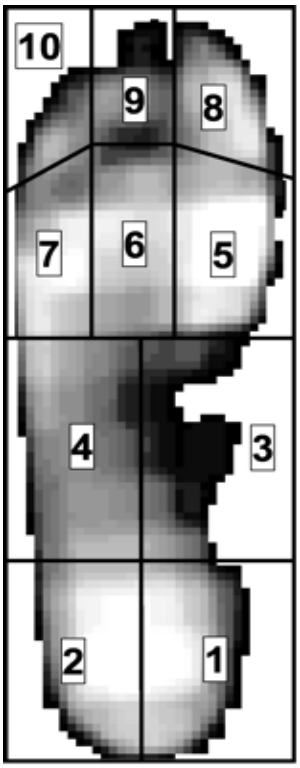

Figure 9: PRC mask classification

Statistical Analysis:

Out of the five experiments, the median was obtained by using SPSS 11.0 bundle for statistical analysis. Before the statistical test could be chosen the data was first tested for normal distribution by using the Shapiro-Wilk test. This test showed that data were not normally distributed. For this reason, Wilcoxon Singed Rank, a non-parametric test, was used. The significance level was accepted if the p value was smaller than 0.05.

RESULTS

Subjects

Three participants did not complete the whole experiment. They experienced too much inconvenience from submerging their feet in ice water. Eventually, twenty subjects in the normal, vest and glasses condition; eighteen subjects in the iced condition; seventeen subjects in the combinated conditions were used in data analysis.

Temperature measurement

Cooling the feet for twelve minutes reduced the skin temperature at three areas under the foot to about 12^0C. The skin temperature differed significantly between the heel and the hallux ($1,5^0$C), the heel and the forefoot ($0,8^0$C),and the hallux and the forefoot ($-0,7^0$C). Table 2 represents the mean temperature of the skin during both the iced and combined conditions.

Table 2. Mean skin temperatures for heel, forefoot and hallux

Position	Mean Temperature ^{0}C	Standart Deviation ^{0}C
Heel	12,9	1,70
Hallux	11,4	1,43
Forefoot	12,1	0,88

The pressure distribution under reduced plantar sensibility

The pressure distribution analysis showed significant changes for peak pressure, contact times, and pressure time integrals under reduced plantar sensibility. The analysis revealed that the peak pressures reduced for some areas and increased for other areas under reduced plantar sensibility (Table 3). The peak pressure under the second toe and the third to fifth toes were significantly decreased ($p \leq 0.05$). However, The increases in the peak pressure under the first, second and third metatarsal head were significant ($p \leq 0.05$). The total contact

time did not change significantly from normal to iced condition ($p>0.05$). Longer contact times, which are the result of earlier and prolonged contact, were found under the first, second and third to fifth metatarsal heads, hallux, second toe, third to fifth toes, yet were not accepted as significant ($p>0.05$). Contact times were found to be significantly shorter under the medial and lateral heel ($p\leq0.05$), medial and lateral midfoot ($p\leq0.05$, Table 3). The analysis of pressure time integral revealed that the reductions under the medial heel, lateral heel, medial midfoot, lateral midfoot, and second toe were significant ($p\leq0.05$, Table 3). However, the pressure time integral was found to be significantly increased under the first , second, and third to fifth metatarsal heads ($p\leq0.05$).

Table 3. Means and standard deviations for parameters of pressure distribution under reduced plantar sensibility

Pressure Distribution	**Peak Pressure (N/CM²)**			**Contact Time(ms)**			**Pressure Time Integral**		
	Normal	Iced	p level	Normal	Iced	p level	Normal	Iced	p level
Total	632±116	665±184	0,384	645±42	648±41	0,658	199±41	204±54	0,42
Med heel	496±148	454±160	0,201	334±68	310±60	**0,010***	78±22	67±16	**0,003***
Lat heel	478±143	436±93	0,438	333±68	303±57	**0,009***	74±20	65±15	**0,006***
Med midfoot	90±56	81±35	0,831	253±55	216±47	**0,013***	15±9	12±5	**0,013***
Lat midfoot	104±38	93±24	0,241	376±83	351±84	**0,008***	25±8	21±6	**0,006***
First MTH	313±167	355±154	**0,011***	512±45	532±47	0,072	81±48	98±53	**0,002***
Second MTH	385±115	450±186	**0,023***	534±34	547±39	0,129	100±24	119±37	**0,001***
Third to Fifth MTHs	316±107	340±67	**0,05***	549±38	556±39	0,581	95±32	107±24	**0,001***
Hallux	400±180	408±230	0,879	484±82	478±91	0,116	85±37	88±46	0,777
Second toe	170±65	135±46	**0,001***	416±74	438±86	0,727	36±15	32±15	**0,016***
Third to fifth toes	145±56	101±37	**0,004***	473±90	494±110	0,219	33±16	28±13	0,184

* $p\leq0.05$.

Values for each of the plantar pressure distribution before and following ice water immersion are summarized in diagrammatic form in Figure 10.

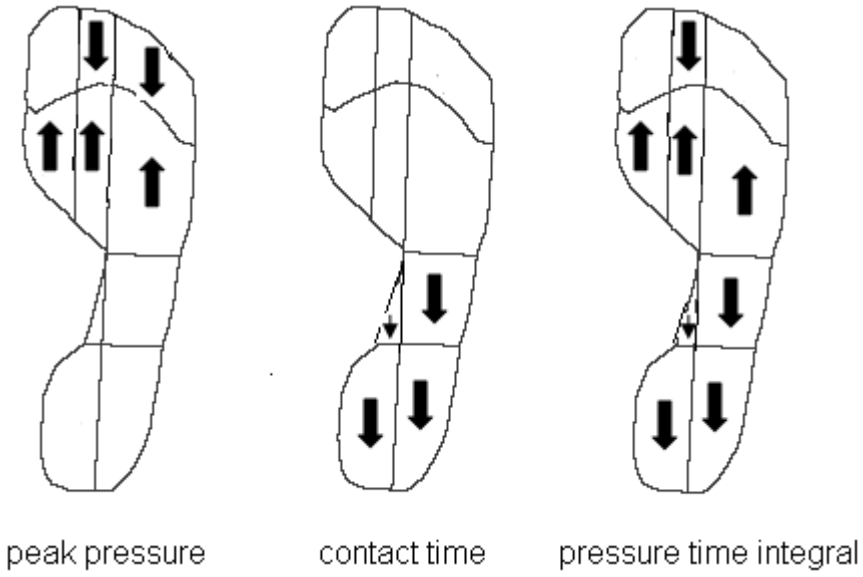

Figure 10: Summary of changes following ice water immersion. Significant changes and the direction of these changes are represented by arrows.

The pressure distribution under blurred vision condition

The pressure distribution analysis showed significant changes for peak pressure and pressure time integral under blurred vision condition. The analysis revealed that the peak pressures increased significantly under the second and the third to fifth toes ($p \leq 0.05$,Table 4). The contact time did not change significantly from normal to glasses condition. Pressure time integral were found to be significantly reduced under the medial midfoot and the second metatarsal head ($p \leq 0.05$, Table 4). The increase in pressure time integral under the third to fifth toes was significant ($p \leq 0.05$, Table 4).

Table 4. Means and standard deviations for parameters of pressure distribution under blurred vision condition

Pressure Distribution	Peak Pressure (N/CM²)			Contact Time(ms)			Pressure Time Integral		
	normal	glasses	p level	normal	glasses	p level	normal	glasses	p level
Total	632±116	620±135	0,466	645±42	641±31	0,356	199±41	195±43	0,411
Med heel	496±148	500±153	0,765	334±68	332±66	0,877	78±22	77±17	0,852
Lat heel	478±143	473±113	0,809	333±68	328±62	0,56	74±20	74±17	0,97
Med midfoot	90±56	79±38	0,775	253±55	235±64	0,063	15±9	12±7	**0,022***
Lat midfoot	104±38	102±34	0,586	376±83	379±90	0,824	25±8	25±11	0,94
First MTH	313±167	300±161	0,257	512±45	516±34	0,635	81±48	78±45	0,433
Second MTH	385±115	392±116	0,364	534±34	535±28	0,854	100±24	98±25	**0,05***
Third to Fifth MTHs	316±107	334±110	0,136	549±38	547±29	0,623	95±32	96±29	0,955
Hallux	400±180	405±159	0,501	484±82	488±88	0,439	85±37	86±37	0,614
Second toe	170±65	180±70	**0.047***	416±74	422±97	0,154	36±15	39±18	0,07
Third to fifth toes	145±56	159±53	**0,031***	473±90	498±84	0,203	33±16	38±18	**0,026***

* $p \leq 0.05$.

Values for each of the plantar pressure distribution before and following glasses conditions are summarized in diagrammatic form in Figure 11.

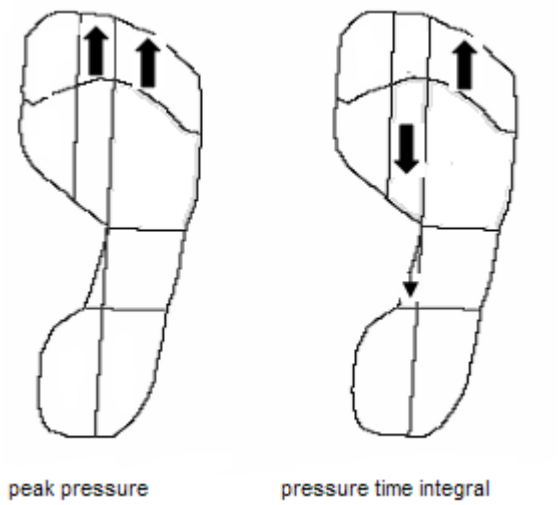

Figure 11: Summary of changes following glasses condition. Significant changes and the direction of these changes are represented by arrows

The pressure distribution under simulated muscle weakness

The pressure distribution analysis showed significant changes for peak pressure, contact time, and pressure time integral under simulated muscle weakness. The analysis revealed that the peak pressure reduced for all except two areas under all conditions, five of which were significant ($p \leq 0.05$, Table 5). The significant ones were medial and lateral heel,lateral midfoot, second, and third to fifth toes.The longer contact times, which are the result of earlier and prolonged contact, were found for all areas under simulated muscle weakness (Table 5). The contact times under lateral mind foot, first, second, and third to fifth metatarsal heads, hallux, second, third to fifth toes were significant ($p \leq 0.05$). The analysis of pressure time integral revealed that reduction under the third to fifth metatarsal heads was significant ($p \leq 0.05$). However, the pressure time integral was found to be significantly increased under the medial midfoot ($p \leq 0.05$)

Table 5. Means and standard deviations for parameters of pressure distribution under simulated muscle weakness

Pressure Distribution	**Peak Pressure (N/CM²)**			**Contact Time(ms)**			**Pressure Time Integral**		
	normal	vest	p level	normal	vest	p level	normal	vest	p level
Total	632±116	538±116	**0,001***	645±42	662±47	**0,003***	199±41	196±43	0,145
Med heel	496±148	583±131	**0,001***	334±68	345±55	0,303	78±22	76±18	0,627
Lat heel	478±143	550±87	**0,012***	333±68	338±53	0,548	74±20	72±16	0,709
Med midfoot	90±56	91±35	0,145	253±55	270±43	0,061	15±9	17±7	**0,025***
Lat midfoot	104±38	93±28	**0,05***	376±83	398±73	**0,007***	25±8	23±7	0,156
First MTH	313±167	288±114	0,575	512±45	544±41	**0,000***	81±48	82±38	0,797
Second MTH	385±115	385±125	0,881	534±34	560±39	**0,001***	100±24	101±35	0,823
Third to Fifth MTHs	316±107	302±107	0,455	549±38	569±38	**0,001***	95±32	87±28	**0,021***
Hallux	400±180	373±152	0,279	484±82	518±75	**0,010***	85±37	86±35	0,502
Second toe	170±65	149±65	**0,013***	416±74	465±84	**0,001***	36±15	36±18	0,627
Third to fifth toes	145±56	126±38	**0,05***	473±90	521±83	**0,001***	33±16	31±13	0,351

* $p \leq 0.05$.

Values for each of the plantar pressure distribution before and following simulating muscle weakness are summarized in diagrammatic form in Figure 12.

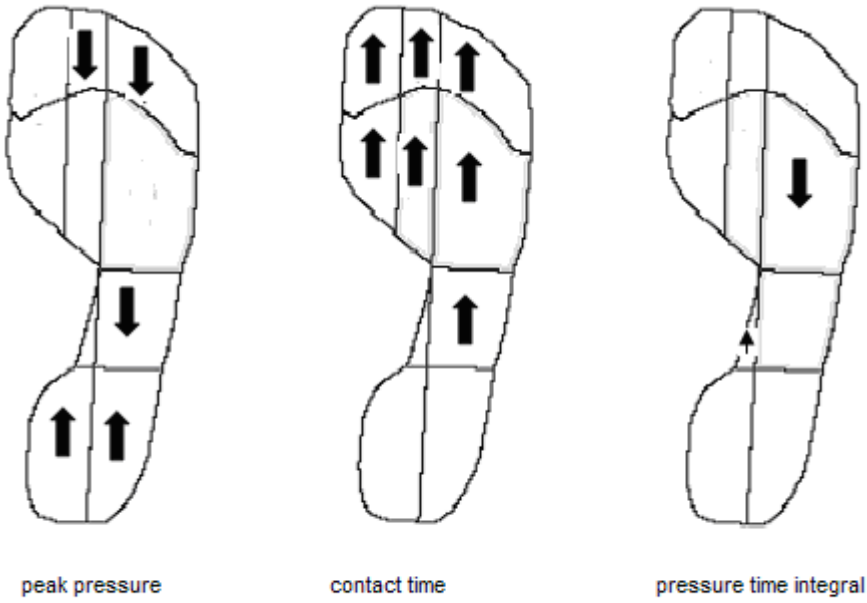

Figure 12: Summary changes following vest condition. Significant changes and the direction of these changes are represented by arrows.

<u>The pressure distribution under combined conditions</u>

The pressure distribution analysis showed significant changes for peak pressure, contact time, and pressure time integral under combined condition. The analysis revealed that the peak pressure increased for all except two areas under all conditions, five of which were significant ($p \leq 0.05$, Table 6). The significant ones were medial, lateral midfoot, first, second, and third to fifth metatarsal heads. Longer contact times, which are the result of earlier and prolonged contact, were found under the first metatarsal head, second metatarsal head, third to fifth metatarsal heads, hallux, second toe, and third to fifth toes, and were all significant ($p \leq 0.05$) (Table 6). The analysis of pressure time integral revealed increases for all areas, seven of which were significant under combined conditions (Table 6)

Table 6. Means and standard deviations for parameters of pressure distribution under combined conditions

Pressure Distribution	Peak Pressure (N/CM²)			Contact Time(ms)			Pressure Time Integral		
	normal	All	p level	normal	all	p level	normal	all	p level
Total	632±116	778±216	**0,003***	645±42	665±42	**0,021***	199±41	270±66	**0,000***
Med heel	496±148	542±187	0,193	334±68	347±50	0,384	78±22	94±20	**0,001***
Lat heel	478±143	500±122	0,569	333±68	340±46	0,823	74±20	89±20	**0,001***
Med midfoot	90±56	116±53	**0,003***	253±55	261±40	0,526	15±9	21±11	**0,004***
Lat midfoot	104±38	119±38	**0,003***	376±83	385±72	0,569	25±8	29±10	0,065
First MTH	313±167	477±225	**0,000***	512±45	559±37	**0,001***	81±48	141±77	**0,000***
Second MTH	385±115	578±157	**0,000***	534±34	572±35	**0,002***	100±24	158±44	**0,000***
Third to Fifth MTHs	316±107	440±108	**0,000***	549±38	578±40	**0,002***	95±32	133±27	**0,000***
Hallux	400±180	469±259	0,097	484±82	524±71	**0,003***	85±37	114±67	**0,013***
Second toe	170±65	166±58	0,551	416±74	490±69	**0,001***	36±15	44±19	0,068
Third to fifth toes	145±56	132±43	0,477	473±90	545±66	**0,001***	33±16	39±14	0,113

* $p \leq 0.05$.

Values for each of the plantar pressure distribution before and following all conditions are summarized in diagrammatic form in Figure 13.

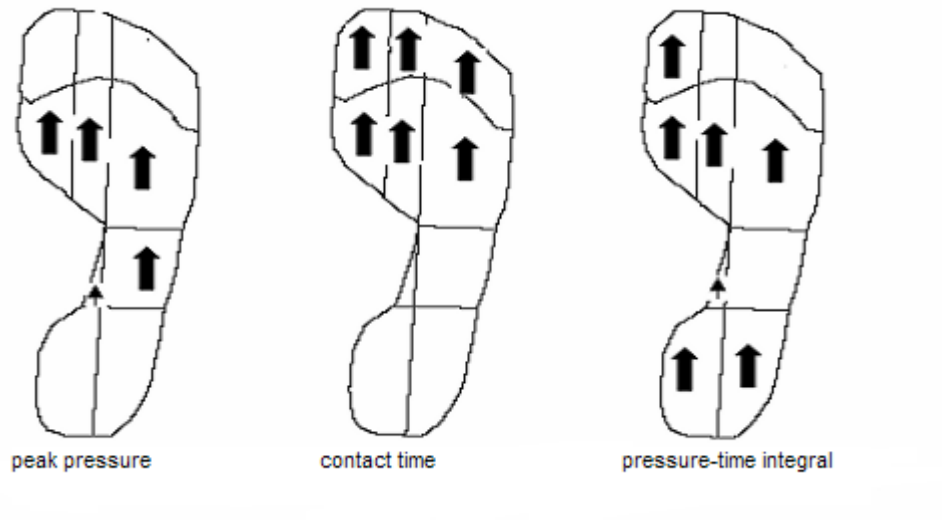

Figure 13. Summary changes following all conditions. Significant changes and the direction of these changes are represented by arrows.

DISCUSSION

The main focus of this study was to isolate and to simulate specific factors that are present in diabetic patients in order to investigate how they contribute to changes in plantar pressure. These factors include reduced muscle strength, reduced plantar sensation and reduced vision. It is expected that these factors contribute to changes in plantar pressure, which can result in the development of foot ulceration. It was hypothesized that reduction in muscle strength, in plantar sensation and in visual acuity would lead to increase in plantar pressure distribution.

This study was based on the manipulation of muscle strength, plantar sensation and visual acuity. The main advantage of this method is the fact that it enables the investigation of one factor at a time something that is nearly impossible to do in diabetic patients. Additionally, the methods used to simulate these factors could easily be combined. On the other hand, the use of simulation also has some disadvantages that have to be taken into account when analyzing data.

The simulation of muscle weakness was performed with the weight vest containing 40% of the subject's body weight. Muscle weakness can be defined as a misbalance between the load on the muscle and load capacity of the muscle. In subjects with muscle weakness the load/capacity ratio, i.e. the ratio between the force that is required and the force that can be generated, is negatively affected. A ratio can be changed by adjusting either the numerator or the denominator. In subjects, the load/capacity ratio is generally affected by a decreased denominator, i.e. reduced muscle strength or power. Presumably, an increase in the load would lead to a similar adaptation of the load/capacity ratio. Increasing the load, i.e. the body mass, provides a relatively easy applicable method to simulate load/capacity ratios (80).

Previous research pointed out that diabetic patients showed mean loss of isokinetic muscle strength in a range of 15% to 40% compared to age-matched controls (13,53,54). Reduction in muscle strength reduces load capacity. An increase of the load by 40% also puts a burden on load capacity and could therefore simulate muscle weakness in healthy persons. The precise "muscle strength reduction" was not measured during this study. However, it was assumed that the subjects had normal muscle strength (100%) and that with the vest on, the

load on the subjects was approximately 140%. The load/capacity ratio is therefore 1.4. In diabetic patients this ratio is estimated to lie between 1.2 and 1.7 based on earlier research (13,53).

The added weight should therefore be sufficient to simulate muscle weakness. The choice was made to minimize the discomfort for the subjects by adding no more than 40% of the body weight. Adding 40% body weight also results in the subject's BMI to increase by 40%. It should be taken into account that people with diabetes type 2 are often overweight. Becoming overweight is a slow process, and during this period people adapt to the increasing body weight. Stronger leg muscles, for instance, are necessary to be able to carry the extra weight. However, in diabetics and the elderly alike, the strength of the leg musculature is reduced instead of increased. The adaptation of a different walking pattern may be a solution to this problem. The subjects in this study became "overweight" in a few seconds. This means that walking felt strange and unfamiliar. Furthermore, not all leg muscles of diabetic patients are affected to the same extent due to the distal proximal character of this disorder. During the simulation with the weight vest, it is assumed that all muscles are affected more equally. This could lead to discrepancies between the subjects and the diabetic patients.

There are many simulation studies which were reduced plantar sensation in different ways (23,24,25,26,50,81). One of the methods to reduce plantar sensation is the use of an anaesthetizing creme (EMLA), which can be applied on the bottom of the feet (81), and another one is intradermal injection (50). Due to the expensive and time consuming nature of these two methods, in our simulation ice immersion approach was used instead. Ice immersion approach, which varies from some points, has been used in other studies (23,24,25,26). In the study of Eils et al., subjects placed one foot in ice water so that only the plantar part of the foot was submerged, while they had been using same pocedure except with grid in different study (23,24). Nurse et al. did not use submerging; instead, they used ice sealed inside a plastic bag and placed both feet on the surface of the bag (49). Taylor et al. used ice water at 2ºC, proceeded for 30 minutes and subjects feet did not contact the bottom of the ice water container (25). In this study, a combination of important points from the previous simulation studies was utilized to reduce plantar sensation. We used submerging both feet in ice water with a grid.

The cooling of the feet affects the mechanoreceptors in the plantar surface of the foot and is an effective way of altering sensor thresholds to pressure and vibration stimuli (26). According to Nurse et al., pressure sensation is difficult to alter through skin temperature, but when the temperature drops below ten degrees Celsius, the sensation is severely limited (26). A pilot study performed by Eils et al. indicated that no additional loss of sensitivity occured after ten minutes of cooling in water at 0ºC (23). This can be explained by the "Hunting Reaction," which states that cooling leads to a vasodilatation reaction. The dilatation results in a small rise in temperature, which can lead to the halt in the reduction of pressure sensitivity (23). Table 2.1 shows the mean temperature of the feet at three places under the foot. It can be noticed that the mean temperature is above the ten degrees Celsius stated by Nurse et al (26). This might mean that the sensitivity was not affected enough. However, the mean skin temperature did differs 1-2ºC greatly from the 10º C mentioned by Nurse. The subjects also experienced walking after the ice water immersion as being strange and different. It is therefore assumed that the plantar sensitivity was drastically reduced in the tests.

A scan of the medical literature yields no relevant studies in which vision was simulated except for ones that endeavor to visually discern loss of vision in diabetic patients through simulations performed by blacking out or blurring certain areas of photographs (82,83,84). In light of this information, we used eyeglasses in order to simulate reduced vision. The glasses were plane, encompassed the field of vision, featured certain areas that were blurred or blacked out, and provided reduced vision throughout the entirety of the two areas.

Some studies on gait in diabetic patients, which point to differences between the gait speed of control groups and that of diabetics, have determined lower speeds in the latter (11,44,67,76,78,79). In order to eliminate this, we ensured in our study that the gait speed of the participants remained constant throughout different simulations. A byproduct of this has been unfamiliar gait patterns due to the inconvenience caused by ice, the changes in field of vision, and the increase in the load placed on muscles.

Supported by several studies, which reveal that elderly patients' risk of falling increases as their sense of vision declines, is the fact that sense of vision constitutes an important component of gait. It has also been manifested in several studies that footcare failure due to a decline in sense of vision is related to diabetic foot ulceration (5,20,72).

However, influences of foot on plantar pressure along with the influences of visual loss on gait has not been shown in the literature. Therefore we simulated the sense of vision on healthy person , and observed high pressure areas under toes as sense of vision declined, yet we did not come across any changes in contact time. Considering the risk of diabetic foot ulceration at high pressure places, which is pointed out in relevant studies, visual loss presumably will cause the risk of foot ulceration to increase. Varying supportive simulations are needed since this study is the first of its kind in the literature.

Our results are similar to those of Nurse et al., who evaluated in-shoe plantar pressure patterns in 10 subjects prior to and following skin cooling of various regions of the foot. When the whole foot was cooled, pressures increased under the metatarsal heads and decreased under the toes and heel (26). This finding, which concerns the heel, toes, and the metatarsal head, matches that of other ice immersion studies and of this study alike (23,25,26). Our findings also parallel those of studies that include neuropathic patients as participants. Diabetic neuropathic patients have expressed that ulcerations are the most widespread on metatarsal heads, where pressure is the highest (10,16,71). It has been found that pressure decrease under the heel and toes occurs more in neuropathic patients than in non-neuropathic ones (23,24).

It has been documented that the cooling approach leads to decreases in neurotransmission and in the affects of skin receptors (23,24,26). Eils et al. and Taylor et al. have noted that ice immersion lengthens the contact time on the front foot (23,25). In a diffent study, Eils et al. emphasized that ice immersion induces the first foot contact to be more restrained (24). Our study has revealed that with reduced feedback, contact time of the sole decreases at the heel and the midfoot. This result has yet to be supported through other studies.

To date, influences on plantar pressure of loss of sensation have been defined in depth (23,24,25,26,81); yet the explications of influences of muscle strength on plantar pressure are not thorough. This study is the first simulation in pertinent literature to reveal influences of muscular weakness on plantar pressure. The main result of the simulation of muscular weakness has been plantar pressure decrease at the toes and the lateral midfoot; plantar pressure increase at the heel; and contact time increase at the toes, metatarsal heads, and the lateral midfoot.

Muscular weakness, in fact, does not directly influence plantar pressure. The foremost of its indirect, nevertheless significant influences is the alteration in gait pattern. Reduced muscle strength is the main factor in the alteration of neuropathic gait pattern at the ankle joint (11). The neuromuscular control of the foot decreases. Additionally, decrease in the balance between invertors and evertors at the plantar and dorsal flexors prevents the leg from elevating in sagital and frontal planes (4), which may result in foot deformity. Foot deformities are important contributary risk factors and predictive of foot deformity (5,57).
Van Schie et al. have noted that toe deformities have been observed in relation with flexor weakness (57). Similar to Van Schie's study, Cavanagh et al. have shown that hammer toe deformity is related to high metatarsal head pressure due to flexor and extensor weakness (22). Through the simulation of muscular weakness, some high pressure areas and some areas of short contact time of the sole have been determined in our disease-free participants, who did not have any foot deformities. Studies maintain that high pressure places and risk of occurrence of foot ulceration are related, and also that risk of ulceration and the contact time of the sole alter correlatively, which indicate that muscular weakness is directly proportional to the risk of occurrence of ulceration. Taking these into account, varying simulations of muscular weakness are needed in order to determine the risk of occurrence of foot ulceration in diabetics.

Since pressure time integral dispalys pressure applied in unit time, it paralleded the changes in peak pressure and contact time in our study, and exhibited significant decreases under some areas and significant increases under others.

Diabetes is a systemic disease. Reduced plantar sensation, reduced sense of vision, and muscular weakness are considered as a whole in diabetic patients. When the combination of these three factors was simulated on healthy person, plantar pressure increase at the medial and lateral midfoot and under the metatarsal heads was observed. Increase in the contact time of the sole at the toes and metatarsal heads was also recorded. Results of studies on diabetic patients and those of this combined simulation study parallel each other.

In conclusion, reduced plantar sensation simulation results in high pressure under all metatarsal heads, reduced vision simulation results in high pressure under the second and the third to fifth toes, muscle weakness simulation results in high pressure under heel. However, combined condition simulation effects all metarsal heads, lateral and medial midfoot, and increase in plantar pressure under these areas. Therefore, combination of these three simulations together effects the plantar pressure heavier than those of individual simulation method, and increase the risk of plantar ulceration.

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Appendix A: The Ethical Committee Report (in Dutch)

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azM

Aan Dr. H.H.C.M. Savelberg
Faculteit Gezondheidswetenschappen
Capgroep Bewegingswetenschappen
UNS 50 kamer 2230

afdeling MED.ETHISCHE COMMISSIE
uw kenmerk MECsecretariaat@ctcm.azm.nl
ons kenmerk 043 - 387 6009
doorkiesnummer MEC 06-3-024.4/pl
datum 24 mei 2006

Geachte dr. Savelberg,

Hierbij bericht ik u dat de Medisch Ethische Commissie op grond van artikel 2.2.a van de WMO op 19 mei 2006 een positief oordeel heeft uitgebracht gelet op het gestelde onder artikel 3 van de WMO met betrekking tot het door u ingediende onderzoeksvoorstel genaamd, **"Onderzoek naar de factoren die leiden tot een diabetisch looppatroon; een simulatie experiment"** (MEC 06-3-024).

De commissie heeft de volgende stukken in haar toetsing betrokken:

- protocol met versiedatum 8 mei 2006;
- proefpersonen- c.q. patiënteninformatie met versiedatum 8 mei 2006 (inclusief de verzekeringsinformatie over de wijze waarop de verzekering ex artikel 7 lid 1 WMO is geregeld);
- toestemmingsformulier met versiedatum 19 mei 2006;
- ABR-formulier met versiedatum 1 mei 2006;
- het curriculum vitae van de onafhankelijke arts;
- de advertentie/wervingstekst met versiedatum 19 mei 2006.

De commissie ontvangt nog graag bericht van de start- en einddatum van genoemde studie. Het positieve oordeel verliest zijn geldigheid, ook als met het uitvoeren van het onderzoek niet is begonnen, binnen een jaar nadat dit besluit is genomen. De commissie ziet graag ieder jaar tijdig, vóór afloop van de geldigheid, informatie tegemoet over de voortgang van de studie onder vermelding van het aantal proefpersonen dat aan het onderzoek heeft deelgenomen.

In een aan deze brief aangehechte bijlage zijn nadere, wettelijke, eisen vermeld waaraan de onderzoeker zal dienen te voldoen of welke door de commissie onder de aandacht worden gebracht.

Met vriendelijke groet,

namens de Medisch Ethische Commissie,

mr. R.C.W. van Gils,
ambtelijk secretaris

dr. C.E.M. de Die-Smulders,
voorzitter

Cc: De heer M.P.W. Lamberti BA, directeur Clinical Trial Center Maastricht
CCMO
UM, BMB/F&BI, verzekeringen MBB 4-6

De volgende leden hebben deelgenomen aan de besluitvorming inzake bovengenoemde studie:

Prof. dr. T. Gorgels, cardioloog (vice-voorzitter)
Dr. J. Offermans, gynaecoloog
Mevr. A. Hilton, verpleegkundige
Dr. P. Portegijs, universitair docent huisartsgeneeskunde
Dr. L. Stolk, ziekenhuisapotheker/klinisch farmacoloog
Prof. dr. M. Prins, methodoloog
Dr. A. v.d. Arend, filosoof
Mevr. H. Tjon-a-Fat, behartiger van de belangen van proefpersonen

Appendix B: The Ethical Committee Report (in English Translation by Hans Savelberg)

This is a short translation by Hans Savelberg of the approval letter of the Medical Ethical Committee of AZM, number MEC 06-3-024.4/pl

Dear Dr. Savelberg,

Based on article 2.2.a of the WMO (law on human research), the Medical Ethical Committee has passed a positive judgment with respect to the research proposal that was submitted by you, titled: "onderzoek naar de factoren die leiden tot een diabetisch looppatroon; een simulatie experiment" (an investigation in factors that cause a diabetic gait pattern; a simulation experiment) (MEC 06-3-024).

For her judgment the committee used the following documents:

- research protocol dd may 8, 2006
- information for subjects dd may 8, 2006 (including information with respect to subject insurance)
- informed consent form dd 19 may 2006
- ABR-form, dd May 1, 2006
- Additional information, dd May 1, 2006
- Curriculum vitae of an independent medical doctor
- Recruitment form dd May 19, 2006

The committee likes to be informed about the exact start and end dates of the study. The positive judgment is valid for 1 year. The committee wants to be informed every year about the progress of the study and the number of subjects included.

Sincerely,

List of members of the MEC that contributed to this decision

Appendix C. İnformed Consent Form:

INFORMED CONSENT

for participation in the experimental study:

Investigating factors that contribute to a diabetic gait pattern; a simulation

I have been informed about the study by the researchers, and I know what I will have to do during the study. I have been given opportunity to ask questions on the study. Moreover I had time to consider my participation in this study. I can decide at any moment to cancel my participation.

I agree in participating in this study, moreover I agree to use my medical and research data in the way it has been expalined to me.

I like not to be / to be **(please, select an option)** informed about the results of the study**.**

I do not / I want to invited **(please, select an option)** for participation in forthcoming studies.

Name:

Date of birth:

Signature: Date:

As responsible research, I declare that the above mentioned subject has been verbally informed about this study.

Name:
Position:

Signature: Date:

Appendix D: Data Form

DATA FORM

Date:…-….-
2007

Subject Name:	
Code:	
Age:	
Body Weight: (kg)	
Body Height: (m)	

Preferred walking velocity (time in seconds):					Remarks
1)	2)	3)	4)	5)	
Mean -5%:					
Mean:					
Mean +5%:					

Condition	Run 1(s)	Run 2 (s)	Run 3 (s)	Run 4(s)	Run 5 (s)	Remarks:
Normal (1)						
Vest (2)						
Iced (3)						
Glasses(4)						
Vest+ıced+glasses(5)						

Fill out what measurements failed with a ‘X’ or was correct and saved with a ‘V’

Condition	Run 1(s)	Run 2 (s)	Run 3 (s)	Run 4(s)	Run 5 (s)	Remarks:
Normal (1)						
Vest (2)						
Iced (3)						
Glasses(4)						
Vest+ıced+glasses(5)						

Appendix E: Randomization plan

1_____
Normal
Vest
Glasses
Iced
Vest&Iced&Glasses

2_____
Vest
Glasses
Normal
Vest&Iced&Glasses
Iced

3_____
Glasses
Vest
Normal
Iced
Vest&Iced&Glasses

4_____
Vest
Normal
Glasses
Iced
Vest&Iced&Glasses

5_____
Glasses
Normal
Vest
Vest&Iced&Glasses
Iced

6_____
Normal
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7_____
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