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Medical Smart Insoles Enable Patient Monitoring and Controlled Weight Bearing After Orthopedic Surgeries

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Abstract*— With the concept of the Internet of Things, communication between devices becomes fast and secure. In addition, new applications are made in the field of health with this technology that has developed in different fields. With the term internet of medical objects, it includes technologies such as smart watches and heart rate monitors, which are produced to facilitate the lives of patients. In this study, an application that aims to both monitor the health of patients with gait disturbance and accelerate the recovery process was studied. Compared to similar studies, this technological development, called smart insoles, preserves the patient's past records, accelerates the rehabilitation process and monitors data with a computer interface. With the PCB (printed circuit board) design and the insoles, the pressure value that the patient will apply to the ground is controlled according to the values defined by the doctor. Thus, in case the patient exceeds the defined value, that is, in case of overload, the patient's health is protected with an audible and vibrating warning from the medical smart insoles provide controlled loading.

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Index Terms*— Controlled Loading, Health, Internet of Things, Smart Insole

I. INTRODUCTION

The Internet of Things (IoT) is an important concept that emerged by Kevin Ashton in 1999 and takes place in today's technological developments [1]–[3]. In this way, communication between devices is easily provided without the need for human and human power. The data received from the sensors that produce electrical signals are transferred to the cloud with the controllers and make it possible to see the data in other devices. Sensors perform data exchange with signals. In this way, the data received with the sensors are easily transferred to the user and stored in a cloud. It also directs the objects with the information sent to the sensors by the user [4]-[7]. This application is used in many parts of our lives. There are examples such as smartphones, smart homes, smart cities, wearable technologies and RFID (Radio-Frequency Identification). In Fig. 1, there are fields of internet of things including smart industry, smart agriculture, smart grid, medical care, smart home and smart cities [8].

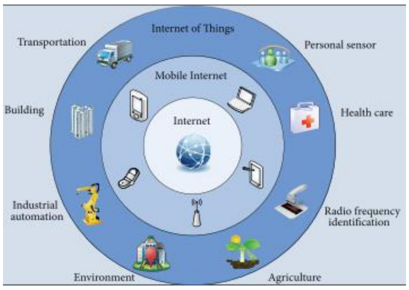

Fig.1 IoT application fields [8].

A type of IoT is Internet of Medical Things (IoMT) which is used in healthcare. Thanks to this technology it is simple to get information from sensors. The data is transferred to the mobile phone or another interface, so the user and the doctor can get the data very quickly. There is also a cloud in this type of technologies. The data are stored there and any time is reachable [9].

II. INTERNET OF MEDICAL THINGS

Thanks to IoMT, difficult diseases can be diagnosed and treated early, and technologies that make people's lives easier are emerging [10]. With this technology every user and doctor can follow the rates such as blood value, level of consciousness and blood pressure from a computer interface [10].

IoMT has other technologies to facilitate the live of the patients and doctors. These technologies are also easy to use in daily life because they have the advantages of beings smaller and lighter, as well as long-lasting thanks to low-energy sensors [10].

There are applications that track and monitor the fall of the elderly. Using the gyroscope, accelerometer and vibration sensors, the position and activity of the patient is determined. In this way, the patient's fall as a result of a sudden loss of balance is transferred to the people to whom the information will be shared via sensors, providing fast and early treatment [10].

Today, simultaneous remote monitoring technology has gained great importance to be used in the Covid-19 epidemic that emerged in Wuhan, China in 2019. Thanks to this development, the follow-up of patients carrying the contagious Covid virus during their stay in quarantine at home has been made possible by obtaining remote data [9].

III. RELATED WORKS

It is an idea that was put forward in 1930 to diagnose foot diseases and gait disorders. However, the first applications were made in 1963 by Bauman and Brand. They suggested to measure the foot pressure with a thin transducer [12].

In 1985, the research on foot pressure distribution was started. This technique was searched by Soames and looked to the relationship between pressure-time [13].

In 1986, it was determined that the basic parameters of time, distance, strength, joint angle, muscle movements and metabolic balance had an effect on walking pressure. The use of transducers is suggested in the study [14]. In Fig. 2 is foot pressure distribution demonstrated.

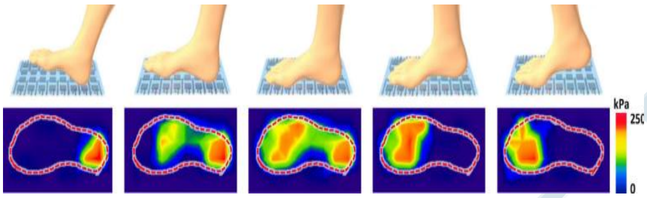

Fig. 2. Foot Pressure Distribution [14].

In 1991, Zhu and other researchers used FSR (force-resistive sensors) to prevent loss of pain and temperature sensitivity of diabetes patients [15], [16].

In 1995, Hausdorff used two FSR but couldn't get simultaneously data. In 1997 Lawrence improve Hausdorff's work and designed a wireless insole [17]-[19]. This application has four main parameters: insole, receiver, transmitter and computer interface [19].

In 2001, Morley add temperature, pressure and humidity sensors to Hausdorff's application [20].

After 2008 first wireless applications and insoles for different fields are designed [21].

According to these works we make a smart insole with FSR sensors, buzzer, vibration motor, accelerometer and SD card.

In the research in 2010, the discomforts that occur in those who wear high-heeled shoes were handled and it was determined that plantar pressure was the cause of these. According to this problem they made measurements by placing sensors at certain points on the sole of the foot. As a result of this study, the importance of shoe selection and the selection of sensor locations has emerged [22].

In 2015, the insoles were designed in two layers consisting of horizontal and vertical electrodes. It's made of carbon embedded piezoresistive material. The measurements were carried out by considering the intersection points of the electrodes. It is possible to follow the pressure distribution of the user on the surface thanks to these electrode strips [23]. However, since there is a study to determine whether there is an overload or not, it is insufficient compared to our study.

In 2016, the insole was designed with integrated textile pressure sensors. This work aims to sense, collect and analyze the pressure values. The data is send to the interface with a Bluetooth module [24]. But they don't try to measure the if the pressure value for a patient. So, our design is different from this work.

In 2017, researcher make an insole for patient patients who have had a stroke. This insole sends an electrical impulse to the nerve in the leg this information is sent to the user for the foot to move. Devices and control units that provide feedback are used by being attached to the waist of the user [25].

In 2018, the sensors were made of polyvinylidene fluoride (PVDF). This material converts mechanical energy to electrical after pressure on the ground [26].

In 2020, the insole is designed with microfluidic sensors. This sensors are stretchable so they are comfortable for the user [26].

In 2021, the works about insole design is changed. They started to use radio-frequency identification (RFID) and battery-less designs. This type of insoles are called RFInsole [26], [27].

IV. SMART INSOLE SYSTEM

Smart insoles are primarily used for patients with walking-related diseases. This application is designed to shorten the recovery time and reduce the cost of patients after diseases such as stroke and paralysis that affect the body's mobility [25].

On the other hand, smart insoles are used in daily life activities such as in sports and dance [25].

The working logic of the smart sole is that the sensors that place it on the base work according to the amount of load falling on it during stepping [28].

There are some examples to this technology like F-Scan, Pedar Sensole System, Moticon and Orpyx. These applications have different features and application fields [29]. For example, with Pedar system is difficult to follow up the system simultaneous because it is designed with 8 small sensors which is difficult to calculate the data correctly. Also, piezoelectric sensors which is used in Pedar system are damaged by prolonged use and exposure to pressure [29]. In Fig. 4 we can examine the system.

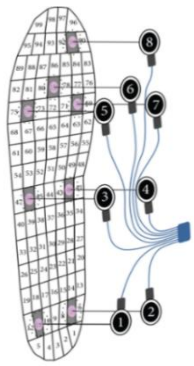

Fig. 4. Pedar Sensole System [29].

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In Fig. 5 is another example which is called F-Scan insole. This system works like Pedar system but it cannot work wireless and cannot transmit the collected data to a mobile phone or another interface. It uses more cables and stretches to the waist, so in our work we use less and short cable for the patient comfort.

Fig. 5. F-Scan System [29].

A. System Features

1) Medical Smart Insole Design Features:

The insoles will be inside the shoes.
It was designed using light and small elements.
It only has a wired connection with the designed card.
It communicates with the designed card.
It can be used on different shoes.
It is protected against liquid contact.
It has vibration and sound warning systems.
It meets its energy needs with batteries.
It does not require much energy consumption.

2) Hardware Design

Medical smart insole design is made with three force sensing resistors (FSR) to measure the foot pressure distribution and the pressure values. These sensors are thin, flexible, can response fast, is resistant to noise and consumes low power [30]. The change in resistance is measured according to the pressure applied to the sensor [18]. With the increase in the pressure value applied to the sensor, the sensor resistance decreases [21], [31].

Sensors are located on the heel, midfoot and big toe like in Fig. 6. We get more reliable data with minimum sensor. The fewer sensors we use, the less data we collect and the faster we process data.

We put three sensors on the sole, because it is simpler and faster to collect the data from the sensors. So, we can analyze the pressure values more quickly and send fast feedback to the user.

The location of the sensors was by observing and measuring which points on the sole of the foot the patient applied more pressure during walking.

However, it is an important issue to select the regions that are most exposed to pressure during stepping.

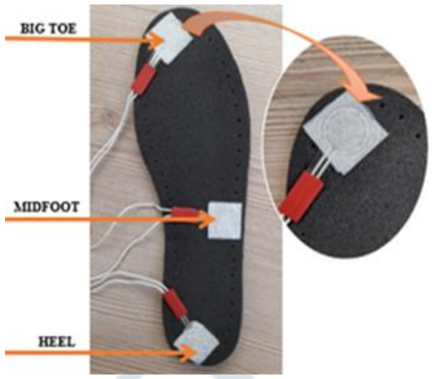

Fig. 6. Sensor location.

ARM Cortex M3 processor is 32 byte and has a great performance with less cost. It is also used in platforms consisting wireless networks and sensors [32].

Nowadays, ARM processor is used in smart phones and wearable devices like smart insoles [33].

In this study, STM32F103CBU6 is used. It is an arm based 32-byte microprocessor. It can work from -40 ℃ to 85 ℃ and has 128 Kbytes memory capacity [34].

A buzzer and vibration motor are used with transistors to provide feedback to the user. Since the transistors used to control the sensors are the switching elements, if the user/patient is overloaded the pressure on the sole of the foot, the vibration motor on the card attached to the ankle activates and vibrates to the user. The user/patient is also exposed to voice command with the buzzer on the card.

In addition, the operating status of the card can be seen and feedback are provided with LEDs.

ADS1115BQDGSRQ1 is an integrate that convert analog data to digital. It also compare the digital data and convert the data very fast [35].

ADXL345BCCZ is an integrate which is used to measure 3-axis acceleration in the card design. Thus, the static and dynamic acceleration values of the user are measured [36].

In this design we collet also the date, month, year, hour, minute and second data with a real time clock (RTC). This microcontroller can communicate with other sensors and work simultaneously. Thanks to this integration, we can track when the patient is overloaded on the soles of the feet. Regardless of whether the user is overloaded or not, it records the time and date with the help of a battery in the background during its operation.

Thus, we protect the doctor against any negativity by keeping a record of whether the values defined by the doctor are exceeded or not. For example, in the cases where the patient, who exceeds the pressure value determined by the doctor, harms himself and sues the doctor. In such a case, the pressure value determined by the doctor and the pressure values applied by the patient are recorded on the memory card with date and time information. During the lawsuit, the doctor can prove that the patient does not comply with the determined values by accessing the past records and protects his rights.

While instantaneous recording of time and pressure values is ensured, these values are backed up on a memory card with a microSD card. Thus, it is possible to access the necessary information from the card if needed.

Since the entire system is powered by a 9V Li-on battery, it consumes low power and is portable. In case the battery runs out, it can be continued to be used by inserting a new battery immediately If the battery is not at a sufficient level for the system, the red LED on the system will flash at long intervals and a long vibration will be felt. The user plugs the system into charge. This procedure is generally done at night when the patient is not up.

A small and portable card is designed with the snap fasteners used to attach it to the user's ankle. The design has been completed with the interconnection that provides data transfer between the card and the insole.

B. System Interface (Software Interface)

The system interface is designed to calibrate the sensors used in the sole. It also has the ability to control and reset the feedback warning systems in the insoles.

On the other hand, the interface provides for which values the insoles should give feedback and how the insoles are controlled. With the computer interface program, we save the data from the user like user's name, surname, identity number, operation and diagnosis date. At the same time, the weight values for each sensor or an average weight for the three sensors are determined by the doctor are entered into this program and the sensors are adjusted according to these values.

After the sensors are adjusted, the user starts using the insoles and feedback systems work in case of exceeding the set values.

At the doctor's appointment or if the person wants to examine their own data, the insoles are connected to the interface. The data taken from the memory of the insoles are examined in the interface according to time and pressure values in the form of graphs and tables.

Unlike other smart insoles applications, calibrating the sensors with the interface, recording the time and pressure values of the data in tabular form and providing access to historical data are the distinguishing features of this application. At the same time, it provides accurate and fast data analysis with few sensors and provides fast feedback without disrupting the user's life.

C. Application Fields

To design ergonomic shoes [37].

In sports, to monitor and analyze the performance of the athletes to contribute to their development [21].

Providing and improving balance control of patients and athletes [21], [37].

In health, to use in the early diagnosis and follow-up of diseases [21].

To facilitate physical therapy and rehabilitation practices [21].

To monitor foot health [21].

To prevent injuries/accidents [21], [37].

V. CONCLUSION

Our project is tested in department of orthopedics and traumatology from 5 different types of surgery with 25 patients, in total with 125 patients. These people are observed during the treatment period determined by the doctor and their foot pressure recorded with smart insole on daily life.

In cases of overload, smart insole makes an audible and vibrating feedback to the patient. Thanks to the warning system, damage materials is prevented in patients who use parts with a high probability of breakage, such as platinum. Even if someone tries to blame the doctor in cases of self-harm by overloading, the accusations are unfounded thanks to the recorded data on the insoles which is accessible only to the doctor who designed the system.

In addition, the main part of the design, except for the insoles, is suitable for reuse.

Instead of the other works in our work we use less sensor to measure the pressure. Our design is more comfortable than the other while we use less cable and this don't affect the daily life and the appearance of the user. We use chargeable battery so the user doesn't have to think about whether the insoles have enough charge or not. In case the battery runs out, it can continue to use using the new battery. The exhausted battery can be used again by charging it later.

Medical smart insoles have been designed and started to be tested in some patients. We think that it will make rapid progress in terms of improvement depending on the period of use, and we are advancing the studies in the direction of improvement and innovation.

In the future, with the development of smart insoles applications, it will be an application suitable for use in every field in daily life. We are planning studies on daily use and different health applications by making the system smaller with the obtained know-how. For our work, in order to make more precise and accurate measurements, studies can be carried out on the new sensor types. Likewise, instead of a rechargeable battery, a different energy source suitable for long-term use can be found.

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