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CUSTOMISED INSOLE FOR DIABETIC PATIENTS USING ADDITIVE MANUFACTURING TECHNIQUE

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Abstract
Designs with adjustable gradient modules have become necessary for applications with special demands such as diabetic insole inwhich the contact stress between the foot and insole is a critical factor for the ulcer development. However, since the adjustment of elastic modulus on certain regions of the insole is hardly achieved through material selection, a porous structural unit with varying porosity becomes a feasible way. Therefore, a porous structural unit associated with adjustable effective modulus and porosity can be employed to construct such insoles by 3D printing manufacturing technology. This study provides a generalized foundation of porous structural design and adjustable gradient in application of diabetic and customized insole, which can be equally applied to their designs with similar demands. This study results in an insole which can reduce pressure in the plantar region by applying a support in the arch region on the foot. This study provides a methodology to produce a customized insole using a 3D printer.

Keywords: Diabetic, Insole, 3D printing, Foot stress, structural design, Rapid Prototyping

I. Introduction

The foot is the most inferior part of the human body. The foot makes human capable of walking, and also perform countless otheractivities. The foot's complex structure involves more than 100 tendons, ligaments and muscles. They move nearly three dozen joints while bones provide solid base structure. According to the structure of the foot is analogous to that of thehand, but because the foot carries more weight, it isstronger and less active. By wearing ill- fitting shoes that are not biomechanically friendly, there might be a large possibility for the onset of foot problems [1]. In order to avoid these cases, a customizedinsole is designed to reduce the abnormal pressures, off-load the pressures equally in the plantar region and to prevent the formation of the plantar ulcers. Most of these ulcers are developed due to the loss of sensation leading to peripheral neuropathy. According to a case study, the thirdleading cause of death is diabetes which is next to heart disease and cancer, approximately 15% ofpatients with diabetes will develop foot ulceration during the life time. Lower extremity amputations are mostly preceded by a foot ulcer. The abnormal pressures acting in the foot affects the nerves in the foot which results in foot ulcer, loss of sensation in foot [2]. To avoid such cases, these customized insoles are used. These insoles are made individually for a patient's own specific dimensions and needs, instead of followingstandard dimensions.

1.1 3D Printer

A 3D printer is a computer aided manufacturing device that creates three- dimensional objects. Like a traditional printer, a 3D printer receives digital data from a computeras input. However, instead of printingthe output on paper, a 3D printer builds a three dimensional model out of a custom material. 3D printers use a process called additive manufacturing to form physical objects layer bylayer until the model is complete [3]. This is different than subtractive manufacturing, in which a machinereshapes or removes material from an existing mold. Since 3D printers create models from scratch, they are more efficient and produce less waste than subtractive manufacturing devices. The process of printing a 3D model varies depending onthe material used to create the object. For example, when building a plastic model, a 3D printer may heat and fuse the layers of plastic together using a process called fused deposition modeling. Whencreating a metallic object, a 3D printer may use a process called direct metal laser sintering. This method forms thins layers of metal from metallic powder using a high powered laser. While 3D printing has been possible since the 1980s, it has been

primarily used for large scale industrial purposes [4]. However, in recent years, 3D printers have become much cheaper and are now available to the consumer market. As the technology becomes more widespread, 3D printers may become a viable means for people to create their own home products and replacement parts.

1.2 Plantar pressure data collection

Feet provide the primary surface of interaction with the environment during locomotion. Thus, it is important to diagnose foot problems at an early stage for injury prevention, risk management and general wellbeing. One approach to measuring foot health, widely used in various applications, is examining foot plantar pressure characteristics. Thus an accurate and reliable foot plantar pressure measuring device is used, as shown in fig 1.1

Figure 1.1: Plantar pressure measuring device

The beginning of 3D printing is related to studies of photography, sculpting, and Landscape design, which took place in America. Much of the technology was not being developed until the mid- 1980s. During this period, 3D printing was known as "RAPIDPROTOTYPING". Chuck Hull, of 3D Systems Corporation, manufactured the first usable 3D printer. Later in the 80's, selective laser sintering technology was synthesized by Dr. Deckard at the university of texas during the commencement of project being done by defense advanced research projects agency. In the 1990s, the technology was further improvised with the advancement of a method that uses UV light to solidify photopolymer, a highly viscous liquid material [5]. In the 20th century, 3D printers were very expensive and were used to print a few numbers of products. Most of the printers were owned by scientists and electronics groupies for research and display. However, advancements in the area of 3D printing have allowed for the design of products to no longer be limited by complex shapes or colors.

1.3 Thermoplastic Polyurethane

Thermoplastic polyurethane (TPU) is an elastomer that is fully thermoplastic. Like all thermoplastic elastomers, TPU is elastic and can be melt processed [6]. Further, it can be processed on extrusion as well as injection, blow and compression molding equipment [7]. It is a common material used for manufacturing slippers, shoes and insoles, as shown in Figure 1.2.

Figure 1.2: Thermo plastic polyurethane

1.4 Porous structure

A porous medium or a porous material is a material containing pores (voids). The pores are typically filled with a fluid (liquid or gas). The skeletal material is usually a solid, but structures like foams are often also usefully analyzed using concept of porous media as illustrated in Figure 1.3

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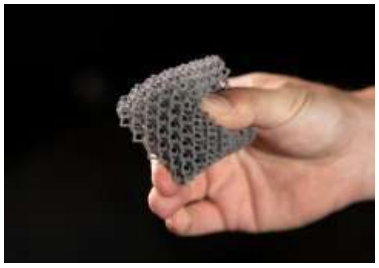

Figure 1.3: Porous Structure

II. Methods and Materials

This chapter discusses the methods and materials used to make different parts. The conceptualization, designing, pressure data analysis is discussed in this chapter. The characteristics of various components and their specifications along with their dimensions are taken into account.

2.1 Conceptual design

The conceptual design of both customized insoles was done with the SOLIDWORKS 3D modelling software. The conceptual design provides an idea of proposed design. The conceptual design of left and right insoles are shown in the Figures 2.1 and 2.2.

Figure 2.1. Left Insole

Figure 2.2. Right Insole

The components of the customised insole are 3D printer and thermos plastic polyurethane.

2.2 3D Printer Specifications

The 3D printer is used to print thedesigned insole using the filament material. Some of the specification of 3D printer is listed below, as shown in table 2.1.

Table 2.1. 3D Printer Specifications

Printed technology	Fused filament fabrication
Built volume	11.2Lx6.0Wx6.1H in[28.5x15.3x15.5cm]
Positioningprecision	XY: 11 microns [0.0004in]: Z: 2.5 microns [0.0118in]
Filamentdiameter	1.75 mm [0.069in]
Nozzle diameter	0.4mm [0.015in]

III. Results and Discussion

3.1 Pressure data analysis for the test subject

It is a type of data analysis which is used to determine the pressure acting in the foot while walking [8]. This pressure data analysis requires a plantar pressure scanner. The pressures from the pressure data test varies from 1 to 30. That is 1 being the minimum pressure till 30 and above 30 being the maximum pressure. The pressure data analysis for the given insole is shown in the Figures 3.1, 3.2 and in 3.3.

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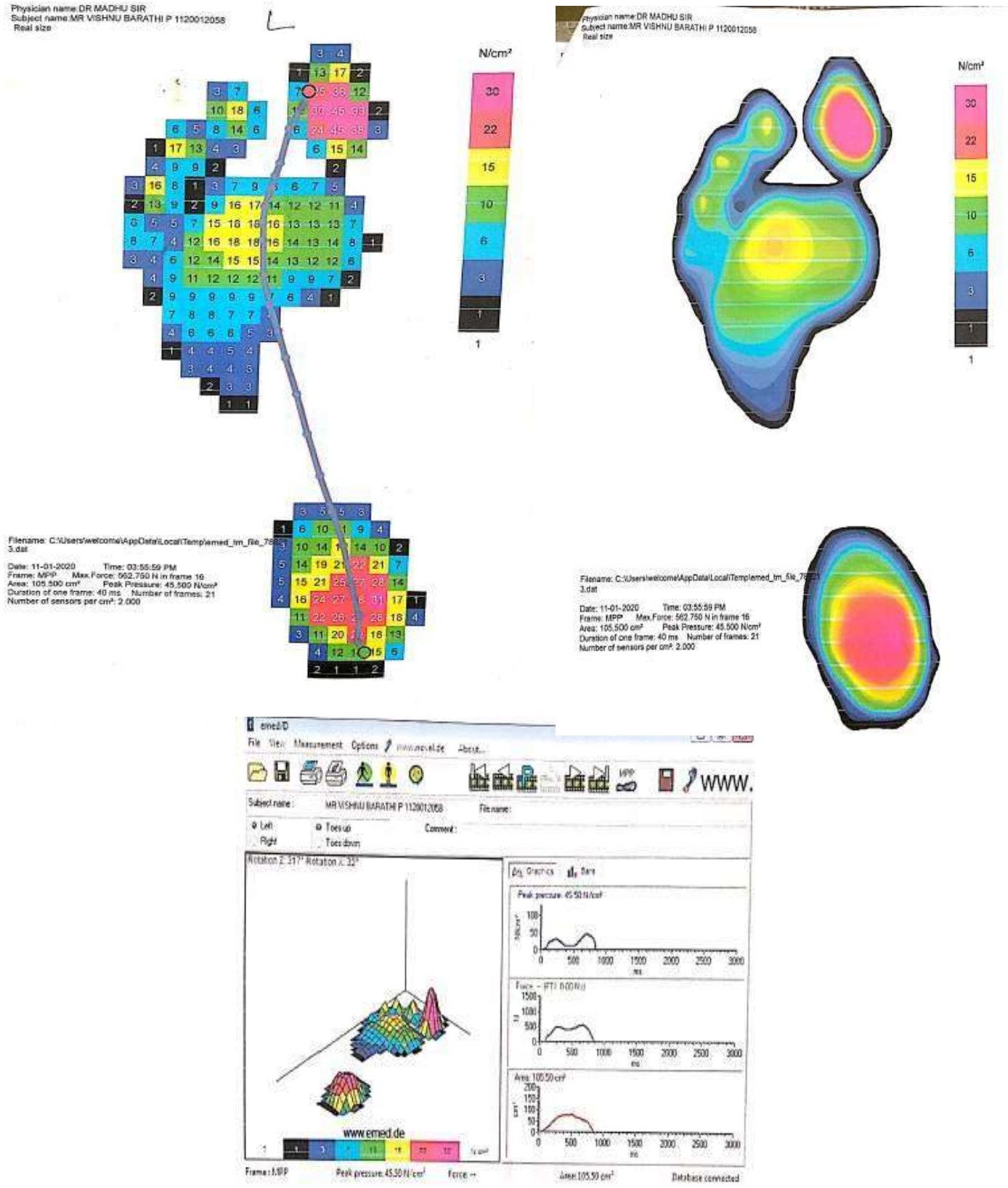

Figure 3.3: Pressure data analysis

Initially porous structure is designed for the insole so as to reduce the abnormal pressure that is acting in different parts of the foot. Theporous structure is made in hexagonal units and is made in such a way that the thickness varies for each pressure points.

3.2 Prototype development

The fabricated prototype is shown in Figure 3.4. The design of the customized insole was done using Solid works modelling software andfabricated using 3D printer and is shown in Figure 3.4. The TPU material available in the market was purchased based on the requirement.

Figure 3.4: Insole Prototype

A 3D model of customized insole is created using Solidworks software under therequirements of our test subject's feet measurements and pressure data analysis result.
The step by step procedure is explained below.

3D-Modeling:3D-Printing begins with creating the3D model with CAD software. The model will be designed with 3D modeling software SolidWorks and saved in a standard file format (.STL).

Thermo plastic polyurethane: TPU is the base material which is used to fabricate the insole, which requires certain temputature condition while 3D printing i.e, platform temperature as 70℃ and extruder temperature as 220℃.

Part modeling: A part was modelled using SolidWorks for the dimensions. Then the model in .STL format was sliced into layer and the numerical tool paths were generated using slicer software.

3.3 Control software and interface

The control software and interfaces used to interact with the 3D printer must smoothly control all parameters like nozzle point, bed, extrusion, three axis movements, etc., The interfaceshould be as simple and user-friendly as possible. We have many open source software for the purpose. But we used makerbotreplicater2x as our 3D printer. Therefore, we used makerbot software for fabricating.

Makerbot software

Makerbot software has a graphical and control interface that ensures compatibility. For proper handling, it was necessary to establish the parameters to manipulate the prototype, where the most important are: speed, position of rest, arm length, print area, and maximum print height. Therefore, this software is simple, user friendly and feature rich for experimenting with the 3D printer.

The 3D design that needs to be fabricated is saved as a STL file and transferred to makerbot software after which certain platform and extruder speed adjustments are made, finally temperature is fixed according to the melting point of TPU. The makerbot work space is shown in Figure 3.5.

Figure 3.5. Makerbot Workspace Screen

IV. Conclusion

After various analysis like pressure analysis tests for bare foot and many tests that are obtained from trial and error method on printed insoles. A proper insole is designed for specific dimensional conditions and it evidently reduced the pressure in the foot. Hence a perfectly recorded trail involves,

- No abnormal peak pressures.
- No abnormality in pressure regions and contact area.
- Reduced using the designed customized insole Consistency in the peak pressure's values.
- Considerations made on both the foot.

The abnormal pressures acting in the foot affects the nerves in the foot which results in foot ulcer, loss of sensation in foot. To avoid such cases, these customized insoles are used. These insoles are made individually for a patient's own specific dimensions and needs, instead of following standard dimensions.

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