ISTANBUL TECHNICAL UNIVERSITY ★ GRADUATE SCHOOL

DEVELOPMENT OF TEXTILE-BASED RESISTIVE PRESSURE SENSING SOCKS IN DIABETES MELLITUS FOR EARLY DETECTION OF DFU

M.Sc. THESIS

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İSTANBUL TEKNİK ÜNİVERSİTESİ★ LİSANSÜSTÜ EĞİTİM ENSTİTÜSÜ

ŞEKER HASTALARINDA DİYABETİK AYAK ÜLSERİ ERKEN TESPİTİ İÇİN TEKSTİL BAZLI REZİSTİF BASINÇ ALGILAYICI ÇORAPLARIN GELİŞTİRİLMESİ

YÜKSEK LİSANS TEZİ

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Abdullah Ömer TOSUN, a M.Sc. student of ITU Graduate School student ID 503211801, successfully defended the thesis entitled "DEVELOPMENT OF TEXTILE-BASED RESISTIVE PRESSURE SENSING SOCKS IN DIABETES MELLITUS FOR EARLY DETECTION OF DFU", which he prepared after fulfilling the requirements specified in the associated legislations, before the jury whose signatures are below.

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To everyone who has an adore for science for the benefit and health of humanity

FOREWORD

Initially, i would like to express my deepest gratitude to my tutor Assoc. Prof. Dr. Özgür ATALAY for his assistance and support.

Sincere thanks to Assoc. Prof. Dr. Gökhan İNCE and Lecturer Phd.Münire Sibel Çetin for their constant support and inspiring guidance.

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JUNE 2024

Abdullah Ömer TOSUN
(Textile Engineer)

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ABBREVIATIONS

KDFC	: Knowledge of diabetic foot care
PDFC	: Practices of diabetic foot care
POF	: Polymeric optical fibers
DFU	: Diabetic foot ulcer
DPSS	: Daid pressure sock system
PDMS	: Polymethyl siloxane
COP	: Center of pressure
SD	: Standard deviation
DSP	: Diabetic neuropathic group
DFU	: Diabetic foot ulcer
NODSP	: Diabetic non-neuropathic group
CS	: Control group
DFUS	: Diabetic foot ulcers
DFC	: Diabetic foot care
DM	: Diabetes mellitus
WHO	: World Health Organization
FPG	: Fasting plasma glucose
AVP	: Arginine vasopressin
LADA	: Latent autoimmune disease
MODY	: Maturity onset diabetes of young
TIDM	: Type 1 diabetes mellitus
TPU	: Thermoplastic Polyurethane
HbA1c	: Hemoglobin A1c
USA	: United States of America
BMI	: Body Mass Index
PET	: Polyethylene terephthalate
PI	: Polyimide
PE	: Polyethylene
PU	: Polyurethane

SYMBOLS

R	: Resistance
p	: Resistivity
L	: Length
A	: Conductor's cross-sectional area
K	: Gauge
C	: Capacitance
E0	: Dielectric constant
E1	: Relative dielectric constant
A-d	: Relative area and distance between two electrodes
ΔR	: Resistance Change
ΔL	: Length Change
F	: Applied Force
GF	: Scale factor
v	: Velocity
w:	: Working Factor
kpa	: Kilopascal

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DEVELOPMENT OF TEXTILE-BASED RESISTIVE PRESSURE SENSING SOCKS IN DIABETES MELLITUS FOR EARLY DETECTION OF DFU

SUMMARY

Today, millions of people suffer from diabetes that will last a lifetime.

The energy necessary for people to continue their daily life activities is obtained from protein, carbonhydrates and fats. These basic nutrients need to be broken down into the smallest pieces in order to be absorbed. The most important of these nutrients are simple sugars called glucose. Cells contain glucose, which the human body needs, It makes it usable with the help of the hormone secreted by the organ called the pancreas. The name of this hormone is insulin. If this hormone does not work properly, the food taken cannot be used as energy.

Diseases that occur as a result of a deficiency of the insulin hormone or not working properly are called diabetes. This disease can occur in people during childhood, or it can occur after the age of 20s and 25th depending on genetic reasons. The disease shows itself as Type 1 and Type 2 Diabetes. Since it is a disease that progresses in a very insidious and painless way, the disease may not be diagnosed for many years.

Since Type 1 diabetes mostly occurs in childhood and youth, this disease is called juvenile diabetes in the literature. These patients have to take insulin hormone externally as a lifelong supplement. In our society, 10% of diabetes patients are Type 1.

Type 1 diabetes is a disease that is included in the group of diseases called autoimmune diseases and continues throughout life. The immune system, which acts for an unknown reason, damages beta cells in the pancreas, which are responsible for insulin production. When this damage exceeds 80%, disease specifications emerge.

The only rule in the treatment of type 1 diabetes patients is insulin therapy. In this type of diabetes, insulin injection is essential and plays a role in saving the patients’ life. In addition to insulin injection, a healthy and regular diet, sports and education should be

an invariable part of my patients' life. In order to maintain these principles and personal care, they should pay maximum attention to these principles. It is essential for patients to keep blood sugar between acceptable levels, to prevent very serious complications such as hyperglycemia and hypoglycemia that may put the person's life at risk and to provide and maintain ideal body weight and protein consumption, consumption of various foods, excess fiber in foods, consumption of simple sugars under the control of a dietitian and regular doctor appointments should not be interrupted. Exercise should be done regularly every day. In order for patients not to be exposed to advanced complications, they should first take all precautions for their own health.

The other disease seen in diabetes patients is type 2 diabetes. Genetic and environmental factors play a role in type 2 diabetes patients. These patients have insulin resistance and insulin secretion abnormality. There are abnormalities in insulin secretion due to genetic factors. Inactivity and desk life trigger this disease as environmental factors. In addition, obesity, one of today's diseases, causes insulin resistance and as a result, diabetes is inevitable.As in Type 1 diabetes patients, Type 2 diabetes patients have to pay close attention to their nutrition, daily physical activity and blood sugar. The person should eat healthy and regularly and avoid foods and drinks that will cause sudden rise and fall in blood sugar. The patient should also regularly measure blood sugar 6 times on an empty stomach and note the averages and not neglect the doctor's appointments. In both Type 1 and Type 2 diabetes diseases, diabetic coma, irreversible damage to vital organs, especially (silent and latent period of diabetes) and in cases where the patient does not receive adequate treatment or neglects the kidneys insidiously and without pain, in the more normal-high stages of diabetes. Bleeding due to intraocular vascular structure can lead the patient to blindness in a very short time.

As a result of the deterioration of kidney functions, the patient may be sentenced to dialysis for life. Depending on the damage to the cardiovascular system, permanent damage may occur in the feet and hand limbs of the patients, and accordingly, these limbs must be cut off suddenly.

Since the blood cannot go to all organs and limbs in the body in an equal and balanced way in diabetic patients, over time, excess pressure and numbness occur in areas with less blood flow and accordingly the areas where numbness occurs should be surgically cut. The best example for this is the foot part of diabetic patients. Depending on the disease, the blood cannot reach every region equally on the soles and fingers of the foot and over time, numbness and pressure increase occur in certain parts of the foot. If the person does not realize this situation in time the damaged tissue is removed by incision method in order to prevent the decay from progressing to other areas comes into play at this point.

In the thesis study, it is aimed to carry out a study in order to make early diagnosis in diabetes patients by integrating switch mechanism that is pressure sensitive sensors under socks.

The working principle of switch sensors is based on short-cut under pressure. The usage area of switch sensors is gradually expanding due to their advantages such as flexibility, accuracy of data, low energy use and sensor design.

The use of key sensors with parallel conductive layers seems more logical in terms of sustainability and convenience.In this thesis, three conductive layers were produced and they were separated from each other by knitted fabrics with different sieve sizes.K nitted fabrics with larger sieve sizes were integrated into the upper side of the layers,while knitted fabrics with smaller sieve sizes were binded to the bottom of the layers.In case of abnormal pressure,the lower conductive layers generate a resistance and short-cut occurs.However,in case of lower pressures,the upper conductive layers create short-cut.The reason for this is that at low pressure,conductive fabrics in the layers with large sieves contact each other more easily and create a short cut.In the case of abnormal pressure,conductice fabrics in the layer with smaller sieve sizes contact each other and create resistance.TPU coated conductive paths were used to prevent short-cuts during data transmission from soft sensors to the center.Otherwise,short-cut may occur at different points during data transmission and deviations and inaccuracies may occur regarding the accuracy of the data.The resistive sensor mechanism was adopted due to it is simple and does not requie any manual dexterity or knowledge of making patterns.In addition,it is clear that there will not be defects caused by sock knitting machine and budget to set up this system is lower than of sock knitting machines.When all these advantages are gathered up,it can be said that resistive sensors are feasible and effective approach to predict diabetic foot ulcer before a possible amputation.

ŞEKER HASTALARINDA DİYABETİK AYAK ÜLSERİ ERKEN TESPİTİ İÇİN TEKSTİL BAZLI REZİSTİF BASINÇ ALGILAYICI ÇORAPLARIN GELİŞTİRİLMESİ

ÖZET

Günümüzde milyonlarca insan ömür boyu sürecek şeker hastalığından müzdarip bulunmaktadır.

İnsanların günlük yaşamsal aktivitelerini sürdürebilmesi için gerekli olan enerji protein, karbonhidrat ve yağlardan elde edilmektedir. Bu temel besin öğelerin emilebilmesi için en küçük parçalara ayrılması gerekmektedir. Bu besin öğelerinin en önemlisi de ‘glukoz’ adı verilen basit şekerlerdir. Hücreler insan vücudunun ihtiyacı olan glikozu, pankreas adı verilen organ tarafından salgılanan hormon yardımıyla kullanılabilir hale getirmektedir. Bu hormonun adı insülindir. Eğer bu hormon sağlıklı olarak çalışmazsa alınan gıdalar enerji olarak kullanılamaz.

İnsülin hormonunun eksikliği ya da sağlıklı çalışmaması sonucunda ortaya çıkan hastalığa “şeker hastalığı” denilmektedir. Bu hastalık insanlarda çocukluk çağında ortaya çıkabileceği gibi genetik nedenlere bağlı olarak 20’li, 25’li yaşlardan sonra da ortaya çıkabilmektedir. Hastalık kendisi Tip 1 ve Tip 2 olarak göstermektedir. Şeker hastalığı oldukça sinsi ve acı vermeyen şekilde ilerleyen bir hastalık olduğu için hastalık uzun yıllar boyunca teşhis edilemeyebilir.

Tip 1 diyabet hastalığı, çoğunlukla çocukluk ve gençlik yaşlarında vuku bulduğundan dolayı bu hastalığa literatürde “Juvenil Diyabette” denilmektedir. Bu hastalar insülin hormonunu haricen ömür boyu sürecek şekilde dışardan takviye olarak almak zorundadır. Toplumumuzda diyabet hastalarının %10 Tip 1’dir.

Tip 1 diyabet otoimmün hastalıklar olarak adladırılan hastlıklar grubuna dahil olan ve yaşam boyunca süregelen bir hastalıktır. Nedeni belli olmayan bir şekilde harekete geçen bağışıklık sistemi pankreas’ta insülin üretimi görevi olan beta hücrelerini zedelemektedir. Bu tahribat %80 oranının üzerine çıktığında hastalık spesifikasyonları ortaya çıkmaktadır.

Tip 1 diyabet hastalarının tedavisinde yegane kural insülin tedavisidir. Bu tip şeker hastalığında insülin enjeksiyonu elzemdir ve hastanın hayatını kurtarıcı bir rol oynamaktadır. İnsülin enjeksiyonuna ek olarak, sağlıklı ve düzenli beslenme, spor ve eğitim hastaların yaşamının değişmez bir parçası olmalıdır. Kişilerin hayatını sağlıklı bir şekilde sürdürebilmeleri adına bu prensiplere ve kişisel bakımlarına azami düzeyde özen göstermeleri gerekmektedir. Hastaların kan şekerini kabul edilebilir düzeyler arasında tutması, hiperglisemi ve hipoglisemi gibi kişinin hayatını riske atabilecek çok ciddi komplikasyonların önüne geçilmesi ile ideal vücut ağırlığını sağlamak ve korumak esastır. Bu bağlamda uygun düzeyde karbonhidat ve protein tüketilmesi, çeşitli besinlerin tüketilmesi, besinlerde fazla posa alınması, basit şekerlerin diyetisyen kontorülünde tüketilmesi ve düzenli doktor randevularının aksatılmaması gerekmektedir. Egzersiz olarak diyabet hastaları için kişiye uygun egzersiz tipi program yapılmalıdır. Egzersiz her gün düzenli olarak yapılmalıdır. Hastaların ileri komplikasyonlara maruz kalmamaları için tüm önlemleri öncelikle kendi sağlıkları için almaları gerekmektedir.

Şeker hastalarında diğer görülen hastalık tip 2 şeker hastalığıdır. Tip 2 diyabet hastalarında genetik ve çevresel faktörler rol oynamaktadır. Bu hastalarda insülin direnci ve insülinsekresyon anormalliği vardır. Genetik faktörlere bağlı olarak insülin salınımında anormallikler bulunmaktadır. Çevresel faktörler olarak da hareketsizlik ve masabaşı yaşantı bu hastalığı tetiklemektedir. Ayrıca günümüz hastalıklarından obezite de insülin direncine neden olmakta ve bunun sonucu olarak da şeker hastalığı kaçınılmaz olmaktadır.

Tip 1 diyabet hastalarında olduğu gibi Tip 2 diyabet hastalarında da kişi beslenmesine, günlük fiziksel aktivitesine ve kan şekerine çok dikkat etmek zorundadır. Kişi sağlıklı ve düzenli beslenmeli, kan şekerinin ani olarak yükselip inmesine neden olacak yiyecek ve içeceklerden kaçınmalıdır. Hasta ayrıca düzenli olarak günde 6 defa aç ve tok karna kan şekeri ölçümünü yapmalı ve ortalamalarını not alıp doktor randevularını ihmal etmemelidir.

Hem Tip 1 hem de Tip 2 diyabet hastalıkları diyabetik komalar, hayati organların geri dönülemez şekilde hasarı (özellikle diyabetin sessiz ve gizli dönemi) ve diyabetin daha normal-yüksek seyrettiği evrelerde hastanın yeterli tedavi olamaması ya da ihmal etmesi durumunda sinsi bir şekilde ve acı hissettirmeden böbrek, göz ve kalp damar sağlığının yanında diğer hayati organlara hasar verebilmektedir. Göz içi damar yapısının bağlı kanamalar hastayı çok kısa bir süre içinde körlüğe kadar götürebilmektedir.

Böbrek fonksiyonlarının bozulması sonucu hasta ömür boyu diyalize mahkûm kalabilmektedir. Kalp damar sistemindeki hasarlara bağlı olarak hastaların ayak ve el uzuvlarında da kalıcı hasarlar oluşabilmekte ve buna bağlı olarak bu uzuvların ansızın kesilebilmesi gerekmektedir.

Diyabet hastalarında kan vücuttaki tüm organlara ve uzuvlara eşit ve dengeli bir şekilde gidemediği için zamanla daha az kan giden bölgelerde basınç fazlalığı ve hissizlik oluşmakta ve hissizlik oluşan bölgelerin cerrahi işlemle kesilmesi gerekmektedir. Buna en iyi örnek olarak diyabet hastalarında ayak kısmı verilebilir. Hastalığa bağlı olarak ayak tabanında ve parmaklarda kan her bölgeye eşit olarak ulaşamamakta ve zamanla ayağın belli bölümlerinde hissizlik ve basınç artışı oluşmaktadır. Eğer kişi bu durumu zamanında fark edemezse çürümenin diğer bölgelere de ilerlememesi için hasarlı doku kesi yöntemiyle alınmaktadır. Bu tezin konusu ve amacı da tam olarak bu noktada devreye girmektedir.

Bu tez çalışmasında çorap altına rezistif basınç algılayıcı yani basınca duyarlı sensörler entegre edilerek diyabet hastalarında erken tanı koyulabilmesi için bir çalışma yapılması amaçlanmıştır. Rezistif sensörlerin çalışma prensibi basınç altında kısa devre oluşması prensibine dayanmaktadır. Esneklik, veri doğruluğu, düşük enerji kullanımı ve sensör tasarımı gibi avantajları nedeniyle anahtar sensörlerin kullanım alanı giderek genişlemektedir.

Paralel iletken katmanlara sahip anahtar sensörlerin kullanımı sürdürülebilirlik ve kolaylık açısından daha mantıklı görünmektedir. Bu tezde 3 iletken katman üretilmiş ve bunlar farklı elek büyüklüklerine sahip örme kumaşlarla birbibinden ayrılmıştır.Daha geniş eleğe sahip örme kumaş tabakaların üst tarafına entegre edilirken daha küçük elek boyutlarına sahip örme kumaşlar katmaların en altına yapıştırılmıştır.Anormal basınç durumunda alt iletken tabakalar kısa devre oluşturmaktadır. Bununla birlikte daha düşük basınç durumunda üst iletken levhalar kısa devre oluşturmaktadır.Bunun sebebi az basınçta büyük eleğe sahip katmanda iletken kumaşlar daha kolay birbirine temas edip kısa devre oluşturmasındandır anormal basınç durumunda ise daha küçük elek boyutlarına sahip katmanda iletken kumaşlar birbirine temas edip rezistans oluşturmaktadır. Yumuşak sensörlerden merkeze veri iletimi sırasında kısa devre oluşmaması için TPU kaplı iletken yollar kullanılmıştır.Aksi halde veri iletimi esnasında farklı noktalarda kısa devre oluşabilir ve verilerin doğruluğu konusunda sapmalar ve yanlışlıklar oluşabilir.Rezistif sensör mekanizmasının basit olması, herhangi bir el becerisi veya desen yapma bilgisi gerektirmemesi nedeniyle benimsenmiştir.Ayrıca çorap örme makinasından kaynaklanan herhangi bir hata olmayacağından ve bu sistemin kurulum bütçesinin çorap örme makinelerine göre düşük olduğu aşikardır. Tüm bu avantajlar bir araya getirildiğinde olası bir ampütasyondan önce diyabetik ayak ülserini öngörmek için rezistif sensörlerin de bu şekilde uygulanabilir ve etkili bir yaklaşım olduğu söylenebilir.

1. INTRODUCTION

Diabetes mellitus patients have a tendency to complex and multiple complications and between them foot ulcer is a prime one. Previous studies demonstrated that 25% of diabetes have a danger of attract to foot ulcer in their lives. It is also reported that %20 of hospital accessions among diabetes patients are as a consequence of diabetic foot ulcer. A recent study showed that the worldwide rate of foot ulcer was 6.3%. North America encompasses 5.1% whereas Oceania 3%, Africa 7.2%, Asia 5.5%. Europe shows 5.1% when Australia covers 1.5% [12]. Patients who have neuropathy show a huge risk of foot ulcer. The main purpose of all studies is to determine the risk and the development of foot ulcer in order to hamper lower limp surgery an even lost. Some studies also show that the patients are not aware of the abnormal pressure in their foot with an average of 45%. It is also overt that inaccurate footwear triggers the biomechanism of patient's foot in a negative manner [12]. Early detection of the unequal pressure is pivotal. For the purpose of early detection some devices and wearable systems are devised. Many research staffs are working on the development of influential and productive foot pressure and gate analysis systems. For instance plantar pressure analysis technique was invented for the design of insert and footwear such as socks. Medical applications;clinical gait analysis, the investigation of the patterns of walking, pathology foot plantar loading and etc. have been studied by the researchers and they're the most studied areas [13]. Dr. Paul Brand was the pioneer scientist who advise the measurement of the pressures among shoe and foot. He tried to notice the caused and the results of high pressures under the foot. It took more than 40 years to advise embedded devices for the patients. Most of them are still prototypes and researchers are still working on them. On the other hand, three companies released some devices. The companies are Novel, Tekscan and Vista Medical companies. These devices are being used with wire connection for the acquisition of data from insole to machine. Furthermore, these devices are not compatible with daily use. This is the main drawback of the current technologies [4].

Some types of plantar pressure systems are available in the current market or in some laboratories which carry out a research regarding this issue. We can mention about two major systems which are platform systems and in-shoe systems. Platform systems are deployed in a walkway. In order to record the plantar pressure distributions with a shoe, in shoe systems are used and they are more flexible than the platform systems [13]. For gait stability and gate event analysis, commercial products are used which comprise F-scan measurement system and "new pedar system" that dynamic in shoe temporal alteration and spatial pressure distributions.On the other hand, both systems require electrical wires to connect in-shoe sensors and data transfer which is not convenient for the long run. They're also not suitable for long term outdoor purposes [13].

Some other types of wireless insoles for gate and pressure control were advised that entail Bluetooth connection or equivalent data transfer appliance, definitely with an energy source. Even though a huge type of systems, both systems have one common disadvantage which is that the layer can distort the correct data of plantar loading under the foot as a consequence of thickness. Moreover, these systems are not affordable and unsuitable for daily use [2]. At this point, socks can be used in order to eliminate abovementioned possibly distorted pressure distribution. This thesis will focus on the wearable socks in order to detect early foot ulcers. Socks can be used in medical and sport fields, during snowboard training and annihilate belated foot ulcer detection.

There are a wide variety of sensor are being used for the socks such as piezoresistive. The structure must be knitted and should be sensible to pressure. Socks can be knitted by knitting machines. It doesn't make a big difference. There is a relation among the load of pressure and resistance [13]. If there is an instant alteration of pressure under the foot it definitely affects the resistance and this helps to detect early foot ulcer. Scientists determine roughly 5 points in the socks in order to analyze pressure change.

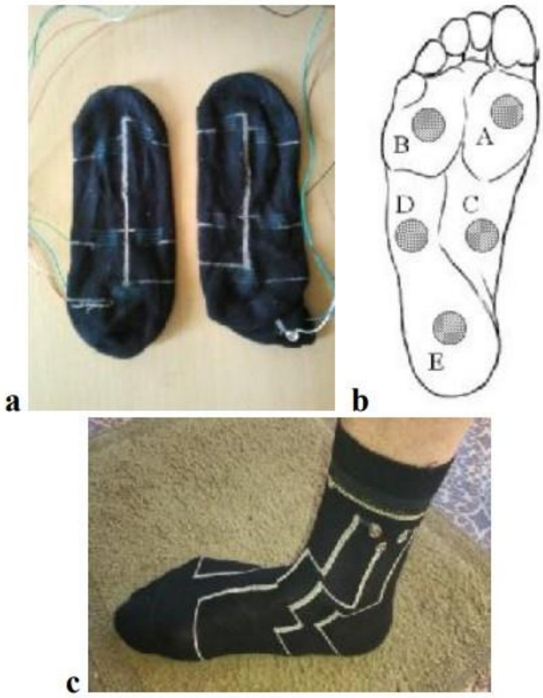

Figure 1.1: Sensors implementation and design [13].

There are also three keys in the studies which are smart socks, central unit and the prediction of the risk for foot pressure ulcer [3]. Central units take part in the upper part of the sock, which made of an electronic circuit and a soft battery and it is integrated with silver-coated fibers. Any change in pressure resulting in a change of resistance values of the piezoresistive fibers is converted to a voltage that is transmitted by conductive fibers such as sliver-coated fibers and it is acquired by the central unit [4]. For instance, a study was carried out by the researchers which is given above. Our thesis will be focusing on the equivalent technique with divergent working principle. There will be also real time biofeedback information in connection with external pressures. The device will be able to observe any pressure change it will cause resistance change in the device than the conductive fibers will transfer datas and finally central unit will collect these datas. In addition to this, datas can be kept in watch, smart phones or laptops if needed.

The conductive materials used along with lower resistant yarn for the one sensor [2]. It is overt that most of the socks are made of classical fibers such as cotton, polyamide and elastane. After that these fibers are knitted with tow or more original fibers. The first one is coated with silver so that it can conduct current. The other fibers should have a piezoresistive impact. Because any normal forces appling onto these fibers change the electrical resistance of the material and this data is significant for the studies [4]. Conductive lines terminated with the metal male buttons snap fasteners, mounted on the upper part of socks while female fasteners were soldered to the lead wired of the data acquisition system. This system gives chance to acquire data from pressure sensors and transfer them via one channel.

After that, the collected data are evaluated by the researchers. As i mentioned previously there are also some other sensor types which are capacitive,piezoelectric,etc.But at this point the working mechanism is different. When the patients apply burden to the foot, the sensors extend and this change affect the ultimate value.

Figure 1.2 : Working mechanism of the design [4].

1.1. Diabetes Types, Symptoms, Causes And Treatments

1.1.1 Diabetes Types

According to latest research and technology, there are ten types of diabetes mellitus. Type1, Type2, gestational diabetes, diabetes LADA, diabetes MODY, Double diabetes, brittle diabetes, diabetes insipidus, neonatal diabetes mellitus and mixed pathologies in TIDM with obesity and insulin resistance.

Even though there are 10 types of diabetes mellitus. Type one and type two are the most prevalent ones [1]. There is also Gestational diabetes mellitus and it occurs during pregnancy [39].

1.1.2 Type 1 and Type 2 Diabetes

Type 1 diabetes is caused by the destruction of pancreatic B-cells which produces insulin and this type of diabetes is a chronic autoimmune affliction. Type 1 diabetes is frequently attributed to insulin-dependent or juvenile-onset diabetes [1]. It is present at 5-10% of diabetes mellitus patients [39].

The symptoms are; Increased thirsty, extreme fatigue, weight loss and cloudy vision [1]. Abdominal pains, headaches and polydipsia are also other symptoms for type 1 diabetes particularly for children [36].

Type 2 diabetes is widely recognized as adult-onset diabetes. Type 1 diabetes is frequently seen in childhood. There is a lack of insulin resistance for the patients in this type of diabetes. Patients show resistance to the action of insulin in this disease. This type of diabetes impacts 5-7% population in the world. Exercise, dietary therapy and some agents are the key treatments for this ailment. It is widely seen family history, older age, obesity and lack of exercise [1].

Globally, 9 millions of people suffer from Type-1 diabetes mellitus whereas 462 million patients suffer from type-2 diabetes mellitus. These numbers are estimated by the WHO. In reality dozens of people are not aware of their current circumstance which means diabetes[2]. According to idf diabetes atlas 537 million people suffer from diabetes all around the world. It is also reported that in every 4 adults 3 of the suffer from diabetes mellitus. The vast majority of patients are located in western pacific and the number of patients is 206 million [37]. It is foreseen that then number of people influenced by diabetes will increase to 700 million by 2045 [2]. Thereby, the outlook of this disease does not seem well.

When a woman is expecting a baby, gestational diabetes can develop. In the progress of pregnancy, huge amount of hormones are released and these hormones might decrease insulin action and induce insulin resistance. This type of disease can be classified as undiagnosed asymptomatic type 2 diabetes [1]. Double diabetes is a combination of type 1 diabetes and type 2 diabetes [1]. Type 1 and type 2 are the prime types of diabetes [38]. In the case of diabetes insipidus huge volumes of dilute urine are excreted as a consequence of vasopressin deficiency. Two main point is important; water intake and AVP resistance [1].

Neonatal diabetes crops up in the initial six months of the life. There is a single gene defect. Pancreas do not release sufficient insulin. Patients do no put weight on as rapidly as anticipated [1]. Due to the thesis will mainly focus on the integration of resistive sensors to socks there is no need to tackle other types of diabetes mellitus. It is worthwhile to tackle the symptoms and causes of diabetes.

1.1.3. Symptoms and Causes

Symptoms of diabetes encompass;

- Enhanced hunger,thirst and urination [1]
- Extremely tired [1]
- Cloudy Vision [1]
- Lack of feeling in the hands or feet [1]
- Nonhealing sores [1]
- Unexpressed weight loss [1]
- Ketone presence in the urine [1]

- Continual infections [1]
- Sexual dysfunctionality for males [1]

Causes of diabetes subsume;

- Obesity [1]
- Exorbitance glucocorticoids [1]
- Exorbitance growth hormone [1]
- Lipodystrophy [1]

Causes of type 1 diabetes

- A genetic suspicion of type 1 diabetes mellitus [1]
- Some precise viruses [1]
- Environmental reasons [1]
- Destruction of pancreas cells [38]
- Lack of insulin hormone [38]

Causes of type 2 diabetes;
It basically occurs when the body of humans develop resistance to insulin or when the pancreas halts releasing sufficient insulin [1]. Obesity and overweight factors are considered one of the most prevalent causes for type 2 diabetes [38].

1.1.4. Treatments

Three types of blood tests are being used in order to diagnose diabetes and prediabetes; [1]

- FPG
- Test of oral glucose tolerance
- Blood glucose level

FPG: If the blood glucose level more than 126mg/dl on three or more tests which is applied in divergent days it means that this patient is attracted diabetes. However, this test must be done 8 hours fasting prior to taking this [1].
Blood Glucose level: This is the easiest test and doesn’t entail any preparation such as fasting before taking the test. The criteria is that if the blood glucose level is 200mg/dl or higher the diagnosis can be confirmed.

Test of oral glucose tolerance: The level of glucose 200mg/dl or higher in 2 hours, prediabetes can be diagnosed if the 2hr blood glucose grade is somewhere 140-199mg/dl [1].

HbA1c: It is mostly used in the hospital in order to determine the average blood glucose in three months.

Treatment for diabetes: It is unique for each person and the type of the disease.

For instance, insulin therapy is mandatory for type 1 patient. It consists of conventional therapy, conventional therapy with a split nigh-time and intensive therapy with a continuous subcutaneous insulin infusion [1].

The blood glucose level should be controlled and fixed at healthy level [38]. Doing exercise, diet and the adoption of healthy life is also vital for this type of patients [1].

Before specifying the treatment of type 2 types. The factors are given below;

- Keeping body weight
- Same feeding habits
- Same level of exercise
- Giving consequnce to blood glucose levels
- Time period of diabetes

Treatments encompass healthy diet, physical activity and the therapy of insulin.

Self-care is also important for all patients. It is not advised to smoke, weight loss, unhealthy beverages and foods, less consumption of fiber [1]. Therapeutic strategy is also important for the patients. Novel drugs should be tried by the doctors [38].

Some drugs are advised in order to keep the glucose level in the blood. Sulfonylureas, meglitinide analogues, biguanides, alpha-glucosidase inhibitors, glicose are mostly and widely used drugs in our societies [1]. In the recent years novel approaches and treatments are also adopted. It encompassed nanotechnology-based systems which enhances precision and productivity of conventional drugs and insulin [39].

When we compare high-income, middle-income and low-income countries, these types of diabetes mellitus diseases take place in high-income countries. Such as the USA, European countries and some part of the far-east [2].

In 2019, diabetes was the main cause of 1.5 million deaths and 48%of people were younger than 70 years old. It is also predicted that 2 million people passed away because of diabetes mellitus and it is going up year by year [2]. 3.2 million people die because of diabetes in every year according to researches and death statistics [41].
The abnormal signal of death and case number is growing. It is also reported that 1.3 billion people will be attracted this disease in the following 30 years. This number should be taken seriously [40].
Apart from WHO, all countries, on-governmental organizations, healthcare organizations should aim to stimulate and propagate the adoption of influential measures for the surveillance, presentation and the control of diabetes monthly [2]. The reports that are published by WHO must be taken into account and concrete steps also must be taken regarding this pivotal illness. Reports also show that, diabetes cause, kidney failure, blindness, heart attacks, stroke and lower limb amputation.
This thesis mainly focus on the prevention of lower limb amputation. Some precautions must be observed prior to surgery [2]. Due to the patients do not feel any aches and pains during this disease, they can not comprehend whether their lower limbs are at risk or not [2]. By the aid of state-of-the-art technology, we anticipate we will compensate the deficiencies of modern medicine.

1.2. Foot Health And Practices In Patients

1.2.1. Foot Health In Patients

Diabetes mellitus is defined as a metabolic disorder characterized by continued hyperglycemia. There can be inadequate insulin being produced or there is a damaged tissue which shows insensitivity to insulin. 422 million people suffer from diabetes. Most of them reside in developed countries. Diabetic foot ulcers contain 12-15% total predicted burden of diabetes in the developed countries, rising to 40% in the developing countries. This ulcer affects 10%of the population [3].
It is overt that continued hyperglycemia causes several DM complications such as, foot ulcers, high danger of sepsis, peripheral neuropathy and peripheral vascular disease. Diabetic foot ulcers often occur as a consequence of diabetic neuropathy. The most common complication of DM is foot ulcer. 7% -11% of patients are accounted for the admissions to hospitals [3].

According to another article which was published in 2020, DFU's are one of the most prevalent diabetes complications with a percentage of 0,4-2.
%20 diabetes mellitus patients are at risk for the development of foot ulcer as a consequence of neuropathy [3]. It is indeed possible to cause gangrene in the extreme cases and amputation could be required in some cases [41].
It is reported that 52%to 68% of diabetic patients with amputation experienced the frailty of stable, loss of movement and important reduction during the lifespan. However, it is possible to hamper amputation by using educational and care strategies. It is overt that DFUS can be seen un undesirable influence on patients more than other complications [3]. Globally, the prevalence of DFUs range from 1.6%to 8.0%. This is anticipated to arrive at 19% by 2045 [3]. According to a research males patients do foot care more than female patients at 4% [41].

1.2.2. Practices In Patients

The therapy lay emphasis on day by day which encompass identifying high-risk patients and educating them by the experts in particular health sector through a multidisciplinary team [3]. Practices is really important due to the risk of limb amputation is significantly higher than general population as compared to diabetic patients [42].
One of the chief problems impact the quality of diabetic foot care is that the lack of enough and relevant knowledge and best practices. Researchers reported that in the case of a lack of adequate knowledge and best practices regarding diabetic foot complications the chances of the patients who suffer from foot ulcer is increased. In order to cut down complications, patients have to learn foot care. The improvement of DFU's is affected by some factors such as educational background, age, weight, DM type, foot care hygiene and practices. Patient education and educational activities develops information and mostly diminish the risk of foot ulcerations and amputations [42].
Foot care is vital at this point. Unfortunately, many patients are able to notice the need of foot care upon developing ulcer or they had an amputation. In this context, some concrete steps must be taken prior to surgery or foot ulcer [3].
A type of study was carried out in selected hospitals in the Volga Region that shed light on the factors affecting DFU [3]. Table 1.1 shows practices of diabetic foot care while table 1.2 shows the socio-demographic and clinical data of diabetes patients.

Table 1.1 : Practices of diabetic foot care [3].

Question	Answers n (%)	
	Yes	No
Wash feet regularly	338 (71.5)	135 (28.5)
Check feet every day for injury	293 (61.9)	180 (38.1)
Wash feet with a hot water	318 (67.2)	155 (32.8)
Walk bare-footed at least once every day	340 (71.9)	133 (28.1)
Trim nails with a sharp device	322 (68.1)	151 (31.9)
Inspect shoes before wearing them	289 (61.1)	184 (38.9)
Wear shoes without socks	238 (50.3)	235 (49.7)
Dry foot after washing it	280 (59.2)	193 (40.8)
Wear closed-tight shoes or high heels	369 (78.0)	104 (22.0)
Feel tight in shoes	293 (61.9)	180 (38.1)

The vast majority of patients wash their feet’s regularly [3]. Female patients do at 2%. 17% of the patients check their foot situation in every day while 73%wash their feet daily [41]. This in an advantage but on the other hand, the huge amount of patients walk bare-footed at least once every day. This practice is completely detrimental for diabetic patients and can result in foot ulcer [3].

As we discussed earlier, age, marital status, educational attainment, employment status, monthly salary, the treatments of diabetes and the knowledge of practices of DFC were not strongly linked to the improvement of DFUS whereas gender, diabetes type, family history, duration of diabetes and the presence of comorbidities strongly affect the development of foot ulcer [3].

For instance, male patients are likely to be attracted fool ulcer 3.35 times more than females. Because female patients show lack important to foot health practice [41]. Family history is also vital at this point. According to the study the patients who have family history are likely 4.66 times more than the patients who do not have diabetic family history for the development of foot ulcer. Patients who has been suffering from diabetes for 5 to 10 years were 3.28 time more likelihood to develop DFUS than those who had less than 5 years. Another point is comorbidities. Patients who had comorbidities were 3.35 time more likely to develop DFU’s than the patients who do not [3]. According to another research males are more likely to attract diabetic foot because they carry weightier items and they’re standing more than female patients daily [43].

Table 1.2 : Socio-demographic and clinical data of diabetes patients (n= 473) [3].

Parameter	Frequency	Percentage
Total	473	100
Gender		
Male	124	26.2
Famale	349	73.8
Age Group		
<30y	52	11.0
30-39y	33	7.0
40-49y	139	29.4
>49y	249	52.6
Marital Status		
Single	34	7.2
Married	423	89.4
Other	16	3.4
Educational Status		
None	106	22.4
Basic	127	26.8
Secondary	185	39.1
Tertiary	55	11.6
Employment Status		
None	99	20.9
Formal	122	25.8
Informal	252	53.3
Average monthly income	**Frequency**	**Percentage**
<500 Cedis.	103	21.8
500-1000 Cedis	207	43.8
>1000 Cedis	163	34.5
Type of diabetes		
Type 1	71	15.0
Type 2	402	85.0
Family history of diabetes		
Yes		
No		
Duration of diabetes		
<5y	170	35.9
5-10y	247	52.2
>10y	56	11.8
Presence of foot ulcer		
Yes	41	8.7
No	432	91.3
Comorbidity		
Yes	152	32.1
No	321	67.9

Average monthly income		**Frequency**	**Percentage**	
		Diabetic foot ulcer		
Variable	**Yes n (%)**	**No n (%)**	**x^2**	***P* value**
OHAs	14 (34.1)	182 (42.1)		
OHAs and İnsulin	13 (31.7)	149 (34.5)		
KDFC			1.51	.283
Good	29 (70.7)	269 (62.3)		
Poor	12 (29.3)	163 (37.7)		
PDFC			0.09	.771
Good	21 (51.2)	211 (48.8)		
Poor	20 (48.8)	221 (51.2)		

The study tried to demonstrate the strong relation among gender, type of diabetes, family history, length of time that a patient has a diabetes, comorbidity and the development of foot ulcer. Knowledge and practices are also important but there is not an overwhelming relation with foot ulcer. Health care workers and other all stakeholders should emphasize the importance of the development of foot ulcer as so irrevocable results can be that can be fatal.

2.DFU

DFU has a long term serious implications for diabetic patients such as lower limb deformities, neuropathy and limb amputation [4]. The problematic foot consists of infection, lack of sensitivity, ulceration or devastation of deep tissues caused by DFU [1].

One million people are at risk of foot ulcer every year [44]. It has been reported that %85 of amputations in diabetic patients are caused as a consequence of DFU. It is also reported that 46% of the patients get accession to the hospitals in US. Another interesting information is that every 30 seconds patients loses their limbs as a consequence of DFU. Apart from the health aspect, there are also social and economic implications such as medication costs, surgical interventions, footwear and in-patient costs [5].

2.1. Indicators of Dfu

In order to foresee the diabetic foot ulcer episode, there are some indicators which are used such as temperature, pressure and ph [5].

2.1.1. Temperature

According to research temperature can be used as a prime indicator in order to show DFU. One of the playing roles is human skin for thermo-refutation of the body. The study says temperature of human body is the consequence of thermal balance among thermal energy generated by core and it's lost to environment whereby conduction, convection, radiation and evaporation. Prior to foot ulceration, the upsurge in temperature under foot can be observed. As body temperature is different in each human, we can not specify a range [5]. As a consequence of poor and unbalanced blood circulation under foot temperature differences could occur and this can be a major indicator of diabetic foot ulcer [44].

In order to surmount this intricacy, one part of the human body with its symmetrical part can be used as a comparative factor. According to studies at home monitoring of temperature, treatment is required if the temperature divergence bigger than 2.2. Celsius degree. (under the foot) [5].

Many other studies focused on the relation among temperature and dfu ant it was found similar datas. If there is more than 2.2 Celsius degree divergence among 2 feet this can be an early warning of diabetic foot ulcer. It means this is a really significant data [46].

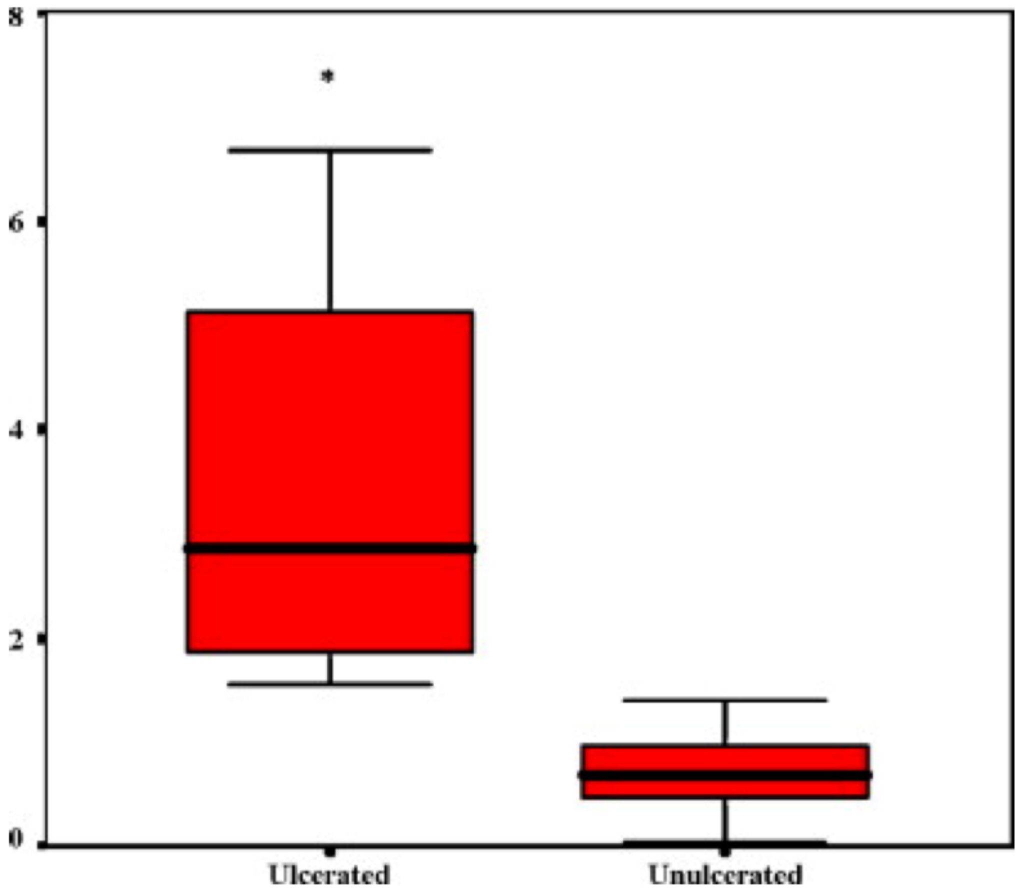

Figure 2.1: Temperature difference between two legs one week before ulceration [5].

The assessment of skin temperature is relatively easy. Some studies have taken advantage of this by letting patients keep log of their foot temperature as part of self-check [5].

2.1.2. Pressure

Diabetic foot ulcers present itself mostly with neuropathy, peripheral vascular disease, tissue and bone deformity which can result in repetitive pressure on distinct parts of the feet. As a consequence of that, inclusion of pressure sensors in a device for DFU estimation is an intuitive choice. Honestly, there is not an extensive and pivotal research and literature review regarding this field. One of the studies tackled the pressure measurements by using static and dynamic evaluation methods. As it is obvious, static pressure occur when a patient is standing and dynamic pressure is evaluated when person is moving. In the presence of DFU and neuropathy abnormal pressure is detected [5]. It is a result of lost of sensation under foot which may induce pressure abnormalities [45].

According to a study which was carried out by Lavery etc. al. (2003) 1666 patients are examined in terms of plantar foot pressure prediction with a high danger of ulceration. The outcomes of the study is given in figure 2.2.

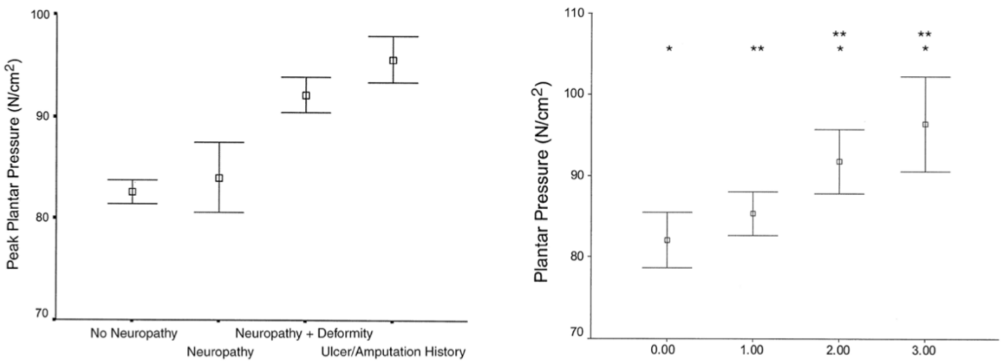

Figure 2.2: Relation between pressure, foot risk and foot deformity a)Peak pressure with respect to foot risk category.Increasing foot risk is directly reflected in increase of plantar foot pressure. b) Effect of forefoot deformity on plantar pressure [5].

That increased number of deformities strongly corelates with increased plantar pressure is directly reflected in increase of plantar foot pressure.

The study demonstrated the relation between persistent pressure and high risk of ulceration. Mostly pressure greater than 6 kg/m3 is considered as a high-pressure side with risk of ulceration. Even though some other studies which were carried out by researchers that targeted only one [5].

Barefoot and inshoe pressure analysis are commonly used in order to investigate relation among pressure and diabetic foot ulcer according to latest researches. Advantages and disadvantages of barefoot and inshoe systems are criticized and it is reported that inshoe systems and pressure sensing are more successful than barefoot analysis due to they're portable, allowing multiple footsteps and assessment of pressure sensing with more sensitivity during walking [45].

Foot, external factors are also important for the detection of pressure change and abnormalities. These various studies point towards use of pressure changes and abnormal pressure values recorded from different region of the foot as a ulceration risk factor, Hence pressure can be used as primary indicator for possible ulceration.

2.1.3. PH

Human skin is a layer among internal body environment and external microorganisms and the changes in the environment. Ph between 4.2-5.6 can be acceptable for the healthy adults and children. On the other hand, body's interior environment sustains near neutral pH. However, there is not a sufficient research with regard to Ph and its relation with DFU. Ali and Yosipovitch (2013) remark in their paper that 'In spite of mounting evidence that skin pH plays vital role in skin function, application of acid mantle concept in clinical care has lagged behind [5].

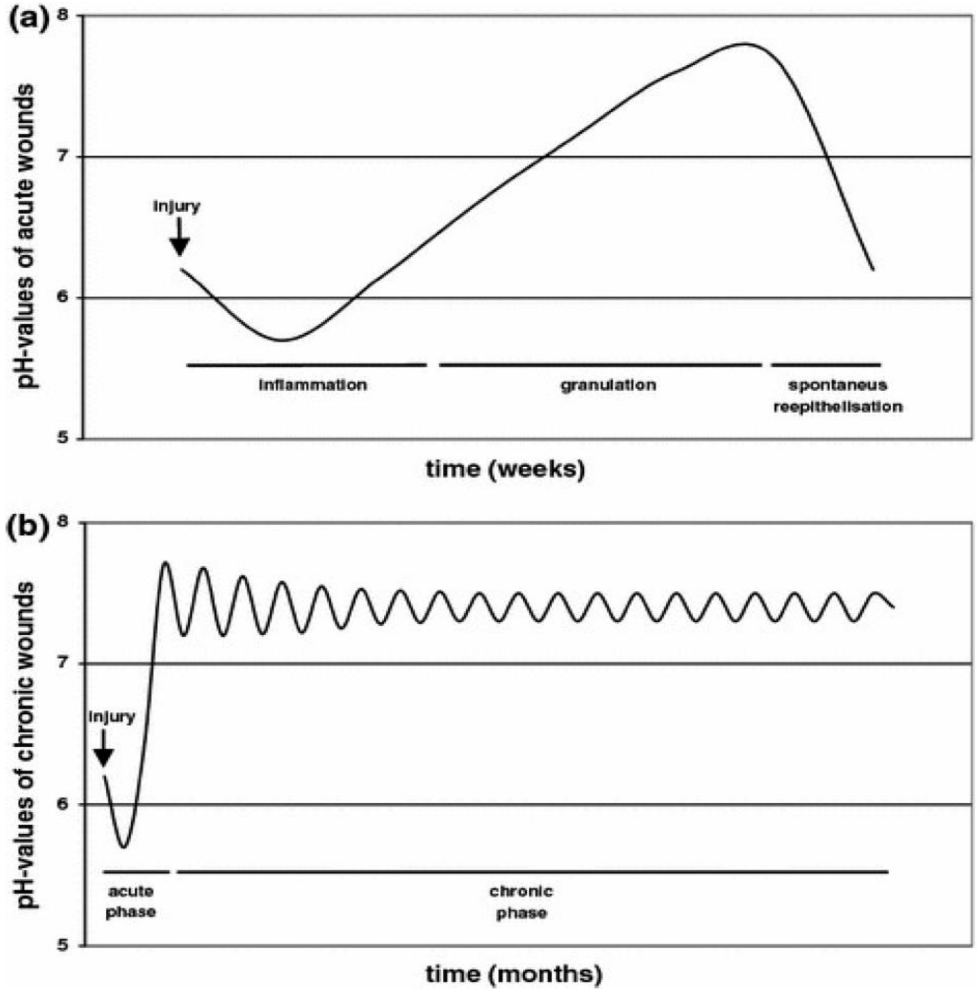

Figure 2.3: a)Changes in Ph milieu for acure wounds. b) Changes in Ph milieu for chronic wounds [5].

There is some literature available which focuses on detecting change in pH values of the wound which indicate presence of infection. Healing wound goes to different phases and each phase shows different value of pH as shown in Figure 2.3. The normal value of healing wound is among 5.5.-6.5 while infectious tissues are bigger than 9. [5]. According to another study Ph was found 7.7 for the wounded areas it indicated the presence of DFU for this outcome [46]. As a consequence of the lack of literature review, Ph can not be used as a primary indicator for ulceration. Apart from this, the external materials that people frequently used affects the ph value such as soap,gel and tap water. Nevertheless, ph measurement can be used as a secondary indicator along with temperature and pressure to help detecting ulceration [5].

2.1.4. Nitric Oxid

Nitric oxide is playing an important role in skin for instance vasodilation, response to UV, infection and apoptosis. So, it affects some many factors that is related to wound healing [52].

Nitric oxide is a paramount chemical for normal wound healing. It is formed by an combination of molecular oxygen and the amino-acid l-arginine [6]. It is produced by two ways Classic L-arginine-No way or nitrate-nitrite-NO pathway [52].

According to a latest research, wound nitric oxide bioactivity can be used as an indicator of DFU. Scientists claim that deficiency of nitcic oxide is detected in the case of DFU so that it does not heal and patients undergo a surgical operation or in the best scenario some critical treatments are used in order to heal DFU [6].

The thing can be inferred from the text is that, enough nitric oxide and produced for healthy patients where as diabetic tissues do not generate enough nitric oxide and this material is vital for the patients in order to thwart amputation.

The relation among wound fluid Nox and diabetic Ulcer Area is given in figure 2.4.

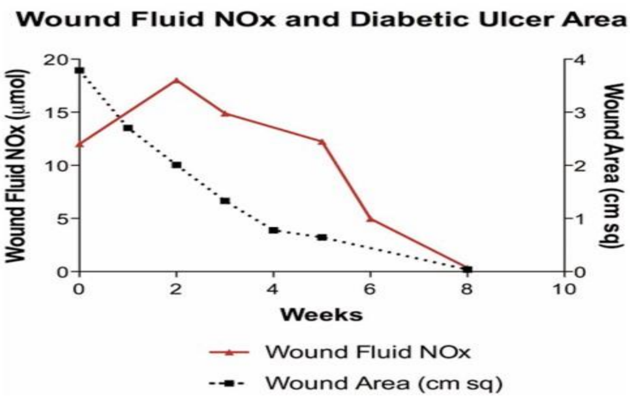

Figure 2.4: Changes in wound fluid Nox and wound area (cm^2) for a DFU-responder subject receiving fibroblast-derived, dermal substitute treatment [6].

In summary, Temperature, pressure and ph can be indicator for dfu. Pressure alterations are detected since one week before ulceration as a consequence of insensitive tissues. Both static and dynamic pressure can be evaluated [4].
Another indicator can be the deficiency of Nitric oxide. However further researches are needed in order to demonstrate relation among nitric oxide and DFU [6].

2.2. Neuropathy

Neuropathy means the problematic foot for diabetic patients that include infection and some other properties. Neuropathy and ischemia are observed together in many cases. Neuropathy can affect the muscle structure so that it can impact the sensitivity and pressure change. It can also trigger [5].
Pain, autonomic dysfunctions that encompass anomalous local vasodilation and decreased sweeet with a loss of skin integration [1]. It has been reported that neuropathy impacts the ability and the awareness of the damage caused to foot. Additionally, in some cases it has been observed that some patients suffer from peripheral vascular ailment that induce blood circulation system. This directly affects lower limbs [5].
Ischemia is also a serious disease. It can be observed in the case of foot infections, ulceration, being blood supply insufficient. This is because of low blood circulation. The risk of the amputations is increased as a consequence of ischemia [1]. It can be seen on the foot as obvious gangrenous tissues [47]. It also reported that 56%of DFU can become infected and 20% of infections give rise to amputation [47].

2.3. Trauma

Trauma means the external factors that can possibly affect the presence of DFU [4]. Trauma can directly induce the amputation. So, at this point the early detection is mandatory and pivotal [5].

2.4. Vascular Disease

The blood supply to the food is provided by three main vessels. posterior tibial artery, anterior tibial artery and peroneal artery. In diabetic patients these vessels are not working healthy so this affects the blood circulation system throughout the body. It is also repeated that every 1% upsurge in HbA1c increase the risk of vascular disease with a percentage of 25-28% [5]. Patients frequently develop micro-arterial dysfunction that begin early in life. This can also affect the mobility of the patients. Through this problematic situation, supply of oxygen and other nutrients to tissue and hence healing is affecting in a negative way. It become more and more difficult to be healed [5].

2.5. Charcot Foot

Scientist say that the presence of Charcot foot can be seen in the presence of peripheral motor neuropathy [5]. It can be also called as Charcot arthropathy which one of the most common devastating outcomes of diabetes. It is also observed mostly in the western world and can be considered that in any patient who has the presence of a warm swollen foot, with or without ulceration [5]. The destruction of joints attribute to the absence of pain. It might present specifications such as deformity, swelling, increased foot temperature and redness.

2.6. Infection

Even though infection doesn't show itself as a consequence of DFU [5] it can be seen extended and increased redline under foot and this possibly indicated infection [47]. But on the other hand, it is reported they neuropathy and PVD makes foot responsible for infections. Rapid bacterias can be developed in the case of damaged or poor skin and soft tissues. Such deep infection results in immediate requirement of amputation in 25-50% of cases [5]. Colored purulent areas and sensible tissues may be an indicator of infection. Infection was defined as a bacterial soft tissue or bone infection [47]. Blood test should be performed in order to diagnose infection in the blood. Furthermore, advanced laboratory studies, physical examination and a clinical history is important for the detection of infection [47]. The way which is going to amputation is given in figure 2.5.

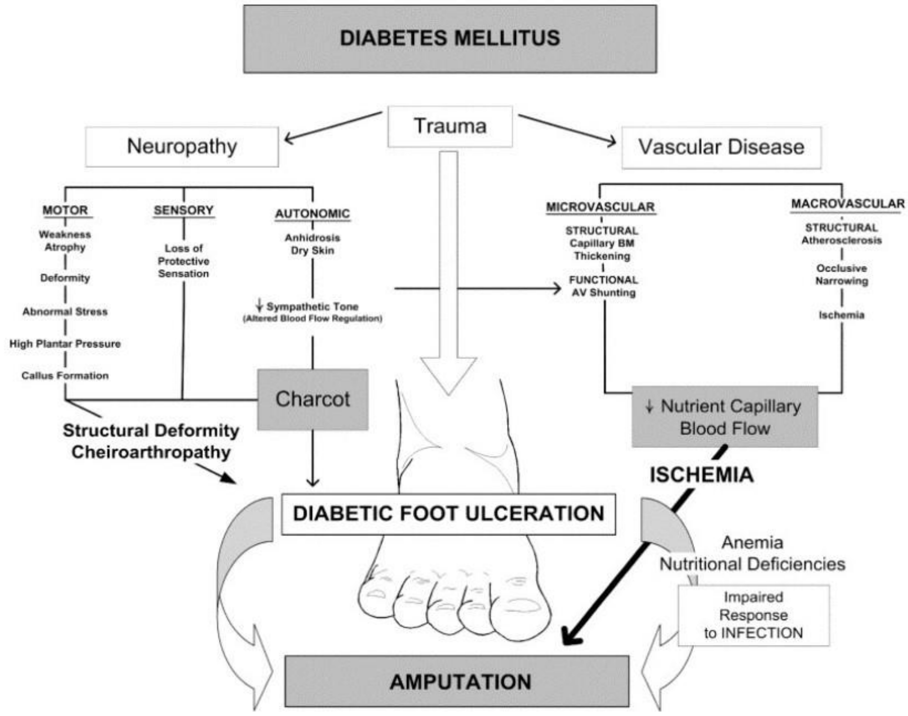

Figure 2.5: Amputation [5].

As we see prior to amputation there are several factors affecting amputation such as neuropathy, trauma, vascular disease, Charcot, ischemia and infection. This case is a bit complicate but if concrete steps are taken, amputation can be simply prevented.

3. GAIT ANALYSIS IN DIABETIC PATIENTS

3.1. Gait

Gaiting includes a series of movement in the forward position. Gait cycle is being measured form heel-strike to heel-strike. It includes stance and swing phases. Stance position is 60% and swing phase is 40%. Adequate and effective step length depends on a healthy mechanical and metabolic efficiency. Healthy gait is also pertinent to nervous system. There are somatic and autonomic functions during gaiting. So that muscles are also pivotal [8].

It is reported that many injuries noticed in the patients of diabetes during gaiting and it can be related to the forces during walking. Many researchers found relation among gait abnormalities and diabetes mellitus [8]. For instance, weak muscles, multiple neuropathies, unbalanced posture can trigger gait abnormalities included undistributed pressure on the foot [50].

Under normal circumstances, nervous system is working perfectly but this is not valid for diabetic patients. Current studies show that the patients who have neuropathy indicates problems in gaiting. If the patient is suffering from DFU, unchanged gaiting pattern is taken place [9]. There are some studies carried out by the researchers. But additional investigations are mandatory in his field.

3.2. Diabetic Sensorimotor Polyneuropathy

Diabetic sensorimotor polyneuropathy is known one of the longest diabetic complication for the diabetic and it is included in the pathogenesis of the diabetic foot. After 10 years of ailment, the rate is 25% for the diabetes. It is reported that it is also related to neuropathy, peripheral arterial disease and retinopathy. So, it really affects the life quality, movement, gait, morbidity and public health [49].

It is overt that diabetic sensorimotor polyneuropathy impacts sensory, motor and autonomic functions and can lead to nerve loss. The deleterious impacts of DSP encompass vibration, tactile and perception sensory loss in the large fibers, and a lack of thermal and pain sensitivity in the small fibers. When the loss of sensitivity surged, the risk for the development of ulcer is also rising. Additionally, the absence of soma to sensory information from the feet and legs for control and postural stability can trigger to the surge in postural sway in stance. It is reported that DSP can lead to postural problems which means swaying [10].

3.3. Postural Alteration and Gait Analysis.

As a consequence of interosseal muscles structural changes can be occurred in the foot. It also includes deformities. Both these problems lead to unbalanced gaiting and accordingly gait alterations. Excessive plantar is also important [10]. This is not only gait problem it is also reported so many injuries as a consequence of postural alterations and gait abnormalities and trauma could occur in some cases [50].

A study was carried out by the researchers and they monitored during treadmill walking. The study also focused on risk for ulceration based on both diabetic gait and postural changes with three dimensional changes [10].

The reported P values indicate the results of the comparison between the DSP and NoDSP groups, the DSO and CS groups, and the NoDSP and CS groups. A value of $P<0.05$ was considered statistically significant(P) [10].

Table 3.1: Clinical characteristic, center of pressure (COP) and time and space parameters (mean and standard deviation (SD) of diabetic neuropathic group (DSP), diabetic non-neuropathic group (NODSP), control group (CS).

	NoDSP		*DSP*		CS		*DSP vs. NoDSP test (P)*		*DSP vs. C t-test (P)*		*NoDSP vs. C t-test (P)*	
Subjects (%)	30.3		39.4		30.3							
Age (years)	63.8 (5.4)		63.2 (6.0)		59.0 (2.9)		0.70		0.004*			
BMI	26.3 (2.0)		25.6 (2.9)		24.0 (2.8)		0.4		0.2			
Years of disease (years)	17.2 (11.7)		22.1 (14.3)				0.2					
Sex (% of subjects)	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**	**F**	**M**
	30	70	42.3	57.7	35	65	0.19	0.07	0.31	0.77	0.17	0.24
Diabetic retinopathy (% of subjects)	40.0		65.4				0.04*					
Microalbuminuria (%of subjects)	25.0		34.6				0.1					
Peripheral vascular disease (%of subjects)	15.0		19.2				0.6					
Autonomic neuropathy (% of subjects)	0		23.0				0.02*					
Type I (% of subjects)	15.0		42.3				0.02*					
Type II (% of subjects)	85.0		57.7				0.02*					
Hb A1c (%)	7.7 (1.1)		7.6 (1.7)				0.1					
Gait velocity (m/s)	1.10 (0.2)		1.10 (0.2)		*1.27 (0.1)*		0.9		0.003*		0.003*	
Stride period (s)	1.13 (0.1)		1.19 (0.1)		*1.1 (0.1)*		0.3		0.4		0.4	
Stride length (m)	1.23 (0.1)		1.20 (0.2)		*1.4 (0.1)*		1.0		0.002*		0.002*	
Stance period (s)	0.66 (0.1)		0.73 (0.1)		*0.5 (0.1)*		0.1		0.000*		0.000	
COP range of excursion AP (cm)	23.6 (3.3)		22.4 (4.4)		*24.6 (2.4)*		0.3		0.07		0.07	
COP range of excursion ML (cm)	1.7 (0.5)		1.9 (0.7)		*2.0 (0.6)*		0.4		0.003*		0.003*	
COP mean excursion ML (cm)	0.18 (0.8)		-0.20 (1.4)		*0.30 (0.9)*		0.3		0.5		0.5	
COP mean excursion AP (cm)	14.6 (2.6)		14.1(3.8)		15.3(2.1)		0.06		0.2		0.2	

When they analyse the outputs of the study, hip joint mobility was observed to be importantly reduced in the NoDSP (P<0.047) as well as in the DSP group (P<0.056) as compared with the CS group. The presence of complications was affiliated with more serious postural alterations.[4]There is also a correlation among microalbuminuria and decreased scapular cingulum. They also observed a vital reduction in pelvic translation with retinopathy while compared with NoDSP subjects without complications [10].

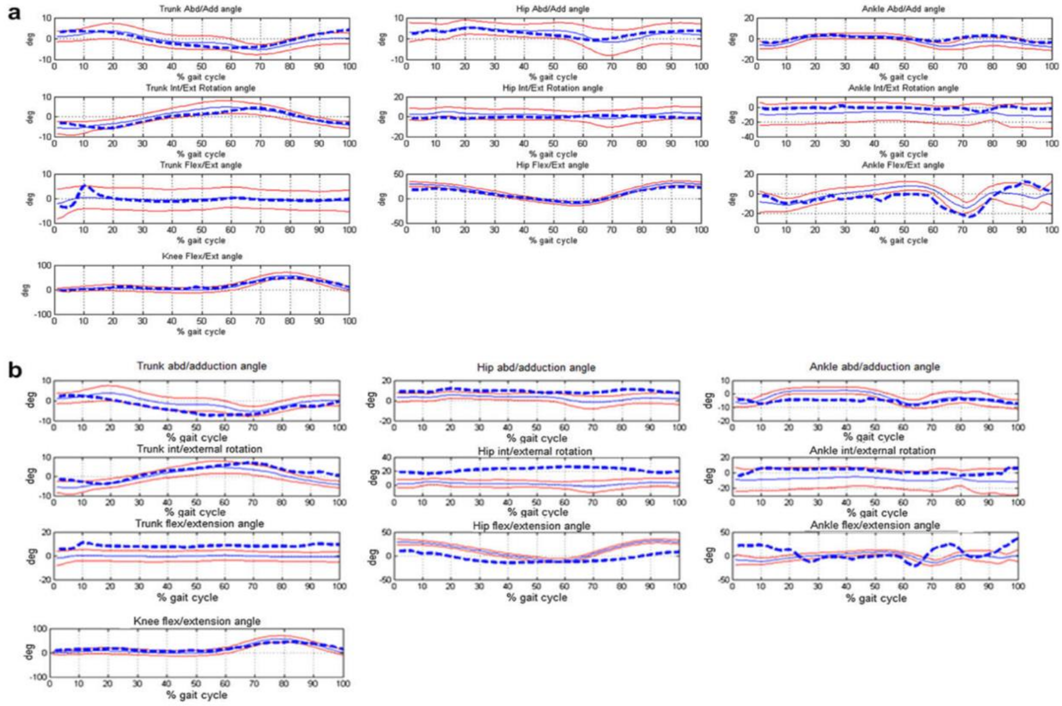

Figure 3.1: Gait anaysis joint kinematic results.Mean joint angels of: (a) NoDSP and (b) DSP, over the normative bands (CS) are reported. Horizontal axis depicts one gait cycle; vertical axis represents (a-b) angles degrees [10].

According to the study many gaiting and posture differences were observed in the diabetic patients as a consequence of deformed muscle structure, unbalanced gaiting and definitely neuropathy. Cardiovascular system is also important but they particularly focused on a different field. Even though cardiovascular system seems a divergent field, it is comparatively associated with diabetes mellitus. As this disease affect entire organs which include hearth, liver, pancreas and circularity system. We can simply infer from the study that neuropathy and foot ulcer are pivotal for gaiting and postural analysis. In the presence of foot ulcer, there is a lack of blood under the feet and due to the fact, that unbalanced and excessive forces occur this is directly affecting posture and gaiting. All required precautions and concrete steps must be taken before the development of ulcer and the presence of neuropathy [10].

Postural swaying, unbalanced gaiting and uneven standing, walking is the result of diabetes mellitus. There is a direct connection among each other. However much more evidences are required in order to analyse the relation among dfu, diabetes mellitus, postural alterations and gait problems deeply [51].

In this report duration of diabetes mellitus over than 10 years, male gender, poor control, neuropathy, foot deformity, high plantar pressures, a history of amputation were significantly related to the presence of foot ulceration [51].

Another study claimed that age is one of the vital factors for the result of gait and posture as well as step length, stride length, foot height, motor functions, BMI, obesity, the perception of sensitivity, athletic performance, muscle mass, walking speed and daily walking habit. For instance, elder patients show an increased unbalanced posture and unhealthy, slow gaiting [11]. Diabetic patients are also more likely to walk slowly. This is another outcome. Patients should be warned regarding injury and falling otherwise serious cases could occur including trauma, tissue impairment and slowly healing cells [50].

Some systems and technological equipments are devised for this purpose but none of them is sufficient for early DFU and neuropathy detection. Another point is that equipments are not flexible and not convenient for daily use. This is significant for the patients.

Further studies and the state-of-the-art technology are required in order to understand the entire relation diabetic patients, gating and postural alteration.

4. SENSOR TYPES

In the last decades, pressure sensors have gained a plenty of importance and research field, in particular for skin-based electronics. Production phases encompass spinning, yarn/fabric production or finishing operations and sensing property can be redounded either of them. From a structural view point, textile sensors are classified as fiber, yarn or fabric sensors. Sensors can be classified the heart of the wearable equipments [14]. Scientists mentioned about that there two kind of sensors which are active and passive. Without any assistance active sensors covert, the input energy into measurable output signals while passive sensors need external force. A vast majority of textile-based sensors are passive and just two types of wearable sensors are researched, electromechanical and electrochemical. Electromechanical sensors are producing signal when there is a mechanical force. Electrochemical sensors give response to the alteration of chemicals [15].

There are two types of sensors, strain and pressure sensors. Strain sensors basically measure strain by following up the signals caused by strain whereas pressure sensors convert precise pressure into the electrical signals that can be classified as, capacitive, piezoelectric and piezoresistive. Piezoresistive type sensors convert pressure into the resistance. There are bags of advantages of piezoresistive sensors such as basic process of fabrication, simple ready-out system and large detection area [16]. As we mentioned about that there are 3 types of sensors and it is overt that there must be some pros and cons of these three types of sensors [17].

Table 4.1: Pros and cons of three types of Psensing apparatuses [17].

Transduction Principles	Pros	Cons
Capacitance	Extraordinary sensitivity, simple structure, big dynamic span, good temperature constancy, fast response, appropriate for small force test	Poor linearity, vulnerable to EM interference, prone to parasitic capacitance.
Piezoresistivity	Simple fabrication process, cost-effective, large deformation, strong anti-interference ability, easy to attain small size.	Poor stability, low sensitivity, poor temperature stability.
Piezoelectricity	High sensitivity, fast response low power utilization.	Poor stretchability, low spatial resolution, only applicable to dynamic testing.

A summary of the reported performance of flexible pressure sensors is also given below;

Table 4.2: A summary of the reported performance of flexible pressure sensors [17].

Transduction Principle	Active Materials	Sensitivity	Minimum Detection	Maximum Detection
Capacitance	PDMS microsturucture organic field-effect transistor	0.55 kPa^{-1}	3 Pa	20 kPa
Capacitance	Graphene-paper	17.2 kPa^{-1}	2 kPa	20 kPa
Piezoresistivity	Vertically aligned CNT/PDMS	0.3 kPa^{-1}	2 Pa	10 kPa
Piezoresistivity	ACNT/G/PDMS	19.8 kPa^{-1}	0.6 Pa	0.3 kPa
Piezoresistivity	CNTs/PDMS interlocked microdome	15.1 15 V kPa^{-1}	0.2 Pa	59 kPa
Piezoelectricity	ZnO nanorod	-	3.5 kPa	31.5 kPa
Piezoelectricity	Perluoroalkoxy alkane	15 V kPa^{-1}	-	2.5 kPa
Piezoelectricity	Polyvinylidene difluoride	-	1 kPa	30 kPa

4.1. Piezoresistive

As piezoresistive sensors have high flexibility, ultralight and perfect mechanical strength, they're widely used sensor types. Piezoresistive sensors convert mechanical forces into the resistive alterations [18].

The piezoresistive impact has been understood by Lord Kelvin in 1856. R=pl/A

R shows resistance, p is resistivity, L is length and A is the conductor's cross-sectional area.

In conductive materials, the alteration of distinct resistance has a minuscule effect, and the geometrical change dominates. The change of resistance for conductive materials can be written as;

$$\frac{\Delta R}{R} = (1 + 2\nu)\frac{\Delta L}{L} = K\frac{\Delta L}{L}$$

K defined as Gauge or the factor of K, embodies the sensivity of strain. K factor is roughly 2. Some in semiconductor materials such as silicon, piezoresistive effect is dominated by the alteration of resistance p, and the K factor even be up to 200 [19].

4.2. Piezoelectric Sensors

Piezoelectric sensors initially defined by the scientist Thompson in 1856. He said that the attitude of iron and copper for the first and their relation among elongation. Hand geometry is vital for resistance of the materials. The factor of gauge is also paramount factor for measure sensitivity. The alteration of the resistance up to geometrical shape and definitely resistivity.

Any distortion in the geometric shape can affect GF (scale factor). Scientist particularly focused on nanomaterials in contradistinction to low-cost microprocessors and conventional silicon semiconductors.

When researchers exert external forces which means mechanical pressure, the piezoelectric materials are manufactured by electric. As a consequence of the pressure which is applied that generate low voltage and moving electrons and material shape distortion [20].

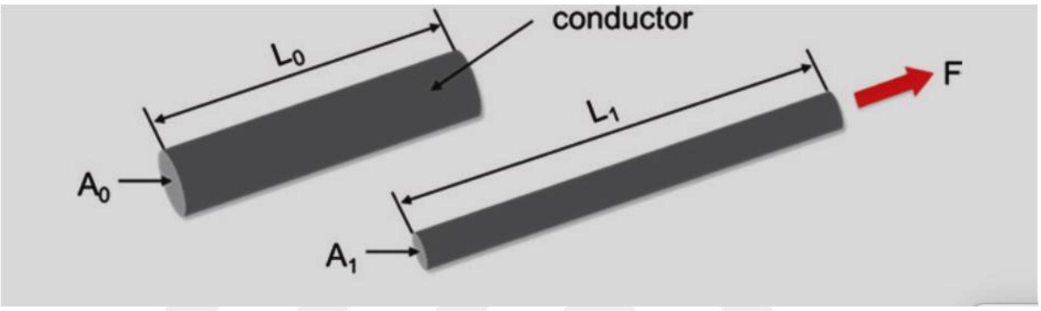

Figure 4.1: The geometrical change of a conductor caused by an applied force F affects the electrical resistance [19].

Some studies also show that piezoelectric sensors indicate a high resolution, rapid feedback and high sensitivity. One of the most used materials is polyvinylidene fluoride and its copolymers because of its low impedance and perfect flexibility. Additionally, piezoelectric sensors can be simply applied due to they're self-powered sensors. This type of sensor generates its own electric by moving electrons. We do not need any additional power or energy source so that it makes piezoelectric sensors effective and influential. On the other hand, there also some drawbacks for it. Piezoelectric sensors have low stretchability and due to the fact that the application area of it is limited [21].

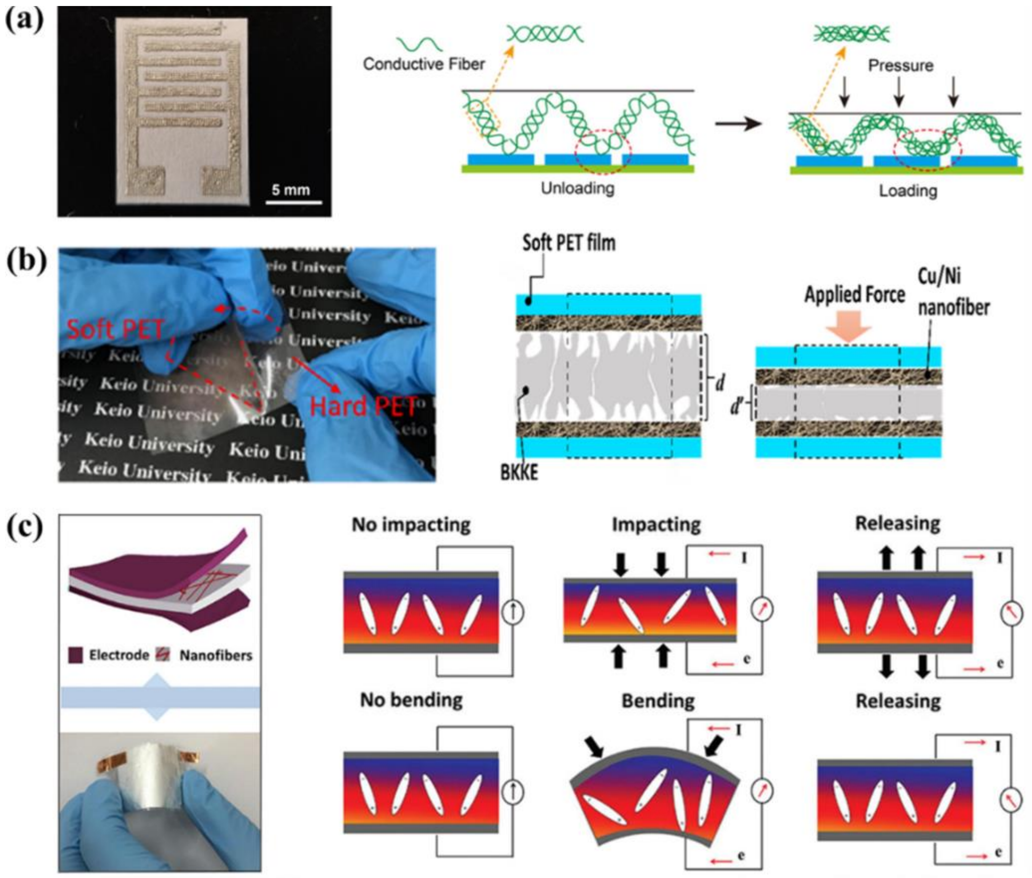

Figure 4.2: Picture and schematic diagrams of the pressure transduction mechanism. (a) Resistive type. (b) capacitive type. (c) Piezoelectric type [21].

4.3. Capacitive Sensors

Capacitive sensors are the center of attention because of better sensitivity and flexibility along with temperature autonomy and pretty lower power consumption and its appropriateness to different areas. Its advantages took place much more as compared to other pressure sensors in two decades [53].

4.3.1. Flexible Substrates

Different types of polymer based materials for instance polydimethylsiloxane, ecoflex and polyurethane are being used for the flexible substrates for capacitive sensors extensively [52].

4.3.2. Electrode materials

The heart of the electrode materials is conductive electrode. Beside the perfect conductivity, some other factors such as mechanical properties and chemical stability must be thought for the selection of material. There are currently some materials used by the researchers. For instance, metal films, carbon materials, graphene and carbon-black. Ionic gels films can be used as a conductive material in order to prepare a double-layer capacitor. It enhances the sensivity of the sensor [22].

4.3.3 Dielectric Materials

For capacitive sensors, the sensivity of the sensors must be increased. For this purpose, a high dielectric constant is applied in dielectric. We can separate dielectric layer materials as polymer and fabric dielectric. In some circumstances, the structure of the polymer dielectric materials must be altered in order to improve sensitivity.

In the case of external forces, capacitive sensor is able to detect the alteration of capacitance. As the figure is given below which shows two layers of electrodes and the capacitive sensor [22]. In textile it is also used dielectric layer among two electrode layers. Voltage is generated according to a pressure and the alteration of length of dialectic layer [54].

The formula is also given below;

$$C = \frac{\varepsilon_0 \varepsilon_r A}{d}$$

C: Capacitance

E0: Dielectric constant

E1: Relative dielectric constant

A-d: Relative area and distance between two electrodes.

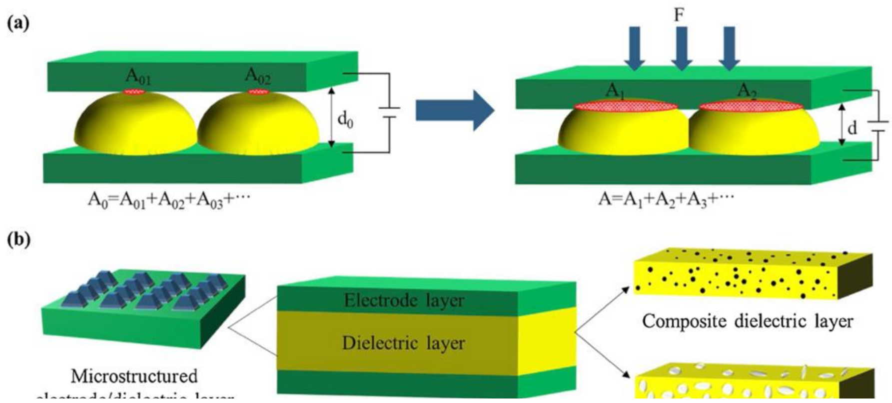

Figure 4.3: Schematic diagram of, (a) variation of distance or area of electrodes of capacitive pressure sensors, (b) three effective ways to improve the sensitivity of capacitive sensor [22].

4.4. Other Types

There are some other types of sensors;

- Iontronic sensors [55].
- Triboelectric sensor [56].

5. MANUFACTURING METHODS

Even though there are plenty of manufacturing methods for soft pressure sensors, a one hundred years ago most studies targeted stiff electrical devices manufactured in the semiconductor electronic platforms. The attention and the interest are changed into the wearable sensing systems that provide flexibility and stretchability. These kinds of wearable materials ensure a huge variety of mechanical characteristics so that it makes tough in order to be produced. The most common method for making soft sensing devices has been to use transfer printing, screen printing, photolithography, microchannel molding and lamination. Even though these kinds of techniques are used there are also some disadvantages. Smart wearable sensible devices, which are made up of flexible and stretchable materials with implemented conducting electrodes, must be ultra thin low modulus, not heavyweight, high flexible, and stretchable to be employed in wearable electronic systems. The curiosity has also increased in flexibility and wearable devices on decades [17].

According to another study, Iots is vital for wearable devices in order to transfer datas which are collected by the aid of conductive materials. It requires wireless network connectivity. Rigid materials and sensors bring about incompatibility with curvilinear and soft human bodies, limits the development of novel human-friendly interactive electronics. At this point flexible and soft sensors can be attachable on the human body with flexibility and they're also human friendly. It is known that wearable smart devices are capable of collecting and transmitting data to the central unit but it is a complex process. At the basic example, we can say temperature, tension and sweat properties of the human body can be transferred [23].

In addition, conventional sensor types include one or two sensing modules, data processing units and power supplies. So novel and further technologies to be satisfied with. These conventional systems are not sufficient for today's [23].

This part will thoroughly examine the fabrication methods of resistive pressure sensors such as conductive fabrics and non-conductive fabric method, laser usage and filtration (conductive film) method. Even though all these available techniques, some further researchers are required in order to ameliorate the process and the materials which are used in the human body.

5.1. Piezoresistive sensors manufacturing

In order to fabrication of piezoresistive sensors, scientists mainly focused on carbon-based materials, graphene and polymers with metal nanowires etc. To increase the effectiveness of the sensors, they use porous sponge or foam, microstructure active layer and divergent active materials [24].

5.1.1. Conductive fabric and spacer fabric technique

Conductive fabric and spacer fabric technique is working according to a pressure which applied over the conductive fabrics then a change in a resistance occurs. Usually, electrically conductive yarns are used for conductive fabrics and mesh fabrics are utilized ad spacer fabric [58]. Adhesive layers are used in order to make connection among conductive fabrics when applying pressure. Finally, oven is used in order to binding entire layers [59].

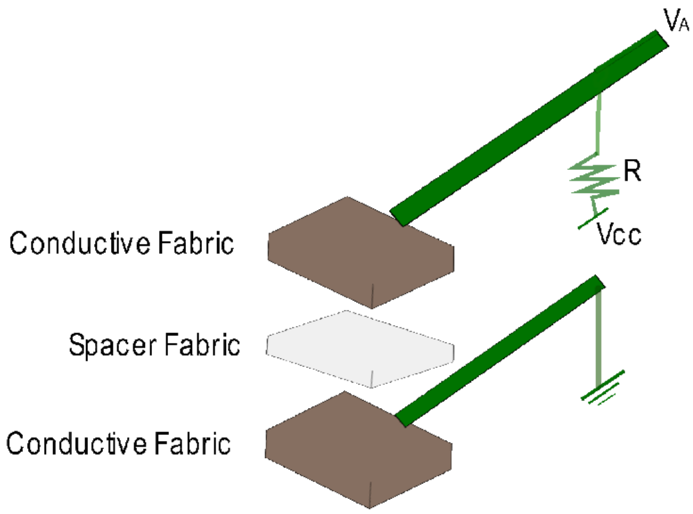

Figure 5.1: Construction of Pressure Sensor [25].

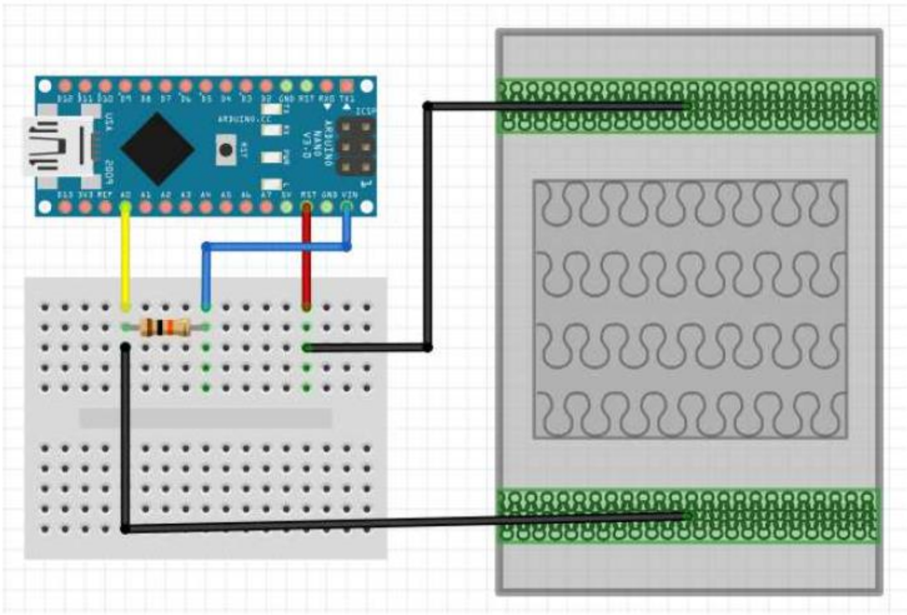

Figure 5.2: Resistance measurement using ardino [25].

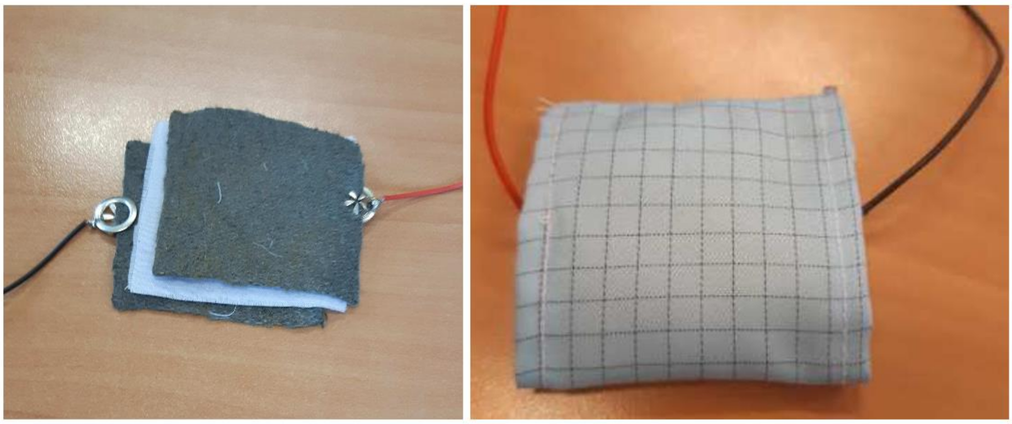

Figure 5.3: Textile resistive pressure sensor,left:internal buildup, right: with cover [25].

One of the studies were carried out by scientists is given between figure 5.1 and figure 5.3, according to the study, resistance which is below 20gr was not evaluated. It showed that the non-conductive character of the sensor at a low pressure. They monitored results only with around 20gr. Above this, the resistance decreased linearly up to around 100gr. Over 2kg the resistance is roughly 153ohm. So, there is a negative correlation among the amount of load applied if length and cross-sectional area are assumed constant as in the experiment [25].

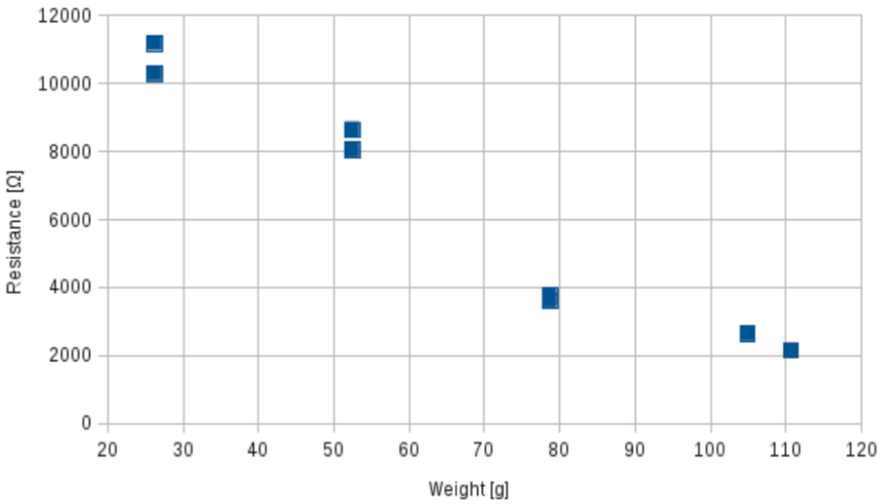

Figure 5.4: Effect of load on resistance [25].

So, in this study spacer fabric is used among conductive fabrics and the change of resistance was evaluated under pressure. There is linkage between the external force and the change of resistance is given in figure 5.4 [25].

5.1.2. Laser Usage

Lasers are used in the case of rapid prototyping processes. It is one of the first methods and the most representative method.It is depended on the material which is used but usually it is classified by the stereplithography process for polymer resin, selective laser sintering for metal nano particles and selective laser melting for metal powders in the event of the photo-curable resin, continuous liquid is required [26]. Because of its major pros of astonishing optical and mechanical features, laser usage replaces conventional manufacturing methods [57].

5.1.3. Filtration Method

Prior to filtration method it is know that many chemicals are used in the production of resistive strain sensors such as PET, PI, PE, PU, Ecoflex and PDMS. Among them PDMS is one of the most used one. Another important thing is sensing elements. The function of the sensing element is to convert external mechanical stimulis into electrical signals [27].

Films are used in order to convert mechanical force into electrical signals. The working systematic of the technique is given in figure 5.5.

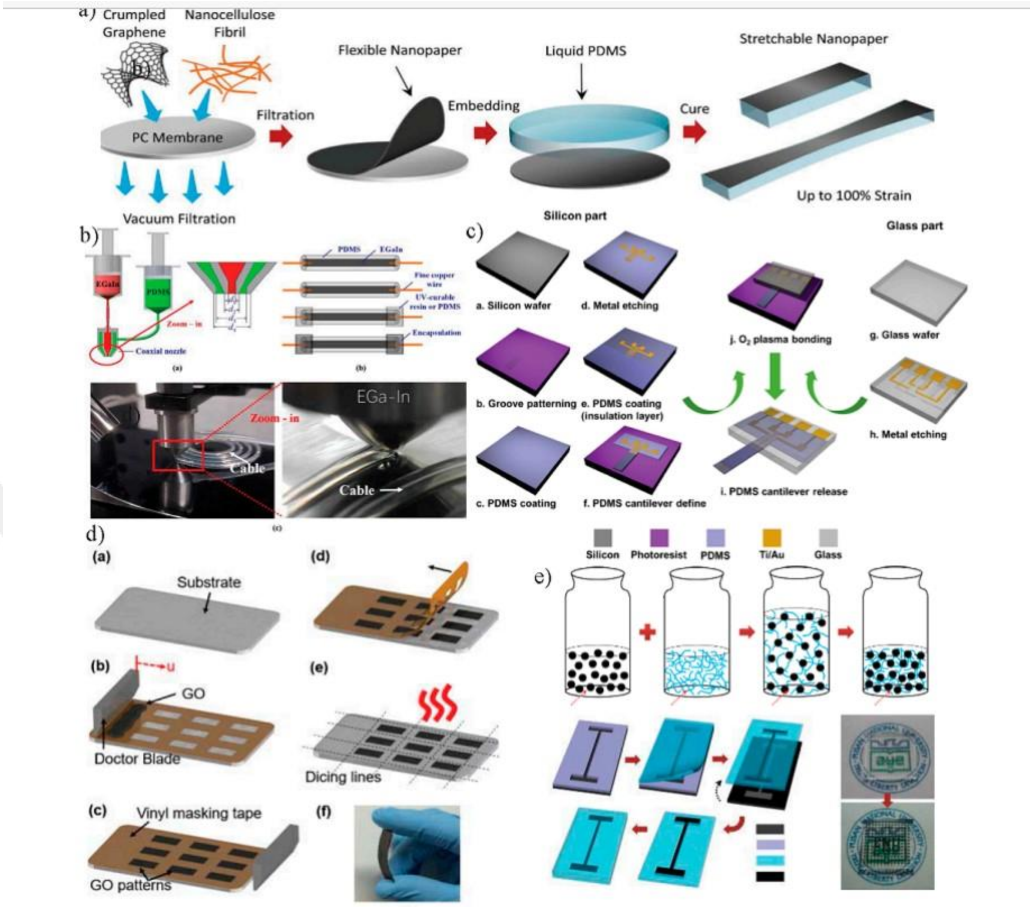

Figure 5.5: Fabrication methods of resistive-type strain sensors based on polymethylsiloxane (PDMS) flexible structures [27].

(a) Schematic illustrations of the fabrication processes for stretchable graphene nano papers. Flexible nano papers were first fabricated and then embedded in a PDMS matrix to obtain stretchable nano papers. (b) The coaxial conductive cable design with EgaIn as the core and PDMS as the shell can directly write for strain sensor. (c) Strain sensor integrated with PDMS cantilever and metal wires. (d) Flexible strain sensor was developed through combination of shear alignment of a graphene oxide dispersion and patterning of multiple rectangular features on PDMS substrate (e) Mixed carbon black nanoparticles with liquid PDMS and micropatterning relies on single-step contact transfer printing [27].

5.1.4. Thread-type Processes

Thread type processes consist of knitting, weaving and embroidering are developed for minimization of wearable textile-based sensors. External forces can also be evaluated which is based on topology or structure [28]. Knit structures provide a huge variety of mechanical properties. Both rigid and flexible parts of the material can be produced homogenously on only one piece by interlock or some other knitting types. Interlock was chosen by the scientist because of its high dimensional stability among the basic weft knitted structures. Although there are plenty of divergent sensor types, this type of sensors covers the vast majority of the sensor market. It has been successful by using conductive materials whereby either knitting conductive yarns or coating knit surfaces with conductors. Intarsia technique can be also used. The conductive realms of the knit sensors are particularly made up for carbon fibers, graphene, silver coated and some other conductive polymers or composites. Conductive compounds importance has gained attention in order to enhance the performance of sensor and the entire process [29-30].

6. MODELATION, FABRICATION, LITERATURE REVİEW

Feet analysis is the basis of medical, sports, health applications. For example, in medicine, foot and gait analysis is pivotal for diabetic patients in order to estimate DFU. In sport applications, foot analysis is important for injuries. So many systems are developed in order to evaluate pressure change under the feet for the people which include textile based and insoles [31]. In the recent years, the vast majority of the studies proved that the plantar pressure is pretty much higher as compared to standard values, in people who are suffering from neuropathy and DFU [32]. Due to this high and abnormal pressure, lesions and damaged tissues are observed [32]. For instance, foot lesions are a huge strain on the budgets in terms of direct and indirect costs. It is reported that the cost of healing for these patients was approximately, 33.000 USD per person the total direct and indirect cost was 245 billion dollars in 2012 [4]. To viewing this pressure for the patients is vital for specifying the status of health for these kinds of people. Most studies carried out by taking care of normal and abnormal parameters in different applications [31].

Some scientist demonstrated that the temperature is also different as compared to healthy people. Temperature can be used in order to assess the risk of DFU, even though this alternative, plantar pressure covers most of the studies [31]. To get rid of foot ulcerations, a true regular feet examination is required. (Such as calluses, hammertoe, abnormal bony structures, aberrations to typical anatomy) [32].

In recent years, smart diabetic socks and wearable textile-based materials are developed in order to help out diabetic patients as they’re flexible, easy to manufacture, compatible and easy to use outside or at home and daily inspection is targeted [4]. It is also overt that, several fatal consequences are detected after DFU. It becomes mandatory to offer novel technologies and services in this field.

Amid all studies regarding this field, Dr. Paul Brand was the pioneer person who recommended the measurement of the pressure between foot and shoe, trying to understand pressure changes for the patients [4].

6.1. Monitoring Systems

There are four monitoring systems in order to predict and evaluate the risk of DFU for the people. Platform systems, in-shoe systems, smart wireless insoles and smart socks [4]. As our major topic is smart socks, we will examine smart socks and its applications in the literature. It is also distinct that other monitoring systems are also significant [31].

6.2. Smart Socks

Smart socks term first emerged in the scientific literature in 2005 with the importance of smart device able to collect motion-related datas and then able to transfer it to the central unit. Smart socks are foot-wearable devices and it is exact to integrate sensors on it which is based on capacitive, resistive or other sensor types. There is also data communication road among devices [31]. There is not a pressure sensor constrain for smart socks so it makes smart socks more feasible. They're easy to wear and fabricate. When we take into consideration the fibers which are used in the fabrication of smart socks, we encounter three types of fibers. The first type of fibers is coated with silver when the other types should ensure piezoresistive impact which aids to evaluate any normal forces exerted onto these fibers alter the electrical resistance of the material. Double silver-coated fibers connected to a piezoresistive fiber can thereby transmit and collect a signal which intensity is a function of the pressure [4].

On the other hand, researchers come across with some disadvantages. For instance, they're not used separately, they have to be attached on the textiles thus they're not fully embedded devices. This may affect the comfort of the end users in a negative way. There is also a problematic situation for flexibility as stable structure occurs upon mounting on the textiles [31].

Due to smart socks encompass electronic circuit, it is not likelihood to be washed. So, at this point washable smart socks should be developed without taking out electronic materials [31]. One of the studies is carried out by an Australian research group which is associated with the scientist who is originally from Israel. They embedded 5 sensors in 5 different places.

Figure 6.1: Placement of the smart sock sensors [31].

Researchers examined the pressure change while walking normally (with a velocity of 3km/h) and walking at a brisk pace (with a velocity of 6 km/h) when the heel strike is present (in walking or running), sensor E is activated, reaching the maximum value before the sensors placed in the front part of the foot. While another type of strike pattern is used when running, Sensor E will reach its maximum value later or at the same time as the other sensors. When one or more of the parts are influenced by a disease, this is directly reflected in the gait. Thus, gait pattern is completely changing. This technology is significant in order to predict early DFU specifications thus lower limp amputation would be prevented [31].

The same research group also developed another smart socks which name is Daid r. The developed system is given in figure 6.2.

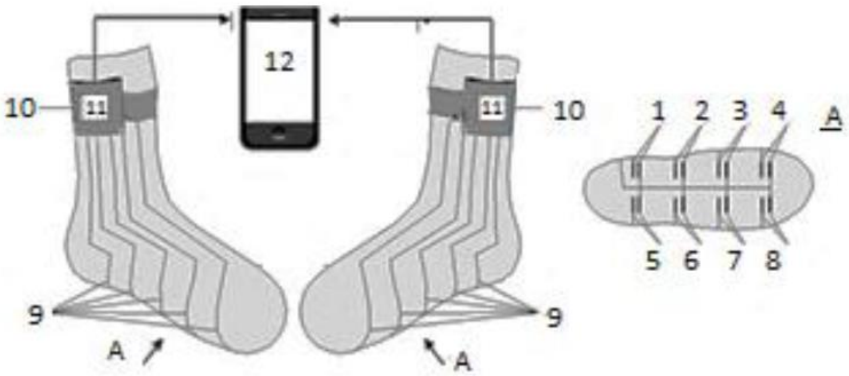

Figure 6.2: Daid Pressure Sock System (DPSS). 1-8: pressure sensors; 9: conductive lines; 10: connectors; 11: data gathering and forwarding component; 12: data processing component [31].

They compared data's during race walking, normal walking and running. Datas collected by conductible fibers and transferred to the central unit by the aid of piezoresistive sensors.

6.2.1. Central Unit

According to a study, central unit is attached in the upper part of the sock, made of an electronic circuit ant it is associated with silver-coated fibers. Any pressure change result in a change in a change in resistance values of piezoresistive fibers is converted into a voltage that is transmitted by silver-coated fibers and collected by the central unit. Data's can be stored in the central unit and can be transferred to watch, smart phone or a laptop [4].

6.2.2. Piozorestive fibers

Piezoresistive fibers show a perfect flexibility so that it makes these fibers easy to integrate. These fibers can be integrated by using traditional methods such as weaving, sewing and knitting. Even though its advantages, they show miniscule working factors (W<=5%) The studies target coating fibers surfaces with some technologies (dip, spray, layer by layer). Plasma technology can also be perfect option for this purpose [33].

6.2.3. Estimation and data transfer

Data transfer is established via Bluetooth or wireless by the aid of piezoresistive fibers. It is collected by central unit and it can be also seen on any kind of device [4].

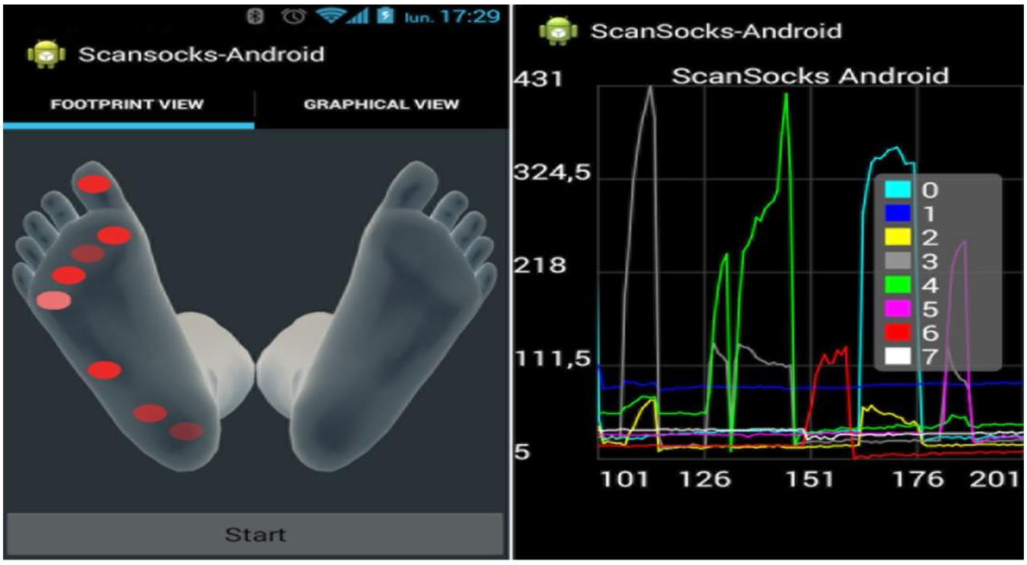

Figure 6.3: Screen shots of the smart-phone application.The pressure values collected for the eight sock sensors are displayed during gait [4].

6.3 Pressure Abnormalities Detection

Divergent researchers offered using smart socks for plantar pressure measurement. Constant pressure changes occur in the case of unhealthy and degenerated foot. In addition, soft sensors are developed instead of conventional rigid sensors as they're easier to fabricate. According to a study, four sensors were integrated during knitting process. Three sensors are attached under the metatarsal heads an done under the heel, these being considered the points that bear the most part of the body weight, consequently they are able to detect the maximum value of the abnormal relative pressure. Flexible piezoresistive materials are used. They used battery-free system.

It is influential to say that it was found a direct relationship among abnormal pressure under foot with diabetic foot ulcer in the case of more than 588 kpa It is due to lack of blood circulation in some parts under the foot. When tissues are not nourished by blood diabetic foot ulcer and high pressures occur [60].

In addition to this study, it was claimed that compressible soft robotic sensors are another type of sensors that were proposed for detecting pressure in a smart sock. Another type is polymeric optical fibers. (POF) which is given in figure 6.4. [31]

Figure 6.4: POF-based knitted sock [31].

It is worthwhile to specify that there are some disadvantages of using optical fibers in smart socks as they're fragile. There is also a limitation for this kind of smart sock [31].

6.4. Temperature Abnormalities

Smart socks can be used in order to monitor both pressure and temperature for the diabetic patients. Many designs proposed in this context for diabetic and healthy patients. These systems are able to detect temperature variations in the feet. These differences are preliminary precautions of DFU and early detection is vital for the patients in order to get rid of lower limb amputation. These sensors acquire body temperature data and then data are transferred by the communication system to smartphone application, where they can be also stored. One of the studies demonstrated they the increased skin temperature and a plantar pressure overload are the signals of foot ulceration [31]. So, one of the most effective ways to prevent these complications daily foot temperature monitoring is emerged [34]. Left and right feet are examined daily. Patients who have constant divergencies in temperature or ‘’asymmetry’’ surpassing 2.22 Celsius degree are the specification of abnormal inflammation and are instructed to reduce ambulation [34].

Another study showed patients with diabetic neuropathy had a higher foot temperature (32-35 Celsius degree) compared to patients without (27-30 Celsius degree) [35].

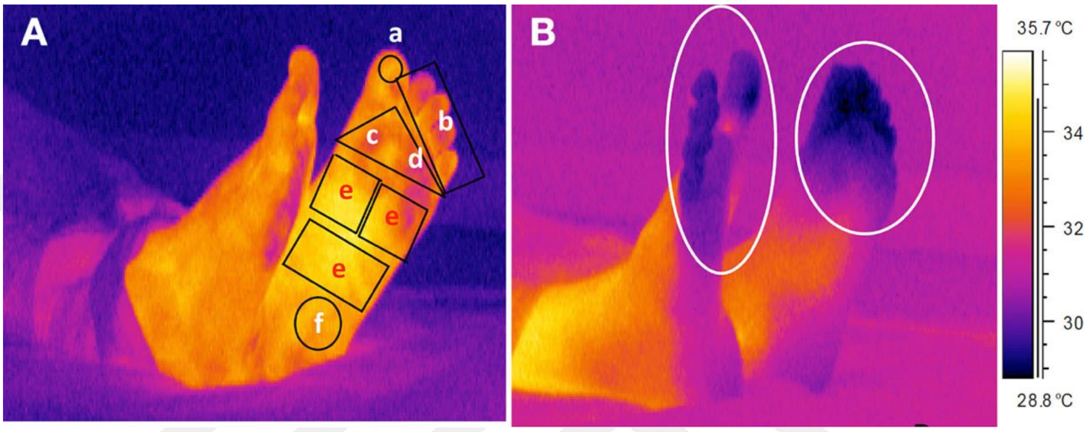

Figure 6.5: Typical thermal image of the foot with (A) hot and (B) cold regions [35].

To sum up, temperature detection is significant along with pressure as when there is a lack of sense awareness in the feet, overload pressure emerged and it occurs temperature differences in the disparate parts of feet. These are the preliminary specifications of unhealthy foot. If the concrete steps are taken on correct time, it means that lower limp amputation can be hampered. This thesis is also targeting this relationship which encompass pressure and temperature detection in order to predict DFU and some other feet problems regarding diabetic patients [35].

7.EXPERIMENTAL STUDIES

7.1 Materials and Methods

7.1.1. Materials

Conductive stretchable silver-plated knitted textile and non-conductive mesh fabrics were bought. Thermoplastic film (3914 Sew free Tape, Bemis Accessories Inc. USA) was used as an adhesive layer during production of soft pressure sensors. Polyester mesh fabric was used because of high resilience to wrinkling. 3 conductive silver fabrics and 2 mesh fabrics were used and 4 adhesive layers were implemented. Tpu coated yarn also used in order to sew soft pressure sensors to the sock. In order to keep the electronic activation of the data from the sensor under pressure properly, the output and the input points of TPU-coated yarn were kept open.

7.2. Methods

7.2.1. Manufacturing of the Sensors

Figure 7.1 shows the manufacturing steps of the soft pressure sensors. Initially, conductive knitted fabrics, non-conductive mesh fabrics and adhesive layers were cut to design via Laser system. (Universal Laser Systems, USA). However, mesh fabrics were cut 3mm larger than conductive fabrics in order to hamper short-cut. After that each component were manufactured and placed Each pieces were bonded under 140 Celsius degree and 4 bar, 5 seconds. Working principle of the sensors were also given in Figure 7.3. To clarify, in the case of normal pressure upper conductive fabrics touch each other and they produce a data and in the case of abnormal pressure which can be a signal of DFU bottom conductive fabrics touch each other. At this point the size of the mesh fabrics is pivotal due to larger size mesh fabric (0,012mm x 0,012mm) were implemented to the top side whereas smaller size mesh fabrics(0,009mm x 0,009mm) were placed to the bottom part.Mesh fabrics are 100%polyester and 70 denier.Larger mesh fabric is 3x1 mesh and smaller mesh fabric is 1x1 mesh.It is effortless for the conductive fabrics (100% silver) to contact each other in the upper part while it is tough for the conductive fabrics to contact in the lower part and it requires pretty much more pressure. At the end of the contact, electrical resistance changes and the electronic circuit collects data from the sensors. Moreover figure 7.2. shows the implementation of the sensors under the sock. 5 sensors were used. Each sensor has 2 exit points and there is only one midline. Consequently, 11 tpu coated yarns were used in order to transfer data from sensors to electronic circuit. Sensors were bonded under the sock with a non-conductive glue and were sewn with tpu coated yarn.

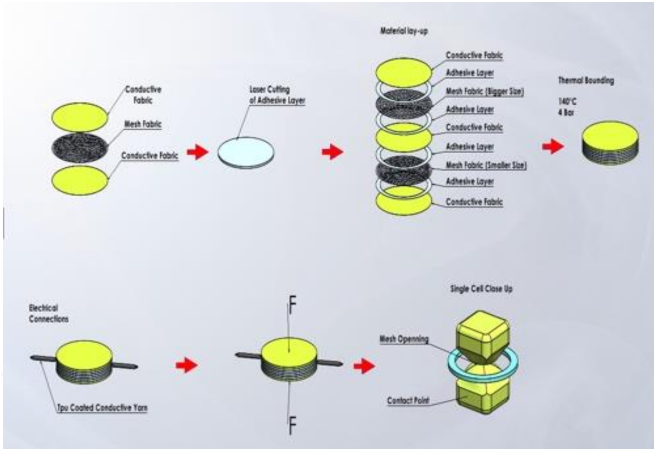

Figure 7.1: Manufacturing of the sensors

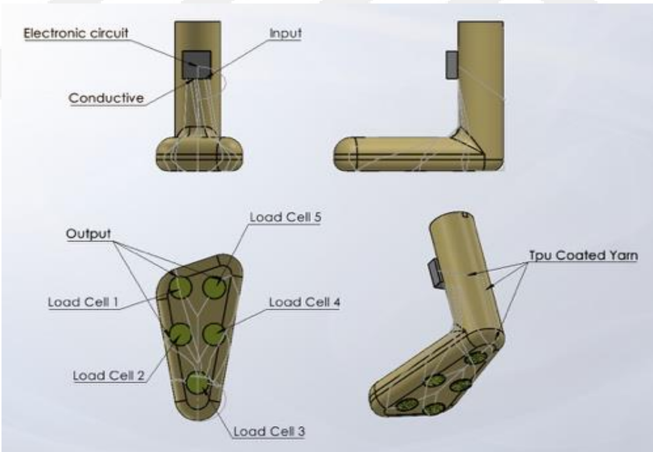

Figure 7.2: Implementations of the sensors

7.2.2. Testing Methodology

Python software was used in order to carry out test while wearing socks. Experimental outcomes found. Working mechanism is shown in the figure 7.3.

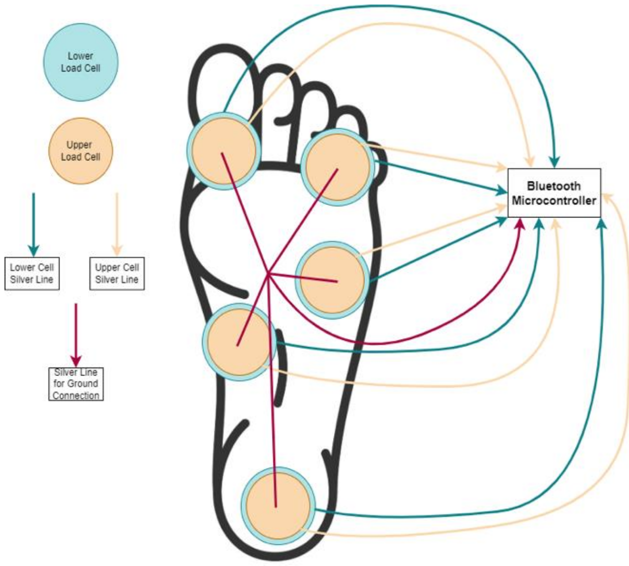

Figure 7.3: Working mechanism of the design

Eleven tpu coated yarn was used and 1 center line was instructed in order to measure low and high pressures. All data were transferred via Bluetooth and data were converted to graphics on the computer programme.

Graphics were created at divergent angles; 10-degree upside and downside, 20-degree upside and downside, standing and during walking.

Outcomes are significantly successful and all sensors are working in accordance with our expectations. Entire tests were carried out while during until 10 seconds and after that periodical movement was analysed. Standing position is out of this measurement. Standing position datas were collected and created graphics at solely stable position.

7.2.3. Characterization of the sensors

An experimental device which is given in the figure 7.4. was used in order to analyze sensors. Mechanical and electrical data were collected and created graphics at the same time.

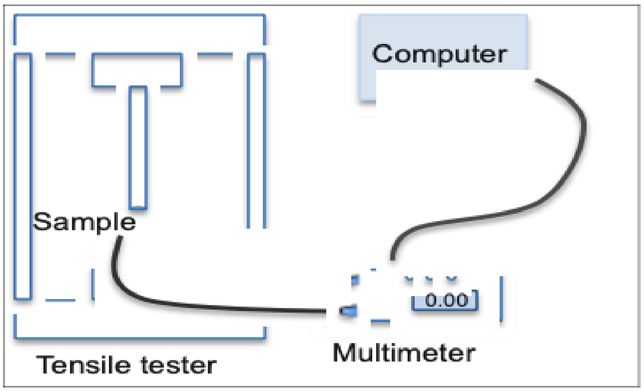

Figure 7.4: Four probe method

The method of four probe is used to measure electrical resistance alteration under divergent pressures. It is also used to indicate relation among pressure and electrical resistance. High cell sensors and low cell sensors become active under different loads as a consequence of the size of mesh fabrics. The toral area of soft resistive sensors were 25 mm x 25 mm, thickness 2mm,100%silver.

8. RESULTS AND DISCUSSIONS

Both results for the socks tests and sensors are satisfactory. At 10-degree downside low and high sensor reactions were analyzed. As seen from the graphics, sensor 5 has mostly been inactive because of lower pressure in the thumb. In some seconds it becomes active because of periodic walking at a 10-degree downside. It is also clear that sensor first and fourth sensors are activated at high pressure because of the angle. Sensor three and sensor 4 become active at different pressures because of the movement.

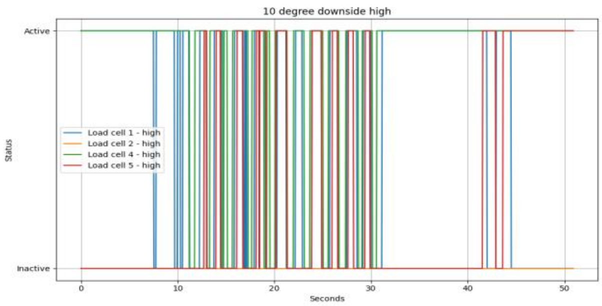

Figure 8.1: 10 degree downside high

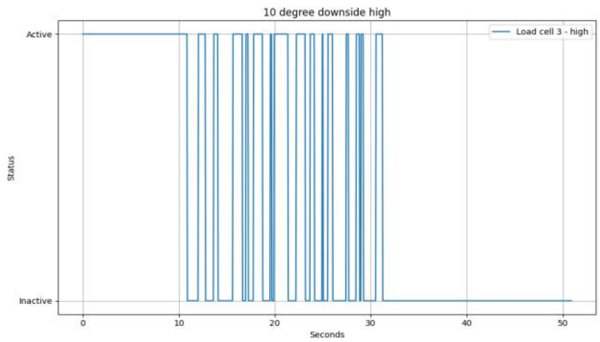

Figure 8.2: 10 degree downside high

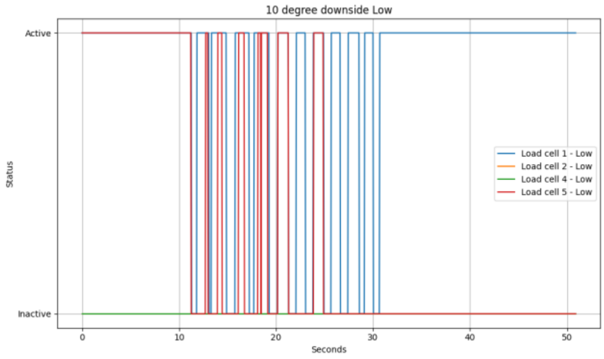

Figure 8.3: 10 degree downside low

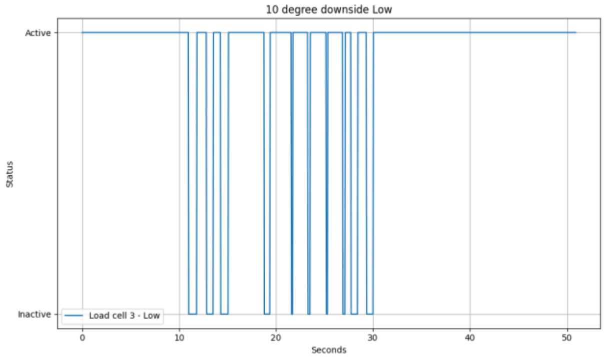

Figure 8.4: 10 degree downside low

As seen from the figures , load cell 2 has always been inactive because of the position of it whereas load cell 3 becomes active at a lower pressure (3kpa). Glitchs are not considered at this point due to the major alterations of sensor 3 at ten degree upside. Sensor 4 becomes active at high pressures while 1, 2 and sensor 5 becomes active both low and high pressures.

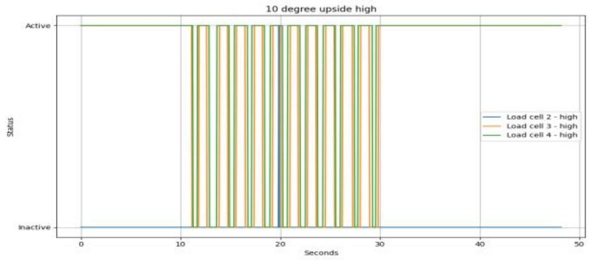

Figure 8.5: 10 degree upside high

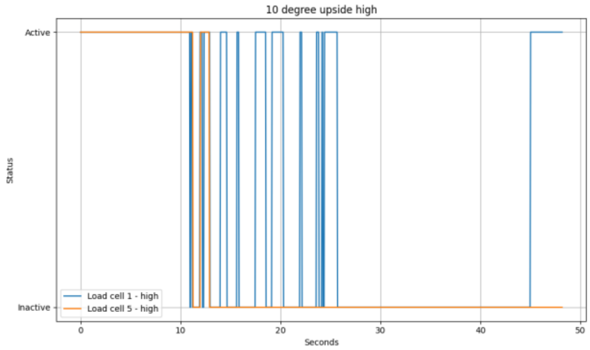

Figure 8.6: 10 degree upside high

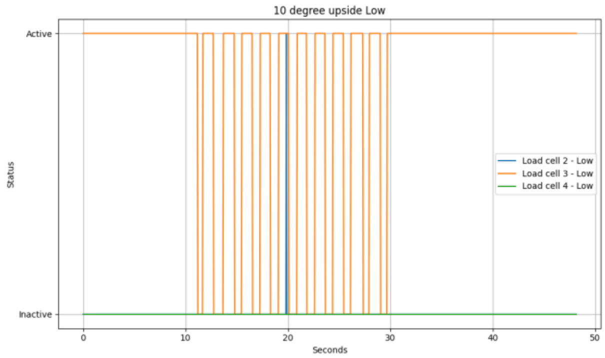

Figure 8.7: 10 degree upside low

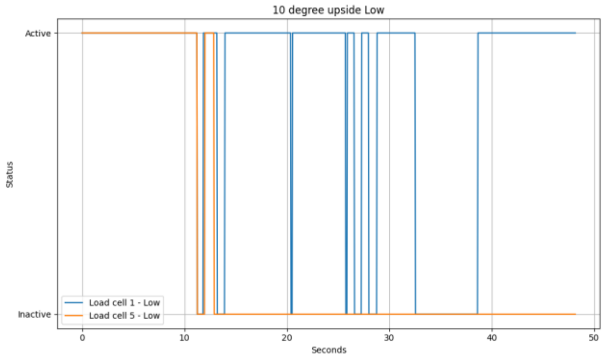

Figure 8.8: 10 degree upside low

At 20 degree downside,sensor 2 and sensor 5 are inactive because of the pressure below 3kpa it means that there is pretty much lower pressure on the sensors at this angle. Sensor 1 and sensor 4 contact each other at a higher pressure case whereas sensor 3 active in both cases. At 20 degree upside, load cell 3 is also acting as a high and low pressure sensor. Sensor 2 becomes active at lower pressure (3kpa) whereas 1,4 and 5 at higher pressures.

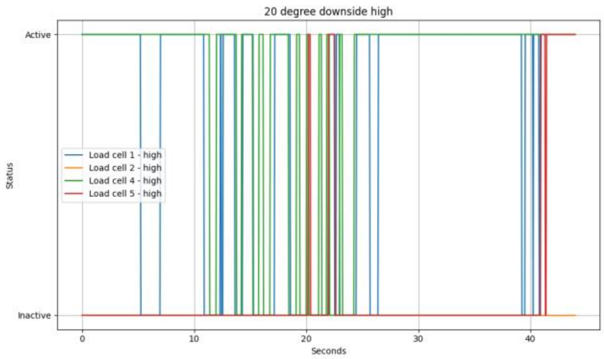

Figure 8.9: 20 degree downside high

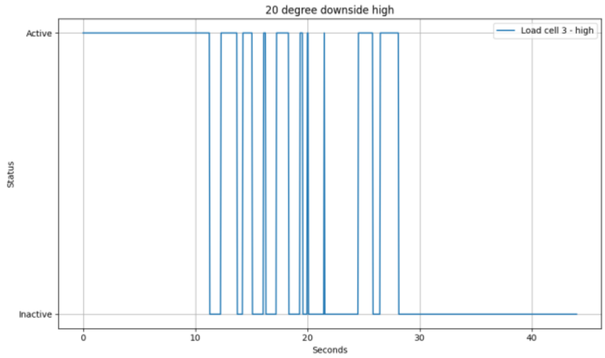

Figure 8.10: 20 degree downside high

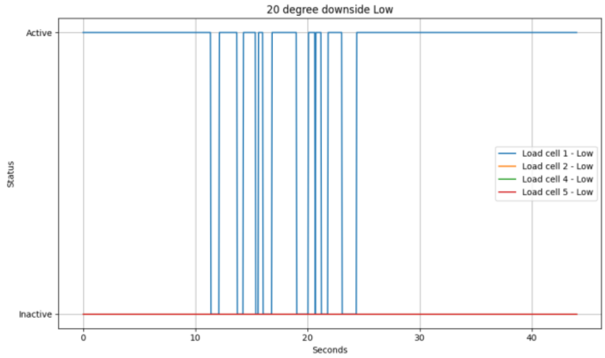

Figure 8.11: 20 degree downside low

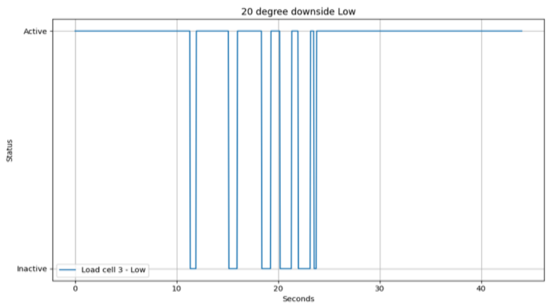

Figure 8.12: 20 degree downside low

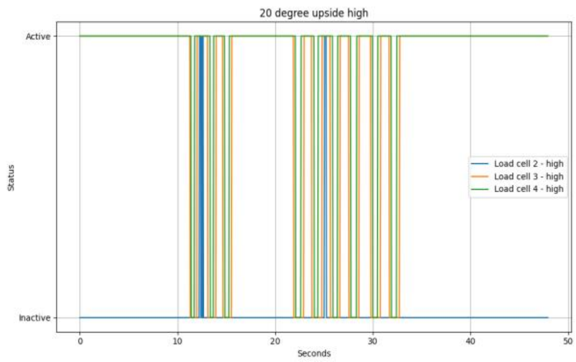

Figure 8.13: 20 degree upside high

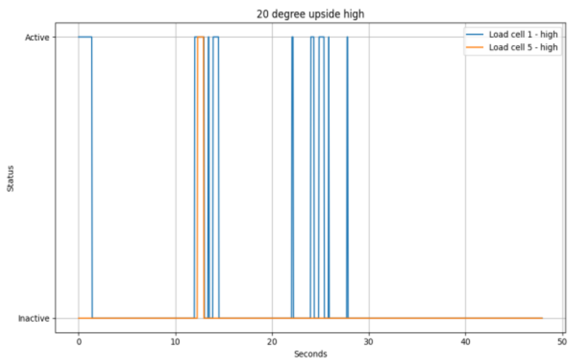

Figure 8.14: 20 degree upside high

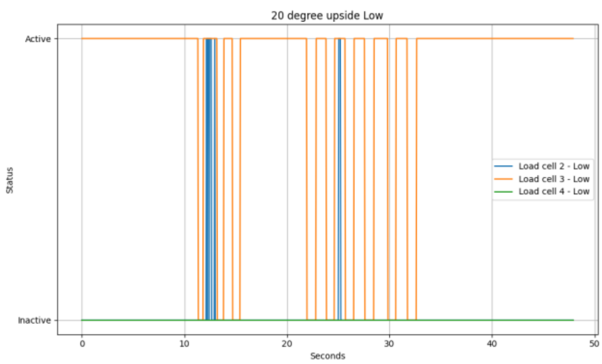

Figure 8.15: 20 degree upside low

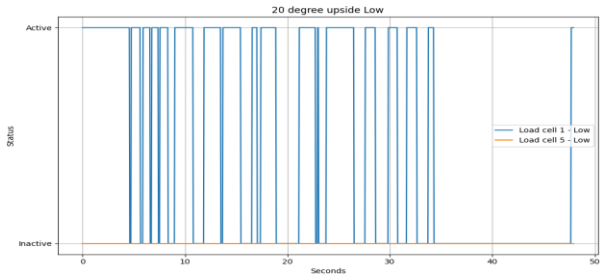

Figure 8.16: 20 degree upside low

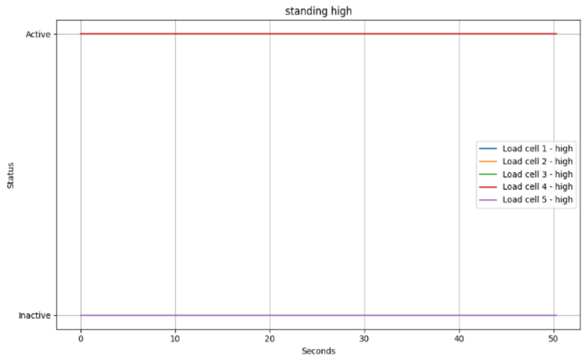

Figure 8.17: Standing high

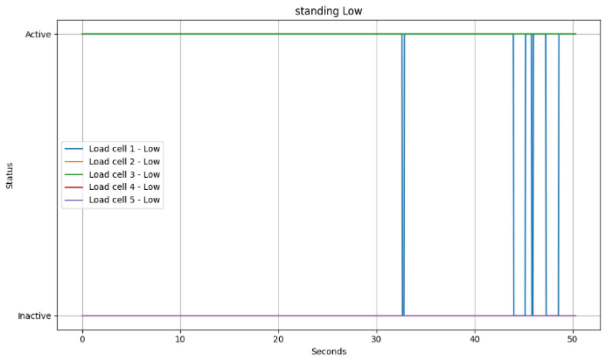

Figure 8.18: Standing low

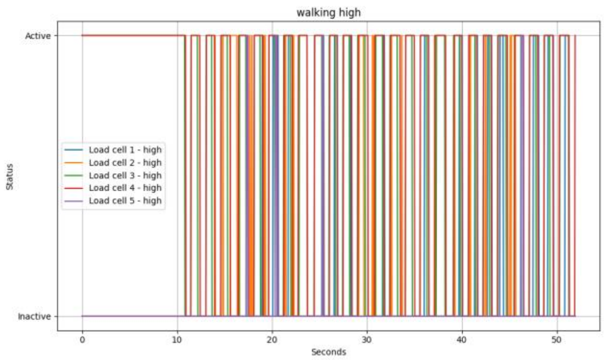

Figure 8.19: Walking high

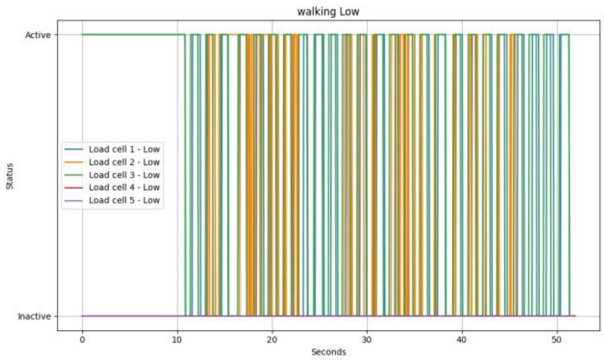

Figure 8.20: Walking low

During standing and walking surprising data were collected and clear graphics were created. For instance, in the stance position, while the second and the fourth sensors give data at 63kpa and above, that is under higher pressure, the sensor five does not give data above 3kpa or 63kpa.This means that lower than 3kpa is required for this sensor in order to obtain electrical resistance. In addition, the first sensor and third sensor are active under low pressure. As given in the sensor characterization, 3kpa is the value which is the first electrical data is obtained at low pressure. During walking all sensors are working according to walking cycle. Gait-related data and analysis need to progress further.

When we take a look at the sensors, first electrical resistance, the relation among electrical resistance and pressure and working range of the sensors were measured and created graphics in order to indicate that sensors are working successfully.

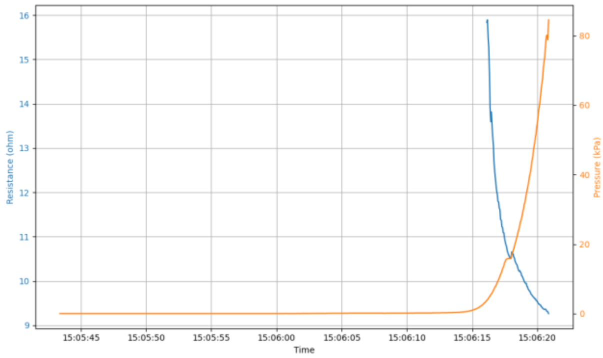

Figure 8.21: Low sensor pressure resistance values

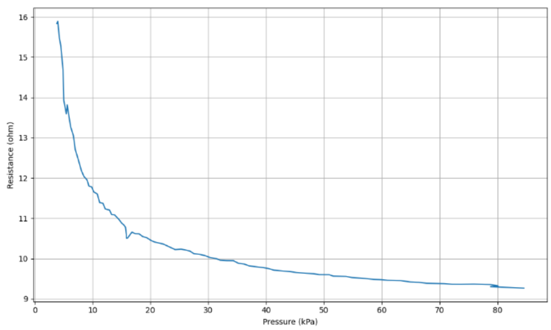

Figure 8.22: Working range of low sensor

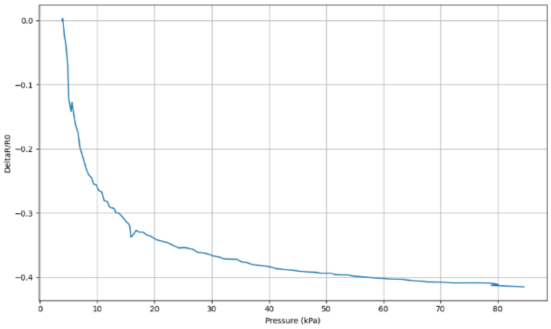

Figure 8.23: Sensitivity of low sensor

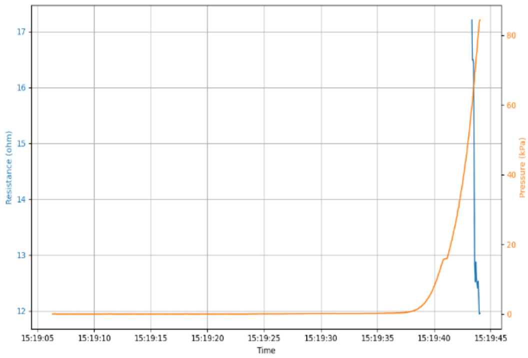

Figure 8.24: High sensor pressure resistance values

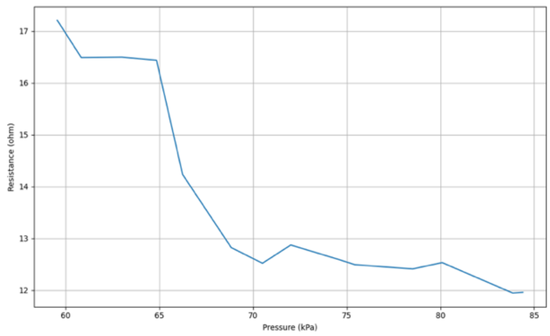

Figure 8.25: Working range of high sensor

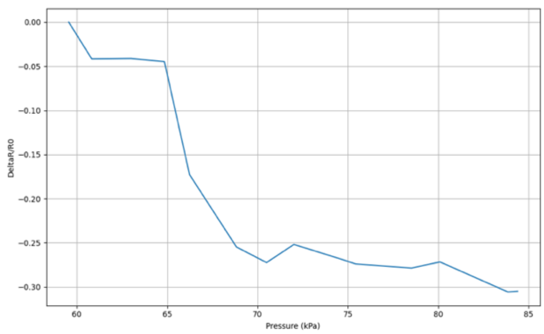

Figure 8.26: Sensitivity of high sensor

The initial resistance of the sensors were measured. Low cell pressure sensor generates electrical resistance at somewhere around 3kpa while the high one produces at 63kpa. So low cell sensors become active more easily as compared to high and this disparity can be used as an indicator of diabetic foot ulcer due to 63kpa is an extraordinary and abnormal pressure for the healthy people.

Working range of the low sensor and initial resistance of the sensor are so clear from the figure of 8.22 and 8.21 . This result because of different mesh sizes. The upper cell which has larger mesh size can contact each other easily and the bottom soft pressure sensors touch each other at a very hard case due to smaller mesh size.

As seen from figure 8.22 and 8.25 both sensors have disparate working range. Please see below table 8.1 and 8.2 for the working range of two different sensor.

Table 8.1: Working range of the low sensors

Low sensor	**Soft Pressure Sensor 1**	
	Working range 1	***Working range 2***
Kpa	3-40	40-80

Table 8.2: Working range of high sensors

High Sensor	**Soft Pressure Sensor 2**	
	Working range 1	***Working range 2***
Kpa	55-70	70-85

Both sensors can be considered as a highly sensitive sensors however it is so clear from the figure 8.23. and 8.26. ; sensors with a bigger mesh size has a higher sensitivity compared to smaller owns as a consequence of the significant change in electrical resistance at lower pressure grades.

On the other hand, lower sensors (upper) have wider working range as compared to high sensors (bottom ones). It is because of gradual contact among soft pressure sensors. These sensors can be also used for tactile sensing due to their high sensitivity and wider working range areas.

9. CONCLUSION

Pressure differences under foot for the diabetes mellitus should be taken as a serious risk as further complication could occur. This pressure alteration and differences occur as a consequence of unbalanced or deficient blood circulation in some part of the patients. If the blood does not reach under the foot completely and regularly, diabetic foot ulcer and abnormal pressure changes can be detected. Sensors are mostly working successfully however gait-related data and analysis need to progress further. Working range of the sensors should be also increased as diabetic foot ulcer is detected in the case of more than 588 kpa according to literature and real patients should be also took into test in order to analyze differences among healthy people and diabetic patients. When we come back to graphs glitches also should be analyzed deeply and corrected in the following researches. Heat map and mobile phone application could be also performed which is related to pressure and electrical resistance change so that patient can see results in anywhere and take concrete steps prior occurring diabetic foot ulcer otherwise limb amputation is inevitable in the further cases. Finally, may help this study to health and care services for diabetic patients and wishing to a roadmap for the researches who is interested in this field.

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