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Review Article

Review of Foot Plantar Pressure—Focus on the Development of Foot Ulcerations

Jessica DeBerardinis[1], Mohamed Trabia[1], Janet S. Dufek[2]

[1] *Mechanical Engineering, University of Nevada, Las Vegas, 4505 S. Maryland Parkway, Las Vegas, NV 89154, USA*
[2] *Kinesiology and Nutrition Sciences, University of Nevada, Las Vegas, 4505 S. Maryland Parkway, Las Vegas, NV 89154, USA*

Corresponding Author: Jessica DeBerardinis; email: deberj1@unlv.nevada.edu

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Abstract. There are many causes of plantar ulceration, which is a painful sore that occurs in the plantar tissue, common in cases of diabetes, peripheral arterial disease, obesity, and even high cholesterol. By way of perspective, approximately 15% of over 29.1 million diabetics in the U.S. will develop foot ulceration [1] and [2]. These causes could be diagnosed using multiple methods with reasonable accuracy; however, ulcers will still occur due to trauma to the plantar tissue. Measurement of the pressures within the plantar tissue has been suggested to be a suitable surrogate to the measurement of trauma; thus, many methods have been developed to measure the pressures and stresses in the plantar tissue. These methods – which include pressure mats, force platforms combined with fluoroscopy or footprint analysis as well as finite element modeling – describe the pressures and stresses that occur within the foot; however, they are limited in their analysis. The limitations include analysis of only the stance phase of gait, measurement of compression stress, and analysis of only healthy individuals. Further studies will be needed to meet the goal of measuring stress within plantar tissues from compression and shear forces during all phases of gait, and using the results to diagnose plantar ulcerations.

Keywords: diabetic ulcer; diagnoses; pressure; stress; gait

1. Introduction

The development of foot ulcerations could be attributed to multiple factors such as diabetic neuropathy, abnormal blood flow, changes in the mechanical properties of the plantar tissue, and structural deformities. Diabetic neuropathy, which is a nerve disorder that causes a loss of feeling, has been universally acknowledged as the most prominent contributing factor [3]. Neuropathy is triggered by several mechanisms, such as the inhibition of nitric oxide, which causes elevated levels of reactive oxygen; potentially, this could cause atherogenesis, which occurs when plaques form in the blood vessels that supply the nerves [3]. Another mechanism that has shown to contribute to neuropathy is the Maillard reaction, where diabetes and aging result in elevated levels of advanced glycation end products [3]. These and other causes, combined, could create a decrease in the myelinated fiber density [4] or, simply stated, a decrease in the nerve density.

Abnormal blood flow to the foot also can be a potential cause of ulceration. It has been discovered that abnormal blood flow could lead to atherosclerotic occlusion [5], an enlargement of the arteries that supply the foot that causes the blood pressure to drop in the foot. A blood-pressure drop normally would cause pain; however, neuropathic patients cannot feel the pain. In addition, it often causes gangrene, causing any potential wound to become infected and to ulcerate [5]. Another problem regarding abnormal blood flow that is common with diabetic patients is arterial wall calcification [3], which reduces the blood reaching the foot, affecting the blood pressure. If an ulcer has started to develop, the calcified arteries are not able to provide the appropriate nutrients to heal the ulcer [3].

In addition to the loss of sensory feedback due to neuropathy, the progression of diabetes alters the mechanical characteristics of the plantar tissue, which may contribute to ulceration. Healthy plantar tissues are soft, which enables them to dissipate pressure that occurs during walking, thus, maintain a relatively uniform pressure throughout the plantar tissue. However, diabetes has been shown to cause stiffer, harder, and thinner plantar tissues [6]. These changes can lead to the creation of abnormal pressure points in the plantar tissue, which in turn may produce an increased probability of trauma due to ulceration of the plantar tissue. Healthy individuals with intact plantar sensation can adjust their gait patterns to prevent injury to the foot, which could occur from abnormally high pressures [7]. Since diabetic patients with neuropathy lose the protective plantar sensation, the patients are unable to sense areas of high pressure or “hot spots.” Therefore, there is no feedback loop to alert the patients of the need to adjust their gait or notify a patient that a change of footwear or walking surface is necessary to prevent the onset of trauma [4].

Further, structural deformities of the foot can lead to ulcerations. These abnormalities can include calluses, abnormal bony structures, hammertoe, or other aberrations to typical foot anatomy. Structural deformities have shown to contribute to the elevated plantar pressure measured in diabetic feet [4, 8]. Mueller et al., found that structural deformities, especially hammertoe deformities, could be used to predict elevated plantar pressures [8]. In addition, calluses are known to cause friction as well as elevated levels of pressure on the foot. In an investigation of diabetic patients ($n = 17$) with calluses, Young et al. demonstrated that removal of the callus could reduce plantar pressure by an average of 26% [9]. In Young’s study, all of the calluses were located below the metatarsal heads.

2. Literature Review

2.1. Current methods to diagnose and prevent diabetic ulcers. A literature search was conducted to determine current procedures and their effectiveness at preventing ulceration. As discussed previously, there are many potential causes of diabetic ulcers. In order to prevent ulcers from occurring, one must consider all potential causes.

Singh, Armstrong, and Lipsky described a method for determining risk and the subsequent preventative steps [10]. They stated that a patient who had diabetic ulcers in the past had a greater risk for further ulceration. In addition, patients were at a greater risk for ulceration that had poor glycemic control, were smokers, or had impaired vision. After assessing the risk level of the patient to develop diabetic ulcers, the authors described several methods that can be used to prevent ulceration. First, the patient would be educated about the condition, and about foot care. As part of this process, the authors stated that the physician typically would prescribe a therapy to prevent the ulcers from occurring. Therapy often included daily foot inspection by the patient, a cleansing and moisturizing regimen, and use of an orthotic. The orthotic was designed to support the foot to prevent high pressures and trauma as well as to wick away the exudate if an ulcer occurred. The patient was encouraged to have a yearly foot examination, or as often as the physician deemed necessary, to reassess the risk of ulceration. In some cases, treatments that are more serious might be prescribed, such as surgery for revascularization or prophylactic reasons.

Neuropathy is a significant contributor to ulceration and, thus, a patient is at a higher risk for ulcers if diagnosed with neuropathy. Various instruments and procedures could be used to test for neuropathy. The most common clinical procedure is the nylon monofilament test, during which a nylon filament structure is pressed into the patient’s foot at multiple sites with enough pressure to bend the filament [10]. If the patient cannot feel the monofilament when applied to the foot at one or several sites, this is associated with neuropathy. This test has a significance dependent upon the number of sites with compromised tactile sense [10]. A biothesiometer, a device that assesses the patient’s perception of vibration, is applied to the toe and the vibration amplitude increased until the patient can detect the vibration. If the patient cannot feel the vibration up to 25 V, it is likely the patient has neuropathy [10]. In a similar vibration test, a tuning fork is used; however, this method is known to be less predictive [10].

To diagnose abnormal blood flow, a pulse palpation usually is performed first. If a pulse can be palpated in both feet, that can rule out significant arterial disease. However, it is not a highly reproducible method, so it cannot be fully trusted to diagnose impaired perfusion within the diabetic foot [11]. Other noninvasive vascular tests, including the ankle-brachial index (ABI) and toe systolic pressure, are used to dispel any uncertainty that results from palpation. However, the ABI test has been known to show ‘normal’ when calcification has caused significant impaired perfusion; moreover, toe pressure is problematic in gangrenous patients or where the toe is missing [12]. Another common noninvasive test used is the transcutaneous oxygen pressure test, which can help identify tissue lesions that may be able to help healing with a more conservative treatment. Nonetheless, this test has shown to be questionable [12]. These tests can be combined, and can suggest whether there is a significant abnormal blood flow, thus suggest if an ulcer may or may not heal; even so, each kind of test has limitations. To address these limitations, a vascular imaging method has been developed by which a systematic angiographic classification is performed. However, this method has not gained large clinical acceptance due to a lack of sufficient validation [12].

A patient must be examined for the risk of ulceration from structural abnormality; this is achieved by examining the pressure on the plantar tissue for both bare feet and in footwear. Devices are available, such as shoe insoles and platforms, to measure the pressure; often, these are expensive and not clinically feasible.

As discussed previously, diagnosis for ulceration risk can be expensive and problematic. To address these concerns, new diagnostic methods have been developed to help diagnose the risk of ulceration. One of the methods is a sweat indicator that can test for diabetic neuropathy [13]. Neuropathic feet tend to sweat less, and the tissue becomes dry. The sweat indicator can measure tissue moisture and, by means of a color change, indicate if neuropathy exists [13]. This test has shown to have a high sensitivity and excellent reproducibility; currently, however, this test is being evaluated regarding its ability to detect early diabetic neuropathy and to predict foot ulceration [13].

Another method recently developed to diagnose neuropathy utilizes a computer system to analyze the thermal response of the feet to a cold stimulus [14]. The response is measured, and abnormalities are associated with problematic areas of the foot. Although promising, this method has yet to be tested clinically, and needs to be refined [14]. A similar method utilizes thermography to obtain thermal images of the foot to assess for inflammation; these images were taken of the feet and analyzed for abnormal temperatures, which were correlated with a risk of ulceration [15]. The conclusions drawn from these thermal images were compared to clinical assessments, and with later follow-up measurements. The research, which is only at the initial stages and has yet to be tested clinically, needs to be refined.

A new method has been developed, termed hyperspectral imaging [16]. This imaging technique obtains spectral data of a measured area and renders it into an image that can provide precision color information. This color information can be analyzed for changes or blemishes within the plantar tissue, which could provide a noncontact and noninvasive tool to detect and classify the pre-signs of ulceration [16]. Liu et al. utilized a statistical method to develop a spectral imaging system that could work with the diabetic foot [16]. Results suggested that the application of a limited number of optical filters could discriminate between signs of ulceration and healthy skin spots with an exceptional specificity and sensitivity (specificity = 96%, sensitivity = 97%) [16]. However, this study used a small dataset, therefore, was not conducted during a live assessment. These limitations must be addressed before this method can be clinically accepted.

2.2. Current methods to measure plantar pressure. Despite the many diagnostic methods and preventive measures, diabetic ulcers still occur. While neuropathy, abnormal blood flow, and structural deformities predispose a diabetic patient for foot ulceration, these do not directly cause ulcers. Ulcerations occur when a trauma on the foot has occurred; thus, it would be beneficial to predict the location of future plantar trauma. In order to do this, it may be useful to focus on measuring plantar pressure, which has been extensively studied, because it is considered to be the "surrogate measure of trauma…and to be important contributing factors to skin breakdown," in diabetic patients [17].

Currently, footwear and off-loading devices are used to alleviate elevated plantar pressures in order to help treat diabetic foot ulcers. These devices include removable casts and specially designed shoes. However, these interventions are typically invoked only after an ulcer has already developed or if there is a history of ulceration [18, 19]. Thus, there is a need to understand the effects of plantar pressure and its relationship to ulceration. Such information may be helpful in the prediction and ultimate prevention or reduction in ulceration development. Most of the research in this area aims to link plantar pressure to deformation or time in order to describe the stress and work exerted on the foot tissue.

Researchers have used a variety of methods to measure the pressure, deformation, and stress of the plantar tissues. There exist a large number of combinations of types of measurements and the methods used to measure plantar pressure. In the following sections, the literature on these methods is reviewed, and the clinical and/or research efficacy is described.

a. Pressure Platforms and Mats. Pressure platforms are electronic devices that can provide a direct quantitative measure of plantar pressure. Armstrong et al. used a platform to measure peak plantar pressures using a mid-gait method to determine if there was a threshold that could predict diabetic ulcerations [20]. A mid-gait method is one where the data was collected while the subject was in mid-stance of the support phase of gait. The subjects in the study had to have a history of ulcers, with the controls being diabetic patients who never had foot ulceration. Control ($n = 149$) and ulcerated ($n = 70$) participants walked across an EMED® pressure platform, and peak plantar pressure was measured at mid-stance of the support phase. Results indicated that the peak plantar pressure values were significantly higher for the ulcer group in comparison to the controls. A receiver operating characteristic (ROC) analysis was used to examine the specificity and sensitivity of a test's ability to predict a specific result, and the optimal point where sensitivity and specificity was optimized. This analysis found that the optimal cut-point to discriminate between the two groups was 70 N/cm^2 of plantar pressure.

The study conducted by Armstrong et al. did not consider the deformation of the foot tissue, which may allow further predictive ability of where trauma could occur. To address this concern, Wearing et al. examined both the pressure and the deformation of the foot [21]. In this work, the sample consisted of 16 healthy adults; the sample size was small because this work was a proof-of-concept study. A mid-gait, barefoot protocol was used to collect the data from both a fluoroscopic device and pressure measured with an EMED® pressure mat. They found that the 21stiffness of the heel pad at initial heel strike was a magnitude lower than the final stiffness of the heel at the support phase of stance [21]. Moreover, it was discovered that the peak of deformation was close to the subject's limit for pain tolerance [21].

Other researchers have used pressure platforms to attempt to classify foot structures that cause increased plantar pressure. As pressure platforms can be expensive, these could be clinically infeasible and potentially time consuming. Thus, the ability to correlate certain foot structures to increased pressure could indicate that a simple foot examination could help predict the occurrence of ulcers. Mueller et al. used a pressure platform in conjunction with structural variable classification to determine if certain foot structures lead to increased plantar pressure [8]. These structural variables included hammer toe, calcaneal inclination, and toe out, which were measured utilizing a spiral x-ray system. The pressure was measured with an F-Scan® system, which allowed for individual, foot-shaped, thin, pressure-sensitive insoles to be attached to the foot. The authors found that hammertoe was the most important predictive variable for forefoot plantar pressure, and theorized that if these structural variables can be evaluated and corrected, this may help prevent ulceration [8].

Waldecker attempted to correlate structures within the foot to pressure by using a group of 210 patients, both diabetic and non-diabetic. These patients were divided into groups based on the primary deformity, such as bunions or other structural deformities [22]. These groups were asked to walk over a pressure platform to measure the force and peak pressure. The time integrals for force and pressure during the support phase were calculated. Results suggested that no pressure threshold distinction between the diabetic patients and the non-diabetic patients existed, which is in contrast to the study done by Mueller, et al. [8].

b. Force Platforms Combined with Visualization Techniques. Pressure mats or platforms are incapable of measuring the deformation, which is a parameter that may help locate where trauma could occur. Force platforms, which are electronic devices that measure orthogonal force exerted on their surfaces, have been combined with visualization techniques to acquire deformation information. These often are combined with various imaging techniques to determine the pressure and deformation on the foot.

Gefen et al. measured the vertical deformation of the human heel pad by utilizing fluoroscopy while measuring the force exerted by the foot with a force platform. This work examined two female subjects using a mid-gait protocol [23]; results suggested that the heel undergoes a rapid compression at heel strike and exhibits a non-linear stress-strain relationship throughout the support phase. However, this protocol only measured compression, and did not evaluate shear stress. Subsequently, these researchers developed a system that utilized inputs from fluoroscopy measurements, and integrated those measurements into a pressure measurement system [24]. This system was able to provide compression, tension, shear, and von Mises stresses, the latter of which is the combination of the three principle stresses in the x, y, and z planes.

In a second proof-of-concept study, Gefen et al. used six healthy subjects and 10 diabetic patients who were not matched for age, body mass, or body mass index [24]. These subjects walked across a pressure-measuring device developed by the researchers, and the results were compared to those obtained from a commercially available Pedar® insole system. The results showed that the device was capable of measuring plantar pressures and calculating stresses similar to Pedar® during walking and other environments [24]. However, further clinical and verification tests have yet to be done.

Again, similar to the pressure platforms, force platforms can be costly; therefore, another, less expensive measurement procedure used in conjunction with a force platform is a footprint evaluation. Footprints can be used to measure the area of the plantar tissue contacting the ground. Older methods, such as ink mat and paper pedography, only could measure the area at mid-stance (full weight bearing) with limited accuracy. The new electronic pedography is able to measure the footprint of mid-stance with accuracy [25]. Fascione et al. used footprints in their study to help determine the differences in inter-individual loading variability [26]. Thirty subjects walked across an electronic pedography system that measured both the force and the footprints of each individual. They found that an increase in the footprint area seemed to be associated with an increase in loading along with other kinetic variables [26]. This research into footprint analysis has yet to be used in diabetic studies, thus, may only have a limited application.

c. Tissue Specimen Analysis. A common problem seen in *in vivo analysis,* such as studies using force/pressure platforms and imaging techniques, is that it can be difficult to measure the pressure and stress of the tissue below the surface of the skin. Thus, *ex vivo* analysis often is conducted on dissected tissue specimens to determine what pressures and stresses are possible in living, sub-surface tissue. Ledoux performed an *ex vivo* study on plantar tissue to examine the shear properties of the tissue [27]. In this study, specimens were taken from frozen cadavers of older people, four from diabetic feet and five from non-diabetic feet. These tissues were subjected to a static compressive strain to mimic combined loading patterns *in vivo*. The specimens then were subjected to shear strains at varying loads. The authors found that diabetic tissue does create a change in the shear mechanical properties of the tissue; most notably, diabetes causes stiffer plantar tissue [27].

However, there is some concern that subjecting the tissue to compression tests before testing the shear properties of that tissue may change the results, in comparison to only testing the shear properties of a tissue. Thus, a study by Pai et al. was conducted where four pairs of tissue specimens collected from diabetic patients were tested, half with compression and then by shear testing; the other half was tested with only shear testing [28]. The results showed that peak pressure and stiffness were greater in specimens that were not subjected to compression testing. More studies need to be conducted to determine the *ex vivo* shear properties of tissue separate from compression testing [28].

d. Finite Element Analysis. Often, it is difficult to conduct research, both *in vivo* and *ex vivo*, on human subjects due to cost, variability, and resources. Thus, modeling often is used in the place of human research, as it is possible to conduct tests in a relatively small amount of time at a reduced cost. A popular modeling tool is the finite element analysis (FEA), in which images and scans – often obtained from previous human subject testing or a database of human models – are turned into a three-dimensional mathematical model built out of small, finite elements. By incorporating the tissue material models, simulations could be developed. Individual elements could be programmed to report pressure, stress, and other parametric values at specific locations on the structure.

Gu et al. utilized FEA to model the rear foot, which incorporated a separate heel skin layer [29]. The model, developed using subject medical images, was used to study the deformation and plantar pressure during heel strike. The authors compared the results of the model to an indentation test performed on the subject. They found that the model had a good agreement with the results measured *in vivo.* This finding established that the model had appropriate properties, and the model could be used to draw conclusions about the heel skin properties. With this model, they discovered that increased skin stiffness had limited effects on the stress and pressure on the heel bones, while decreasing the skin stiffness caused a measurable decrease in peak plantar pressure [29]. It has been suggested that decreased skin stiffness could actually cause higher stress levels in the bones of the heel.

Gu et al. only analyzed the heel properties, however. Fernandez et al. developed an FEA to study the effect of tissue stiffening on plantar pressure and von Mises stress for the entire foot [30]. They used the Visible Human Database [31] to create a finite element model that was customized to a subject. Then, gait experiments were performed using human subjects, and data was collected on kinematics, kinetics, and foot pressure. This data was compared to the FEA simulated for the gait cycle. They found that the internal stress could be up to 1.6 times the surface pressure, suggesting that trauma caused by pressure may not be visible at the surface [30].

3. Discussion

Plantar pressure in general and more specifically peak plantar pressure have been extensively studied as the surrogate measure of trauma in diabetic patients with peripheral neuropathy [17, 32–34]. Much of the research in this area aims to link plantar pressure to deformation or time in order to describe the stress and work exerted on the foot tissue. This paper presented a variety of techniques to measure the pressure, deformation, or stress of the plantar tissues by attempting to describe how pressure or stress affects the plantar tissue, and at what tolerance levels these variables must be at to initiate ulceration development.

The current methods have limitations, however. Studies that utilized pressure mats suffered from the limited ability to analyze the plantar deformation resulting from foot compression; therefore, they were unable to fully describe the stresses the plantar tissue experiences. In attempt to address this shortcoming, visualization techniques, such as fluoroscopy and foot print analysis, were used to measure both compression and shear deformation.

Researchers have yet to study subjects who suffer from diseases as diabetes or peripheral arterial disease that can change the mechanical properties of the plantar tissue. Efforts have been made to characterize the tissue utilizing *in vitro* plantar tissue specimens; nonetheless, these are few in number, and it is difficult to validate and replicate the results. Additionally, characteristics measured *ex vivo* specimens may differ from what can be measured in the plantar tissues, *in vivo*, for a fully intact human foot. Finite element analysis has been used to model compression and shear stresses in the foot. Yet, these methods are limited by the data available as model input, and may not be able to accurately model the variations associated with a diseased state. Furthermore, a dynamic study has yet to be conducted that analyzes the plantar tissue stresses during the full footstep, including heel strike, stance, and toe-off phases.

4. Conclusion

In summary, further research is warranted that concurrently measures the pressure exerted during gait, the deformation when the foot contacts the surface, and the internal shear stresses. In addition, examination of large samples of healthy individuals as well as individuals, with and without neuropathy, will augment our understanding the onset and progression of plantar ulcerations.

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