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Research Article

Biomechanical Solutions for Diabetic Foot Complications: Material and Design Approaches

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***Abstract*-**Many of the foot problems are concerns for diabetics, and even the mildest can lead to severe ones. The majority of diabetic patients have neuropathy, or damaged nerves, and in conjunction with other factors, this leads to foot problems. Peripheral artery disease and neuropathy are the products of active diabetes as a result of the summation of all the elaborated metabolic reactions. Coexistence of peripheral neuropathy, peripheral artery disease and ischemia might allow the possibility of foot ulcers. Diabetes mellitus is a hyperglycemic state due to abnormalities in insulin secretion and action and results in chronic hyperglycemia and metabolic changes. A multitude of physiological changes and interactions precede diabetic foot conditions. In diabetic foot syndrome, there exists clear evidence of significant threats regarding ulceration and amputation. New material research for orthotic insoles underlines the importance of material stiffness and pressure distribution properties. However, standardization of quantitative methods to determine suitable materials and design in diabetic neuropathy management is still lacking in the literature. In this review, the different studies on the mechanical compatibility of heel and insole are comparatively analyzed, considering their methodologies, used materials, and obtained results. This paper assembles various findings aimed at investigating optimum geometries of support and single material properties in personalized footwear design to enhance the quality of life of diabetic neuropathy patients. It also discusses some of the methodologies that can be employed in establishing ways of minimizing plantar pressure to avoid complications, such as finite element modeling and biomechanical tests.

Keywords – Diabetic Neuropathy, Orthotic Insoles, Foot Ulcers, Plantar Pressure Optimization, Finite Element Modeling.

I. INTRODUCTION

Diabetic neuropathy represents a significant complication for patients with diabetes mellitus, predominantly affecting the lower extremities. Approximately 6% of diabetic patients develop foot diseases that can lead to severe complications such as infection, ulceration, and tissue degeneration, which ultimately diminish the quality of life and limit social interactions and independence. In severe cases, the risk of amputation can range from 0.03% to 1.5% among diabetic patients, emphasizing the critical need for early intervention and proper foot care to prevent ulcer development [1]. The spectrum of foot problems associated with diabetes varies from mild sensory loss to severe outcomes like amputation, with diabetic neuropathy being a primary cause of foot complications [2]. Neuropathy generally affects the legs and feet first, causing a loss of feeling that could render injuries harder to detect until serious infections or skin deterioration occur [3]. Furthermore, circulation is hampered by diabetes-related vascular damage, which makes the healing of wounds even more difficult [1]. Peripheral artery disease (PAD) is another major consequence of diabetes that causes tissue ischemia by oppressively reducing blood force to the extremities. When neuropathy and PAD attend, there's a significant increased threat of developing foot ulcers. Untreated foot ulcers can lead to gangrene and need amputation [3]. Poorly selected shoes are considered a major risk factor for the development of foot ulcers since they may lead to excessive tissue damage in soft and skin owing to elevated pressure points [1]. Diabetic neuropathy can present in a plethora of ways; there may be muscle weakness, diminished reflex responses, discomfort, pricking sensations or hypersensitivity in the affected area, and balance and coordination problems [3]. Foot disorders associated with diabetes can aggravate due to such musculoskeletal deformities like pes cavus or claw toes. Diabetic neuropathy must be diagnosed early if the strategies for preventing the occurrence of ulcerations are to be implemented. This is predominantly done by conducting peripheral neuropathy and PAD clinical checks [1].

Osteoarthritis and lower limb skeletal abnormalities have a major impact on musculoskeletal gait problems, which can cause non-neurological walking deficits in grown-ups. These conditions frequently cause a restricted range of motion and challenges with bearing weight, which show up as symptoms like limping. In an attempt to reduce pain, patients commonly alter their stride patterns by transferring their weight away from the limb that is injured, which can worsen irregularities in gait [4,5]. In instance, osteoarthritis is a common disorder that causes long-term suffering and is typified by the deterioration of joint cartilage, which results in pain and reduced function [4,6]. A comprehensive understanding of mortal walking biomechanics necessitates a detailed kinetic analysis of muscle strength and activation patterns, particularly fastening on the tibialis anterior (TA) muscle, which is essential for maintaining dorsiflexion during gait [7]. Weakness in the TA muscle and limited ankle range of stir are common in people with diabetes mellitus. These findings are correlated with elevated blood pressure and soft tissue thickening, which together decrease joint mobility in a considerable fraction of patients with type 2 diabetes [8]. Also, balance and collaboration problems are common in people with diabetic supplemental neuropathy (DPN), a condition in which both motor and sensitive neuropathies seriously impair these abilities, increasing the likelihood of falls [8,9]. Cases with diabetic neuropathy experience significant biomechanical changes in their stride, especially with relation to foot kinetics and muscular collaboration, which can make ulceration more likely because of disabled dorsiflexion [8,10]. Studies on orthotic insoles have shown how important they're for treating diabetic foot problems. These insoles' severity and effective pressure distribution might greatly lower plantar pressure, reducing diabetes- related problems. There's still a lack of standardised procedures for choosing suitable insole materials and designs suited to the operation of diabetic neuropathy, despite the current understanding of the biomechanical risk factors for diabetic foot syndrome [11]. This emphasizes the need for additional research and standardization in the development of orthotic therapies intended to reduce the dangers related to the modified gait mechanics in individuals with diabetes.

This paper aims to compare and analyze several studies on heel and insole materials and geometries in pursuit of the best solutions, to improve the living conditions of patients with diabetic neuropathy. Further, certain methodologies, including finite element modeling and biomechanical testing, will be discussed that indicate the best options for minimum plantar pressure to prevent severe foot complications due to diabetic conditions.

II. MATERIALS AND METHOD

Both neuropathy and foot ulceration pose a significant challenge in the clinical management of diabetic patients as they induce a huge impact in combination. These are primary clinical objectives with clinical approaches divided into three: true prevention, intervention of footwear, and targeted care strategies. Among approaches that clinicians usually employ to minimize stress on the feet and decrease the risk development of ulcers, there are pressure offloading techniques, orthotic devices, and alterations of shoes worn. Of these, customized insoles are of utmost importance in achieving the objectives of pressure redistribution and comfort enhancement among diabetic patients. Such interventions are at times selected as per varying conditions of the patients such as the level of neuropathy, the amount of foot deformity, and the material characteristics used to give the maximum support and cushioning. This is going to be of importance in the evaluation, because these kinds of techniques tend to improve the outcomes of patients and their quality of life to a significant extent. The objective of this review therefore assesses the different approaches employed in the recent studies in order to understand better the contexts, the materials evaluated, and the conclusions attained aimed at establishing the practices preventing or treating diabetic foot disease complications [12].

Understanding how the diabetic foot works is an essential area of study, given the number of complications that occur such as foot ulcers and amputations among diabetic patients. The development of diabetic foot ulcers can be due to the presence of some neuropathic and ischemic factors, which in one way or another change the foot mechanics. Sustained pressure and constant stress increases the risk of ulcers because of a combination of neuropathy where protective sensation is decreased, and the patient often does not notice wounds and areas with excessive pressure [13]. It has been observed that the distribution of plantar pressure in subjects with diabetes is abnormal, resulting in susceptibility to ulcers as the pressure exerted on the tissues causes it to erode further on already neuropathic affected tissues [14]. Furthermore, the presence of foot deformities, such as Charcot foot, can exacerbate these biomechanical issues by redistributing weight unevenly across the foot, leading to increased localized pressure under specific areas, notably the metatarsal heads [15,16]. Tissue changes such as tissue stiffness changes or their redistribution to the foot centers, which is relatively common among many individuals with diabetes, will usually also help to detect even new foot problems evolving these hints that plantar soft tissue deformation will make today's days ulcer risk higher for the body [18,19]. Furthermore, relevant competent pediatrics reported that their patients successfully underwent customizable orthoses and tendon dragging that treated the structural factors of the diabetic foot and regained foot function with no subsequent ulceration [20]. The two aspects of these curatives which, in one of their definitions, may be rehabilitation addressed to the redistribution of plantar pressures and training addressed to the more normal gait pattern costs for the prevention of the reappearance of foot ulcers. Overall, understanding the biomechanics of the diabetic foot is crucial for developing effective preventive and therapeutic strategies to mitigate the risks associated with diabetic foot complications. The investigations encompassed within the various studies were performed using differing methods to assess the biomechanical characteristics of insoles and how well they address diabetic foot problems. The compressive stress of the Ethylene Vinyl Acetate (EVA) materials used in diabetic shoes was specifically examined by Ghazali et al. (2021) using the Finite Element Method (FEM) and a randomized controlled trial strategy in order to potentially relieve plantar pressure [21,36]. The authors also created two different foot models in detail: the Whole Foot Model (WFM) and the Skeletal Structure Model (SSM) Figure 1(a). Because of the skeletal components added in SSM, successful pressure distributions across the foot were made during the simulations since patients who are at risk of developing ulcers require such information. The research results suggested that using EVA insoles helped reduce plantar pressures, and the research forwarded worked out a model considering various weights of patients for advisable insole thickness as well; these contributed to devising cheaper diabetic shoe manufacturing processes [22].

Nouman et al. (2022) aimed at evaluating parameters influencing plantar pressure in the diabetic neuropathic foot using a validated Finite Element Analysis (FEA). This study focused on creating a 3D model of a left foot with no load as scanned through CT, paying special attention to advanced segmentation of the bones and the soft tissues for accurate anatomy. Another innovative element in this study was the engineering of a three-layered cushioning material interface (CMI) Figure 1(b) with EVA, Nora® Lunalastike, and TPU materials. This stack was to alleviate peak plantar pressure by assessment of differential pad configurations because of the needs of patients suffering from nerve problems [23,35].

Unlike the first two studies, Nouman et al. (2021) sought to understand the implications of different custom-made insole materials on plantar pressure alleviation as well as on frictional stress in the diabetic neuropathic foot. This study also used a 3D finite element model but aimed to simplify the analysis by merging the 26 bones of the foot into one body Figure 1(c) . Peak contact pressure and friction stresses were used to assess the performance of two different types of bespoke insoles that were made: single-layer and two-layer insoles. The study made it possible to compare softer and harder materials, demonstrating the significance of material qualities for the successful prevention of issues related to diabetic foot. It also indicated that, in light of the many clinical issues that have been observed, customized methods to diabetes management are required [24,27].

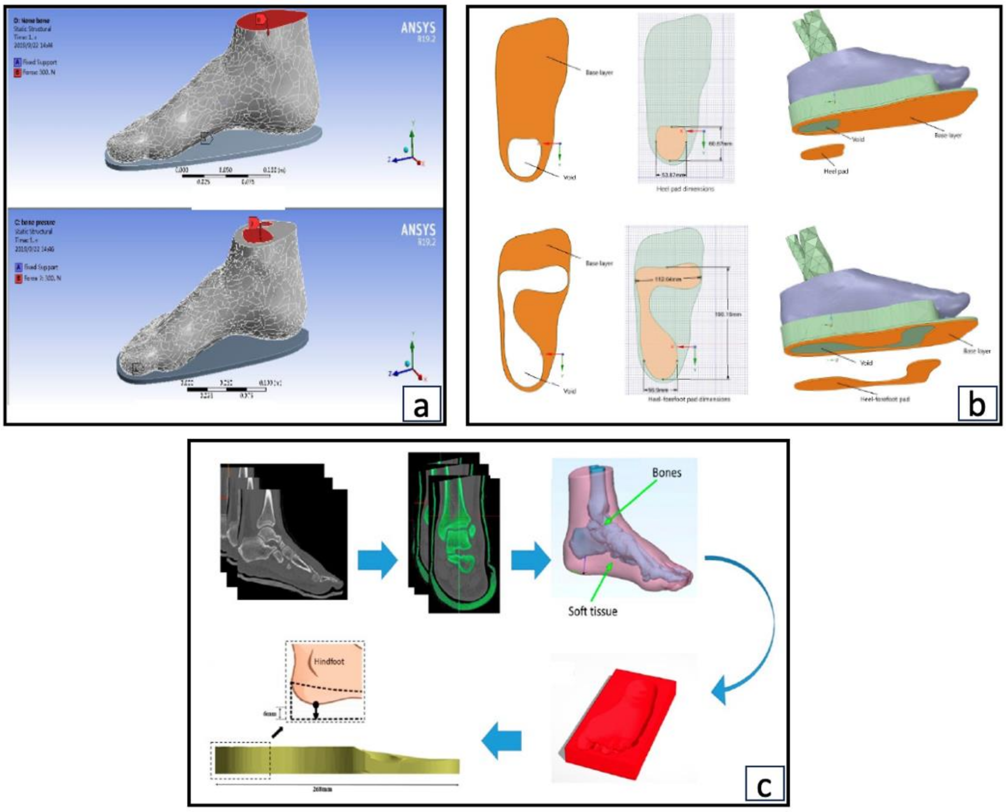

Figure 1. (a) Loading definition of FEA model of the whole model (WM) and the skeletal structure foot model (SSM) [36] ,(b) The heel pad and heel–forefoot pad added to the base layer [35] ,(c) Finite element model generation through various steps including the computerized tomography (CT) scan images of foot, processed CT images with segmentation, reconstructed foot model with bones and soft tissue, subtracted foot from box to construct a custom-made insole (CMI) and CMI dimensions following the foot morphology and length [27].

III. RESULTS

A number of insole designs and materials have been investigated in the management of applied plantar pressures in diabetic individuals. Several studies have been done regarding the comparison of such studies and their findings. Ghazali et al. (2021) demonstrated that these modified EVA insoles could decrease the plantar pressure by using WM and SSM techniques [25,36]. A computer model designing an appropriate shoe and mathematical modeling that gives optimal insole thickness with respect to patient's weight is crucial in shoe manufacturing technology [26]. The application of the validated finite element analysis (FEA) technique as demonstrated by Nouman et al. (2022) in assessing the ability of the three-layer cushioning material interface (CMI) to relieve plantar pressure while performing various tasks [35]. A combination of different materials such as TPU, Nora® Lunalastike and EVA was the pressure distribution behavior with the appropriate combination of materials. This study also demonstrated that material attributes directly or indirectly relate to diabetic foot biomechanics and that designs can help address conditions faced by patients with neuropathy [28]. Nouman et al. (2021) advanced knowledge of custom-made insoles by testing two different types of insole designs for reducing peak contact pressure and frictional stress: a single-layer and a two-layer insole. The results indicated that elastomeric materials and polymeric materials, in general, present certain risks of reducing contact stresses too effectively [29,27]. However, there was a shortcoming because only one subject was used, limiting the generalizability of these results; thus, more research involving multiple subjects is needed to confirm such findings across other patient populations [30].

IV. DISCUSSION

Despite the fact that all the studies in question brought something new to the context of diabetic footwear interventions, they also had significant drawbacks that should be considered. Ghazali et al. (2021) utilized computer modeling, which raises doubts about whether the results can be implemented in real life [27,36]. The complications arising from dealing with actual shoes and variations among patients can hardly, if at all, be represented by a finite element model, pointing to the fact that any subsequent research should involve some fieldwork [31]. Nouman et al. (2022) reduced the properties of soft tissues and insoles to linear elasticity, which is limited to quasi-static approximations and fails to accurately incorporate dynamic walking, is a major drawback of the study [32,35]. It may limit the generalizability of the results to the entire diabetic population. Other limitations pertain to the 'ideal' standing position that the subject maintains and within which only one foot model is utilized, potentially leading to biased measures on the performance of the cushioning materials. On similar lines, the findings of Nouman et al. (2021) are limited to one subject and hence cannot be generalized. The foot was modeled in a way that did not take into account the actual anatomical arrangement of the foot muscles, which may have been essential to its functions. Such a limitation points out the necessity for a larger research sample and a more accurate model of anatomical features for future studies [28,27]. The study by Wawro et al. (2021) demonstrated that custom orthotics significantly improved gait parameters in patients with diabetic neuropathy, particularly in terms of walking speed and stride length, thereby enhancing overall mobility and quality of life for these individuals [33]. Meanwhile, Gupta and Thakur (2024) highlighted advancements in technology for monitoring plantar pressure, which is crucial for assessing the effectiveness of orthotic interventions and ensuring optimal foot health in diabetic patients. These studies highlight the importance of customized solutions and innovative monitoring technologies in terms of managing diabetic neuropathy and improving patient satisfaction [34].

V. CONCLUSION

Restrictions enumerated in these studies can be removed through advanced statistical modeling and a more representative sample of those with diabetes in the future. This expansive understanding of diabetic footwear interventions will be beneficial for clinical application as well as for the creation of particular strategies addressing the specific concerns of the diabetic population aimed at decreasing the occurrence of foot ulcerations and complications thereof.

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