Recent Developments in Smart Footwear for Diabetic Patients

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Abstract

There is a significant increase in the number diabetic patients throughout the world. The main reason for such an increase is the inactive urban lifestyle, reduced physical activity and unhealthy food habits. The loss of sensation and feeling in the feet is a common symptom among the diabetic patients. In most cases, patients are unaware of any cut/wound in their feet. As a result, in instances where the infection is aggravated, it leads to the foot ulcers and ultimately resulting in amputation of the feet/leg. It is a huge cost burden to the existing medical system. One of the non-evasive medical treatments to address this problem is the early detection of such cuts/infections and foot ulcers. It can be possible with the help of smart orthopedic footwear, whereby the diabetic patient is immediately alerted of the situation and takes care of the wound. Affordability of such types of footwear is also another factor which needs to be addressed. In this work, a 3D foot scanner was used to scan the feet to design custom type insoles and 3D printing was used for making prototype customized insoles. A smart sensor was integrated with insoles to provide the communication and monitoring function along with a layer of recycled polyester needled felt used as feet support layer in the foot bed. The results show that smart footwear is a promising system to reduce the medical cost as well as assisting in addressing the sustainability issues in the footwear area.

Keywords: Diabetic footwear; circular economy; needle-punched felt; 3D printing; 3D foot scanning

I. Introduction

Diabetes is a chronic disease and it is prevalent throughout the world. Majority of these cases are coming from the low-and middle-income countries and resulting in approximately 1.5 million deaths/year. The number of cases is steadily increasing over the past decades and in some countries one in every third person is a diabetic (WHO, 2021). Some of the main reasons for the diabetes is reduced physical activity, high-fat, high-sugar diet that accompanies an inactive urban lifestyle among other health related factors.

One of the commonly used non-evasive medical treatments for diabetes is the orthopedic diabetic footwear. In case of diabetes and other neuropathies, the loss of sensation and feeling in the feet is a common problem (Malik et al., 2020; Vogel et al., 2020). If there is a minor cut/wound in the diabetes patient's feet, they are unaware of it due to lack of sensation in the feet. In most cases, it causes wound infection and if this infection is aggravated, then it leads to the foot ulcers and amputation of the feet/leg. The whole process which can lead to the losing a leg or feet is a life changing situation for the patient as well as a financial burden to the medical insurance companies. It was reported that diabetic foot care accounts for a substantial expenditure as compared to cancer. Since it is a chronic global disease, if the diabetic foot ulcer is reduced by one third, it could lead to substantial savings (£250 million) in the UK (Kerr et al. 2019). The key to address this problem as well as to reduce the medical expenditure is the early detection of such cuts/infections and foot ulcers. It can be only possible through smart orthopedic footwear, whereby the diabetic patient is immediately alerted of the situation and takes care of the wound.

It is also known that patients with diabetes may have a swollen foot at dawn due to reduced blood circulation and increased amount of sugar in the blood (Yick, K. -L. &Tse, 2021). Therefore, above patients wear over-sized shoes with additional straps and elastics as a supporting aid. Wearing of an over-sized shoe may cause excessive shearing stress at the interface and may result in soft-tissue breakdown. Such shoes are available in the market but are very expensive, at the same time the shoe is not a smart system to communicate with the patient about the diabetic foot ulcers. Foot orthotic treatment is one of the primary means of handling diabetic foot problems. Custom-made orthopedic footwear that offers proper support can be worn to reduce the magnitude of patient exposure to uneven pressure and if such footwear seamlessly integrated with sensors, then it will address the current global non-evasive health challenge.

The shoe typically consist of 4 parts, outer sole (mostly based on rubber), midsole (spongy molded ethylene vinyl acetate (EVA) layer), insole (a fabric layer, a nonwoven felt (in some cases), a foam part or gel or leather) and then the mesh/knitted outer layer. The insole is one of the critical components of the diabetic footwear as the feet rest on it. The design of the smart footwear is based on the appropriate insole design and textile material component of the insole, which is basically known as the foot bed.

With the 4th Industrial revolution, additive manufacturing is already gaining a massive momentum in many sectors including textile and footwear areas due to rapid prototyping ability without wasting many resources and quick turnout time for multiple products. 3D printing is a part of additive manufacturing. A 3D foot scanner is used to scan the feet to design custom type insoles and 3D printing is used for making prototype customized insoles (Ma et al., 2019; Peker et al., 2020; 3D printing industry; 2021). In this work, a 3D printed lattice structure was used which assisted in even weight distribution, increasing patient comfort, and reducing weight of the shoe. Designs can be custom made as per the foot profile of the patients. Such issues are not addressed in the currently available customized footwear.

The felt part of the insole is made from the recycled polyester fibres. Some of the shoe components can be recycled or upcycled for certain use, but most of them discarded as waste after regular use. The sustainability issues also apply to the footwear sector where focus is on the use of sustainable or recycled materials with minimum carbon footprint.

This work is a part of an ongoing project based on developing smart diabetic footwear from sustainable materials. It is a multi-disciplinary project involving personnel from Clothing and Textile Technology, Mechanical Engineering, Design, Podiatrist fields. It is a funded industrial project and the market gap was identified by the industrial partner. The insoles are integrated with a pressure sensor to inform the patient of any abnormalities or lack of sensation in the feet, so that the occurrence of foot sores can be avoided and along with reduction in medical cost.

II. Materials and Methods

The focus is the insole development. The first step is to scan the feet, feed the scanned data to a 3D printer and then 3D print the insole. Then the insole will be laminated/bonded with the needle-punched felt. A 3D laser foot scanner (USOL 3D Laser Foot Plantar Scanner) was used for scanning both feet. It takes about 5-8 seconds to scan a foot. The data from the foot scanner is processed and fed to the 3D printer to design the insole. A 3D printer (MINGDA, model: MD-6H) was used for developing 3D lattice structure. Thermoplastic polyurethane (TPU) filament was used for 3D printing. This filament was melted at 250°C for lattice structure insole design. The printing speed was 50 mm/s.

(a) (b) (c) Sensor with insoles

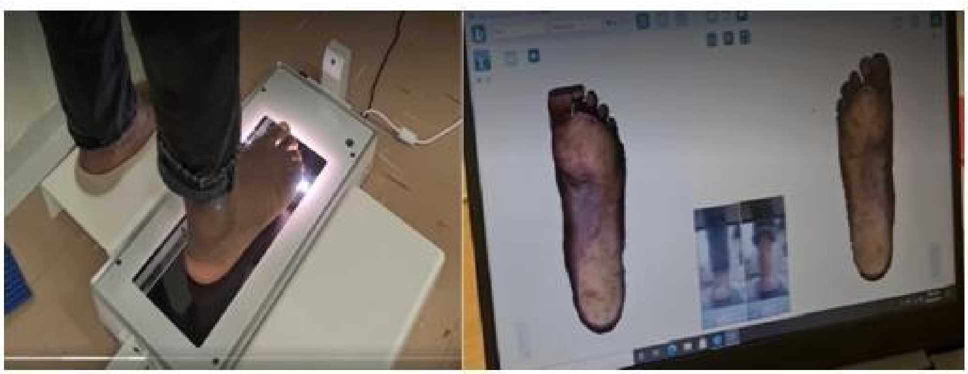
Figure 1: (a) 3D laser foot scanner; (b) 3D printer; (c) Sensor and it'sintegration with the insoles.

The needle-punched felt was made from recycled polyester fibres with the following specifications, 6.7 dtex, staple length 55 mm. For preparing the nonwoven mat (1000 g/m^2 and 500 g/m^2), individual fibers were first opened on a bale opener. Then, the fiber web was cross-lapped on a cross lapper and needle-punched on a needle-punching machine to bond a fiber web. The sensor part was handled by the industry partner and it was imported from Sennotech, China. This is a pressure-based sensor and can be seamlessly fitted inside a shoe insole. It is a removable sensor and charged via USB cable. The diagnostic system is an artificial intelligence based portable Gait Analysis System. The diagnostic system is based on big data models for a high level of accuracy. The information from the sensor can be displayed on the cell phone or smart watch. Figure 1 shows the 3D laser foot scanner, 3D printer and sensor integrated with the insole.

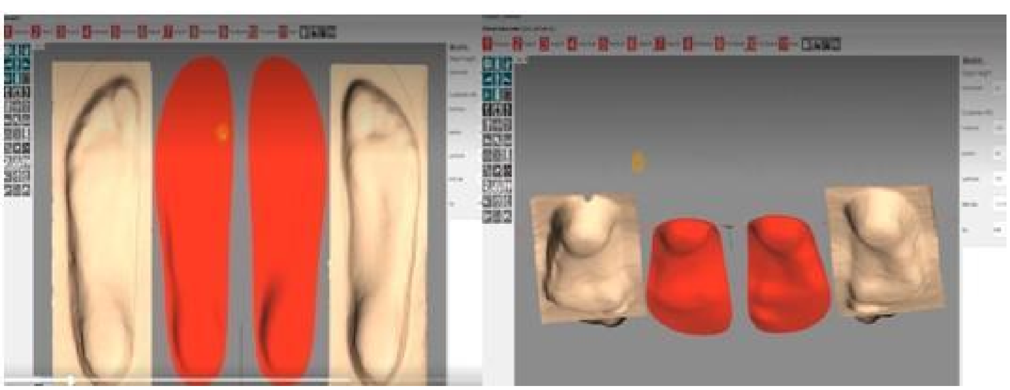
III. Results and Discussion

3D foot scanning and 3D printing

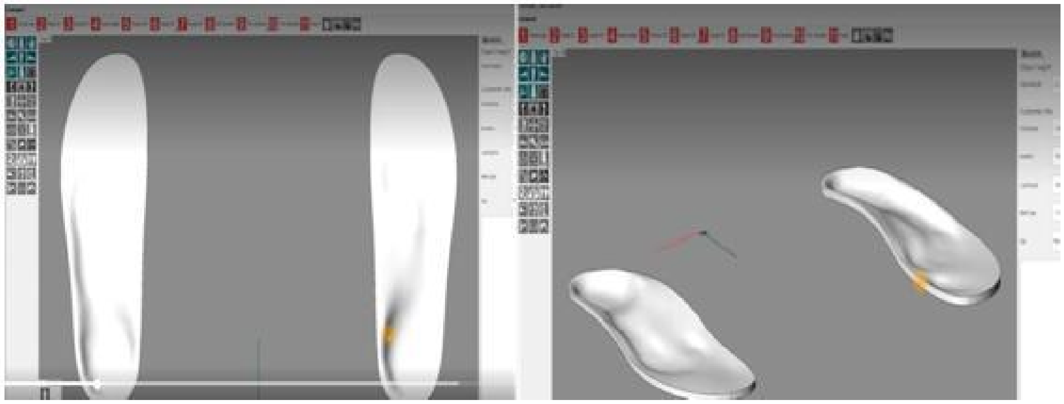
Customized footwear is developed for individuals. Therefore, foot scanning is a necessary step in this process. The scanner is portable and can be easily transferred to the desired place for mass scanning. The sequence of 3D foot scanning and 3D printing results for a person is shown below (Figure 2) and this process is repeated depending upon the requirement. Once the data was obtained from the foot scanner, it was further analyzed by the scanner software for designing insoles with contour and arches. This data was fed to the 3D printer and with the help of CAD software, it shows the formation of base layers with lattice structure (Figure 2 g). It took 2 hours to produce the finished insole (Figure 2 j). At this time, the printed insole is TPU and does not contribute to the sustainable aspect. There is ongoing work looking at eco-friendly materials which can contribute to the circular economy.



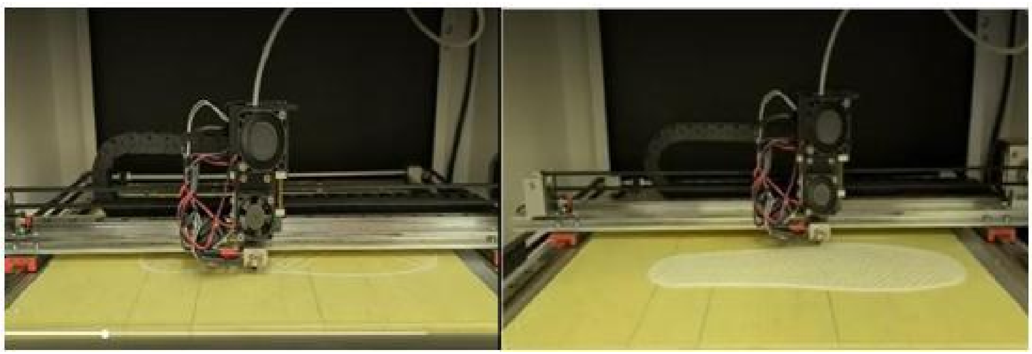
(a) (b)



(c) (d)



(e) (f)



(g) (h)

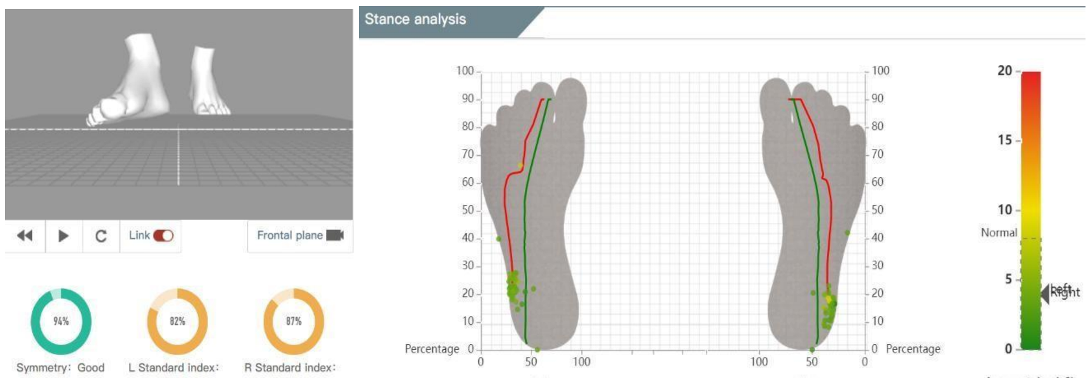
(i) (j)

Figure 2: (a) 3D laser foot scanning; (b) Scanned image and data analysis; (c), (d)use of CAD to design insoles; (e), (f) front and top views of the insoles; (g), (h); 3D printing with the formation of base layer of the lattice structure; (i) 3D printed insole with prominent arch; (j) finished 3D printed insole.

Sensors integrated with insoles and gait analysis

The next part is the integration of the sensor with the insole. A seamless integration of the sensor is important so that it does not create any hindrance during movement as well as does not contribute to damaging soft tissue. Other requirements are it's performance is not affected by sweat, also it can be easily removable from a shoe that can be fitted with another shoe of similar size. Based on the above reason, the sensor is placed at the back of the insole (Figure 1 C). The recycled nonwoven felt can be glued/laminated with the 3D printed insole and sensor placed at the back. The feet rest on this and it contributes to the circular economy.

Gait analysis (Figure 3) is widely used in understanding biomechanics of human movement and can be used to identify posture-or movement related problems in persons with injuries (Sennotech, 2020; Gait analysis, 2020).



(a) (b)

Figure 3: Gait analysis of the walking movement, (a) Symmetry and Standard index; (b) Stance analysis.

Symmetry: Good, it indicates good muscle strength balance and body coordination. Standard index: Normal, it indicates proper movement pattern not differing from normal pattern.

Stance analysis: Heel landing position is excessive towards the outer side, (LF/RF). It is shown by the red lines as compared to the green base line. This warning/alert sign for the wearer to take necessary precautions, so that any feet and other related problems can be avoided. In this way, the smart system is currently assisting in solving the above problem. There are other bio-mechanical parameters, but it is not discussed here.

IV. Conclusion

Non-evasive medical treatments for diabetic patients in the form of the smart diabetic footwear is reported in this paper. It is well known that diabetic foot is a global health burden. One of the key problems with existing diabetic footwear is the affordability and lack of smart footwear function which can inform the patient about potential cuts and wounds so that the patient can take necessary steps. 3D foot scanning, 3D printing and smart pressure sensors were used in developing the insole or foot bed of the diabetic footwear. A layer of recycled needled felt used as a foot support layer in the foot bed. The results showed that a footwear integrated with smart insoles can alert the patient about the cuts and wound through apps and smart watches so that the patient can take necessary precaution. Use of sustainable textile materials and affordability will be key drivers in diabetic footwear field in the coming year.

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