

# An Experimental Approach to Footwear Design with Orthosis for Diabetes Mellitus Patients at Low Risk of Plantar Foot Ulcers

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## ABSTRACT

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This paper discusses the prevalence of diabetes mellitus in India and the importance of therapeutic footwear in managing the condition, along with the challenges that people with diabetes face. Diabetic foot ulcers (DFUs) are a common complication in India, which can significantly reduce the quality of life for diabetic patients. Specialized footwear can play a critical role in preventing skin problems, controlling blood glucose levels, and protecting feet from injuries, thus improving the quality of life for diabetic patients. Therapeutic footwear is designed to reduce pressure, provide support, and accommodate deformities, which can help prevent these problems. Custom-made footwear for individuals with foot deformities can also be helpful.

The paper describes a study conducted in Hyderabad, India, which aimed to document the opinions of people with DFUs who were using specialized footwear. The study categorized these opinions to come up with acceptable footwear designs. The top suggestions included the availability of footwear in various colors and styles, a closed footwear design for the winter season, and soft, adjustable Velcro straps to accommodate different foot sizes and shapes. In summary, this paper highlights the risks and challenges that diabetic people face, and the importance of appropriate footwear to alleviate these issues. It provides guidelines for footwear design that can reduce problems and improve the quality of life for people with diabetes.

Keywords : Specialized Footwear Design, Therapeutic, Type 2 diabetes, DFU, Orthosis pads

## I. INTRODUCTION

Diabetes Mellitus (DM) is a major problem worldwide, especially among older people. In India, more than 70 million people suffer with diabetes. According to the World Health Organization (WHO), in 2014, 8.5% of

adults aged 18 years and older had diabetes. Diabetes was the direct cause of 1.6 million deaths in 2016 and in 2012, high blood glucose was responsible for another 2.2 million deaths. [4]. About 98 million people in India may have Type 2 diabetes Mellitus in 2030.

Diabetes is a growing challenge to India, with 8.7% of diabetic patients under the age of 20 and 70.

An open skin sore on the feet is also called a foot ulcer which can grow and infected. About 15% people with diabetes will suffer from a DFU, which is extremely common in their lifetime risk. Diabetic foot ulcer (DFU) is most common among people with diabetes over 60 years of age. DFU is reducing the quality of life for diabetic patients. Aged people, smokers, those who wear inadequate footwear for diabetics, etc. have risk of serious complications.

Diabetes skin problems can be prevented by controlling blood glucose. The use of footwear for people with diabetes plays a vital role. Specialized footwear is widely believed to cure many foot injuries ulcers, etc in people with diabetes. A specialized footwear design for the right person gives the possibility of reducing the occurrence of injuries.

Generally, Footwear is an integral part of human life, which protects the feet from extreme temperatures, moisture and mechanical trauma. Footwear covers outer portion of feet. It supports body weight bearing, mobility and protects the feet from injuries. Mostly, fashion is adapted. Fashion has dominance; comfort and narrow footwear are desired. Largely, Commercial footwear has no toe room, which rises crowding and pressures, etc. [1]

In addition, any footwear made for people with foot deformities must be customized based on the type of deformity, body mass index (BMI), and remaining skeletal and muscle structure, among other considerations. Individual motivation in terms of job satisfaction, motivation, or passion for work, as well as stress levels or emotional disturbance, can all be decreased with the correct adjustment for persons who have foot deformities and can not afford proper footwear.

Plantar foot ulcers on the forefoot necessitated the use of therapeutic footwear that is designed to protect and off-load the injured area of the foot. Off-loading is frequently accomplished by transferring plantar load to the rearfoot through a rocker mechanism with a

small contact area between the footwear and the ground. Although these shoes are intended to be worn for short periods of time, a balance must be struck between functionality and the risk of lower limb joint gait changes.

Many foot deformities are treated with forefoot offloading footwear. Furthermore, foot ulceration on forefoot is thought to reduce forefoot load, promoting proper bone and soft tissue healing, and preventing pain and post-operative complications. As shown in the Figure 1 below, a wide range of footwear with orthosis pads are utilized for this study according to individual foot condition.



Figure 1 Orthosis pads for deformed feet and foot ulceration.

There has been an effort to optimize modalities for screening diabetic patients for hypoesthesia in order to prevent foot ulcers. However, there have not been definitive prospective studies that compare the effectiveness of available tests.

## II. METHODS AND MATERIAL

This study was conducted in Hyderabad, India in cooperation with various hospitals for people with diabetes mellitus who are at low risk of plantar foot ulcers. The study participants included individuals affected by DFU who visited the hospital during the period July 2021 to August 2022.



Figure 2 People with DFU

The opinions expressed by the patients who were using the footwear regularly were documented. These were those who were reluctant to use the designs of the footwear, or were not satisfied with the footwear model because of any other reason, along with their suggestions to improve the acceptability of footwear. Their opinions were further categorized according to predefined themes to come up with acceptable footwear designs.

A total of 110 patients ( $45.2 \pm 10.0$  years) were given footwear with Micro Cellulose Rubber (MCR) along with orthosis pads between July 2021 and August 2022. Among them 110 patients (80 males and 30 females) initially, were obtained from individuals who had foot ulcers. Based on the primary data, and feet impressions and pressure distribution, foot ulceration indicated by the foot impression data sheet. Based on this, insoles were created, after which the footwear was created. Most of the participants were unsatisfied with the regular footwear they were provided with as before, and were carefully observed periodically to make suggestions to improve their acceptability of the footwear.



Figure 3 Footwear with Orthosis pads for People with DFU.

#### Quality Assessment:

As studies of different designs and scientific quality could be included, a general quality rating scale was used, which in principle is applicable to studies of different designs. In addition, we interviewed various doctors in the city before starting the survey.

### III. RESULTS AND DISCUSSION

Overall, the top five suggestions expressed by patients were: Footwear with MCR should be available in various colours and styles (85%), a closed footwear design for the winter season (60%), soft adjustable velcro straps to accommodate different sizes and shapes of feet (75%), fitting of an micro cellulose rubber insole into commercially available footwear (30%) and a well-fitting insole (2%), which can be inserted into any shoes or footwear. The choice of suggestions expressed is different for males and females. Footwear with colours and designs was the highest choice expressed by female patients, while only few of the male patients mentioned it.

The healing rate of foot ulcers is increased due to off-loading footwear. Wearing the appropriate footwear is one of the most important components of any Diabetic foot ulcer (DFU) disability prevention program. MCR is useful in facilitating the healing of ulcers as well as in preventing recurrence. The MCR reduces the pressure on the plantar surface of the foot and has been the choice of protective footwear among health professionals for patients.



Figure 4 New possibilities of footwear with Orthosis pads for People with DFU.

**Discussions:**

**General summary:**

This study describes the impact of a plantar offload device used to prevent DFU on static and dynamic balance control [3]. There are two main forms of diabetes: type 1 and type 2 diabetes mellitus. Type 1 diabetes is also known as insulin-dependent or childhood-onset diabetes. Type 1 diabetes occurs when the pancreas does not produce enough insulin. Type 2 diabetes is also known as non-insulin-dependent or Adult-onset diabetes. Type 2 diabetes accounts for 90% to 95% of all diabetic patients. Type 2 diabetes was previously found only in adults, but it is now increasing in children. The development of DFU is a major key indicator of mortality risk for people with diabetes. As a result, more than 50 percent of people with diabetes who develop a foot ulcer will be dead within five years, mostly from cardiovascular disease and complications of diabetes.

**Footwear:**

A majority of these patients expressed the need for footwear in more colours and designs to wear during various occasions instead of using same the footwear for all the occasions. The females especially wanted different footwear for different occasions. One of the suggestions was to provide only the insole, which can easily be inserted into any other shoes. Plastozone or memory foam insole can be utilized further. As shown in the Figure 4 below, provide a new conceptual ability for diabetic foot ulcers.

**Insole and Cushioning:**

Plastozote or memory foam is used for the top layer of shoe socks. It has anti-microbial and non allergenic properties, ideal for people with sensitive skin. Closed cell polyurethane foam is used on the bottom layer of shoe socks. It provide super cushioning, rebound, and insulating properties. The socks with a gelatinous elastomeric composition of footwear are used for skin treatment.

Hindustan cork (HC, Haryana) produces cork based insole that is skin friendly and comfortable. Seamless shoe socks and lining are recommended for people with sensitive skin. To reduce the risk of developing stressed pressure on the feet because shoe socks and lining touch the skin directly.

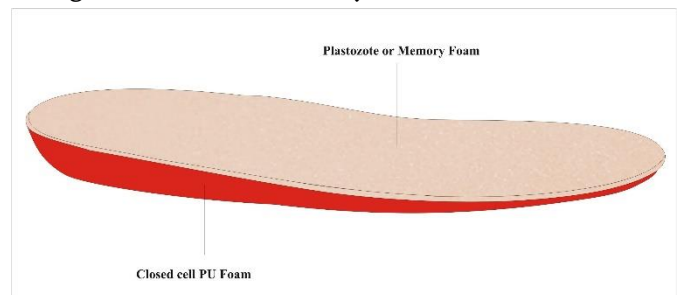


Figure 5 A Special socks for people with Diabetic Foot ulcer.

**IV.CONCLUSION**

It is also to be noticed that the discussed method would facilitate the requirements of people with DFU. From this brief analysis, it can be inferred that proper fit,

design, and colour are the main factors in footwear acceptance. Additionally, several of the patients were truly prepared to spend the higher price to obtain decent and appropriate footwear.

Furthermore, the preferences of the patients were not taken into account while developing footwear; as a result, patients who are dissatisfied with the sandals offered may not use them, which could result in injury to their feet. In this study, an effort was made to incorporate patient comments to better understand their needs and create the footwear of their choice.

This paper puts forth two fundamental ideas. First, being to understand the parallel relationship between DFU and different factors. Secondly, how design solution tools can be used to appropriate footwear with orthosis pads. These projects are presented as examples of the new possibilities for appropriate footwear with orthosis pads for diabetics' foot ulcer.

#### **Limitation:**

The patients included in this study are from Hyderabad. A representative sample from both urban and rural areas could be used to create a more comprehensive picture.

#### **Recommendation:**

The necessary modifications, with individualized customisation are the key to better acceptability of the footwear and prolonged use, which in turn will reduce the secondary impairment due to diabetic foot ulceration. Appropriate materials with microcellulose rubber and ethyl vinyl acetate may offer a new solution for DFU patients. In addition, the durability of the shoes can be improved.

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