

## Design and development of diabetic footwear

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### Abstract

**Background:** Diabetic shoes, which are commonly referred to as therapeutic shoes and extra depth shoes, can be categorized under comfort shoes or orthopedic shoes. The purpose of these specially designed footwear options is to preserve and improve foot health by reducing the risk of skin breakdown for those diagnosed with diabetes and suffering from foot abnormalities or deformities. Improper and poorly fitting footwear can cause problems such as calluses, ulcers and blisters that can lead to infection and ultimately even amputation.

**Objectives:** To decrease footwear problems by designing and developing diabetics and orthopedics footwear. To design, simulate and manufacture a diabetic shoe and to contribute to the further development of diabetic footwear as reasonable products for the consumer market.

**Methods:** The design process involved of calculating and optimizing the orthotic insole thickness which has a direct effect on the performance of the shoe. Elasticity theory is applied and the optimum insole thickness is determined based on the critical properties of resilience and compressive stiffness. Furthermore, a SOLIDWORKS static simulation is done and demonstrated that the calculated insole thickness can be effectively used in the production of the shoe. Finally, a case study is done by selecting a 27-year-old study subject with diabetic foot problems and producing a shoe that matches her.

**Results:** Under the assumption of a constant maximum compressive force, a rigorous theoretical analysis showed that the diabetic shoe should be constructed from an insole material with a minimum thickness of 6.66mm. A SOLIDWORKS static simulation showed that, under the application of a maximum compressive force, the maximum compression of the insole material is about 0.211mm. This proves that the insole material has the right resilience and compressive stiffness for the thickness computed.

**Conclusion:** This study proved that the produced shoe is indeed comfortable and effective for peoples with diabetics.

**Keywords:** Diabetic foot, diabetic shoe, orthotic insole.

### Introduction

Poorly controlled blood sugar can damage many parts of the body including the nerves and vessels that go to the feet. Because of these, peoples with diabetes have an increased risk of developing foot problems (Watson 2016). In most cases, the shoes that are manufactured in the footwear industries have an increased risk of causing foot gangrene to many diabetic patents. In this project, the researchers have tried to see the causes of the foot problems. The footwear that we recommend for the patients are listed and designed properly for the patients and are already tried by the people with diabetic cases and accepted by them and the diabetic association.

Most of the time in Ethiopia, people with diabetes don't know that they have to wear a properly made footwear that is specially made for them and that they should protect their foot. In this case, if the shoes that they wear causes some damage, they might think it is usual because of the inflexible nature of the shoes itself. However, the fact is that, the small damage in their feet will be the reason to lose their foot and leg forever, by causing gangrene and nerve damage.

**A diabetic foot:** is a foot that exhibits any pathology that results directly from diabetes mellitus or any long-term (or "chronic") complication of diabetes mellitus. Presence of several characteristic diabetic foot pathologies such as infection, diabetic foot ulcer and neuropathic osteoarthropathy is called diabetic foot syndrome (Goonetilleke 2014). Heel spurs, ingrown toenails, ageing feet, diabetes bunion/toe deformities, osteoarthritis, blisters, sweaty feet, heel pai, corn, and callus and are the common foot problems associated with diabetes mellitus. Patients with diabetic neuropathy (peripheral nerve dysfunction) have a reduced ability to feel pain. This means that minor injuries may remain undiscovered for a long while. People with diabetes are also at risk of developing a diabetic foot ulcer. Estimated lifetime incidence of foot ulcers within the diabetic community is around 15% and may become as high as 25%. Peripheral nerve dysfunction with peripheral arterial disease (PAD) causing poor blood circulation to the extremities (diabetic angiopathy) is a problem. Around half of patients with a diabetic foot ulcer have co-existing PAD (Foot 2015).

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Patients can avoid foot problems by controlling their blood sugar levels, keeping good foot hygiene, checking their feet every day, washing their feet every day, keeping the skin soft and smooth, wearing shoes that specially made for them and socks at all times and protecting their feet from hot and cold (Goonetilleke 2014).

**Diabetic Shoes:** are commonly referred to as therapeutic shoes and extra depth shoes, can be categorized under comfort shoes or orthopedic shoes. The purpose of these specially designed footwear options is to maintain and improve foot health by reducing the risk of skin breakdown for those diagnosed with diabetes and suffering from foot abnormalities or deformities. Improper and poorly fitting footwear can cause problems such as calluses, ulcers and blisters that can lead to infection and ultimately even amputation. A diabetic shoe must have a removable shoe insert or insole, for added depth to accommodate prescribed or custom orthotics. Together, diabetic shoes and diabetic insoles can prevent foot injuries and complications while improving mobility (Anon 2017).

**Benefits of Diabetics Shoes:** Shoes for diabetics are made from softer, stretchable materials designed with added features for adjustability and customization for sensitive and difficult to fit feet. Diabetes is the leading cause of lower extremity amputations not due to trauma and can be prevented more often than not with proper diabetic footwear (Anon 2017). Sometimes called extra depth or therapeutic shoes, diabetic shoes are designed to minimize the risk of skin ulcers and breakdown in diabetics...especially those who are already suffering from a foot disease (Behnke 2014).

**What makes diabetic shoes different from other shoes?** Diabetic shoes are different from our normal footwear's in more ways than one. For starters, they are wider and deeper than average. This ensures that the feet can freely move about without brushing against the shoes' interiors. What's more, many of shoes are built in a way that doesn't include any seams. The average shoe-wearer doesn't mind seams. But for diabetics, seams can be troublesome as they can rub against the feet (Behnke 2014).

**Diabetic shoe versus Regular shoe:** Unlike the regular shoes, the diabetic shoes are specially designed and made from other materials like Zennon, real leather and others. These materials are specially used to improve the situation of a diabetic foot. Also, the designs of these diabetic shoes are specifically drawn for different purposes. Examples of these are the shoes great for people suffering from bunions, hammertoes, corns, neuromas and poor circulation (Anon 2017). These features set diabetic shoes apart:

- Removable insoles to provide added depth to fit custom orthotic insoles.
- A deep toe box that is wider and rounded at the toe to accommodate forefoot deformities.
- Soft, non-abrasive lining that is typically seamless, breathable and antibacterial.
- In addition to a deeper, wider build and some options with seamless interiors, these therapeutic shoes also tend to provide greater stability-reducing the likelihood of twisting the ankle or stumbling.

### **Materials and Methods**

**Materials utilized:** Padded collar Orthotic insole, soft fabric cushioning midsole, foam padding rubber outsole (PU) and soft leather air pockets were among the used materials to manufacture diabetic footwear.

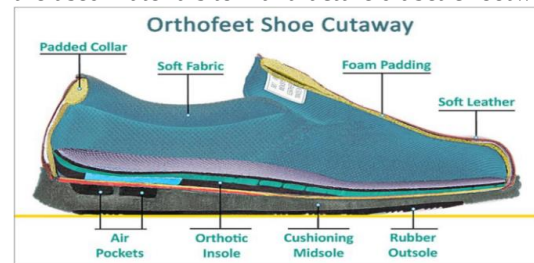


**Figure 1: Orthofeet shoe cutaway**

**Mechanical Design of Orthotic Insole:** Foot ulcerations are a debilitating and costly complication for people with diabetes. Foot ulcers mainly develop as a result of sustained high pressure and mechanical stress on a particular area of the foot, frequently over bony prominences, such as the plantar surface of the toes and forefoot, which lead to necrosis and eventually the amputation of the foot or even the entire lower leg. Foot orthotic treatment is one of the primary means to handle diabetic foot problems. Custom-fabricated orthotic insoles that offer proper arch support can be worn to reduce the magnitude of patient exposure to pressure by redistributing the force of body weight acting through the feet over a large and accommodative surface so as to prevent neuropathic ulceration (Lo et al. 2014).

In most cases, the choice of foam materials is subjectively determined based on the experience of individual orthotists and practitioners. Despite anecdotal and clinical evidence of the beneficial effects of foot orthoses for the prevention of ulcerations on the neuropathic diabetic foot, there is a scarcity of scientific work that provides a comprehensive evaluation of orthotic materials and specifications for the development of foot orthoses. The physical and mechanical properties - durability, resilience, compressive stiffness, and coefficient of friction - are generally taken as the key requirements for the evaluation and selection of suitable fabrication materials for orthotic insoles. Particular attention is

also paid to the pressure redistribution performance of the materials. (Lawrence 2012).

**Determination of optimum insole thickness:** To determine the optimum insole thickness, the mechanical properties of resilience and compressive stiffness are compared.

$$\text{Resilience} = R = \frac{[\text{Energy}]_{\text{Released}}}{[\text{Energy}]_{\text{Absorbed}}}$$

As discussed previously, materials with low resilience (high damping or low deformation) are utilized for diabetic foot wear applications. As a result, our goal is to **minimize the resilience of the insole material while at the same time getting the right compressive stiffness.**

To do the analysis, a simplified model of the insole material having a cross-sectional area of 1 square units and thickness  $t$  is considered.

In the above equation, the source of the absorbed energy is taken as an impact loading that results from the person's legs. From elasticity theory, this impact energy per unit volume is given by;

$$U = [\text{Energy}]_{\text{Absorbed}} = \frac{1}{2E} \sigma^2$$

Where,  $E$  and  $\sigma$  represent the modulus of elasticity of the insole material and the compressive stress on a given cross section respectively (Lawrence 2012).

Similarly, the released energy is the same as the strain energy density of the material which is given by;

$$u = [\text{Energy}]_{\text{Released}} = \frac{E\epsilon^2}{2}$$

The strain  $\epsilon$  is given by  $x/t$  where  $x$  is the deformation and  $t$  is the thickness of the material. Hence, the strain energy density becomes; [7]

$$u = [\text{Energy}]_{\text{Released}} = \frac{1}{2} E \left( \frac{x}{t} \right)^2$$

Therefore, the resilience  $R$  will be;

$$\text{Resilience} = R = \frac{\frac{1}{2} E \left( \frac{x}{t} \right)^2}{\frac{1}{2E} \sigma^2} = \frac{\frac{1}{2} E \left( \frac{x}{t} \right)^2}{\frac{1}{2E} \left( \frac{P}{A} \right)^2}$$

$$\text{Resilience} = R = \frac{E^2 \left( \frac{x}{t} \right)^2}{P^2}$$

Note that  $E$  for the polyurethane insole material (PU) is 0.0034GPa.  $P$  represents the compressive force applied by the person's legs. To determine  $P$ , the amount of force produced by a 75kg person when standing on only one forefoot is considered as a standard value. If pressure is evenly distributed, the interfacial pressure for every 31.2 mm<sup>2</sup> foot plantar area approximates 2.3 MPa [1]. Hence, the compressive force is given by;

$$P = \sigma A = (2.3 \times 10^6) (31.2 \times 10^{-6}) = \underline{\underline{71.76N}}$$

Inserting numerical values, we obtain;

$$\text{Resilience} = R = 2,244,879.2 \left( \frac{x}{t} \right)^2 \text{-----1}$$

The compressive stiffness (CS) is given by;

$$\text{Compressive Stiffness} = CS = \frac{\text{Compressive stress}}{\text{Compressive strain}}$$

A material of low stiffness and rapid deformation may be necessary to ensure the insole is able to mold sufficiently to the contours of the foot and, thus, redistribute pressure away from bony prominences. Hence, our goal is to minimize compressive stiffness (maximize deformation) while at the same time getting the right resilience.

$$\text{Compressive Stiffness} = CS = \frac{P/A}{x/t} = \frac{P}{\left( \frac{x}{t} \right)} = \frac{71.76}{\left( \frac{x}{t} \right)} \text{-----2}$$

Note that both equations 1 and 2 are functions of the strain  $x/t$ . A normalized Matlab plot of equations 1 and 2 is given in figure 2 of the results and discussions section.

## Results and discussion

A normalized Matlab plot of equations 1 and 2 is given below with the optimum strain value indicated.

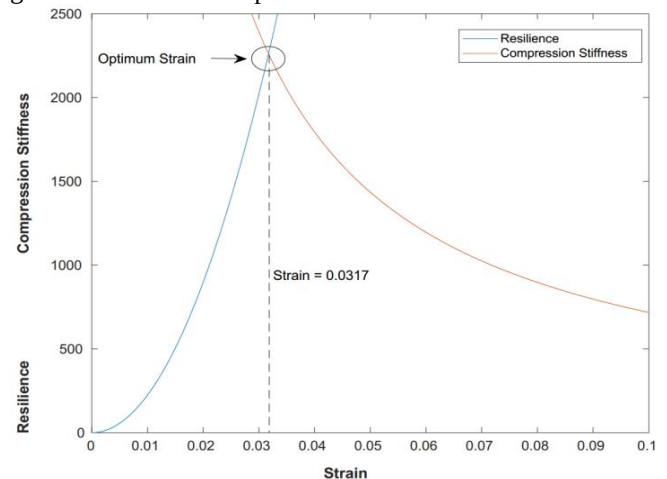


**Figure 2: Resilience and Compressive Stiffness Vs Strain**

As can be seen from the plot above, the point where the resilience  $R$  and the compressive stiffness  $CS$  meet is taken as the optimum value of the strain  $x/t$  which is approximately 0.0317. From this, one can compute the optimum insole thickness for a given value of the deformation  $x$ . For the calculations, the maximum deformation  $x$  resulting from the compressive force  $P$  is used which is approximately  $2.11 \times 10^{-4}$  m (0.211mm). Hence the optimum insole thickness becomes;

$$\frac{x}{t} = 0.0317 \Rightarrow t = \frac{x}{0.0317}$$

$$\therefore t = \frac{2.11 \times 10^{-4}}{0.0317} = 6.66 \times 10^{-3} = \underline{\underline{6.66mm}}$$

### Compression simulation of the insole material

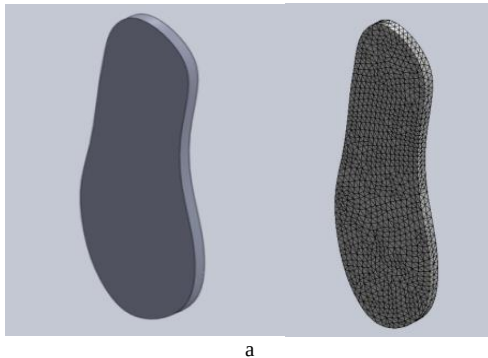
**Description:** The static compression computer simulation attached herewith describes the performance of the insole material under maximum loading conditions. A simple model of the PU insole material with the previously calculated optimum thickness of 6.66 mm is used to simulate the static compression test. The model is loaded with the maximum pressure that can be provided by the wearer's leg. Methods utilized for analysis purposes and results of the simulation are discussed.

#### Simulation assumptions

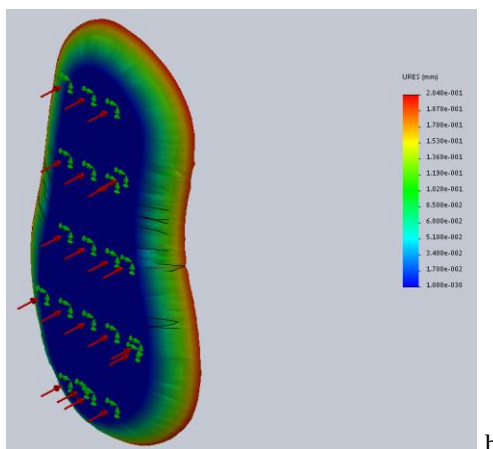
- Static compression test
- Constant physical properties
- Simplified geometries are used
- Meshing parameters are taken to be the default values in Solid works static analysis
- Maximum compressive force on the insole surface

**Table 1: 3D model of the insole and mesh information**

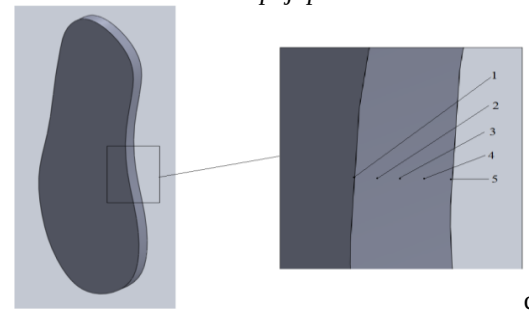
| Mesh information |                      |
|------------------|----------------------|
| Mesher Used      | Curvature based mesh |
| Jacobian points  | 4 Points             |
| Element Size     | 0.00458831 m         |
| Mesh Quality     | High                 |
| Total Nodes      | 17728                |
| Total Elements   | 10313                |



a



b



c

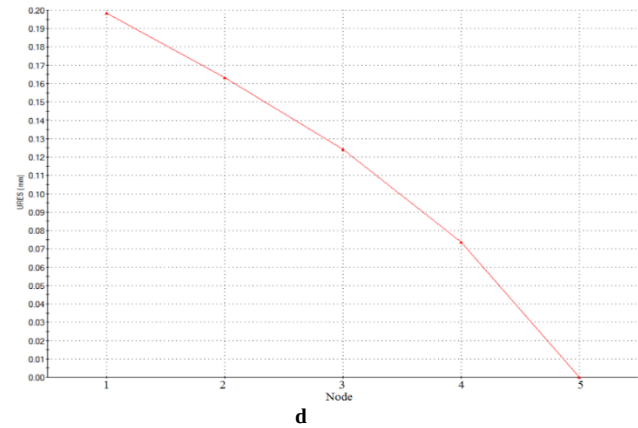


**Figure 3: Compression simulation results;**  
**a= Meshed insole material,**  
**b= Deformed profile of the insole material,**  
**c=Selected nodes on the insole material**  
**d= Deformation vs node plot**

As we can see from the above simulation, the maximum compression of the insole material (0.2mm) closely matches with the previously calculated static compression value of 0.211mm. Therefore, the simulation is acceptable with a 5.2% marginal error.

**Case Study:** In this study, in order to make the sample product, someone who was suffering with diabetic and had a natural orthopedics problem in both of her legs was chosen. She was a 27 years old lady working as a finance manager. She has been walking only by hertoese throughout her life, which makes walking very difficult for her. But, to remedy this, she has been wearing some kind of sandals. However, as she has been grown up and her body gets heavier, her feet has gotten difficulty to carry her body properly because of imbalances in her feet which leads to BUNION. And so, she can't eventually wear any shoes except sandals. As she has witnessed, it becomes difficult to handle the condition of her feet. If she wants to buy a shoe, its size must be 39 and above which is greater than her original size by 2. Before she starts to wear the shoe that she buys, someone with a big size must wear it for several weeks to make it flexible. The study subject had worried about her feet because she had not obtained a shoe which was properly made and

become comfortable to her. The available one results bunion and this might continue to change the shape

of her feet which could lead to other complications like infection and neuropathy.



**Figure 4: The condition of the client's foot and how to measure it the size of the foot to prepare the shoe**

Designing shoe for our client was not easy like designing other shoes since it was not possible to find the last shape which could compatible with legs of the client, especially for the left foot. For that reason, initially it was attempted to design and produce bunion pad from soft leather. This bunion pad

benefited the client by making her leg to have normal shape through time. After measuring the bunions width and client's feet, size of 38 was taken to have an extra space for toes in order to to permit adequate movement. The shape of client's feet was considered for the final design of the shoes.



**Figure 5: The final look of the diabetic shoe produced (top) and other bunion reducer and diabetic shoes produced with the same process (bottom)**

## Conclusions

The design and manufacture of diabetic shoes is presented as a solution to the foot ulcer problems of people with diabetics. Different orthotic materials were studied to be used for the design and production of the diabetic shoes. Due to satisfactory mechanical properties and easy availability in the market, Polyurethane insoles were selected as raw material. To maintain the required constant maximum compressive force, the

diabetic shoe is recommended to be constructed from an insole material with a minimum thickness of 6.66mm. A SOLIDWORKS static simulation showed that, under the application of a maximum compressive force, the maximum compression of the insole material is about 0.211mm. This proves that the insole material has the right resilience and compressive stiffness for the thickness computed which can give the right

comfort needed for people with diabetic foot

problems.

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