Development of an open-source digital fabricated diabetic foot monitoring system

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Abstract

Preventing recurrence of diabetic foot ulcers in high-risk patients with current standard methods of care remains a challenge [1]. In collaboration with a FabLab and a medical supply store, an open-source diabetic foot monitoring and feedback system integrated into an orthosis was developed and evaluated. The developed system could prevent worsening of the disease, although further technical and clinical validation is needed. The FabLab was used as an environment to combine modern digital fabrication techniques with traditional orthopedic craftsmanship and its expertise. A sprint challenge was developed to facilitate the process from ideation to prototyping using agile innovation methods. The prototype consists of embedded temperature and pressure sensors that monitor disease progression and trigger an alarm when threatening values are reached. Digital fabrication enables customized placement and design of the sensors. In addition, a manufacturing process was designed that could be easily implemented by the medical supply store. In the future, measurements of disease progression will also be shared with the orthopedic technicians and physicians, so they can intervene earlier when drastic changes occur. Ultimately, the aim is to contribute to the development of locally manufactured products in the orthopedic industry through open innovation.

Keywords

Sensor-based monitoring system, digital fabrication, open innovation, FabLab, medical supply store

1 Introduction

Diabetic neuropathic osteoarthropathy, also known as Charcot foot, is a chronic and progressive disease that can have threatening effects on affected feet [2,3]. Charcot foot can occur among people who suffer from peripheral neuropathy [4]. Without proper treatment, the disease can lead to the progressive destruction of the foot skeleton, disability and even amputation [5]. Amputation as a result not only increases mortality by 15-25% [6], but also doubles the cost of treatment [7.8]. Treatment includes immobilization and complete pressure relief of the foot, e.g. by using an ankle-foot orthosis [9]. Delay in diagnosis and continued weight bearing can lead to severe deformity and ulceration [10]. Due to polyneuropathy, overloads and infections may not be noticed by the patient and are therefore often recognized and treated too late, making therapy a challenge for the patient, doctor and orthopedic technician [1]. The course of the disease is usually painless, so that patients sometimes do not consider it necessary to wear an orthosis [11]. Another complication associated with this, according to the orthopedic technicians, is the possible improper application of the orthosis by the patient. In the case of swelling, the orthosis can then be applied too tightly, resulting in pressure on the dorsum of the foot. This can lead to worsening of the condition and open sores on the foot [9].

This paper reports about the development of a diabetic foot monitoring system embedded in an orthosis that collects data on the condition of the foot and informs about complications during therapy which could prevent worsening. To do this, the system needs temperature sensors to monitor the development of infections and pressure sensors to track force distribution. In particular, a pressure sensor on the back of the foot is required to check the load when the orthosis is put on. The system can also be used to monitor how often the orthosis is worn by the patient. This information could help the doctor to detect and control complications during therapy at an early stage [12]. It also could help the orthopedic technician to follow the fitting process in case of complications and saves the patient from further health problems [12].

Within this paper, digital fabrication techniques used in FabLabs have been applied to create several prototypes, as these techniques offer rapid product development with high accuracy and tremendous flexibility in custom fitting. The development process with a medical supply store (MSS) was determined as an open innovation process and thereby provides all results open source [13]. FabLabs provide extensive equipment of various manufacturing techniques. Medical technology companies could benefit from using the FabLab environment, as a platform for open and collaborative development of innovative products. Through this research, the MSS can create individualized sensor-based systems using digital fabrication technologies and new materials. The goal is to develop a manufacturing process for a foot monitoring system that the MSS can easily implement in its own workshop.

2 Innovation Process

Motivated by the lack of professional, digitally manufactured orthopedic devices available as open-source hardware [14] and with the goal of driving a change in the medical care system, a novel process of product development was initiated. Maker-based prototypes are to be further developed into professional solutions in a co-creative exchange and subsequently published. As part of the MakeOpaedics project, this paper follows the approach of a new innovation process in which MSS cooperates with FabLabs and works together on innovative solutions based on an open innovation challenge. The orthopedic technicians from VitalCentrum HODEY KG were the experts when it came to finding a challenge, providing feedback and input, while the FabLab was responsible for the implementation. Collaboration thus played a central role in the design process and was carried out both theoretically and practically in the MSS and in online workshops. First a design challenge was created together in an orthopedic workshop and the requirements were elaborated in a product backlog (figure 1). Short design sprints including design thinking and fabrication trials were done. A digital whiteboard (Tactivos, Inc. dba MURAL, San Francisco, USA) was used to track the current status of work, challenges and requirements. Due to this concept, various versions of a sensor-based insole were developed in fixed time boxes (sprints) of one or two weeks.

The manufacturing process took place at the FabLab Kamp-Lintfort and the Open Innovation Lab Düsseldorf. The FabLab facility makes it possible to quickly create a prototype. Through the cooperation, the MSS was able to gain an insight into digital manufacturing processes and the FabLab. Both the methodological approach and the direct exchange through working in an interdisciplinary team illustrate the advantage of this project.

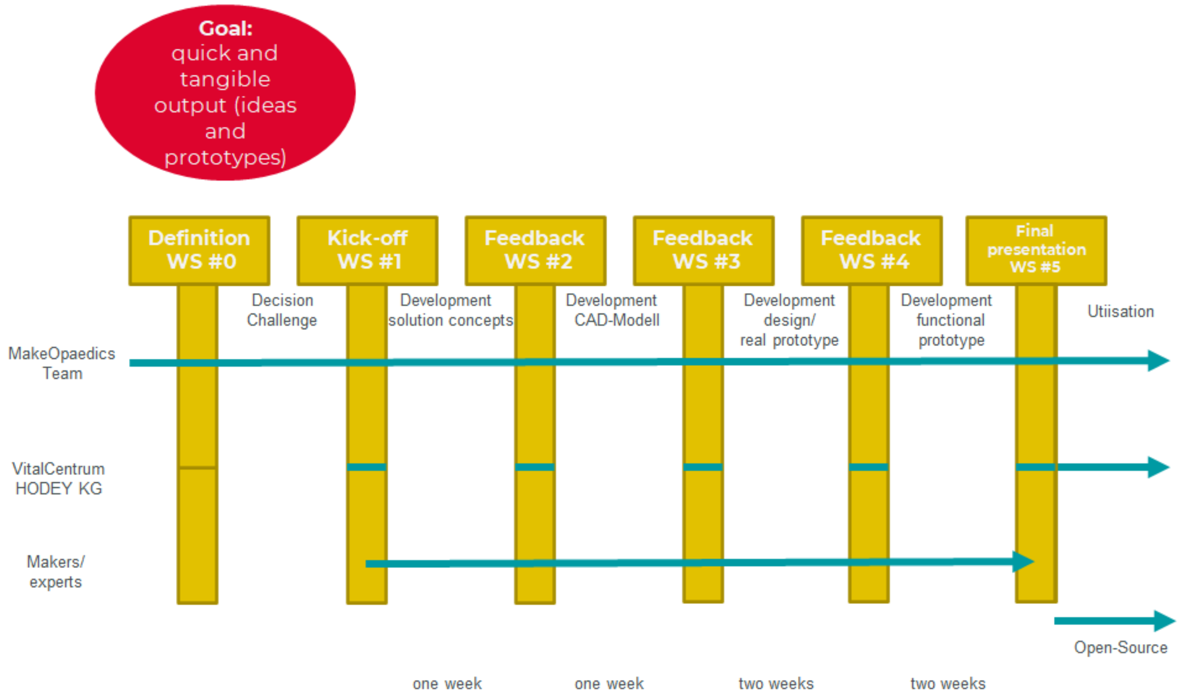

Figure 1: Methodical approach of the open innovation challenge

3 State of the Art

The market offers various types of intelligent systems for the rehabilitation or prevention of diabetic foot syndrome. During research, the following novel systems were found: Motus Smart (Sensoria Health Inc, Redmond, WA, USA), Orpyx Si (Orpyx® Medical Technologies Inc., Calgary, Canada) and Siren Socks (Siren, San Francisco, CA, USA). The Motus Smart product is a rehabilitation system. It offers an assembled orthosis with an integrated smart system with pressure sensors that records the number of steps, active minutes, wearing time and communicates this information to the patient and physician. The orthosis embeds the patient's foot individually by adjusting the shore hardness of the sole. For rehabilitation solutions, the iFoot project was launched [15]. The prototyped system consists of a smart bandage equipped with pressure, moisture, pH and temperature sensors that monitor the patient's health and supply status. Siren Socks and Orpyx Si, on the other hand, are prevention systems. Orpyx Si is an individualized insole with temperature and pressure sensors that indicate poor pressure distribution via an application. Siren Socks is a temperature-based sock that works without an application. However, these are prefabricated products where neither the placement, number or size of the sensors can be customized. Due to the different deformations of the Charcot foot, individual adaptation of the sensor-based system is required [16]. Through this research, customized sensor-based system for a Charcot patient that can be easily integrated into an orthosis by an orthopedic technician appears to be a novelty.

4 Prototyping

Requirements of the system:

- Pressure sensors and temperature sensors with high linearity and reproducibility, large force sensitive range and low hysteresis
- System (especially the sensors) must not cause any pressure points
- Easy implementation and individualization through digital fabricated techniques
- Durability of the system at least eight months
- Embedded and fixed system; only orthopedic technicians can remove it
- Water and sweat resistant
- Has no influence on the biomechanics of the orthosis
- Simple monitoring and visualization for patient, orthopedic technician and doctor
- Cost-efficient, lightweight and wearable system

4.1 Design Concept and Design Considerations

A sensor placement procedure was developed in collaboration with orthopedic technicians. Charcot foot can lead to different deformities through microfractures, which is why individualization in sensor placement is necessary [16]. The following areas of the foot are severely affected and require monitoring: Toe joints (D1 and D5), metatarsophalangeal joints, medial and lateral longitudinal arch, and heel [17]. Patients experience higher pressures, especially at the metatarsal heads [18]. With eight individually placeable pressure sensors in customized sizes, all affected areas that require monitoring can be equipped with one sensor each.

The temperature sensors are also placed individually under the foot according to the anomalies. Six temperature sensors are used for measuring the temperature [19]. They are mainly placed near pressure peaks so that temperature fluctuations are detected in time. The differences arise at the points where overloads damage the tissue [20]. In routine clinical care, the temperature of the healthy foot is used as a reference to detect inflammation or active foot ulcers on the diseased foot [21]. To meet this requirement, two sensors are used as a reference point and positioned as far away as possible from the inflammation.

To control whether the orthosis is put on correctly, a pressure sensor is attached to the strap where the greatest forces act on the orthosis. This is usually at a 45° angle to the floor, from the rearmost part of the heel to the instep [22]. If the orthosis is then not applied correctly, the buzzer warns the patient.

4.2 Sensor Selection

Before prototyping, various DIY pressure sensors, commercial force sensors and temperature sensors were tested and compared. Force resistive sensors can detect physical pressure, squeeze, and weight. They are manufactured according to the sandwich principle: the semiconducting material is placed between two conductive layers [23]. Due to the semiconductive material, the sensor itself is a variable resistance that changes its value depending on the pressure intensity [23]. To find out which sensors are suitable for this system, the force sensitivity range must be determined. For this purpose, existing pressure measurement soles for gait analysis evaluations (FastSCAN, Savecomp Megascan GmbH, Hannover, Germany), (pedar®, novel GmbH, München, Germany), such as the MediLogic® system (T&T medilogic Medizintechnik GmbH, Schönefeld, Germany), which has a measurement range of 0.6 to 64 N/cm^2 with up to 240 sensors, were used as a reference value. The pressure force depends on the size of the foot area and the weight of the patient [17]. Moreover, certain areas of the foot are more stressed than others, especially during walking [24]. However, the range depends on how many sensors are distributed in the area and how large the individual sensor areas are [25]. A previous study showed that the optimal threshold, determined by a balance of sensitivity and specificity, is 70 N/cm^2 for screening neuropathic ulceration [26].

The aim of the tests was to find out how sensitive and accurate the sensors behave in an unloaded and loaded state. Table 1 shows the results of the tests of Velostat (Adafruit, NYC, USA), EeonTex (SparkFun Electronics®, Colorado, USA) and Rigid Conductive Foam (Distrelec Group AG, Nänikon, Switzerland).

Material	**Velostat**	**EeonTex**	**Rigid Conductive Foam**
Size (in cm²)	9	9	9
Linearity	Low	High	Low
Hysteresis	High	Low	High
Repeatability	High	High	Low
Force sensitive range	Low	Low	Low

Table 1: Results DIY sensors

In summary, the EeonTex provides accurate values to work with. However, the force sensitive range was very low for all materials. Thus, for comparison with the EeonTex, another prototype is made with the commercial FlexiForce A301 sensors (Tekscan, Inc, South Boston, USA), since these have a wide force sensitivity range.

To identify the appropriate temperature sensors, two types of sensors were tested: PTC (positive temperature coefficients), (SMD 0805, M222, PCB 1325, Heraeus Nexensos GmbH, Kleinostheim, Germany) and NTC (negative temperature coefficients), (DHT0B103F3553SY, Thinking Electronic Industrial Co., Ltd., Kaohsiung, Taiwan), (NTC 0365 0078, B+B Thermo-Technik, Donaueschingen, Germany). These sensors are also variable resistors. For NTC thermistors, the resistance decreases as the temperature increases [27]. With PTC thermistors, it increases instead [28]. The purpose of the tests was to examine how the sensors behave under the diabetic footbed (closed-cell EVA foam) and how accurate they are. If there is an ulcer or infection on the foot, the temperature at the affected areas drops or rises by 2.2°C [29]. To detect this, the temperature sensors must operate with an accuracy of up to 0.1 increments. The results of the test showed that the DHT0B103F3553SY sensor is the most reliable and has higher linearity than the other sensors. In addition, the sensor is very thin, which facilitates embedding.

Based on the results of the tests, it was decided to make a prototype with the EeonTex and another prototype with the FlexiForce sensors. Both systems use the NTC (DHT0B103F3553SY) as temperature sensors. The FlexiForce sensor is also used for the instep system.

4.3 Fabrication of a Flexible Sensor Insole

For the development of the sensor-based insoles, various digital manufacturing methods were tested using the vinyl plotter, digital embroidery machine, 3D printer and laser cutter. The design was created using a 3D scanned foot sole so that the eight pressure sensors could be placed individually on the pressure peaks. Depending on how intense the pressure was in the respective areas, the size of the pressure sensors was adjusted. The positioning of the sensors is shown in figure 2.

Figure 2: Design of the eight-sensor insole

Three different pressure measurement soles made of EeonTex (figure 3) were developed and compared.

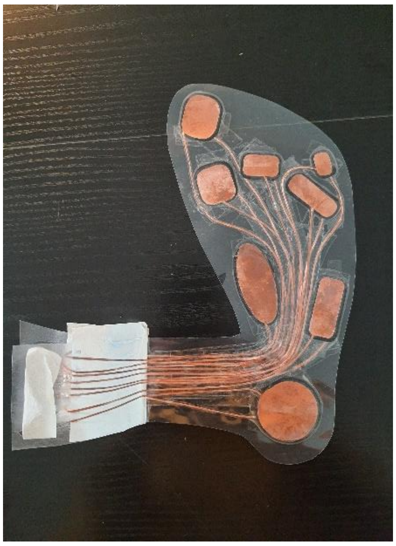

Figure 3a: Vinyl plotter insole

Figure 3b: Embroidered matrix

Figure 3c: Embroidered insole

The following Table 2 shows the comparison of the fabrication of the three prototypes.

Prototype	**Vinyl plotter sole**	**Embroidered sole with eight sensors**	**Embroidered Matrix**
Materials	• Copper foil • EeonTex • Lamination foil • Cables	• Copper thread • EeonTex • Tread • Non-conductive fabric • Ribbons or cables	• Copper thread • EeonTex • Thread • Non-conductive fabric • Ribbons or cables
Approx. costs for materials (in €)	12	12	12
Time expenditure (in h)	3	1.5	1
Costs for time expenditure (in €, calculated with 64.50€/h)	193.50	96.75	64.50
Hardware	• Vinyl plotter • Laminating machine	• Embroidery machine • Sewing machine (optional) • Laser-cutter (optional)	• Embroidery machine • Sewing machine (optional) • Laser-cutter (optional)
Approx. costs for hardware (in €)	• 300 for vinyl plotter • 40 for laminating machine	• 2000 for embroidery machine	• 2000 for embroidery machine
Benefit	• Simplicity of manufacturing process • Easy integration in SME • Low material costs • Simple to use (hardware and software)	• Very flexible insole • Fabric already used in MSS • Low time expenditure • Low materials costs	• Very flexible insole • Fabric already used in MSS • Low time expenditure • Low materials costs
Disadvantage	• Placement of copper foil is time-consuming • Unstable sensor values	• High costs for the hardware • Instruction for embroidery machine necessary	• High costs for the hardware • Instruction for embroidery machine necessary • 38 cables to cover

Table 2: Comparison of the three prototypes

The temperature sensors need to be embedded to ensure that they do not interfere with the biomechanics of the diabetic foot and do not move over time. Two approaches were followed: the first embedding was done using laser-cut recesses on the top layer of the diabetic footbed material (closed-cell EVA foam) and the second method was performed using orthopedic cast foam. For this purpose, 3D-printed sensor dummies were created and a mold of the sole was made to cast the foam with the dummies. After pouring the foam, the commercial sensors were attached. In both variants, the embedded sensors were not noticeable on the foot. Castable orthopedic foam was also used to embed the sensors of the FlexiForce prototype.

4.4 Data Acquisition Module

Since the orthosis relieves the foot by partially absorbing the patient's body weight [30], it is important to ensure that the control unit is not placed on a load-bearing element. Due to the design of the orthosis, the control unit can only be placed either on the instep or below the tibial condyle. However, since the flap on the instep is removable, routing the sensor-based insole cables there is not possible. For this reason, the instep system was separated from the main board. This allows it to be offered as a separate system, which simplifies the transfer of the system to other orthoses. The circuit boards were developed with the EAGLE software (Autodesk Inc., San Rafael, USA).

The microcontroller used in both boards is the ESP32-WROOM (Espressif Systems, Shanghai, China), as it already has an integrated Wi-Fi and Bluetooth module to transfer the data to the application. It was programmed with the Arduino IDE (Arduino LLC, Boston, USA). A lithium charging module (Nanjing Top Power ASIC Corp., Nanjing, Jiangsu, China) is included to charge the battery. Both boards are double sided and have a GND layer.

The instep system includes a pressure sensor and a buzzer (figure 4). A voltage divider circuit is generated to create the sensitive pressure [23]. Only components that were required for the application were added to keep it as minimalist and small as possible.

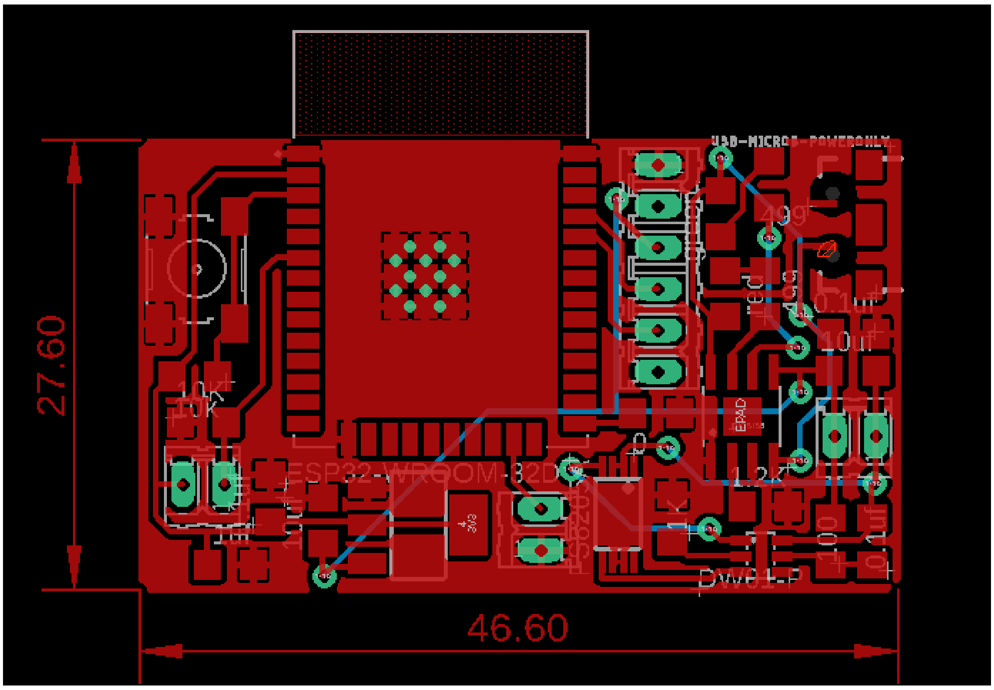

Figure 4a: Instep system board layout

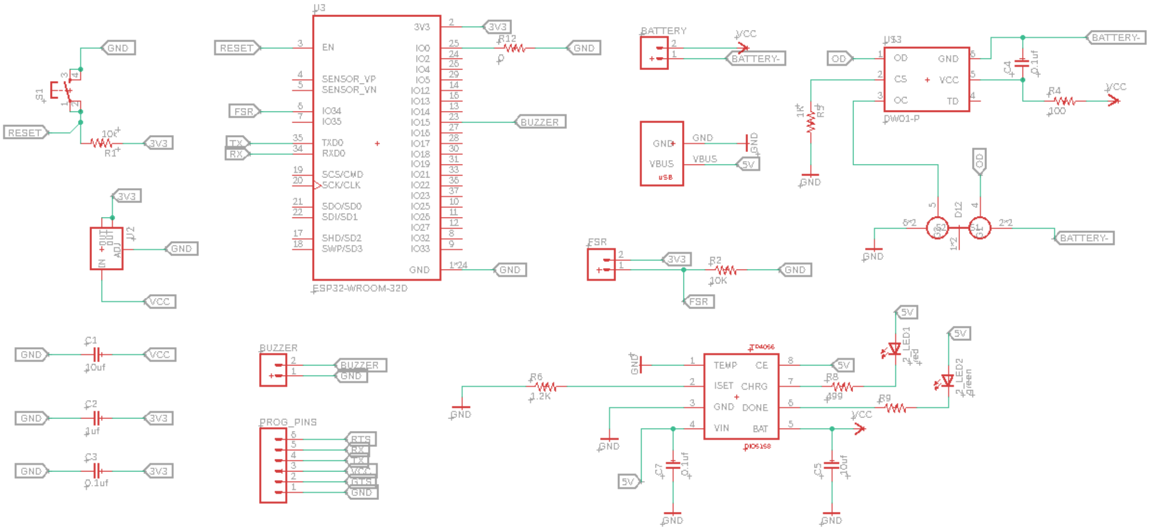

Figure 4b: Instep system schematic layout

On the main circuit board there are two 8-channel multiplexers (Nexperia, Nijmegen, Netherlands) to extend the pins of the ESP32, one for the eight pressure sensors and the other for the six temperature sensors. The signal pin of the two multiplexers is pulled down with a resistor to create the voltage division circuit. Because the patient wears pants over the orthosis and the control unit, this setup was kept as minimalist and small as possible, see figure 5.

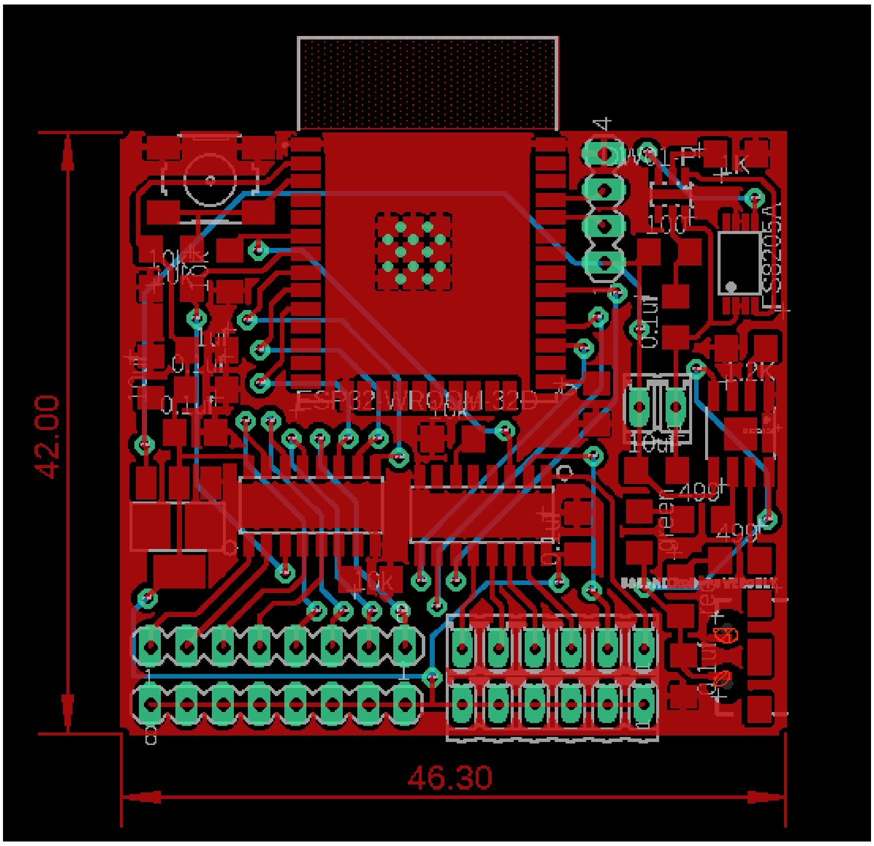

Figure 5a: Main circuit board layout

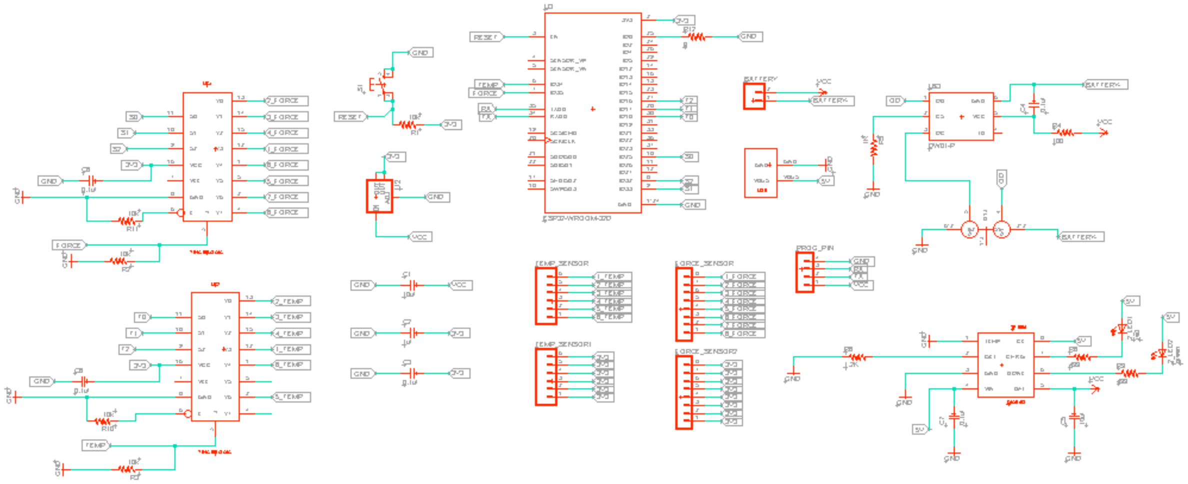

Figure 5b: Main circuit board schematic

4.5 Visualization

For real-time visualization of the pressure peaks and temperature changes, the data is processed by the microcontroller using the Processing software (GitHub, Inc., San Francisco, USA). The interface provides an image of a foot sole equipped with eight pressure sensors and six temperature sensors (figure 6). To make it easier for patients to use the application, the interface design is kept simple. A color system is used to visualize the pressure peaks, representing the relative magnitude of the applied pressure. The pressure load is represented by three colors changing from green (minimum pressure) over yellow to red (maximum pressure). Warning signals were used to visualize the temperature changes. The symbols are grayed out. As soon as the temperature of a sensor rises or falls by 2.2°C, the symbol at that point turns red and warns the patient. The temperature is measured every hour, while the pressure is constantly recorded to detect alarming pressure values. The application is accessible for the patient as well as for the doctor and orthopedic technician, so that all can observe the progress of the treatment.

Figure 6: Interface of the foot monitoring system

4.6 Physical Implementation

The novelty of the prototype lies in the permanent embedding in the orthosis. This should allow measurements over the entire time span of the fitting process and thus enables continuous monitoring of the current state of health. Due to very difficult skin conditions of diabetics [17,31], no direct skin contact is allowed, so the system must be hidden in the orthosis. The sensor-based insole is therefore inserted under the top layer of the diabetic-adapted footbed (figure 7 embedded without top layer). In order to not influence the biomechanics of the footbed a slim design was developed. Due to the even elevation, the insole with the sensors is no longer noticeable. A cable channel integrated into the orthosis allows the cables to be routed underneath the padding material from the foot section laterally of the lower leg to below the tibial condyle (figure 8). A 3D-printed electronics box with the control unit and the battery is placed laterally below the tibial condyle and connected to the insole via cables (figure 9). For the lamination process a dummy of the electronic box is used to attach it without large overhangs after completion of the orthosis. Since the entire system is inside the orthosis, the patient cannot injure himself/herself. Only the box with the electronic components is visible on the outside of the orthosis. The pressure sensor of the instep system is also located under the upper padding layer. From there, the cables are routed to the top of the orthosis flap and connected to the circuit board. When embedded, no cables are exposed (figure 10).

Figure 7: Embroidered insole in the orthosis

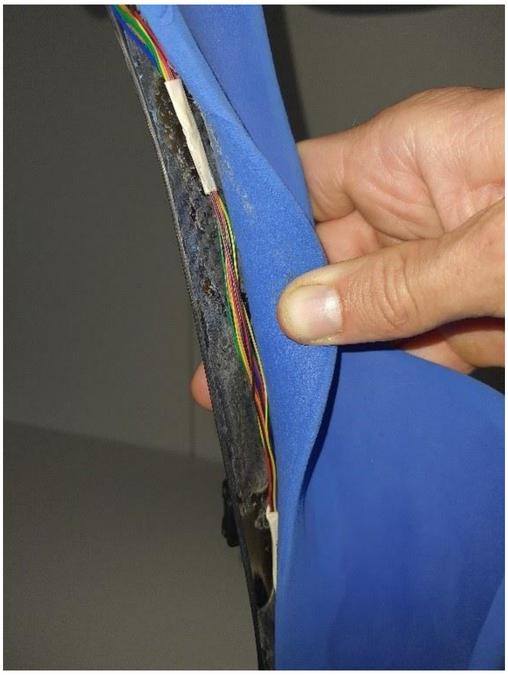

Figure 8: Embedding of the cables

Figure 9: System with electronic box

Figure 10: Electronic box for instep system

5 Proof of Concept

The prototypes were placed on top of the footbed of an orthosis for evaluation. A lab partner then volunteered to stand on the sole to test the responsiveness of the sensors. This revealed that each prototype provided very different readings and some sensors were more sensitive than others. The embroidered sole with eight sensors was very sensitive to touch compared to the FlexiForce prototype. Due to the size of the sensors (>4 cm²) and the low force sensitivity range of the EeonTex, the readings reached their maximum even at minimal load. A solution to this problem could be to develop smaller sensors [25] with EeonTex or to use another semiconducting material. During testing, the XactFSR material was discovered which has a higher force sensitivity range and could be used instead of EeonTex. In comparison, the FlexiForce prototype still provided sufficient readings, even under normal loading, to detect extreme forces on the foot caused by running or trauma. However, this technology does not offer the ability to resize the sensors. This means that using eight sensors with fixed sizes may not be sufficient for some patients. Therefore, a process would have to be developed to easily integrate commercial sensors into the system. In order to reduce the size of the sensors in the embroidered sole and still have a large monitoring area, a matrix of 256 sensors was made from EeonTex. Since the sensors have a size of >1 cm², the force to be absorbed is smaller and therefore provides sufficient readings. To test whether the prototypes could be easily embedded in an orthosis without affecting the sensitivity of the sensors, the matrix was deep drawn into the sole bed. The result was that deep drawing did not have a major impact on the sensitivity of the sensors.

6 Discussion

The innovation of a plantar pressure and temperature measurement system integrated into an orthosis presented in this paper offers a new additional care option for patients, physicians and orthopedic technicians. Long-term monitoring of foot pressure with the ability to provide feedback when alarming pressure values occur is a promising development in Charcot foot [26,32]. In addition, daily monitoring of foot temperature can detect local increases in skin temperature, which can significantly reduce the occurrence of foot ulcers and even amputations [19,32]. Since the high number of diabetics and the long duration of the disease have a significant impact on the health care system [7,33], the development of this prototype could reduce the cost of treating diabetics.

Every Charcot patient has problem areas on different parts of the foot that can vary greatly in size and shape [16], which is why an individual fitting is inevitable and of great importance. With the help of the system presented here, digital manufacturing techniques are used to realize another individual solution in the MSS. The process of flexible and precise positioning of all sensors based on a 3D-scanned foot not only enables a customized solution for the patient, but also an easy implementation for the MSS. Moreover, a new digital manufacturing process with the embroidery machine is integrated into the MSS. The introduction of such processes makes the classic workshop routine and its manufacturing process very extensive. In particular, the individualization of products can be realized more precisely and faster with the help of these technologies. However, working with corresponding systems is currently not part of the education program. To be able to work with these systems, additional training for technicians would be required. If it is possible to carry out the complete process of developing the sensor-based insole in the MSS, there will be no need to outsource any steps involving patient-related information. This facilitates data protection and ensures that the expertise of the orthopedic technicians remains in-house.

Since orthopedic technology is largely based on traditional orthopedic craftsmanship, digital manufacturing processes are a boost for the industry. However, many SMEs still face the hurdle of adopting innovative approaches. The system described here offers a simple entry into the digital world that, if adapted consistently, can give MSS a decisive advantage in the manufacturing process. Indeed, many manual manufacturing steps, such as material heating, material curing and manual work control, lead to long waiting times in production. The integration of digital processes can also be a great advantage, due to the shortage of skilled technicians, which can lead to more efficient work hours, cost savings and standardized manufacturing steps. As a result, the MSS either can serve more patients or technicians have more time for their patients.

In addition to faster implementation and individualization, the presented system could be a new technology in MSS where technicians can learn to implement sensor-based systems. This can also be transferred to the treatment of other diseases, reaching a wider range of patients. Not only the MSS, but also the health insurance companies could benefit from this system, as the data would be visible to them in the future, allowing them to track the progress and success of the treatment.

The collaboration of the project partners with the MSS has settled down very quickly with regard to the development of the requirements within the sprint sessions. The meetings planned for this purpose, both online and in person, fulfilled their purpose of a lively exchange and good communication. However, it became clear that the sprint deadlines for the parallel development of hardware and software could not be met. Delivery shortages in times of Corona have also decelerated the process. Compromises had to be made, sometimes resulting in late meetings or less development work. Nevertheless, several prototypes were created within three months, which can now be further concretized. The methodical approach can therefore be emphasized as very positive in every respect, as all participants were able to exert an influence and the technicians gained an idea of how digitalization can find its way into the MSS.

7 Conclusion and Future Work

The system presented in this paper is in the prototyping phase. Therefore, there are still challenges that have not yet been solved or tested. This includes the behavior of the embedded sensors over time and their durability over a usual supply period. Furthermore, the forces acting on a Charcot patient's foot need to be further studied to establish accurate limits for the sensors. The experience of the distributed pressure in Newton between healthy subjects and Charcot patients needs to be evaluated. Also, the dynamic forces acting on the system still need to be considered. Further experiments with test subjects must be conducted for this purpose.

The further procedure includes the development of a prototype with the XactFSR material and the continuation of the matrix-sensors-system. The systems must then also be evaluated in terms of cost, time and technology. In addition, a user-friendly interface for the matrix needs to be developed. The interface needs to be transferred to a phone application and an algorithm to detect critical pressure distribution patterns needs to be implemented. Further, an artificial intelligence still needs to be developed that can process the values and trigger an alarm in case of complications. In the event of a deterioration in the care process, the application then prompts the patient to see a doctor. The physician can see in the application exactly which sensor was triggered, simplifying diagnosis and treatment options. If changes need to be made to the orthosis, the orthopedic technician can also view the pressure points in the application. This simplifies the adjustment of the orthosis, as overloads that have already occurred can be precisely processed and other conspicuous areas can be observed and adjusted. The development of such an interface could be a suitable representation of the actual fitting status for health insurance companies.

Acknowledgement

The MakeOpaedics project was launched by the matrix gGmbH and its project partner, Rhine-Waal University of Applied Sciences. The Federal Ministry of Education and Research (BMBF) is supporting the project as part of the "Open Photonik Pro" funding initiative within the "Photonik Forschung Deutschland" program. The authors acknowledge the technicians from VitalCentrum HODEY KG, especially Christian Lußem and Kathrin Kamps, for their commitment. Furthermore, the authors thank Peter Selders and Leen Nijim for performing the tests with the temperature sensors.

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