

# Design and Prototyping of a Flexible Foot Protection Layer for Diabetic Patients

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**Abstract** - Diabetic foot complications are a major cause of morbidity, often leading to ulcers, infections, and lower-limb amputations due to prolonged pressure, reduced sensation, and impaired wound healing. Effective foot protection plays a crucial role in preventing these complications. This project focuses on the design and prototyping of a flexible foot protection layer specifically intended for diabetic patients to reduce plantar pressure, enhance comfort, and minimize the risk of tissue damage. The proposed system emphasizes the use of lightweight, flexible, and biocompatible materials capable of evenly distributing pressure across the foot surface while adapting to natural foot movements during walking. The design incorporates ergonomic considerations, shock-absorbing properties, and moisture resistance to improve durability and hygiene.

**Keywords** - Flexible Foot Protection Layer, Patient-Specific Foot Care, (TPU) Ergonomic Foot Design.

## I. INTRODUCTION

Diabetes is a growing global health concern. The most common and dangerous issues is diabetic foot syndrome, which results from reduced sensation and poor blood flow, leading to wounds and infections. Despite the availability of footwear solutions, many patients find them uncomfortable, ineffective and unaffordable. This project addresses the need for a more flexible, affordable, and comfortable foot protection layer that can reduce prevent injuries. By applying engineering design methods, product lifecycle management, and user-focused design, we aim to develop a prototype that provides practical and impactful protection for diabetic patients. Diabetes mellitus is a chronic metabolic disorder that affects millions of people worldwide, often leading to severe complications, particularly in the lower extremities. Among these, diabetic foot ulcers (DFUs) are one of the most common and serious conditions, frequently resulting in infection, amputation, and reduced quality of life. The primary contributing factor.

[1] Obesity as a body mass index (BMI) of at least 30 kg/m<sup>2</sup> is a public health issue of paramount importance with far-reaching musculoskeletal and orthopaedic consequences. The WHO also subdivides BMI into overweight (25-29.9 kg/m<sup>2</sup>), Class I obesity (30-34.9 kg/m<sup>2</sup>), Class II obesity (35-39.9 kg/m<sup>2</sup>), and Class III or morbid obesity (> 40 kg/m<sup>2</sup>).<sup>1</sup> These categories are of prognostic significance to orthopaedic outcomes because higher BMI is significantly associated with greater functional limitation, pain, and surgical burden. [2] These shortcomings limit generalizability and the calculation of the true CPTS experienced in daily life. More advanced CPTS-models that include more input parameters increase the accuracy of CPTS assessment. [3] We assumed that slipper degradation would result in increased heel pressure and stress concentration

in the calcaneus due to reduced sole thickness and uneven sole support. We also hypothesized that foot inversion would further increase the load on the heel, as the altered foot positioning may compromise plantar stability.

[4] Custom-made footwear designed specifically for indoor use increases footwear adherence in people with diabetes at high ulcer risk. The design and biomechanical requirements of such footwear are important if they are to safely replace regular custom-made footwear for indoor use. We aimed to compare indoor-specific versus regular custom-made footwear for design characteristics and biomechanical function.

[5] In recent years, many studies have adopted wearable sensor platforms and advanced analytics, including but not limited to machine learning models, to support diagnostics, rehabilitation monitoring and footwear evaluation. The present study therefore addresses a fundamental issue. We examine the extent to which plantar pressure values differ when researchers use different commercial systems, test protocols or usage environments. By documenting these discrepancies, we provide evidence that should caution researchers, product developers and clinicians in any application area, from traditional gait analysis to emerging artificial intelligence pipelines, against pooling or directly comparing data sets collected with incompatible methodologies. Establishing standardised procedures and verifying agreement between devices are essential prerequisites for any robust real-world deployment of plantar pressure technology.

[6] Another factor that studies should consider its isolated effect is the insole material/structure. Sun et al. conducted an axial compression test to compare two insole materials (silicone and thermoplastic elastomer (TPE)). They conducted the study involving two materials characterized by three hardness values each (Shore-C 15°, 20°, and 25°), and varying thicknesses spanning 6, 8, 10, 12, 14, and 16 mm. The materials were securely positioned and subjected to compression using a predetermined loading-unloading rate (525 and 525 N/s), mimicking the forces experienced during actual walking steps. The simulation aimed to replicate a peak impact of approximately 1.5 times the body weight of an individual weighing around 70 kg. [7] The force was fluctuated between 0 and 1050 N using a load control mode. Notably, after 20 cycles, a considerably more substantial decrease in the hysteresis loop was observed in the silicone material compared to the TPE. proposed a method to increase the efficiency of shoe insoles in various usages tailored by 3D printing. This study used Poly Flex thermoplastic polyurethane (TPU) 90 A, because of its suitable properties to produce the shoe insole. In this study, the design of the insole was taken from the "Genola Software".

[8] These future investigations will also include the use of microscopy to determine the mechanism(s) that lead to the observed changes. This will help determine if the wear performance follows a pattern common to many materials, which exhibit an initial drop in friction followed by a plateau for a specific number of cycles, and a final drop again when the materials are completely worn out (Abdulbari, 2025). [8] Twenty-five healthy participants were recruited through poster advertisements at the Toronto Rehabilitation Institute, University Health Network. Participants were included if they were between 20 and 65 years of age, were able to walk on ice, and had no history of falls or injuries within the last six months. Participants were excluded if they were pregnant, had a history of vestibular dysfunction, or had any physical, cognitive or medical condition that might affect their gait.

[9] A high-heeled shoe is traditionally composed of more than 60 pieces per pair. However, new production possibilities are appearing with the arrival of new manufacturing technologies, notably 3D printing. This enables the design of more complex parts and the capacity to merge different footwear assemblies into one monolithic part, thereby reducing the risks of defects due to the assembly, as well as accommodating shoe disassembly followed by repurposing (remanufacturing or recycling) at its EOL state. [10] Slips and falls on ice are among the common causes of emergency department visits and hospitalizations during the winter season. These injuries are costly and can place a financial burden on healthcare systems and municipalities. Using slip resistant winter footwear is a key factor in reducing the risk of slips and eventually falls. In this study, we developed an Artificial Intelligence model that classifies high and low slip resistant footwear based on images of their outsoles. Our model was trained on a unique dataset which consisted of images of 266 winter footwear outsoles. [11] This dataset included footwear outsoles made from rubber (n = 89), Arctic Grip (n = 101), and Green Diamond material (n = 76). The slip resistance of all footwear samples was tested and rated with a human centered protocol called the Maximum Achievable Angle test. We applied a transfer learning technique to develop a 2D convolutional neural network to classify the outsoles as having high and low slip resistance.

[12] One of the key strengths of the model lies in its ability to treat the shoe not as a simplified monolithic structure, but as an assembly of multiple components, each with different thermal and physical properties. [13] This approach is more in line with the reality of technical footwear, particularly in high performance or protective applications such as mountaineering boots, which can contain more than twenty materials that are unevenly distributed depending on their function, from insulation and waterproofing to breathability and mechanical support.

[14] As compared to PZTs in series, in parallel, repeated continuous spikes with less differences between the highest and lowest power output were observed. In real scenarios, where a circuit is used for charging a battery, a continuous electrical energy with less to no fluctuation is preferred at larger intervals. [15] The highest voltage recorded in the case of PZTs in series was 14.6 V and highest current of 18.16  $\mu$ A whereas, in case of PZTs in parallel, the highest voltage was 6.24 V, and the highest current was 66.70  $\mu$ A. Although, the PZTs connected in parallel generated lower voltage than the PZTs connected in series, the generated power in a single foot strike was observed to be larger in the parallel combination. Future studies considering

theoretical models to assess the device's performance across series, parallel, and while charging the batteries will be helpful in better understanding the observed behaviour.

## II. METHODOLOGY

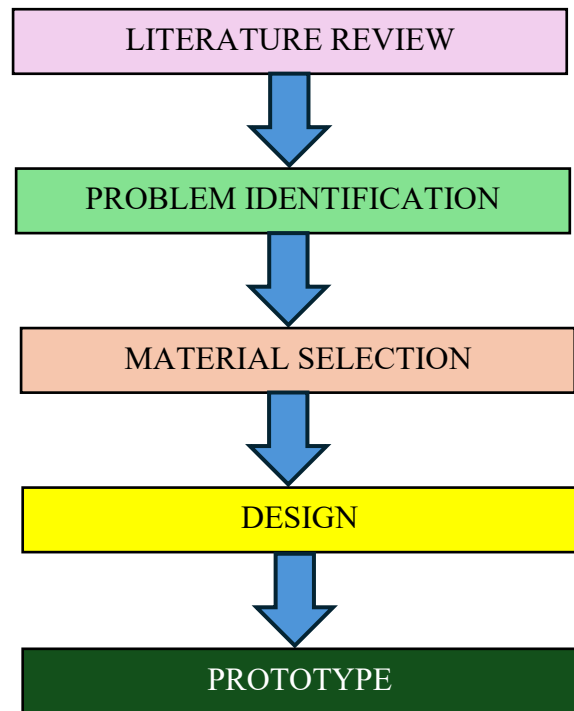


Fig.1: Flowchart Methodology

### 1. Literature Review

The Initial phase of the project involves an extensive literature review to gather comprehensive information about the air conditioners and coolers. This review focusses on understanding the current state of cooling techniques and principles of how the evaporation works. It also explores existing studies about material properties, flow configuration, evaporation rate etc.

Previous research about overall air conditioning systems gave the understanding of how the coolers works. The review makes research further by adding the valuable points about coolers and cooling devices.

### 2. Problem Identification

The literature review helps to identify the advantages and disadvantages of vapor compression cycles and evaporative cooling cycles. The vapor compression cycles have a better cooling rate compare to evaporation cooling cycles but it impacts the environment.

The major drawback of the vapor compression cycle is it impacts the climate change and the refrigerants used in vapor compression cycles impacts the ozone layer and it's the major factor of ozone layer depletion. Another drawback of the vapor compression cycle is the energy consumption. According to a study half percent of the building electricity is consumed due to vapor compression cycles.

On the other side evaporative cooling cycle is environmentally friendly and it's the major concern of today.



Fig.2: Finger Toe Injured

The reason the evaporative cooling is noted today due to the environmentally friendly nature. According to data, today ten percent of the air conditioning units works on evaporative cooling and 2035 estimated 20 percent of the air conditioners worked by a principle of evaporative cooling. The drawback of the evaporative coolers is the cooling capacity. The project focusses on increasing the cooling capacity of dew point evaporative coolers that benefit the future.

### 3. Material Selection

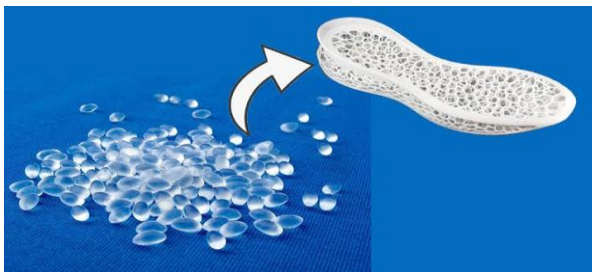


Fig.3: (TPU) Pellets

TPU A95 refers to Thermoplastic Polyurethane with a Shore hardness of 95. This places it near the harder end of the soft rubber scale it's flexible, yet tough. Key Properties of TPU A95: Shore Hardness: A95 (almost rigid, but still flexible) Tensile Strength: ~30–50 MPa Elongation at Break: ~300 – 600% Abrasion Resistance: Excellent Impact Resistance: Good Transparency: Often transparent or translucent Chemical Resistance: Good (resists oils, greases, and many solvents) Temperature Range: -40°C to +80/100°C (depends on grade).

Thermoplastic Polyurethane (TPU) is a versatile elastomer widely used in medical and wearable products because it combines flexibility with mechanical strength. It exhibits excellent elasticity, allowing it to stretch and return to its original shape without permanent deformation, which makes it suitable for cushioning and adaptive foot protection layers.

TPU has good softness that can be tuned by adjusting its hardness (typically measured in Shore A), enabling designers to balance comfort and support for diabetic patients. In terms of thermal behavior, TPU offers moderate heat resistance, generally withstanding temperatures up to around 80–120 °C depending on the grade, while maintaining its structural integrity and flexibility under normal usage conditions. It also has strong abrasion resistance and durability, meaning it can endure repeated loading during walking without rapid wear. Additionally, TPU provides good biocompatibility and can be processed through methods like injection molding or 3D

printing, making it ideal for customized, flexible foot protection systems.

**Table 1:** Mechanical and thermal properties TPU Used in Flexible Foot Protection Layer.

PARAMETER	VALUE
Nozzle Temperature	200 ~ 240°C (230°C recommended)
Build Platform Temperature	Room temperature (40°C recommended)
Build Surface Material	Tempered glass, Build Tak, Carbon fiber plate
Nozzle Diameter	Φ0.4 / 0.6 mm (Φ0.6 mm recommended)
Cooling Fan	50 – 100%
Layer Thickness	0.12 – 0.3 mm
Printing Speed	30 – 150 mm/s (60 mm/s recommended)
Travel Speed	60 – 120 mm/s
Ambient Temperature for Printing	Room temperature – 40°C
Retraction Distance	0.3 – 1 mm
Retraction Speed	30 – 50 mm/s

TPU (Thermoplastic Polyurethane) pellets are first properly dried because TPU is highly hygroscopic it absorbs moisture from air. If you skip this or do it poorly, the filament will have bubbles, weak spots, and inconsistent extrusion. Typically, pellets are dried at around 50 – 60 °C for several hours in a dehumidifying dryer. Once dried, the pellets are fed into a filament extrusion machine, where they pass through a heated barrel. Inside the barrel, a rotating screw conveys, compresses, and melts the TPU gradually at controlled temperatures (usually between 180 – 220 °C depending on grade). The molten TPU is then forced through a precision die nozzle to form a continuous filament strand.



Fig.4: (TPU) White Filament

#### 4. DESIGN

Curved, Ergonomic Shapes the foot bed appears contoured to fit the arch and heel ideal for comfort and support. The rounded toe and heel region support natural foot movement. Thickness Variation Looks like you've added a thicker sole for cushioning and durability a thinner strap section (especially the grid structure), which allows flexibility across the top of the foot this is great for TPU, which benefits from that deformation.

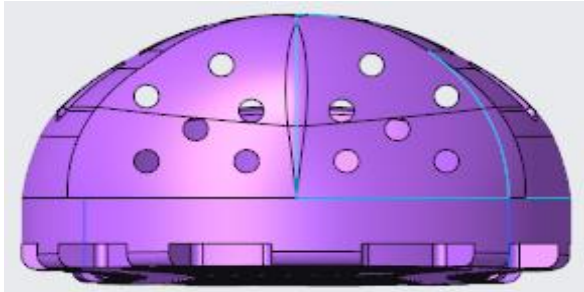


Fig.5: Front View

The proposed slipper design incorporates a perforated forefoot region consisting of uniformly distributed micro-circular ventilation openings to enhance airflow at the wound interface in patients with Diabetic Foot Ulcer. These strategically placed perforations facilitate continuous air exchange, reducing moisture accumulation and maintaining a dry microenvironment, which is critical for effective wound healing and infection prevention. The ventilation layout is designed to balance breathability with structural integrity, ensuring that the protective function of the slipper is not compromised while promoting improved thermal and moisture regulation.



Fig.6: Top View

The top-view design of the proposed slipper integrates a dual-functional surface comprising strategically distributed ventilation perforations and acupressure nodules to support wound healing in patients with Diabetic Foot Ulcer. The

forefoot region incorporates an array of micro-perforations that facilitate continuous air circulation, thereby reducing moisture accumulation and maintaining a dry microenvironment essential for infection control and tissue repair. In parallel, the insole surface is embedded with anatomically positioned acupressure elements designed to stimulate plantar regions associated with improved blood circulation. This combined approach aims to enhance localized perfusion, reduce tissue stress, and accelerate the healing process while maintaining user comfort and structural stability. The integrated design provides both mechanical protection and physiological support, offering a comprehensive solution for diabetic foot care.



Fig.7: Back View

The rear-side (outsole) design of the proposed slipper incorporates a flexible, high-friction grip pattern to enhance stability and prevent slipping in wet and slurry-prone environments, which is critical for patients with Diabetic Neuropathy. The outsole is engineered with a textured tread geometry that improves surface contact and traction, thereby reducing the risk of accidental falls and secondary injuries. The flexible material composition allows the sole to adapt to varying ground conditions while maintaining consistent grip performance. This design feature not only enhances user safety but also supports confident mobility in daily activities, addressing a key risk factor associated with diabetic foot complications.

The outsole is designed with a high-friction, slip-resistant surface to enhance traction and stability during walking. The textured tread pattern increases ground contact and effectively reduces the risk of slipping, particularly on wet or low-friction surfaces. This feature is especially important for individuals affected by Diabetic Neuropathy, where reduced sensory feedback increases the likelihood of imbalance and falls. The combination of flexible material properties and optimized grip geometry ensures improved safety and controlled movement during daily use.

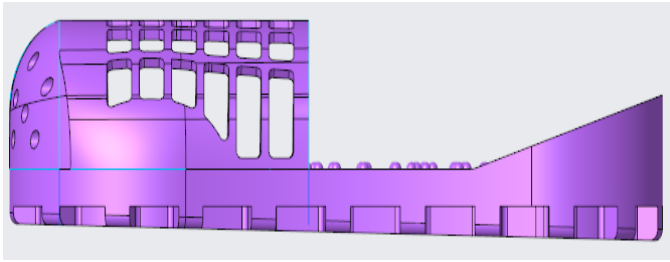


Fig.8: Side View

The side-view design of the proposed slipper illustrates a flexible and ergonomically contoured structure developed specifically to enhance safety and wound healing in patients with Diabetic Foot Ulcer. The profile incorporates an elevated and ventilated midsole architecture that facilitates continuous airflow beneath the foot, promoting a dry and temperature-regulated microenvironment essential for tissue recovery. The flexible construction allows natural foot movement while maintaining adequate support and protection against external impacts. Additionally, the design ensures uniform weight distribution along the plantar surface, reducing localized stress on vulnerable regions. This integrated approach combines safety, comfort, and therapeutic functionality, making the slipper suitable for daily use in diabetic foot care management.

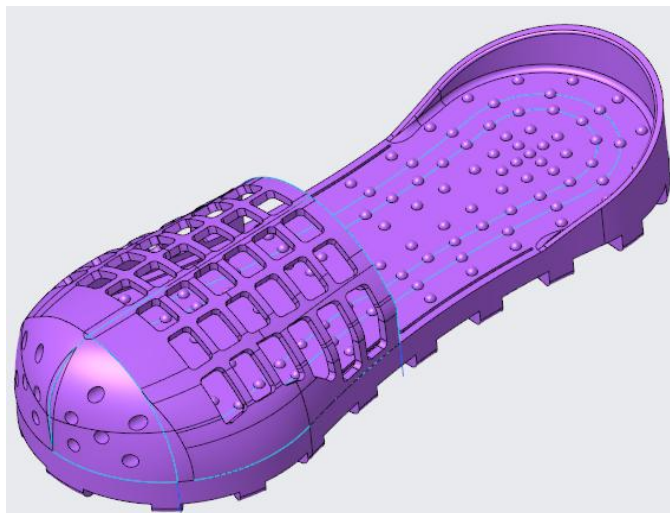


Fig.9: Isometric View

The increasing prevalence of foot-related complications in diabetic individuals necessitates the development of effective protective solutions that address both mechanical and physiological factors associated with wound formation and delayed healing. In particular, patients affected by Diabetic Foot Ulcer require continuous protection from external stress, excessive moisture, and poor circulation, all of which contribute to tissue breakdown. The present work focuses on the design and prototyping of a flexible foot protection system that integrates ventilation, pressure distribution, and safety features into a single wearable solution.

The proposed design is based on a thermoplastic polyurethane (TPU) structure due to its flexibility, durability, and adaptability to complex geometries. The slipper incorporates an anatomically contoured profile that conforms to the plantar surface of the foot, enabling uniform load distribution

and reducing localized pressure points that commonly lead to ulcer formation. Unlike conventional footwear that primarily relies on cushioning, the current design adopts a multifunctional approach by integrating engineered ventilation pathways within the forefoot region. These micro-perforations are strategically distributed to facilitate continuous air circulation, thereby maintaining a dry and temperature-regulated microenvironment at the skin interface. This feature is particularly critical in minimizing moisture accumulation, which is a known factor in bacterial growth and delayed wound healing.

## 5. PROTOTYPE

The prototype of the proposed flexible foot protection system was fabricated using thermoplastic polyurethane (TPU) material through fused deposition modeling (FDM) on a Bambu Lab 3D Printer. TPU was selected due to its high flexibility, abrasion resistance, and suitability for wearable medical applications. Prior to printing, the TPU filament was properly dried to eliminate moisture content, ensuring consistent extrusion and surface quality. The printing process was carried out under controlled thermal conditions to achieve optimal layer adhesion and dimensional stability. A nozzle temperature range of 210 – 230 °C was maintained to ensure smooth material flow, while the build plate temperature was set between 40 – 60 °C to improve bed adhesion and minimize warping. The print speed was reduced compared to rigid materials to accommodate the elastic nature of TPU, thereby preventing filament buckling and ensuring geometric accuracy. The completed prototype demonstrated good flexibility, structural integrity, and surface finish, confirming the suitability of the selected material and process parameters for fabricating a functional wearable device.



Fig.10: Bambu Lab 3D Printer

The prototype of the proposed flexible foot protection system was fabricated using thermoplastic polyurethane (TPU) filament through fused deposition modeling (FDM) on a Bambu Lab 3D Printer. Prior to printing, the TPU filament was properly dried to eliminate moisture absorption, ensuring consistent extrusion quality and preventing defects such as bubbling and poor layer adhesion. The printing process was carried out with a nozzle temperature maintained in the range of 210–230 °C, which is optimal for achieving uniform material flow and interlayer bonding in TPU. The build plate temperature was set between 40–60 °C to enhance bed adhesion while preventing excessive softening of the initial layers. A reduced printing speed of 20–40 mm/s was employed due to the flexible nature of TPU, allowing controlled extrusion and minimizing filament

deformation during deposition. Retraction settings were minimized or disabled to avoid stringing and material clogging,

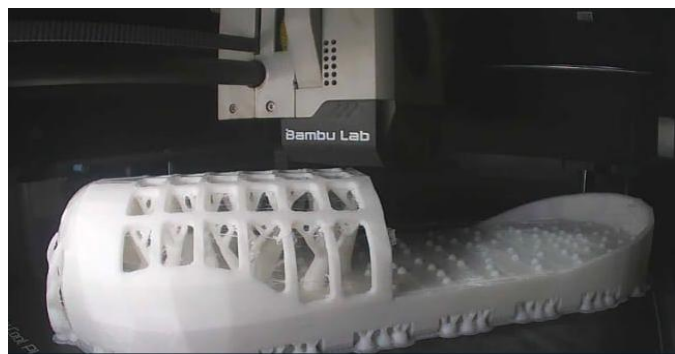


Fig.11: (TPU) Material Printing on 3D Printer

which are common challenges in flexible filament printing. Additionally, a direct-drive extrusion system was utilized to ensure precise filament feeding and improved print stability.

**Table.2:** Thermoplastic Polyurethane (TPU) Behavior and Print Parameter Considerations in Additive Manufacturing

Material Behavior Awareness	Property	Behavior During Printing
Flexibility	Soft filament	Can bend and compress in extruder
Flow Behavior	Viscous melt	Smooth but sensitive to temperature
Stringing	High tendency	Causes thin unwanted threads
Layer Adhesion	Strong bonding	Good interlayer strength
Warping	Low	Minimal shrinkage
Moisture Effect	Absorbs water	Leads to bubbles and weak layers
Surface Finish	Slightly rough	Depends on cooling and speed

The layer height was maintained at approximately 0.2 mm to balance surface finish and structural integrity. These controlled parameters enabled the successful fabrication of a flexible, durable, and geometrically accurate prototype suitable for functional evaluation in diabetic foot care applications.

The outsole of the slipper is engineered with a high-friction, slip-resistant tread pattern to improve traction on various surfaces, including wet and uneven conditions. This is particularly important for individuals with reduced sensory feedback due to Diabetic Neuropathy, where the risk of accidental slips and falls is significantly increased. The combination of flexibility and grip ensures both safety and stability during daily activities.

## 5.1 Final Output Product



Fig.12: Top View Prototype

The final prototype of the proposed slipper was successfully fabricated using TPU material through additive manufacturing, resulting in a flexible and functionally integrated foot protection device. The developed model was designed to accommodate a unisex size range, ensuring adaptability and comfort for a wide spectrum of users.



Fig.13: Back Side View Prototype

The prototype demonstrated effective integration of key features, including ventilation perforations for enhanced airflow, acupressure-inspired insole elements for plantar stimulation, and a slip-resistant outsole for improved safety. The flexible structure allowed the slipper to conform to the natural contours of the foot, promoting uniform load distribution and reducing localized stress on vulnerable regions.

These characteristics are particularly beneficial for individuals affected by Diabetic Foot Ulcer, where protection, moisture control, and comfort are essential for wound management. Overall, the fabricated model exhibited satisfactory performance in terms of flexibility, fit, and functional design, indicating its potential as a supportive and preventive solution in diabetic foot care applications.

The flexible structure facilitates uniform load distribution across the plantar region, thereby reducing localized stress

concentrations associated with tissue damage. These combined features are particularly relevant for individuals affected by Diabetic Foot Ulcer, where pressure management and moisture controlled.

### III. FUTURE WORK

Further improvements will include the integration of embedded pressure and humidity sensors for real-time monitoring of foot conditions, enabling early detection of high-risk zones. In addition, material optimization will be explored to enhance durability, biocompatibility, and long-term comfort through advanced polymer blends.

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