Design Specifications of Proper Footwear to Prevent Diabetic Complications and Enhance Ergonomic Comfort

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Abstract:

Foot-related complications are common among people with diabetes and are important causes of hospitalization and amputation. Recommendations for persons with diabetes include wearing suitable shoes to reduce foot complications, but such shoes are generally not readily available. This study aims to improve foot comfort and prevent foot complications by modifying conventional design requirements for shoes. Traditional requirements include lightweight construction, good plantar contact, anatomical last, and good side support. However, many commercial shoes deviate from these requirements, leading to interest among occupational therapists. The study focuses on well-structured shoes with ergonomic comfort, focusing on the design of the last and shock-absorbing element. It also suggests foot orthoses and shoe dimensions that approximate the natural plantar contour to prevent ulceration in diabetic neuropathic feet. The ultimate objective is to reduce healthcare costs for hospitals, factory workers, and mountaineers by providing proper footwear. The research aims to provide better autochthonous windy footwear and address the growing diabetic population's needs. Proper footwear is represented by a specific area in the footwear field, which has as its main objective providing biomechanical support in a comfortable way for the entire biological variation of the human foot. Findings: The study illustrated a precise quantitative grid of the scientific findings in the area of diabetes-related foot complications and also in the technological advancements for creating the proper shoe. It provided an updated footwear design specifications based on the feedback obtained from expert fitting specialists. Also, a set of updated standards for classifying the established specifications, checking their relevance to these stakeholders' competence and daily work activity has been designed. A convenient criteria from the study which might significantly influence a favorable position and unique function regarding the appropriate foot presentation concerning footwear ergonomics was concluded.

Keywords:

Foot-related complications, Diabetes, footwear design, ergonomic comfort, Foot Health

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1. Introduction

Lower extremity disease due to diabetes includes ulcers, gangrene, and Charcot arthropathy; these eventually require amputation. When foot ulcers occur, the risk of infection increases rapidly, and healing becomes very difficult with adjacent osteomyelitis. Most diabetic foot ulcers are caused by neuropathy, peripheral artery occlusive disease, and foot deformity. The standard treatment for diabetic neuropathy has not been established, but some drugs are effective in preventing the progression; furthermore, exercise is also effective. However, the progression of neuropathy cannot always be prevented. Surgical treatment for abnormal foot alignment can relieve mechanical overload and diabetic foot ulceration. To avoid progression to Charcot arthropathy, customized footwear can be effective in preventing repetitive mechanical stress on ulcer sites. The customized footwear reduces the deviation of alignment of the foot and the chance of pain to enable patients to bear walking **(Zwaferink et al.2020)**.

In a clinical study, clinical efficacy of the customized indoor footwear in the treatment of neuropathic forefoot ulceration in diabetic cases has been evaluated. Since training at a camp, at which various specialists taught how to produce the indoor footwear, there has been no relapse or exacerbation of the

patients. In this paper, some side-lining apparatus to produce the customized indoor footwear for forefoot ulcers is newly shown. Optimal footwear can enhance walking efficiency and protect the plantar skin from damage during exercise, and protect the plantar skin and pulled web mound from disease due to diabetes. Diabetic complications with feet are often seen as diabetic ulcers and diabetic foot necrosis, and so on **(Sandhu et al., 2020)**.

The paper discusses the issue of heel size in mass production of outdoor footwear, focusing on healthy feet, diagnosing plantar diseases, and designing footwear to prevent diabetic complications and enhance ergonomic comfort. It suggests that mass production with appropriate length and width could be a solution. The paper suggests using 4E width, Smart Pointer Shock Absorbing Comfort sole, and New Construction T-type Outdoor Sandal for diabetic footwear. These shoes improve mobility and reduce skin damage, providing a protective effect for patients. **(Orr et al.2022)**.

Foot-related complications are common among people with diabetes and are important causes of hospitalization and amputation. Recommendations for persons with diabetes include wearing suitable shoes to reduce foot complications, but such shoes are generally not readily available. This paper explores the essential design specifications of suitable shoes. A model developed in prior research was used, comprising studies of the mechanisms of disease development and prevention, which included biomechanical aspects. The model applied apparatus resembling the foot that was equipped for measuring the expansions at nine locations under various measured aspects of the foot. The results showed that most incidents of suboptimal footwear occurred in areas other than the metatarsus **(Wukich et al.2022)**.

Diabetes is a devastating disease that can lead to severe disabilities, diseases, and complications, including premature death. A significant portion of the cost of treating diabetes is attributed to the treatment and prevention of complications. Common issues include narrowing arteries and arterioles, which can cause ulcers and amputations. Foot-related complications are often overlooked, but are a major concern among people with diabetes. In 1990s, nearly 70,000 foot and leg amputations were performed in the United States, with one-third of them related to diabetic ulcers. **(Mandal, 2020)**.

1.1. Background and Rationale

Diabetes mellitus is a chronic disease that is a very common source of both ischemic and neuropathic feet. It is known that such conditions cause psychological, physical, and economic burdens. Consequently, in clinical diabetes care, the primary goals are preventing CNS structural changes and promoting wound healing, thereby ameliorating the patient's quality of life. Foot-related problems impose a significant burden not only on healthcare systems but also on the individual patient, as they lead to lower mobility, increased mindfulness-related anxiety, and greater discomfort in the foot. If neglected or left untreated, a diabetic foot ulceration is commonly complicated by infection and may lead to a severe outcome of lower limb amputation **(Edmonds et al., 2021)**.

Additionally, approximately 50% of diabetes patients receive inappropriate treatment because of their use of poorly designed shoes. Protection against external stress, such as elevated pressure and modified tissue deformation properties, may help prevent both short- and long-term complications and enhance physical function. As a result, the primary goal for patients wearing footwear for the diabetic foot should be to avoid potential harm and provide physiological support to the human foot. In addition, when foot health is compromised, off-loading is necessary to eliminate undue stress, strain, and inflammation.

1.2. Scope and Importance of Proper Footwear Design

Studies have been conducted on diabetic footwear designs, but the criteria for diabetic footwear design are not standardized. Proper specifications are crucial for professionals like orthotists, pedorthotists, shoe technologists, and computer scientists to provide the best services and beneficial products for diabetic wearers. Understanding these specifications helps design appealing, elegant, and reasonable diabetic footwear. The objective of this study is to identify the necessary specifications for diabetic wearers to design suitable footwear equipped with smart technologies that can detect foot ulcers at an early stage. This is part of a larger research project aimed at preventing diabetic complications and motivating diabetic wearers to regain confidence and socialize. Future studies will explore poor foot complications prevention among diabetic patients, review the current diabetic footwear design, and consolidate standard specifications for the lower limb medical prevention system of the diabetic aspect **(Collings et al.2021)**.

1.3. Statement of the problem

Most people recognize the importance of appropriate and well-designed footwear for various activities and occupations. Some conventional requirements of good shoe construction are lightweight, good plantar contact at rest, the so-called "last" being basically anatomical to the foot shape including heel width, toe spring, arch, midfoot, and the first metatarsal joint, and good side support. In addition, other important aspects such as adequate cushioning and shock absorption during contact and push-off, and necessary conditions of air exchange, heat removal, and moisture refraining have been more precisely defined and added to the specific and more or less traditional design requirements of both men's and women's shoes. Unfortunately, many commercial shoes available today deviate psychosomatically from these requirements. The necessity of modifying certain conventional design requirements or adding new ones

aimed not only at facilitating foot comfort but at preventing foot complications has recently aroused interest among some occupational therapists. In fact, recent trends of natural foot reduction show that the shoe is returning to its original purpose of protecting the feet for work and health purposes. With this in mind, a preliminary design outlined in this study should serve to give better autochthonous windy footwear **(Miranda et al.2021)**.

Research on foot comfort is limited, mainly focused on medical needs and foot abnormalities. However, sport shoes are specialized for comfort, good contact, and durability. This study investigates the needs of the foot with a generalized classification of well-structured shoes with ergonomic comfort, focusing on the design of the last and shock-absorbing element. With the increasing diabetic population, suggestions are given for foot orthoses and shoe dimensions that approximate the natural plantar contour to prevent ulceration in diabetic neuropathic feet. The ultimate objective is to reduce healthcare costs for hospitals, factory workers, and mountaineers by providing proper footwear **(Robert & Al Dawish, 2020)**

1.4. Objectives

Chronic complications in diabetic patients result in prolonged sedentary periods and significant alterations of the foot, leading to biomechanical issues. Proper footwear is represented by a specific area in the footwear field, which has as its main objective providing biomechanical support in a comfortable way for the entire biological variation of the human foot.

General objectives:

There are two general objectives of the study, these are to:

- Synthesize a list of updated design features reflecting the multifunctional aspects of proper footwear for diabetic patients, to which similar agents need to comply.
- Classify the established specifications into four categories, linking subjects with the four important ergonomic design criteria, namely the precise measurement of anthropometric details, the wear situation, the design process of the shoe components, and the fabrication process.

Specific objectives:

Built on these general objectives, the following specific objectives are generated:

- Illustrate a precise quantitative grid of the scientific findings in the area of diabetes-related foot complications and also in the technological advancements for creating the proper shoe.
- Round up an updated manner of proper footwear design specifications based on the feedback obtained from expert fitting specialists.
- Design a set of updated standards for classifying the established specifications, checking their relevance to these stakeholders' competence and daily work activity.
- Conclude a convenient criteria from the study which might significantly influence a favorable position and unique function regarding the appropriate foot presentation concerning footwear ergonomics.

2. Understanding Diabetic Complications

Diabetes leads to chronic complications such as retinopathy, nephropathy, neuropathy, and microvascular diseases. Peripheral neuropathy is the primary factor contributing to diabetic foot ulcers, resulting in lower extremity amputation. Autonomic and sensory polyneuropathy, two types of sensory polyneuropathy, affect 50-60% of diabetic patients, affecting sensory nerves in the feet, leading to impaired sensation, numbness, and tingling. Management of these symptoms is crucial to minimize traumatic insults leading to foot ulcers. Improperly fitted footwear on insensate feet can create biomechanical compromise, exacerbate structural failure, and contribute to foot ulcers. Diabetic foot ulcers can result in adverse infections, gangrene, and amputations, with a high mortality rate. Therefore, proper and specific footwear is essential for preventing complications in diabetic feet. Autonomic neuropathy controls osteoblast secretions, which are crucial for bone health. Its dysregulation can cause bone density loss. Improperly fitted footwear on insensate feet creates biomechanical compromise, exacerbates structural failure, and contributes to foot ulcers. Diabetic foot ulcers have complications such as adverse infections, gangrene, and amputations, with a high mortality rate **(Tsaklis and Tentolouris2024)**. Proper footwear is crucial in preventing complications related to diabetes, such as skin loss, infection, calluses, corns, foot ulcers, and Charcot deformities. Peripheral neuropathy can lead to insensate feet, increasing the risk of heat-induced microtrauma. Patients may develop calluses and plantar callosities due to restricted joint function and gait abnormalities. Most of these complications can be prevented by wearing appropriate shoes **(Miranda et al.2021)**.

Severe diabetic lesions often result from inappropriate footwear due to various reasons, including disease complications, altered joint mobility, recurrent heel fissures, plantar keratosis excisions, foot deformities, dry skin, peripheral vascular disease, controlled infection, oedema due to dependency, inappropriate user behavior, and uneven surfaces. These issues can lead to loosening, infection, falling, poor trauma healing, limb amputation, or other injuries. Adequate toe box is crucial to avoid contracting and pressure in bunions, calluses, and bone protrusions. Wearing non-specialized socks, particularly non-cotton ones, increases the risk of negative skin-related events. Additionally, the financial burden of acquiring necessary footwear is essential for diabetic patients

(Dewi & Hinchliffe, 2020).

Diabetes causes medical complications due to an increase in blood sugar levels, which damages the circulatory and nervous systems, primarily in the legs. Impaired circulation leads to peripheral neuropathy, numbness, and impaired oxygen and nutrient supply. Minor injuries, unnoticed, can cause ulcers or gangrene. Impaired circulation and a failure to perceive pain can lead to ignoring skin injuries, which can lead to microorganisms and fungal growth, causing ulcers, cellulitis, and gangrene. Regular foot examination is crucial for diabetic patients to prevent the recurrence of healed ulcers **(Mauricio et al., 2020)**. Diabetic ulcers and their complications require special care due to uncontrolled diabetes, which can damage nerve pathways involved in peripheral blood supply and circulation. High glucose levels can damage cellular functions essential for preventing deformation in the plantar region of the foot's skin. Diabetes damages the regional skin, leading to harmful conditions that distort the normal shape of the plantar foot skin and uneven weight distribution during standing and walking. The pressure exerted by shoes on the newly formed skin at contact points can further damage sensitive areas, causing calluses, which contribute to the development of diabetic foot ulcers. **(Reardon et al.2020)(Moore et al.2021)**.

2.1. Overview of Diabetic Neuropathy and Peripheral Arterial Disease

The focus here is on designing footwear that protects people with diabetic neuropathy and peripheral arterial disease from developing complications and improving occupational ergonomics. Diabetic neuropathy, caused by uncontrolled hyperglycemia, can lead to pain, poor posture, and weakened pressure adjustment. Inappropriate footwear can cause non-nociceptive damage, blister induction, unnecessary pressure points, and local compression. Peripheral arterial disease, a vascular complication linked to diabetes, increases the risk of severe complications like chronic ischemic ulcers, local peripheral artery embolism, and soft tissue infection. Telemedicine can help diabetic patients follow their specialists' advice for proper footwear, ensuring prompt and optimal therapeutic performance. Standard requirements for diabetic footwear include adequate depth of construction, protective forefoot and forepart characteristics, lack of seams, stretch upper, lightness, radii of curvature, ventilation, removable insoles for custom orthotics, and flexibility **(Sousa et al.2023)**.

Diabetes mellitus, a rising global health issue, is particularly prevalent among older adults and is the leading cause of morbidity and mortality. Improper shoe design can lead to foot complications, potentially resulting in lower extremity amputations. These complications are costly, impact daily activities, and impose significant pressure on caregivers. Diabetic foot injuries, often combined with poor circulation, are the leading cause of non-traumatic lower extremity amputations in the United States. The disease can cause nerve and arterial damage, inadequate blood circulation, and a lack of nerve functioning. Neuropathy is the primary risk factor in 90% of diabetic foot ulceration cases, which can lead to complications if not managed appropriately. Diabetic foot complications can be detected through deformities like Charcot's joint, hammer toes, bunions, tendon contracture, great toe subluxation, and calluses. Reducing these complications can be achieved through early recognition, close monitoring, and proper foot care, shoe wear, and orthotic devices **(Haque et al.2023)**.

2.2. Overview of Diabetes and Foot Health

The global population growth has led to an increase in chronic diseases, including diabetes mellitus, which affects millions worldwide. Diabetic foot ulceration is a common complication of diabetes, causing disability and hospitalization for diabetic patients. The formation of ulcers is a result of the delicate balance between various factors, including the loss of plantar pressure sensation and autonomic vascular neuroregulation. Unperceived excessive plantar pressures and discomfort from other foot deformities also contribute to ulcer formation. The study of diabetic foot problems and prevention of ulceration are crucial, as most ulcers and amputations can be prevented if necessary measures are taken. Therefore, understanding and addressing diabetic foot problems is crucial for preventing ulcers and amputations **(Edmonds et al., 2021)**.

Diabetic neuropathy and peripheral vascular diseases are major causes of lower extremity complications in diabetics, leading to foot ulcerations, infections, and gangrene, potentially requiring amputation. However, these complications can be managed through supportive, protective, and preventive measures. Implementing a diabetic foot renal program is crucial, and various neurological and vascular assessment methods are widely adopted. Offloading strategies are used to unwrinkle wounds and prevent recidivism. Advancements in materials and processes, such as dressings, orthotic devices, and footwear, are used to prevent and treat common diabetic foot problems **(Soyoye et al.2021)**.

2.3. Common Diabetic Foot Complications

Diabetic foot complications include neuropathy, vasculopathy, and skin infections. Neuropathy is a common cause of foot deformation, leading to ulcers and infections that can cause foot amputation. Vasculopathy and foot ulcers may be secondary consequences of diabetes associated with neuropathy. Diabetic patients at high risk of foot ulceration can reduce their foot risk conditions by engaging in self-reported foot care activities and self-management activities. This can result in enhanced comfort from footwear designs that match their actual foot conditions, as these patients can benefit from self-reported foot care activities **(Jais, 2023)**.

3. Ergonomics and Footwear Design

The existence of over 108 million people with

diabetes in 1980 and the expected increase to 221 million by the year 2010 seriously points to a major health and economic problem associated with the disease. A common complication of diabetes, which is particularly disabling, is diabetic neuropathy. To prevent these severe complications from developing in the lower limbs (and more particularly in the feet) of diabetics, the orthotic features of the insole need to provide the supporting elements just proximate to the plantar surfaces of the feet. The shoe, on the other hand, should be designed to accommodate the orthotic and the foot. There is a vast amount of implicit and explicit information and some research on footwear. It clearly indicates that the selection of proper footwear for specific use can enhance existing foot health, prevent foot injuries, and prevent or delay, in many cases, the onset or escalation of foot afflictions or general discomfort derived from foot postural stress **(Agresta et al.2022)**. This section will address the following four subtopics and then close with a set of general conclusions:

(1) Ergonomics and Footwear,
(2) Ergonomic Considerations in Footwear Design,
(3) Design Criteria to be Met,
(4) Methods of Evaluating Fit.

3.1. Principles of Ergonomics in Footwear Design

The main characteristic of therapeutic diabetic footwear at the first level of analysis refers to its maximum anatomical and physiological adaptation to the patient's foot without constricting movements. The second specificity is the inclusion of a specific insole that evenly distributes the loads in the post-changed foot with ulcerations, both in the envelope's form and in the calcaneus/forefoot axis. Finally, there are important reminders about the choice of adequate materials and the design of certain detailed components needed for correct use. Studies regarding the number, lifestyle, and preferences of the users themselves indicate the need for improvement of this type of footwear that does not always correspond to four major functions: protect, support, accommodate, and properly distribute pressures **(Ulbrecht & Bus, 2020)**.

The evidence has shown that appropriate footwear, proper offloading of the foot, self-care, and the provision of proper information result in the reduction of the risk of developing diabetic foot ulcers. In the early phases of diabetic foot ulcer management, therapeutic footwear, along with cast immobilization and/or different off-loading options, correct any bony deformities. This paper describes the design specifications of therapeutic insole-based diabetic footwear following foot reconstruction surgery. The development of the footwear requires a complete mold design of the last and the calculation of the inner volume allowing for the freedom to select the most suitable style from the choice of all the existing commercial options. The modular insole must be adjusted to the final shape of the upper to avoid the patient's foot holding incorrectly, adding excessive or insufficient pressure or significantly offsetting the 3D soft interface **(Alves et al.2024)**.

3.2. Risk Factors Associated with Improper Footwear

A long-term chronic disease, such as diabetes mellitus, can bring serious complications, and the patient's life expectancy can also be shortened or greatly influenced. A foot ulcer in a diabetic patient is a significant factor that causes damage to the patient and increases health care costs. The prevention of foot ulcers in these diabetic patients begins with proper footwear. A lack of proper footwear may affect the foot's function and increase the risk of foot ulceration because the physical characteristics of footwear can accentuate the pathomechanical aspects of the neuropathic foot. Improper footwear is by far the most important independent factor in foot ulcer formation; normal sensation with proper protective footwear resulted in only 33% of the cases being ulcer-free after 11 months. Many risk factors, such as dry skin, bony prominences, calluses, limited joint mobility, pes planus or pes cavus, and limited or excessive joint motion, have to be considered. In some cases, ulcers are formed by pressure due to a stiff relaxed foot; in others, the ulcer forms due to prolonged mechanical pressure. Diabetic patients should wear specially designed protective and accommodative footwear that is easily adjustable for their deformities. These risk factors have become necessary considerations for the design specifications and development of the intended footwear. Injury-reducing footwear design is of paramount importance. The objective of this study is to create design specifications for proper footwear to prevent diabetic complications and enhance ergonomic comfort. Furthermore, according to these requirements, proper protective and accommodative footwear will be designed by employing functional design theory techniques **(Malki et al., 2023)**.

Outside of what clinicians often say about managing the diabetic foot, there exists much misinformation and myth regarding the issue, particularly sprouting and propagated by the hyperbole and sophistry that climate the internet. The affected people are often desperate and willing to listen to messages that, while they would be wonderful if true, border on the preposterous. That said, only a few, quite simple things can be done to help the diabetic foot. One of those things is wearing the right footwear **(Schaper et al.2020)**.

Footwear plays a bigger part in keeping foot complications at a minimum than most people think. The bad effects of not wearing proper shoes are easily understood when it is recognized that the human foot is not a particularly robust structure, regardless of how large, powerful, and deliberately employed in sports it may be. Furthermore, diabetes is a disease of the skin and the vascular and nervous systems, and because of that, it affects the entire foot in predictable ways. When it comes to footwear that should be avoided, some factors raise issues more often than others. They are general wear from the shoe toe, heel, sock liner, and outsole; inappropriate size, narrow toe, or restricted space **(Ferreira et al.2020)**.

Footwear more commonly can be the root cause of

such loss of sensation and incapacitated gait because it accumulates pressure and shear forces and "attacks" the skin of the foot in isolated places over and over, and not daily in a corrective way, as when the ground is massaging the healthy foot skin with irregularities in the ground. A good shoe, in contrast, cushions and spreads these forces and irritations or completely disallows their creation at the least sensitive but important sensory sites on the bottom and side aspects of the foot. Sufficient space, bilaterally even shoe tongue edges, adequate cushioning of the heel, sole, and midsole of the shoe, and good fixation all reduce susceptibility to foot problems. These statements are based on principles that always underlie regular fashion or sports footwear because the human foot in its diabetic form does not like it **(Blagorodov, et al.2020)**.

3.3. Importance of Proper Footwear for Diabetic Patients

One of the major problems faced by diabetic patients is a greater potential for developing foot ulcers and calluses. These complications may be caused by impaired sensory and circulatory function. Improper design of shoes may worsen calluses by providing excessive pressure on the plantar skin, and it can induce ulcers by providing unusual shearing force, which becomes a risk factor for the foot. Despite recognition of the need for properly designed shoes, the conflicting needs of these patients and the fact that extra-depth or custom-made shoes are often unattractive visually have kept the extensive use of therapeutic shoes to a minimum. In addition, procuring appropriate footwear that addresses these concerns may be a definite problem for patients. With proper guidelines, ideal thermal comfort is another factor that needs to be considered in the design of custom-made shoes for diabetic patients to encourage regular use of such shoes **(Naemi et al.2020)**.

In managing diabetic complications, preventing the formation of these complications is the best method. This prevention requires the identification of possible reasons and the best modes of protection against risk factors for correct treatment. One of the reasons for chronic complications observed in diabetic patients is their impaired metabolic regulation mechanisms. Specifically, peripheral neuropathy, peripheral vascular disease, foot deformities from long-term abnormal foot pressure, and decreased soft tissue fluid content make the diabetic foot vulnerable by increasing the potential for neuropathy and infection. For diabetic patients, wearing shoes that are compatible with their pathological conditions is a crucial parameter. The main aim of this study is to optimize footwear design that can protect against foot problems for diabetic patients, who are very prone to chronic complications in their foot region. In this regard, footwear design for the specific foot problems of diabetics will be examined. The importance of therapeutic footwear, which should be lightweight, low profile, deformable, and comfortable, will also be emphasized and evaluated **(Bellomo et al.2022)**.

It is observed that wearing inappropriate footwear can cause complications for many people, such as deleterious deformity progression, ulceration, foot pain, and callus formation. The characteristics of footwear are the reasons for the formation of these problems. Especially in diabetic patients, where metabolic regulation is impaired, suitable footwear is extremely important. It is concluded that diabetic therapeutic footwear should be made light, be easy to put on and take off, reduce high pressures with good cushioning and good shock absorption, reduce shearing without being too stiff, and look stylish. This suggests that the general conditions of the desired therapeutic footwear should be lightweight, low profile, deformable, and comfortable. In summary, general footwear design criteria for diabetic patients have been identified. It is recognized that therapeutic shoes can be modified or changed according to specific forefoot problems. In addition, it was found that the use of therapeutic shoes reduces the pressure in the forefoot region **(Chicharro-Luna et al.2021)**.

3.4. Impact of Ergonomic Design on Foot Health

Footwear is crucial for maintaining a painless existence by protecting the feet from injuries. It offers dynamic foot protection and functionality by dividing support, pressure, and shearing forces. Footwear acts as a second skin for the foot, facilitating movement and affecting postural stability. It maintains control of the foot and manages injury repair. Corrective and orthopaedic footwear use biomechanical materials and technological innovations to provide supportive comfort. These technologies meet proper biomechanical demands, ensuring users adhere to the footwear, especially during times of urgency and need, for success **(Hinton, 2023)**.

Footwear's ergonomic importance must be suitable for both the user and the foot caretaker. Not just foot construction affects design; the user's lifestyle, thermal needs, medical conditions, and work-related environmental factors impact fit and wear. Engineering standards for preventive and intervention demands differ. The type of footwear structure affects whether a foot desires security, control, or degrees of flexibility. Sport, fashion, or external security rather than central security conditions are common features of engineered footwear. Different intervention properties are required. Education on the correct options, inspection of back weighting, separate form-fitting, selecting off the rack, custom shoes or custom inserts, and ensuring materials are in good condition are other ideas to be remembered. To stimulate these concepts, contemporary technologies are available for all footwear designs. In the absence of appropriate ergonomics, however, the feet are not safe **(Lee et al.2022)**.

4. Key Features of Diabetic-Friendly Footwear Design

Diabetes mellitus mainly causes complications to the diabetic foot if left undetected at the primary stage. Diabetic footwear plays an important role in preventing foot complications and maintaining ergonomic comfort for the patients. A number of objectives regarding foot complications have been defined by medical professionals. The present work

aims to justify the design objectives of the activities involved in footwear design. Design features, such as sole design, interior design, Velcro strap, toe box, low heel height, weight, material, ventilation, toe-off, etc., have been justified based on the findings. It is also explained that every design step is supported by medical doctors and paramedical staff. Thus, the present work is a justification of the design specifications defined in the field of diabetic footwear **(Ning, 2024)**.

People with diabetes are predisposed to foot ulceration and infections, which remain a major global medical, social, and economic problem. In the early stages of diabetes, patients most commonly experience neuropathy. A consequence of diabetic peripheral neuropathy is loss of sensation; patients who suffer from neuropathy do not feel that trauma is being inflicted on their feet. The patients do not notice minor injuries in the pressure-bearing parts of the foot. These minor injuries can develop into deep ulcers without the patient being aware of it. The problem will result in 15% of patients being subjected to ulcers during their lifetime. It was stated that diabetic foot conditions were caused by improper footwear. Because of foot discomfort and fashion trends, diabetic patients are attracted to improper footwear. Therefore, it is necessary to take into account the design concerns of diabetic shoes, as well as the needs and wants of diabetic patients. As a result, the objectives of the present study are to justify the design concerns using supporting information in the field of diabetic footwear **(Schaper et al.2020)**.

4.1. Cushioning, Support, & Shock Absorption

The purpose of footwear design for preventing diabetic complications is to protect the foot and also provide the necessary ergonomics and cushioning features. For that, and considering the importance of the midsole in cushioning and supporting the foot, it is necessary to develop proper footwear materials. The foot ground reaction produces internal shocks in the body, especially in the anatomic structures of the foot. Consequently, there is an undesirable part of the ground reaction called a shock wave. When the shock wave reaches the foot, it becomes divided into two parts by the heel's superior surface. The first one continues downwards to the plantar surface of the heel. The second part reaches the foot's interior, going through the calcaneus. It is then conducted through the tarsus, metatarsus, joints, and finally through the interspaces of the toe, distal nerves, and phalanx. Normally, the shock wave is absorbed in the intervening tissues. However, if there is a reduction in the systems that absorb the shock or an alteration of foot condition suffering pain, shock is harmful. It is considered that footwear that absorbs shock can protect the diabetic foot in the prevention of ulceration in sites of angioma overlap by decreasing the transmission of pressure and shear **(Castro-Martins et al.2023)**.

The cushioning capacity of footwear is a complex process involving multi-factorial interaction. The shock wave that arrives at the tibia is absorbed in the skin and bone, with the calcaneus playing a significant role in this process. The tomographic biomechanical quality evaluation criterion helps manufacturers create optimum cushioned footwear structures using elastic synthetic materials. These criteria evaluate diverse biological tissues, including bones and other connecting tissues, and other structures subject to large mechanical strains. The quality of a material is evaluated based on its ability to store maximum elastic energy during mechanical loading. Materials must exhibit great flexibility during mechanical strain with total recoverable deformation. Using these criteria, authors have developed a new concept considering moments of forces acting on room axes and strain energy determined in biomechanical processes for sports footwear **(Asghar & Naaz, 2022)**.

Cushioning in the design of sports shoes is much more important than in standard shoes. Consequently, the materials used to provide cushioning are a critical factor in the design of sports shoes. Regardless of the materials used, the cushioning system should provide suitable compliance, which is to say that the cushioning should absorb shock and permit some compression to disperse the forces acting on the foot during tasks such as walking, jogging, and running. The cushioning material should not bottom out, and the cushioning system in the shoe should have internal shear movement to store, then release, the energy created during impact. Shock absorption. The importance of shock absorption in walking and running has focused a great deal of attention on the midsole. The midsole is fundamental for the walking/running process and materials play a relevant role in midsole behavior; therefore, the development of new materials might enhance midsole performance. Newly designed midsoles have been introduced, in which stiffness, thickness, and other mechanical properties of the midsole are localized according to the functional demands of the different parts of the sole. These proposals are related to negative effects detected using excessive cushioning materials that can lead to instability and an increased risk of injury, breaking the rule of the 'more is better' paradigm **(Isherwood et al., 2021)**.

4.2. Roomy Toe Box and Seamless Interior

The importance of adequate footwear in the avoidance of foot complications in diabetes patients cannot be overemphasized. Diabetes mellitus can result in one or more complications, including neuropathy, peripheral arterial disease, foot ulcers, calluses, corns, hammertoe, Charcot foot, infections, gangrene, nail changes, oedema, improper balance and gait, ingrown nails, fungal infections, proprioception deficiencies, or a combination of these. The progression to or severity of the majority of these conditions can be delayed, as well as pain minimized, with the use of proper footwear constructed according to specific design criteria **(Rossboth et al.2021)**.

The biomechanical function of the foot can be disrupted if the natural toe spread created by the metatarsophalangeal joint is confined by the shape of the shoe. Since the forefoot is covered by the toe box, and the toe box, especially when constructed with

traditional narrow geometry, has a tendency to reduce the natural toe spread, energy is absorbed during functional activities. Inflexible, tight-fitting footwear can force the toes together with significant disadvantage to the patient with diabetes mellitus by reducing the range of motion and increasing the load which can lead to functional compromise and a wide range of complications **(Rose & Martorana, 2023)**.

4.3. Adjustability and Fastening Mechanisms

The fastening mechanism for diabetic footwear should be adjustable to accommodate fluctuations in oedema, be simple and easy to use, and provide even pressure to prevent local pressure complications. The patient should not rely on tonic muscles to hold the footwear on their foot. A combination of fastening mechanisms is provided for in-depth or custom-made orthotically manufactured footwear. The strap should be firmly anchored on the inner part of the shoe, vertically adjustable, and wide with padding for comfort. The fastening mechanism should widen the shoe for easy access, allowing the foot to be slipped directly into the shoe. The mechanism should not be irritating to mental acuity if it impacts the contralateral shoe. Although footwear can be switched on and off without lacing, the sense of proper footwear should not be lost **(Faerber et al.2024)**.

5. Materials and Technologies in Footwear Design

In recent years, many materials and technologies have been developed for the design and production of medical footwear. There are two different points in specifying these technologies in diabetic shoes: the body should be stable in the footwear, and the shoe should be breathable, moisture absorbent, and washable. In particular, wool, silk, polyamide, acrylic, and polyester are suitable for the lining **(Rodrigo-Carranza et al.2024)**. Certain materials are suitable for the top material. Diabetic static and dynamic insoles should also be placed in the shoe. Enhancement of the shock-absorbing feature of shoes is possible by placing viscoelastic materials at the heel and/or midfoot zones. Moreover, the technology of microcapsules for the shoe linings, which is used to control the pH level, is available for diabetic foot care. Footwear designs produced using these materials and technologies are expected to be easier and more comfortable to wear, and the blood circulation of users will not be hindered **(McCann & Bryson, 2022)**.

In brief, it is important to provide good ergonomic comfort and to minimize lower extremity pressures. Cushioning at insoles, metatarsal pad, shock-absorbing sole, rigid midsole, stiff shank, supportive heel counters, deforming the shape and area with flexible panels, and cushioning ankle joints are features incorporated in proper diabetic footwear. Also, stabilizing foot features support different designs of shoes. Heat-molded heel improves fit, and it conforms to the foot. These shoes have a mild rocker sole configuration, rigid plastic support, appropriate lining with good absorbing quality and adequate resistance. Besides, to enhance the physical functions and ethical properties of existing technologies, the use of novel functional materials in footwear production, natural fibres, polymeric nano/microparticles, pigments, plant extracts, and essential oils added in some or all parts of the footwear have also become popular in recent years. These features make wearable footwear more comfortable and protective for the foot, reducing pressure exposure and shear stresses **(Cha, 2022)**.

5.1. Material Selection for Diabetic Shoes

Selection of the right shoe for a diabetic is based on several factors, including disease status, activity level, and financial considerations. For some special patients, such as those with previous ulceration or some pre-existing foot deformity, patient education is also critical to achieve a successful outcome. Several features of prescribed shoes for this special class of people are critical to their success. These features are a result of decades of informal clinical trials developed from experience in the efficient and effective healing of foot problems in these people with diabetes. Although the exact nature of how these shoes generate their beneficial effects is highly controversial, shoes with the following features are problem-solving and well-tested prevention strategies for this high-risk group of people with diabetes. The selection of shoe material has a significant impact on the foot protection outcome. It is proven that an appropriate selection of shoe material used in diabetic footwear is significant in foot protection **(Orr et al.2022)**.

Diabetic shoe manufacturers are increasingly using a variety of materials to create shoes that are machine washable, reducing infection risk and enhancing compliance. A single upper made of multiple materials could be beneficial, as it can be tailored to specific needs of the forefoot, midfoot, and heel. Additive manufacturing is an interesting method for producing diabetic shoe uppers, as it has a relatively low annual cycle of production requirements and can be economically advantageous due to the low number of shoes produced. The ability to produce different patterns in fluorescent or natural colors could further individualize each shoe. This approach could help reduce costs associated with traditional diabetic footwear production **(Chatzistergos et al.2020)**.

Specific materials are selected to provide specific components and characteristics of shoes for an intended purpose. To avoid and reduce some diabetic complications due to foot injuries, improper shoes, and certain medical conditions for diabetic patients, the following material characteristics are included in the problem-avoiding shoes: a new air cushion, semi-resilient/semi-rigid design, V-shape and toe flap, heelless profile, embedded magnetized circular insert, and specific local area tension straps. These selected materials have been picked and experimented with by following several design concepts and criteria related to diabetes and foot injuries **(van et al.2020)**.

Some of the common materials and available technologies may include any of the materials used in making the outsole, midsole, insole, upper, and insole

support, cushioning foam or semi-reticular midsole, and a good upper support design to allow more dorsiflexion than traditional athletic footwear. A proper choice of the shoe mould cavity's toe profile can comfortably yet effectively shield at least portions of the reshaped foot region from the radiant energy emitted inside the shoe. The smart design makes the present shield protective device effective against other diabetic foot injuries. Optional memory foam padding devices located in the shoe insole cavity cushion the reshaped foot and reduce the risks of resultant foot skin injuries. The shoe with the front opening and toe strap combination assists the diabetic patient with foot conditions, allowing it to be donned and doffed easily. The shoe with binding straps and non-irritating interior construction does not traumatize any sensitive areas **(Stokes, 2020)**.

5.2. Breathable and Moisture-Wicking Materials

Choosing suitable materials makes an impact on the breathability and moisture-wicking properties of the footwear. Various studies were done to compare the different materials and their combinations. Natural materials, like leather and cotton, were widely used for the upper in dress shoes, but they are not suitable for modern athletic shoes or casual shoes because they do not have breathable performance. The combined friendly natural material and feature technology to have the desired breathability and strength were compared and evaluated. Knitted fabrics also show more moisture removal ability than nonwoven fabrics that are widely used currently. By comparing nylon filament mini surf and non-woven tows, researchers found the woven net structure of nylon markedly influences moisture wicking by capillary action. Studies show that moisture management is the most important property monitored when comparing conventional wool and fine wool **(Gorade et al., 2021)** .

Many researchers combined a variety of materials to obtain enhanced results. For example, it was found that sheep wool fabrics show strong potential to fabricate outdoor clothing in hot, humid environmental conditions. It was suggested that transitional fabrics, which are made with blends of wool and synthetic fibres, offer a way to improve the comfort of single-layer wool clothing. It was further discovered that water sorption does not simply depend on the individual properties of the single fibres in the blend. Wool, nylon, and polyester microfiber were combined to increase the water evaporation area; quick cotton/wool can possess thermal and physiological capability, etc. The criteria used by several researchers for evaluating the material properties of wool garments were 55% wool, 30% synthetics, 10% polypropylene, and 5% other **(Kim, 2023)**.

The shoe's upper shall be made of breathable and fast-drying fabric to remove moisture from the skin surface to keep the foot dry and prevent bacteria from growing. To develop microclimate sensation fabric value for breathability, approximate W = 2373.06 and M = 3.319. To get the moisture-wicking effect, that is M w = 100%, then M = M of M w = 100%. The moisture-wicking concept is of knit warp knit structure that has the three-dimensional fibre arrangement of front and reverse knits, which provides a three-dimensional capillary action for high absorbency rate and also leads to fast-drying capability **(Jhanji, 2021)**. The use of wave-like fabric surface arc parts can make the foot microclimate achieve 100% dryness. The capillarity power of the air bearing means the reverse process of drawing air out from the fabric to the space. The inward capillary and wick effect make the moisture evaporate from the skin surface. By using breathable and moisture-wicking fabric that can quickly drain the sweat from the foot to keep it dry and remove the moist heat flux to change the microclimate in footwear, the hot humid microclimate can be quickly removed. When the humidity inside the footwear reaches close to 100%, it is necessary to drain the sweat and let the hot humid microclimate be quickly taken from the skin. After having cool airflow removed, the sweat evaporates, and air exchange is necessary for the comfort of the foot. Removing the hot humid microclimate can further prevent heat disease and athlete's foot and discomfort of wearing footwear **(Yick & Tse, 2021)**.

5.3. Orthotic Inserts and Insoles

Another feature of consideration for a well-designed diabetic shoe is the option of using orthotic inserts or insoles. The mechanical properties of the diabetic foot can be improved biomechanically by customized insoles and orthotic inserts. A proper orthotic insert should be capable of absorbing excessive shearing and compression forces and reducing the elevated perpendicular pressure. Additionally, such an insert should be made of a material that exhibits high-impact resilience and stiffness, with added energy return. The total integrated support system provided by customized insoles and orthotic inserts can help prevent the onset of skin breakdown in persons with diabetes. These insert and insole features are designed to stretch and conform to the weight distribution pattern under weight-bearing of a foot at rest, while also mitigating plantar pressure profile discrepancies during the gait cycle in persons with diabetes **(Yick & Tse, 2021)**.

Foot-related biomechanical discrepancies induced by inappropriate footwear and high-pressure profiles are the reasons for the vulnerability of skin breakdown in persons with diabetes. A system of silicone or foam insoles with various stiffness, cushioning, or customized shape can serve as an integrated solution for preventing the onset of skin breakdown in people with diabetes. Furthermore, proper pressure distribution with certain areas of shield pressing reduces the deployable amount of pressure underneath the ulcer location. Especially, customized insoles and orthotic inserts reduce the deployment of vertical plantar stress on certain locations on the foot during weight-bearing activities in persons with diabetes. During foot locomotion, it is the plantar stress and footprint distribution at the support phase of one's gait pattern that increases the probability of developing diabetic foot ulcers. Therefore, customized orthotic inserts made of viscoelastic polymers use the patient's

weight distribution data to relieve excessive stress in the portions of the foot that are more prone to develop diabetic ulcers. In addition, the insoles can counteract and correct excessive pronation, malalignment of both the tibia and femur to the foot, inversion of the subtalar joint, and calcaneal valgus to reduce the risk of ulcers and amputations and enhance comfort in persons with diabetes. Therefore, integrated cushioning-shaping insole designs allow for roll-over shapes during gait and also elevate comfort for the individual with diabetes **(Zubair & Fatima, 2021)**.

5.4. Sole Construction and Traction

The human foot provides both balance and propulsion as it interacts with the ground or floor. Thus, the primary aspect of footwear construction is the traction and stabilizing quality of the shoe's sole. The external foot surface has a high coefficient of friction with dry surfaces, which allows for the rapid application of a spatial relationship with the ground necessary to maintain balance during forward walking. The foot's distal end can also adjust its shape and angle to conform to the ground surface irregularities, providing the traction necessary to overcome slips. Thus, if excessive walking and slipping prevention are desired, a shoe upper should fit snugly, and the bottom portion of the shoe should have adequate traction properties. However, since foot surfaces have poor bending or torsional rigidity and fewer mechanical properties than shoe soles, the sole itself should display this large coefficient of friction. This sole traction property of outsoles is perhaps the most important feature of work shoes, especially slip resistance on dry, oily, wet, or soapy surfaces **(Iraqi et al., 2020)**.

Good sole construction provides proper foot dorsiflexion and allows for pronation and toe-side flexion. Sole attachments should be made of flexible and wear-resistant materials that utilize the foot's dynamic forces to mould and contour to individual foot shapes effectively within a short period. This allows for improved traction at the necessary shoe sole and floor contact points by preventing slipping on oily surfaces. The sole should have a shape that benefits from its planned use and can vary in shape and thickness. Since the most significant use of sole wear made by individuals is on the plantar surface of the toes, the thickness of the outsole should taper to a much thinner pad located underneath the metatarsophalangeal joint. Such sole tapering increases the flexibility of the wear-resistant outer sole at the necessary flex point for improving traction over slippery substances. The outer sole flex groove can be moulded into the outer sole at the flex point to increase traction and reduce bending and stress on the shoe material. The sole itself can be an oil-resistant soling material that also provides static dissipative protection. Dynamic interaction support is also assured between the shoe sole material and the floor surface to facilitate location-specific traction **(Behling et al.2020)**.

6. Customization and Personalization in Footwear

Morphological and physical differences prevent the development of an individual and personalized footwear solution for every person. Human feet have many individual and common features such as shape, dimensions, mechanical properties, injuries, and diseases. Personalized foot and footwear models and their combinations have gained much attention to deal with this diversity without relying on different moulds and product numbers in the mass production stage of footwear. There are many kinds of customizable insole technologies to provide comfort and prevent common foot morphological complications encountered during long-term standing and walking within the diabetic and normal populations. However, the feature of swelling in the diabetic foot due to both accumulation and contamination of glucose and increased body weight amplifies the challenges to developing effective diabetes, foot, and footwear-related healthcare **(Firtikiadis et al., 2024)**.

Customizing footwear renders it difficult and costly as it requires automation to close the gap and relieve economic, time, and labour force constraints. Despite all the benefits, customized footwear with high quality and quantity output has still been deficient in diabetic foot healthcare. Mass customization has not yet been standardized in footwear despite the many research efforts to address it. Therefore, there are many shortcomings and research points to making cost-effective customized diabetic foot healthcare. Some of the product, process, information, and integration research points are elaborated on to provide ways for future studies. The technology directions, such as principles, modelling techniques for personalized mass production, and proper footwear for diabetic persons, are also suggested for future research and standardization purposes. Their shortcomings are addressed to provide solutions for developing or adapting manufacturing concepts and technologies in the diabetic foot healthcare sector. Their challenges are addressed to provide a methodology for evaluating the effectiveness of the diabetic person-specific footwear design. Finally, some approaches are presented to contribute to the advancement of the potential and future work for diabetic foot healthcare **(Zhang et al.2022)**.

6.1. Gait Analysis and Individual Needs Assessment

The design of footwear for diabetic patients should be tailored to each patient's specific needs and activities, ensuring accurate, effective, and affordable production. This approach is crucial as it avoids the need for a single design standard for millions of diabetic patients worldwide.

Designing shoes with a handmade approach is also beneficial as it prevents patients from having to visit other healthcare professionals for expensive diagnostic tests and acquire additional medical devices like hearing aids and dentures. These devices are designed to fit each patient's specific needs but often neglect potential complications until they require surgical amputation. This strategy is costly and uncertain for the healthcare system. The development of technologies that allow for the production of patient-adapted footwear at low cost

and in a suitable time is another objective of this investigation. By identifying the most relevant aspects of daily and occupational activities and determining the specifications for prescribed materials, tools, and procedures, the design of footwear for diabetic patients can be tailored to their specific needs and preferences. In conclusion, the design of footwear for diabetic patients should be tailored to each patient's specific needs and activities, ensuring accurate, effective, and affordable production. This approach will also help reduce the need for expensive diagnostic tests and unnecessary medical devices, ultimately benefiting the global healthcare system. **(Chatzistergos et al.2020)**.

6.2. 3D Printing and Custom Footwear Solutions

Overlapping issues of pressure, friction, and shear stresses were studied about the pressure offloading effects of a 3D printed footwear insole in diabetic patients, as well as the stiffness and cushioning effects of 3D feet scanning and printing custom footwear for diabetic feet. Appropriate cushioning keeps the foot injury-free and aids in healing. An in-depth biomechanical analysis of the diabetic foot under various conditions like overloading on a bony prominence, peripheral neuropathy, increased plantar pressures, and an excess of ischemic complications was presented, along with the development of clinically relevant foot pads using 3D printing. Rehabilitation pads produced using the additive manufacturing method were also studied to prevent pressure ulcers **(Nouman et al., 2021)**.

Proper footwear usage reduces injury and improves patient mobility. Using 3D scanning, custom footwear for diabetic patients was created, and a customized sole was attached to a shoe designed for diabetic patients to effectively protect the feet and reduce the probability of ulcer formation, which can eventually lead to amputation in severe cases. An enteral foot orthosis was designed using three different manufacturing techniques, and a custom proprioceptive insole was prototyped in diabetic patient shoes for enhanced balance. It was suggested to replace classic semi-rigid casts with ventilated and hygienic 3D-printed versions. High foot comfort helps patients utilize them and contributes to good health. An innovative and promising insole design and production approach using 3D milled cork was provided **(Rukmini et al.2024)**.

7. Case Studies and Best Practices

Najafi & Mishra, (2021) states that a company has developed socks for diabetic and neuropathic patients, focusing on technical and ergonomic design. The company began selling fingered socks in 1999, making them suitable for any sport. The company aims to provide comfort while considering technical features like reducing overheating, blister formation, quick drying time, and fine mesh protection. The latest collection of stockings is made with modern and lighter materials, designed for specific markets and consumer needs. The company aims to alert patients to the importance of socks and footwear, demonstrating the benefits of comfort and injury prevention. By making informed choices when purchasing, consumers will use the most appropriate products for their daily activities. The company's goal is to ensure that toes can move freely and independently, meeting the usual clothing specifications.

7.1. Diabetic-Friendly Footwear Successful Examples

We have searched for diabetic footwear products from a variety of vendors. We analyzed the product specifications and the benefits provided for diabetic foot safety. Although not comprehensive, we include a few available examples in our shortlist that meet all or most of our design specifications for diabetic-friendly shoes, including the ergonomic comfort demand as well. We note that one nonspecific product feature we cannot verify from the available product descriptions is whether and how well therapeutic shoes meet requirements for 'proper size and fit' and 'human factor issues of customer experience' that are essential for enhancing the protective performance of the shoe. If they do not, customization will be necessary. These selected examples are from various brands. Some changes have been made to the original specifications and features in the consumer products. However, even those with less-than-perfect compliance with our design specifications can still provide an information source for one or more diabetic-friendly functions and indicate areas of future development. The patient's medical indications should also be taken into consideration **(Ermakova et al.2020)**.

7.2. User Feedback and Clinical Studies

This study presents the development of a lightweight, comfortable diabetic insole designed to prevent discomfort caused by diabetic complications and enhance walking efficiency and confidence. The insole was created in collaboration with patients, physiotherapists, and users, with the goal of providing a reliable, low-cost solution for diabetic patients. The device monitors foot problems, guiding patients and specialists in decision-making to prevent discomfort from diabetic complications, especially elderly patients at risk of foot ulceration. The insole was tested in clinical intervention settings, with surgical mask plates undergoing evaluation for pedological techniques. Safety and durability were considered primary requirements, as the device is used daily. A preliminary user awareness survey was conducted to gather feedback and suggestions from ideal users before products are released in the market. The survey allows target users to give their opinions, ensuring they feel confident that the solution can positively influence their health without any damage. The goal is to provide a reliable and low-cost solution for diabetic patients, enhancing their comfort and preventing future walking-related morbidities **(Hatton et al.2024)**.

8. Regulatory Standards and Compliance

As diabetic individuals are a high-risk group concerning foot problems, improper footwear design can produce harmful complications. In the United States, footwear products are generally regulated by the appropriate safety commission, while safety

requirements for various personal protective equipment products are determined according to the type of product. For family-sized footwear concerning general performance requirements, safety, and logistics, there are no predetermined standards that the products must adhere to. To enhance user comfort and satisfy user demand, designers are encouraged to explore various design dimensions and to seek the best design alternatives. Concerning attempting to prevent diabetes-induced foot problems, this paper focuses on the design specifications determining proper footwear that can curb such complications and provide ergonomic comfort. Moving forward, the defined design objectives and specific design attributes can be used as a reference or a set of guidelines by footwear designers **(Chicharro-Luna et al.2021)**.

Currently, for diabetic footwear, the requirements are protected under relevant standards. These requirements focus on those shoes for preventing diabetes-related foot problems resulting from cutting, shock, pressure impingement, and swelling. Various national regulations and standards have customized diabetic footwear regulations for diabetic individuals and others. This paper aims to explore the proper shoe specifications for everyday wear, which can be family-sized and satisfy the ultimate consumer's overall requirements. By summarizing the possible causes of diabetes-induced foot complications and user demands for proper footwear, a better understanding can be demonstrated. Such an understanding can then be transformed into appropriate design objectives and design attributes. Future work could select case studies of those attributes and then evaluate related products. Additionally, the definitions can be used as a reference or as a set of guidelines by general footwear designers **(Sousa et al.2023)**.

8.1. FDA Regulations for Medical Footwear

In the U.S., there are regulations governing medical devices as well as medical footwear. There are different classifications of medical devices: Class I, Class II, and Class III, which correspond to high, moderate, or low risks to users. The category of medical footwear is Class I. The purpose of medical footwear is not to cure a disease or correct deformity but to avoid skin damage, ulceration, and non-union healing in diabetic, in-hospital, and geriatric patients. The footwear also helps to protect sensitive feet from acquiring a vascular injury. In cases of ulcers, there must be an appropriate approach for wound dressing. The design specifications of proper footwear for preventing complications in diabetes patients should guide the various functions and the appropriate materials to accomplish these functions **(Reichenbach et al.2020)**.

Diabetic footwear has to reduce weight-bearing pressure during gait, thereby reducing the chance of foot complications and ulceration. Data from clinical studies showed that better ulcer healing rates come from orthopaedic shoes and custom-made orthopaedic footwear than from standard therapeutic depth shoes and non-removable cast walkers, and casting can protect the feet from any pressure on a diabetic foot wound in management. On the other hand, these solutions rigidly set the foot and bear the increased pressure on the opposite side. Therefore, adjustable shoes should be used to eliminate these mechanical factors and enhance foot protection. The use of orthopaedic shoes in diabetic patients with complicated wet wounds contributes to advantageous long-term effects through the improvement of the microcirculatory bed, a decrease in inflammation and oxidative stress, as well as normalization of metabolic skin processes **(Zhang et al., 2022)**.

8.2. ISO Standards for Footwear Safety

In Minimum Personal Protective Equipment (PPE) requirements, classification, and labelling of professional footwear, the performance requirements for professional footwear provide some aspects of a work environment specific to the footwear designation of specific groups of footwear. This standard may not contain all the information necessary for designing or producing professional footwear, but it contains the relationship between the wearer and the footwear, as well as other attributes that affect the human body, which will ensure that no adverse effects have been introduced. It is also necessary to note that chemical splash resistance requirements are not applicable for industrial footwear, and the optional conductive properties are the only protection against the risk of voltages between the feet inside the boot and the earth. Footwear for the protection against chainsaw injuries and food industry use forms an exception to industrial footwear, and all parts of this standard are applicable. However, it is not necessary for footwear for food industry use to meet all of the other resistance requirements, except for flat footwear. The bottom density may not be the only way to reduce the transference of materials on the floor, but sole specifications are subject to laboratory determination **(Bodoga et al., 2024)**.

9. Future Trends and Innovations

Proper shoe design is critical to maintaining foot health for diabetic patients. Shoes with these specifications can avoid complications and injuries, which, in severe cases, may lead to amputation. Tight shoes and shoes with seams, multiple layers, heels, and slip-on characteristics should be worn infrequently or not at all. Healthcare professionals need to be aware of the diabetic foot issue and educate patients to wear proper shoes and to check their feet regularly. Researchers and manufacturers can incorporate the shoe specifications into the regular design of shoes so that customers can purchase readily available shoes with these specifications. The sustainability issue should also be considered by using environmentally friendly materials and techniques. Although many shoe aspects have been examined, these aspects have yet to be systematized. Consequently, future research can consider organizing shoe fit, insoles, materials, and designs using a standardized method. Additionally, training to increase awareness of appropriate shoes and foot care practices in

individuals with diabetes is another important consideration, as poor knowledge can lead to non-compliance. With the cooperation of both healthcare professionals and shoe designers, proper, healthy shoe designs for diabetic patients that are also stylish and functional could be a reality shortly. Since shoes, foot problems, and related therapy are so specialized, this effort continues to be critical. With advances in the multidisciplinary field of shoe biomechanics, the future is wide open for breakthrough technologies. The day may not be far off when all people walk 'better.'

There are no consensus standardized design guidelines for the production of diabetic footwear that can be included in a professional manual yet, which is essential if the goal is to create functionally suitable shoes while considering the required safety considerations. Recommendations for innovations and novel techniques emphasizing beneficial potential are explored in this research to support future studies, to promote design education, to improve clinical interventions in diabetes care, and ultimately, to fast-track the development of advanced footwear by applying a regulatory Quality Seal. Topical, innovative categorical structures for the design and construction of the ideal diabetic footwear, which apply academic training and a multidisciplinary view toward the empowerment of designers and users, are proposed. These novel insights are progressively synthesized and initially applied to those who design and construct appropriate footwear for people with diabetes, a potentially growing at-risk population. Therefore, the contribution of designers to the educational, supportive, and innovative approach of knowledge and practices should promote scientific-technological growth toward an efficient and effective standard of end-user trust, satisfaction, and foot-protection requirements **(Jones et al.2020)**.

Since polyurethane is one of the most traditional and studied biomaterials, and is used in midsole production for various applications, its appearance in additive manufacturing by 3D printing appears to increase the likelihood of its use within specific niche markets. In terms of novelty, it is important to encourage the application of this technique in orthopedic treatments for diabetic complications **(Chang et al.2022)**.

When polyurethane footwear is produced by 3D printing techniques, the concept of the shoe could be entirely reinvented, incorporating diverse structures. 3D printing allows the designer to take advantage of the potential of different properties of the material, managing where the material has compaction or different densities. In the end, these custom qualities could be prepared according to individual properties. The individual intricacies of the foot could be measured through 3D scanning, generating a subsequent 3D model, so that the designer, using 3D printing concepts, could finally fit in and assemble a unique shoe for the user. **(Zolfagharian et al.2021)**

9.1. Smart Footwear and Wearable Technology

The evolution of wearable technology to provide different types of products in the shoe market quickly and conveniently is worthy of consideration. The micro-sized sensors can be further seamlessly integrated into shoe materials to maintain the appearance while recording and analyzing data to improve the health and cognition of the user. Furthermore, the role of innovative wearable technology in various stages of the footwear industry, from product innovation, design, customization, and manufacturing to product sales, is outlined. The purpose is to present not only the innovation in the industry but also its impact on fashion and apparel design trends. The footwear industry is undergoing radical technological developments with advances in applied science, engineering, and technologies such as 3D printing, mechanical testing, additive manufacturing, data processing, and data acquisition technologies. The combination of different types of electronic and functional devices with wearable technology composes footwear at the border of advanced textile materials and high technology. In addition to physical barriers, health problems limit people's mobility. The surge in healthcare costs can be partially attributed to diabetic complications and their impacts on the diabetic population in both developed and developing countries. Special emphasis is placed on the proper choice, necessity, and importance of the features and design specifications of footwear intended to prevent complication onset and diminish the diabetic individual's risk of advancement of foot complications. With its emphasis on human factors and risk assessments in ergonomic comfort, the importance of the biomechanics of the human body, in this case, a diabetic individual, is presented **(Keukenkamp et al.2022)**.

9.2. Eco-Friendly Footwear Solutions

In recent years, the concept "sustainability" has become everyone's goal due to mass production and mass consumption, seen as a detailed benefit of the era. Two major problems that arise from this wide acceptance are the amount of waste that we produce and the way this waste will be managed. Apart from the very well-known general environmental pollution effects, many categories of waste are not sustainable either, in terms of energy consumption or terms of shortage of initial materials. Mass-produced shoes have also been placed in the system of solving the supply chain system. Nonetheless, the initial fact of using glue to connect many parts of a shoe eliminates the possibility of reformulating or reusing outdated shoes. As a result, these will not be squandered but will be thrown into the environment. The sole of a shoe has been calculated and designed to have a life cycle of approximately a thousand years according to the chemicals and polymers that it consists of. However, as the soles are discarded, they are melted and reborn as new shoe raw materials **(Van et al.2020)**.

To overcome the problem of not being able to reuse or recycle shoes made traditionally, there is the possibility of constructing a shoe without using glueing materials and components, to be disassembled and restructured by the next user who wants to purchase a new shoe. This idea has been expressed by

companies that see shoes and feet from a broader perspective and, through a range of numbers and sizes and bearing extra parts, are selling just one pair of soles to meet the purchaser's design needs. This could be a significant step in the development of mass production. Other sustainable solutions include the use of natural materials, such as algae, for creating structures of the upper and sole parts of the shoe. Biodegradable materials, such as apple skin waste, also offer a necessary solution to the production of comfortable shoes using a management approach that offers the minimum environmental impact possible. Conference shoes can be used more efficiently. In the process of reshaping, people just need to replace the upper by changing the cover of the shoe and recombining it with the sole **(Pervez, 2022)**.

10. Conclusion and Future Directions

In conclusion, to reduce possible foot pressure and shear stresses that may lead to ulceration in diabetic patients, properly fitting shoes are particularly important. In footwear biomechanical research, most studies used insole plantar pressure to assess the effectiveness and safety of insole design for diabetic foot. This study adopts general shape features, which may contribute to high plantar pressure and shear stresses, to construct design specifications for proper footwear. If the suggested shape features are known, manufacturers can pay more attention to the shape design of footwear during the manufacturing process to lower the possibility of foot complications for diabetic patients. To enhance the comfort of diabetic shoes and promote patient compliance, the study also provides recommendations regarding the combined shank stiffness selection for different footwear conditions. In future work, a few possible directions can be examined for further verification. First, to enhance the reliability of shape feature measurement and foot biomechanics data, more trial subjects should be recruited. Second, since there were only eight shapes of footwear tested in the research, the variety of shoe designs might be potentially larger in the future. Finally, from another perspective, exploring the relationship between foot shape, plantar pressure, and shear stress may be a possible direction based on the data of various foot shapes and biomechanics information.

10.1. Summary of Key Findings

Morbidity and mortality in diabetes result from many different complications that can affect virtually every system. Diabetic peripheral neuropathy, a major risk factor, frequently leads to detrimental foot complications with important consequences. Footwear is one of the most decisive factors determining these complications. The ideal shoe is designed, especially for diabetic patients, handcrafted to mold to the patient's feet, ensuring that the interior of the upper does not produce pressure on the feet, and the sole is soft enough to avoid pressure under the feet and to accommodate the foot's plantar arch. Until now, no commercial shoe satisfies these design characteristics. However, taking these parameters into account, we have selected commercial shoes to make orthotic modifications to turn them into "ideal shoes." The footwear procedure proposed to prevent skin lesions or ulcers should be available to patients at a reasonable cost.

Foot ulceration, infection, osteomyelitis, gangrene, and surgical amputation are the most recognized severe foot complications that can be encountered in patients with diabetes. Long before the appearance of skin lesions or ulcers, diabetic feet develop complications, the most severe being diabetic peripheral sensory neuropathy. The shoe chosen by a patient with diabetic neuropathy is one of the most determining factors in developing foot lesions. However, there are only a few reports of these neuropathic alterations in foot modelling. In diabetes, peripheral sensory neuropathy is the first and most severe clinical characteristic among the three major types of diabetes neuropathy. The goal of this publication is to review the design characteristics of proper footwear to prevent skin lesions or ulcers and severe foot complications, which frequently have tragic consequences related to diabetic peripheral neuropathy.

10.2. Design Guideline for Diabetic Footwear

Footwear is the most meaningful extrinsic factor for diabetic patients to prevent diabetic complications like ulceration, and amputation, and to affect their comfort of gait. As a necessity for protecting the feet of diabetes patients, proper footwear should respect various design specifications to fulfil multiple goals: firstly, protecting the feet from damage, abrasion, and ulcerations; secondly, accommodating or relieving foot deformities or diseases; finally, enabling an ergonomic internal environment of the feet to produce satisfactory comfort while wearing. Although various prescription guidelines for prophylactic footwear have been established by diabetes care professionals, how to design a pair of proper footwear de novo is still a great challenge for footwear manufacturers. This section aims to provide some preliminary information concerning the footwear design specifications for preventing diabetic complications and enhancing wearable comfort. **(Menz2021)**

As a proliferation of definitions, this proposal respects that four important modifications should be considered to constitute therapeutic and comfortable benefits for diabetic patients: accommodated internal shape, selected material properties, required mechanical features, and optimum environmental conditions. Briefly, therapeutic prescription footwear must be characterized by footwear lasts with unique foot orthoses that impress and fit the grading of pedal deformities in diabetes patients, non-wrinkling stabilized exterior leather, softly sensitive lined interior material, longitudinal stiffness in the shank region, material characteristics that cushion, absorb and rebound shock, resist slipping accidents and infections, protect from sweaty uncomfortable feelings, and have acidic pH and bacteriostatic ability. Design-related guidance involving anatomical supports, midsoles of the shoes, outsoles with nonskid

properties, and protective footwear's interior materials is introduced in this section. **(Barbara and Horton2022)**

11. Recommendations

Foot care is an important issue for patients with diabetes. Foot complications are a significant public health problem for diabetes patients worldwide. The improper footwear of diabetes patients could lead to serious complications, such as ulcers, infections, and amputation. People with diabetes need to take extra care of their feet, endeavoring to prevent such complications. Therefore, the current study aimed to design footwear specifications for maintaining and restoring the foot in proper function and preventing foot complications in diabetes patients. The guidance objectives of this study include differential diagnosis and comprehensive knowledge of foot pathology, mechanical principles in the design, principles for weight-bearing protection and prevention of ulcers, as well as the fit, construction details, and material aspects known as therapeutic shoe concepts.

Foot and leg problems are serious complications in patients with diabetes. High plantar pressures during gait increase the risk of diabetic foot ulcers in diabetes patients. The improper underfoot pressure distribution while walking on a firm surface is associated with foot ulcer formation. Appropriate footwear can promote proper foot function and weight distribution, relieve pain while accommodating deformity, and help to prevent joint motion through support and motion control around the ankle and hind foot. The overall consideration for foot structure and footwear style should be for appropriate shoes that have extra width, depth, and length needed to accommodate deformity and protect the weight-bearing surface, foot padding, and callus formation. Therefore, our study emphasized particular design features specific to people with diabetes to protect their feet from complications and deformities. We recommend that extra-depth and extra-volume footwear be offered. Also, extra-depth and extra-volume footwear could provide a square or round-toe bed and lift an extra-depth shoe to insert for a good fit. In addition, extra-depth and extra-volume footwear could have extended soles and insoles for total foot contact of diabetic patients.

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