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DIABETIC FOOT CONSIDERATIONS RELATED TO PLANTAR PRESSURES AND SHEAR

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Keywords

Diabetes; shear and pressure; instrumentation; skin ulceration; Charcot neuroarthropathy

1. Clinical Significance of Diabetic Foot Ulceration

Diabetic foot ulcers (DFU) are one of the most common complications to diabetes mellitus. Globally, the annual incidence of diabetic foot ulcers is 9.1 – 26.1 million, with 15–25% of people with diabetes developing a foot ulcer within their lifetime.[1] The most common complication of foot ulceration is infection/and or amputation, with over 50% of ulcers becoming infectious. [1,2] Once the ulcer has formed, approximately 20% of moderate to severe ulcer cases require amputation.[2] In assessing the mortality rates for foot ulceration and diabetes-related foot amputations, after 5 years the mortality rate of DFU is about 30% and increases to about 50 to 70% after amputation. [2,3] A compounding issue for the clinician is the reoccurrence of DFU once they've healed. Within 1 year post healing, patients have a 40% risk of DFU reoccurrence. This risk increases to 60% within 3 years and 65% within 5 years. [4] The factors that increase the risk of ulcer reoccurrence include but are not limited to: a hemoglobin A1C value above 7.5, presence of osteomyelitis, and a geriatric depression scale score greater than or equal to 10 (Figure 1).[2]

As evidenced by the statistics above, DFU is a significant issue in health care settings as well as to patient wellbeing and clinical outcomes. The etiology of DFU is multifaceted (Figure 1) and stems from prolonged periods of poor glycemic control (Figure 2).[5,6,7,8,9] It has been well documented that poor glycemic control results in the disruption and dysregulation of the motor, sensory, and autonomic nervous systems resulting in peripheral neuropathy as well as cardiovascular disruptions. [2,10,11] Peripheral Arterial and/or Vascular Disease (PAD and PVD) are compounding risk factors that aid in the development of DFUs. Approximately 10–20% of people with diabetes will develop peripheral arterial disease. [12] PAD causes damage to blood vessels including, atherosclerotic blockages, increased thickness of capillary basement membranes, and arteriolar wall hardening.[13] This vessel

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damage restricts the blood flow through vessels, which decreases overall circulation through body tissues.

Peripheral neuropathy has been demonstrated to disrupt normal gait, causing unsteadiness, gait abnormalities, and pressure distribution changes. [10,14–18] In addition to gait disturbances, peripheral neuropathy also impacts the skin integrity. These disruptions include increased skin dryness, which increases the likelihood of skin breakage, decreased skin integrity as a whole, and decreased muscle-tone which alters the surface area of the foot and disrupts normal load distributions.[13]

There has been a well-established relationship between high pressure distributions under the foot (greater than 6 kg/cm^2 or 588.4 kPa) and the development of diabetic foot ulcers.[19,20] Periods of high pressure or prolonged applied pressure damage the tissues on and under the applied pressure as they do not allow blood vessels to replenish the nutrients to maintain healthy tissue. Additionally, the decreased circulation from neuropathy and diabetes will further restrict the body's ability to replenish required nutrients. This creates further damage through tissue ischemia and results in pressure ulcers that will not heal.[21] In fact, peripheral ischemia in branching blood vessels leads to ulceration at a case rate of 35%.[13]

However, areas of high pressure are not always indicative of pressure ulcer development in the feet. In fact, only 30% of ulcer locations correlate with peak pressure areas under the foot. [22] Shear is another biomechanical parameter that has assisted in identifying the cause of DFU in areas of the foot. Shear significantly decreases the required applied pressure to cause tissue ischemia.[21] In physics, there is rarely a case where there is an applied pressure force and not some sort of applied shear force (Figure 3).

Current clinical guidelines for DFU treatment include wound debridement, dressings, off-loading and glycemic control.[23] However, these treatments are successful when the foot is offloaded sufficiently, and the ulcer diagnosed early. When utilizing pressure measurements to assist in the assessment of the correct offloading footwear, the offloading capacity of the footwear is increased and the risk for re-ulceration decreases by 46–65%. [24] Bus *et al.* demonstrated that when footwear treatment for DFU is designed according to pressure measurements (in this case decreasing the peak pressure experienced in the foot by 20%), patients saw a decrease in the rate of ulcer reoccurrence when compared to treatments not specifically designed through pressure measurement.[25] The caveat here is that patients must adhere to the prescribed wear time of the footwear. Similarly, Ulbrecht *et al.* demonstrated that treatment orthoses developed based on foot shape and barefoot plantar pressure, decrease the reoccurrence rate of diabetic foot ulcers.[26]

2. Shear versus pressure.

Pressure and shear measurements undoubtedly play an important role in the prevention of diabetic foot ulcers (Figure 3). From a simplistic standpoint, pressure patterns under the foot are considerably easier to measure and interpret. Both patients and clinicians can appreciate the concept of high plantar pressure. Interpretations of shear, or frictional forces are considerably more challenging. For example, it may be common to think that pressure and shear are simply related by the coefficient of friction, yet, for patients stepping on a pressure platform, pressure and shear are almost never related to each other [27]. In fact, shear can often be zero at the point where pressure is highest (Figure 3). Visualizing pressure may be straightforward (Figure 4A). However, trying to determine what leads to a particular shear pattern (Figure 4B) requires combining influences of foot twisting, sliding and frictional differences across multiple sensors. Finally, shear can occur in multiple planes, including the sagittal and frontal planes. The current focus is on plantar pressure and shear. It is possible that downward movement of metatarsal heads relative to tissue interspersed between these structures could lead to vertical shearing that in turn could attenuate blood supply to vulnerable tissues (Figure 5).

While the emphasis has generally been on the magnitudes and locations of peak stresses, the *ratio* of pressures and shear magnitudes is also altered in patients with diabetic neuropathy. This may be indicative of future ulcer development. [28, 29] In considering shear on the plantar surface of the foot, Davis [30] referred to the “wrinkled carpet effect”. While simplistic, the concept illustrates the challenge of combining shear and pressure data. Pressure values can be considered alone – as evidenced by hundreds of publications on pressure thresholds, locations, and integrals over the gait cycle. All that is needed are pressure values at each location under the foot. These data lead to the common graphic (Figure 2A) depicting “hills and valleys” of pressure information. When shear data are included, the situation becomes more complicated, much like the scenario that leads to a wrinkled carpet! In this case, it is not only pressure that needs to be considered, but also shear, *at locations other than where pressure is being monitored*. A carpet becomes wrinkled when there is a combination of high pressure (due to the leg of a table) and some horizontal force at a different location that causes a portion of the carpet to slide. Naturally, there are multiple places where horizontal forces can be high, which means that for 100 pressure measurements, with each one being paired with shear measurements in anterior, posterior, medial and lateral directions, 400 shear/pressure ratios may need to be analyzed. If one then adds the possibility that a foot is twisting about a vertical axis during stance, then the options for determining risk of skin damage increase even further. To the authors’ knowledge, there have not been any studies examining these combinatorial loading scenarios and ulcer risk.

3. History of the plantar pressure and shear measurements as related to ulcers

Given the weak correlation between peak pressure and ulcer location [10,31], it is believed that some form of shear (possibly coupled with pressure), is likely to contribute to ulceration [32–34]. Prior to 2000, few researchers investigated skin shearing due to the difficulty in constructing devices capable of measuring frictional forces [35–37]. Most devices were uni-directional, leading to underestimates of true shearing stresses [38–42]. In the early 1990’s, Lord and colleagues [43] developed a bi-directional sensor that could be placed in an inlay to permit in-shoe measurement. One limitation of this form of discrete sensor is that prior knowledge is required about the areas of interest in order to determine its placement (e.g., under a metatarsal head). As a result, areas experiencing high stresses may remain undetected if they do not coincide with the areas of interest determined *a priori*.

Additionally, in the 1990's, Huo and Nicol [44] reported on the development of a 3-D force distribution measurement system using strain gauge technology. The device consisted of an array of 336 sensors. Although no pressure or shear data were described, the authors reported that the device was suitable for investigating foot loading conditions during the takeoff phase of the high jump.

Over 20 years ago, leaders in diabetic foot research [45] commented "the measurement of shear stress continues to be an elusive goal". Not much has changed since that time! For the past 30 years, numerous companies have entered the market with new technologies related to pressure (most commonly) or shear (rarely). In general, the devices on the market are for assessing overground pressure profiles or, less commonly, in-shoe stresses. There are currently no companies selling in-shoe products for assessing frictional forces. Part of the reason for this relates to physics – a sensor that is placed between a shoe and a subject's sock measures shear that may not accurately reflect the actual shear that skin experiences. In this regard, the presence of a sock can result in measurements that are underestimated by between 86% and 92% [46]. In other words, skin may experience shearing of 100 kPa, but the sensor may only detect 10kPa! Coefficients of friction between sensor and sock, or between sock and skin, together with sock stretchiness, all affect the accuracy of these measurements. The ability for future in-shoe shear sensor technologies to address the effect of sock material is still an open question.

While sock materials may have some effect on pressure readings, the influence is likely minimal. For this reason, most commercial efforts to develop stress sensors have focused on pressure as opposed to shear. Novel GmbH, Munich, Germany, with U.S. offices in St. Paul, MN, is generally recognized as the technical and market leader in plantar pressure measurement systems. Comparisons between Novel's technology and other commercial systems (Table 1) highlight the reasons for their popularity in foot ulceration studies. They offer both platform (Emed) and in-shoe (Pedar) devices that come in a variety of models that are based on a well-established capacitive sensor system. This approach results in a system that exhibits excellent linearity and hysteresis characteristics. The Pedar system provides highly conforming elastic insole pads that cover the entire plantar surface or sensor pads for the dorsal, medial, or lateral areas of the foot. Insole pads are available in various shoe sizes that can provide up to 1024 sensors, which can be scanned at a rate of 20,000 sensors per second.

4. Charcot Arthropathy and Foot Ulceration

As evidenced by the above information, diabetic foot ulcers are one of the most common complications of diabetes mellitus. Another complication of diabetes that is important for physicians is the development of Charcot arthropathy. While Charcot arthropathy of the foot is not as prevalent as DFU, approximately 35% of people with diabetes and peripheral neuropathy develop Charcot.[47] The disease outcomes for DFU and Charcot are as equally devastating to the patient.

Charcot Arthropathy of the foot is a devastating degenerative disorder that derives from the dysregulation of the cardiovascular, musculoskeletal, and neurological system. Charcot is characterized as a progressive degradation of the midfoot joint (Figure 6). If left untreated, the disease can progress to ulceration (DFU), midfoot arch collapse, infection, amputation, or death. Current clinical evaluation for Charcot consists of temperature measurements on each foot, x-ray imaging, and clinical observations (swelling, redness, etc.).[24] Some have suggested utilizing CT scans to track bone mineral density (BMD) and potentially identify those at risk for developing Charcot from peripheral neuropathy. These studies were able to diagnose those who already developed Charcot and predicted Charcot development at 14%.[48]

The exact etiology of Charcot development is not completely understood. Multiple theories exist; however, none have been concretely determined as the sole rationale for Charcot development.[49] The one clinical consensus that exists is the presence of inflammation before the radiological presentation and concrete development.

In addition to similar disease development between DFU and Charcot, (the dysregulation of multiple body systems and a previous peripheral neuropathy diagnosis), DFU and Charcot are also inherently related. For example, a person with diabetes and peripheral who have had a previous diagnosis of foot ulcers developed Charcot at a rate of 18%.[50]

Recent advances in Charcot and DFU research have pointed to a similar methodology for potential monitoring and diagnosis, the use of pressure and shear measurements underneath the midfoot. Multiple studies have illustrated the potentiality of the usefulness of utilizing pressure and shear in clinical evaluation for both DFU and Charcot development. [28,29,51–53]

5. Future Research in Foot Ulceration Monitoring

The future of DFU research is focused on prevention, early detection, and accurate intervention. This is currently achieved through the use of wearable sensors, AI/machine learning, and smart technology. For example, some researchers are developing algorithms that can be applied to images of the feet. These algorithms can identify areas of the foot at risk for ulcer development; allowing the physician to focus clinical monitoring of that area.[54] Additionally, the use of photographs and computer algorithms can allow for at home monitoring which could decrease the amount of lead time between DFU symptom onset and clinical intervention; thus, increasing patient outcomes.

Since there is a consensus among researchers that inflammation is a precursor to DFU, researchers are determining ways to measure temperature under the foot as an indicator of inflammation changes. Armstrong *et al.* has introduced a novel way to measure plantar temperature through a hand-held infrared temperature probe.[55] Others such as, Frykberg *et al.*, have approached plantar temperature monitoring through in-home smart mats, (Podimetrics Mat), that can measure plantar temperatures and send the results through a cloud-based system to clinicians for review.[56] Doremalen *et al.* illustrated the viability of using smart-phone based infrared cameras to monitor plantar temperature for DFU detection.[57]

Wearable sensors are also on the horizon for DFU research. Siren Care are smart textiles made into socks that measure plantar temperature as a person walks and performs activities of daily living.[58] Wearable sensors can also be utilized to track pressure and shear stresses that are known to be a component in DFU development. Raviglione *et al.* suggested the use of smart socks (pressure sensor around a band) and a phone app to measure plantar pressure at home.59] Due to the poor mismatch between areas of high plantar pressure and ulcer development, some researchers have suggested using shear as a metric to monitor for ulceration risk.[60] The ability to accurately measure shear forces under the foot using measuring techniques such as insole insoles is still in its infancy stages.

Finally, another facet of the future of DFU research is to increase patient compliance and wear time of interventions used to mitigate DFU development. Systems such as "@monitor" and Orthotimer are sensors integrated in prescription footwear that can measure the amount of wear time a patient has with their footwear while at home.[61,62] Some researchers have even utilized smart watches to provide alerts for adherence or instructions on better offloading to minimize plantar pressure peaks. In-shoe sensors measure for adherence or pressure and connect to a smartphone app which then will send the data to the smart watch which then sends out the alert. [63,64]

Summary

Diabetic foot ulcers are a complex, multifaceted, and widespread complication of diabetes mellitus. While there are a multitude of risk factors contributing to diabetic foot ulcer development, pressure and (more recently) shear stresses are two biomechanical metrics that are gaining popularity for monitoring risk factors predisposing skin breakdown. Other areas of diabetic foot ulcers under research include plantar temperature measuring as well as monitoring wear-time compliance and machine learning/AI algorithms. Charcot arthropathy is another diabetes complication that has a relationship with diabetic foot ulcer development, which should be monitored for development alongside DFU development. The ability to monitor and prevent diabetic foot ulcer development and Charcot neuroarthropathy will lead to increased patient outcomes and patient quality of life.

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Key Points

1. Diabetic foot ulcers are one of the most common complications of diabetes mellitus, with 15–25% of these individuals developing a foot ulcer within their lifetime.
2. In the presence of neuropathy, there is convincing evidence linking high pressures to the development of diabetic foot ulcers. However, the location of skin breakdown does not correlate well with sites of elevated pressure.
3. Given the weak correlation between peak pressure and ulcer location, it is believed that some form of shear (possibly coupled with pressure), is likely to contribute to ulceration.
4. Measurement of shear or frictional forces is not routine clinical practice, due to technical issues, the infancy of research in this area, and challenges associated with physical interfaces that are affected by moisture, weave patterns and sock stiffness.

Synopsis

Diabetic foot ulcers are a complex, multifaceted, and widespread complication of diabetes mellitus. While there are a multitude of risk factors contributing to diabetic foot ulcer development, pressure and (more recently) shear stresses are two biomechanical metrics that are gaining popularity for monitoring risk factors predisposing skin breakdown. Other areas of diabetic foot ulcers under research include plantar temperature measuring, as well as monitoring wear-time compliance and machine learning/AI algorithms. Charcot arthropathy is another diabetes complication that has a relationship with diabetic foot ulcer development, which should be monitored for development alongside ulcer development. The ability to monitor and prevent diabetic foot ulcer development and Charcot neuroarthropathy will lead to increased patient outcomes and patient quality of life.

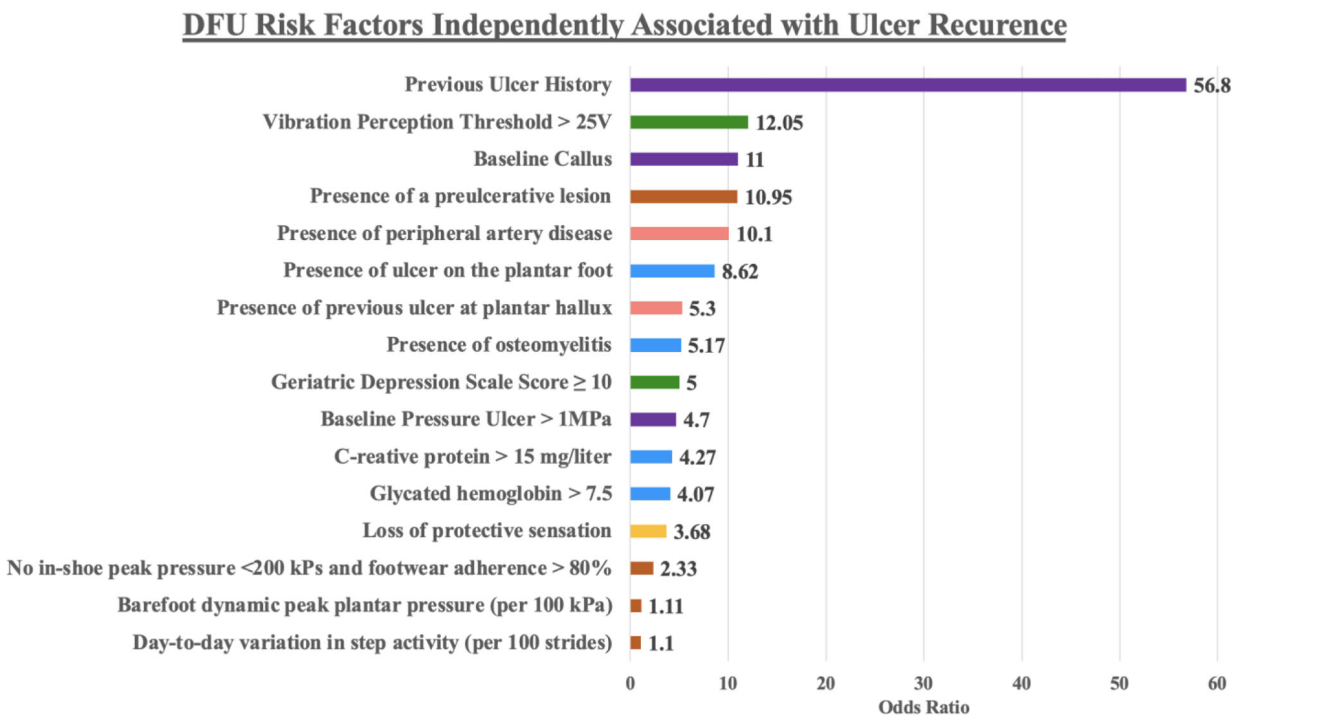

Figure 1:

DFU risk factors independently associated with ulcer recurrence from five different studies. Results from Dubský *et al.*[5], Reiber *et al.*[6], Monami *et al.*[7], Waaijam *et al.*[8], and Peters *et al.*[9], and Murray *et al.*[10] are illustrated in blue, yellow, green, burnt orange, pink, and purple, respectively.

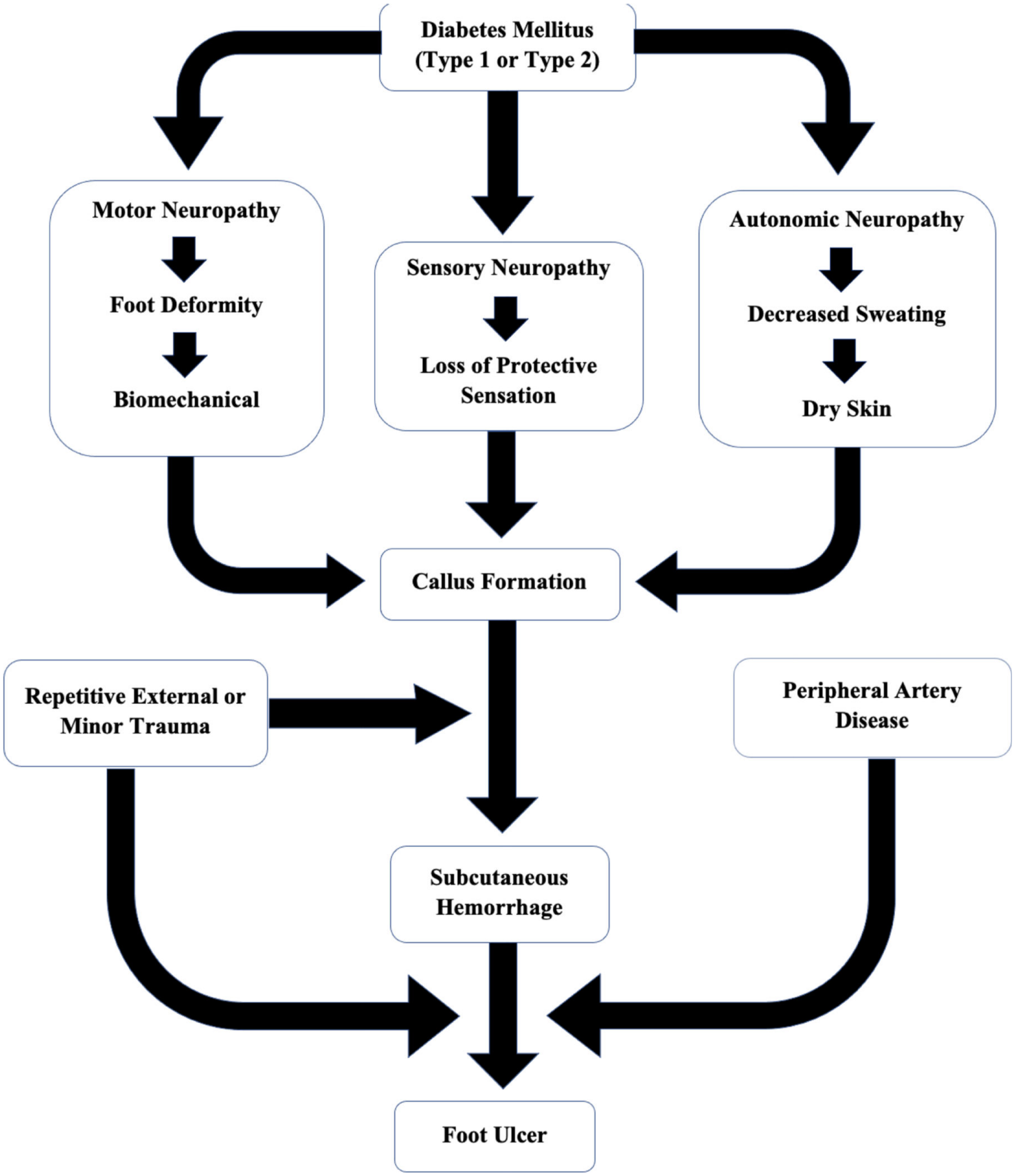

Figure 2.
Flow diagram of the common etiology of DFU development.

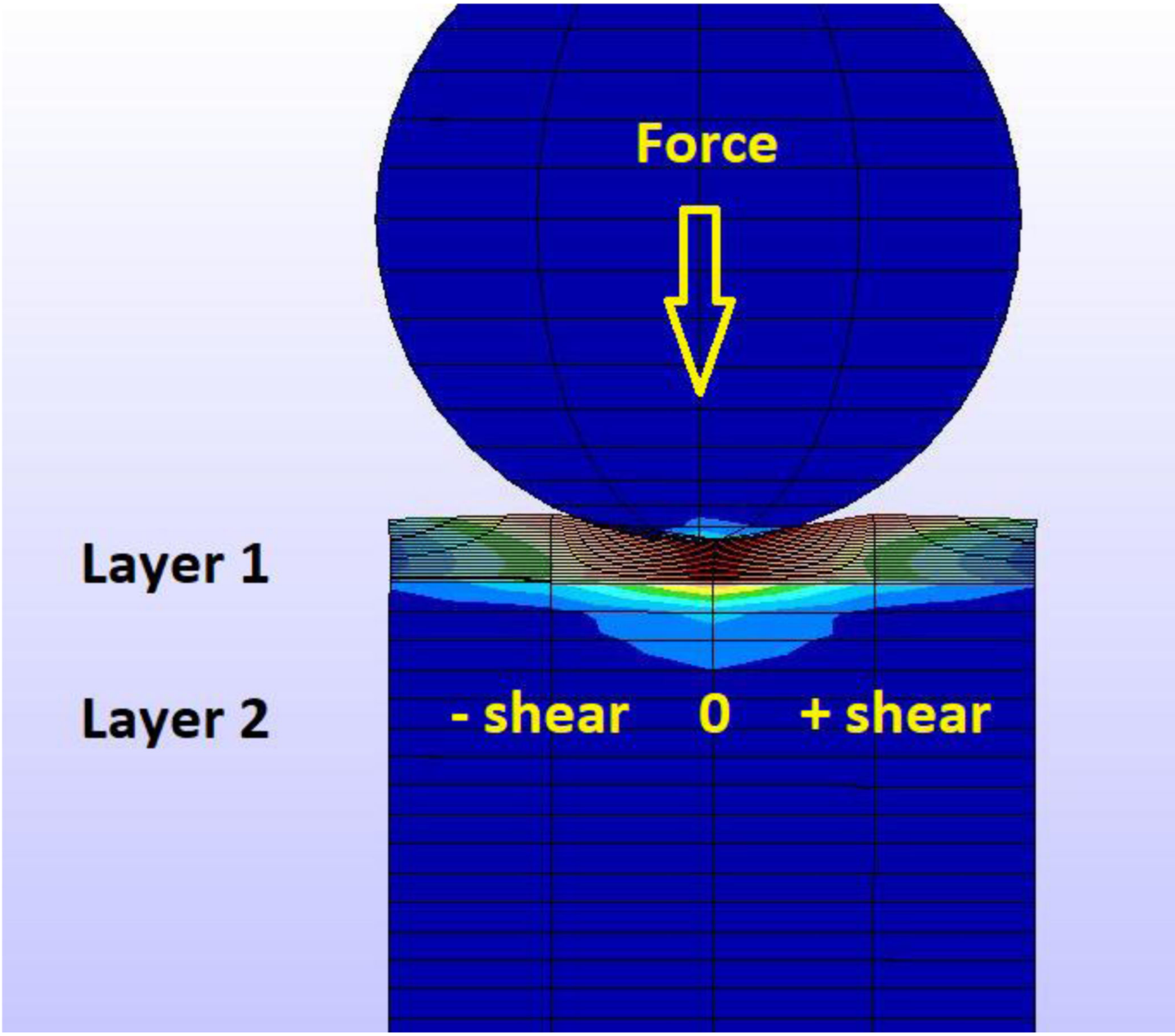

Figure 3.
Simple physics model illustrating (i) shear is zero where pressure is highest, (ii) shear stresses have opposite signs on either side of highest pressure, and (iii) discontinuity between dermal layers.

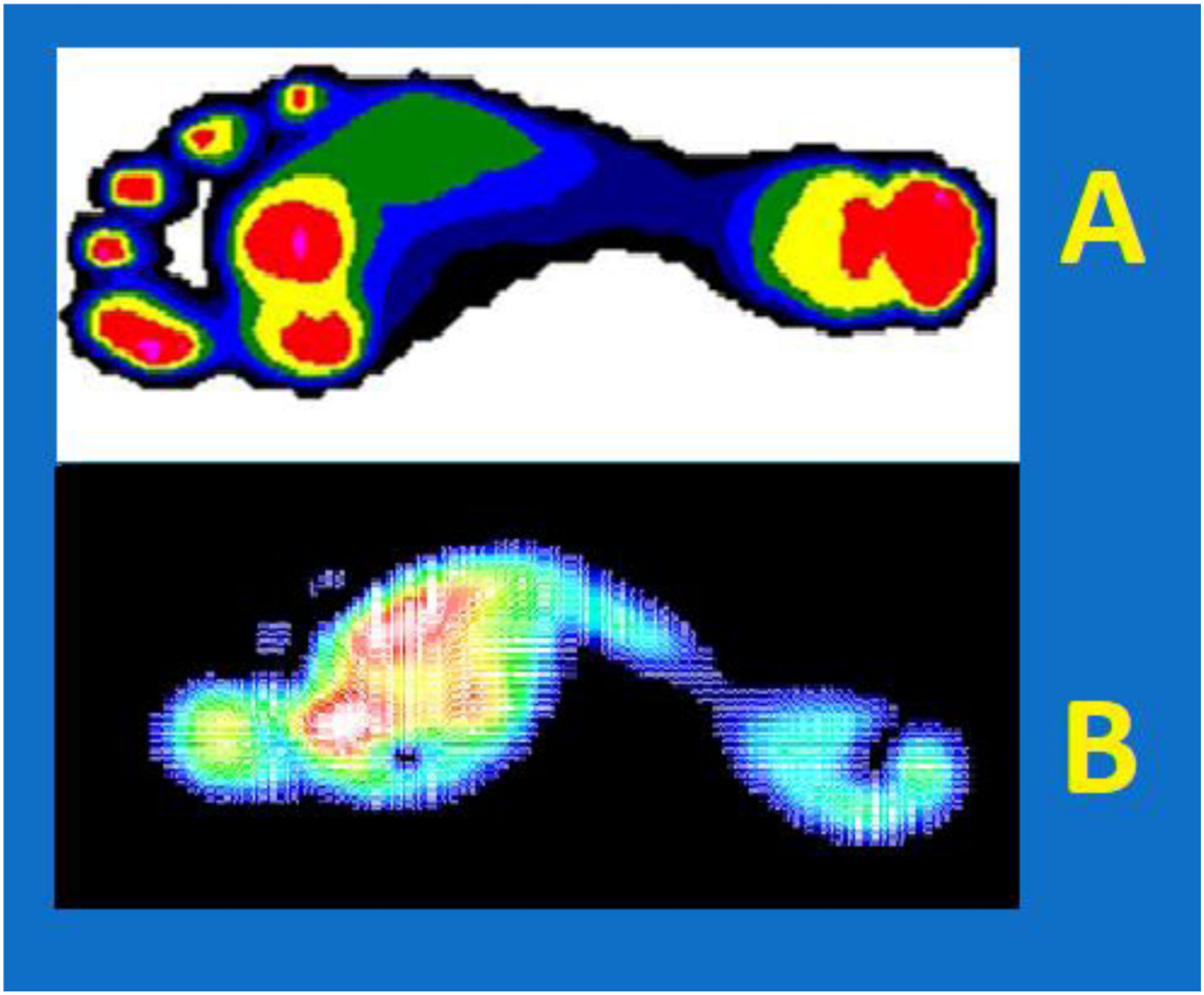

Figure 4.

A: Peak pressure recordings under a patients foot. B: Shear stress distribution. Note that shear can be zero (black regions) where pressure may be high, and (ii) shearing under the heel does not resemble pressure mapping.

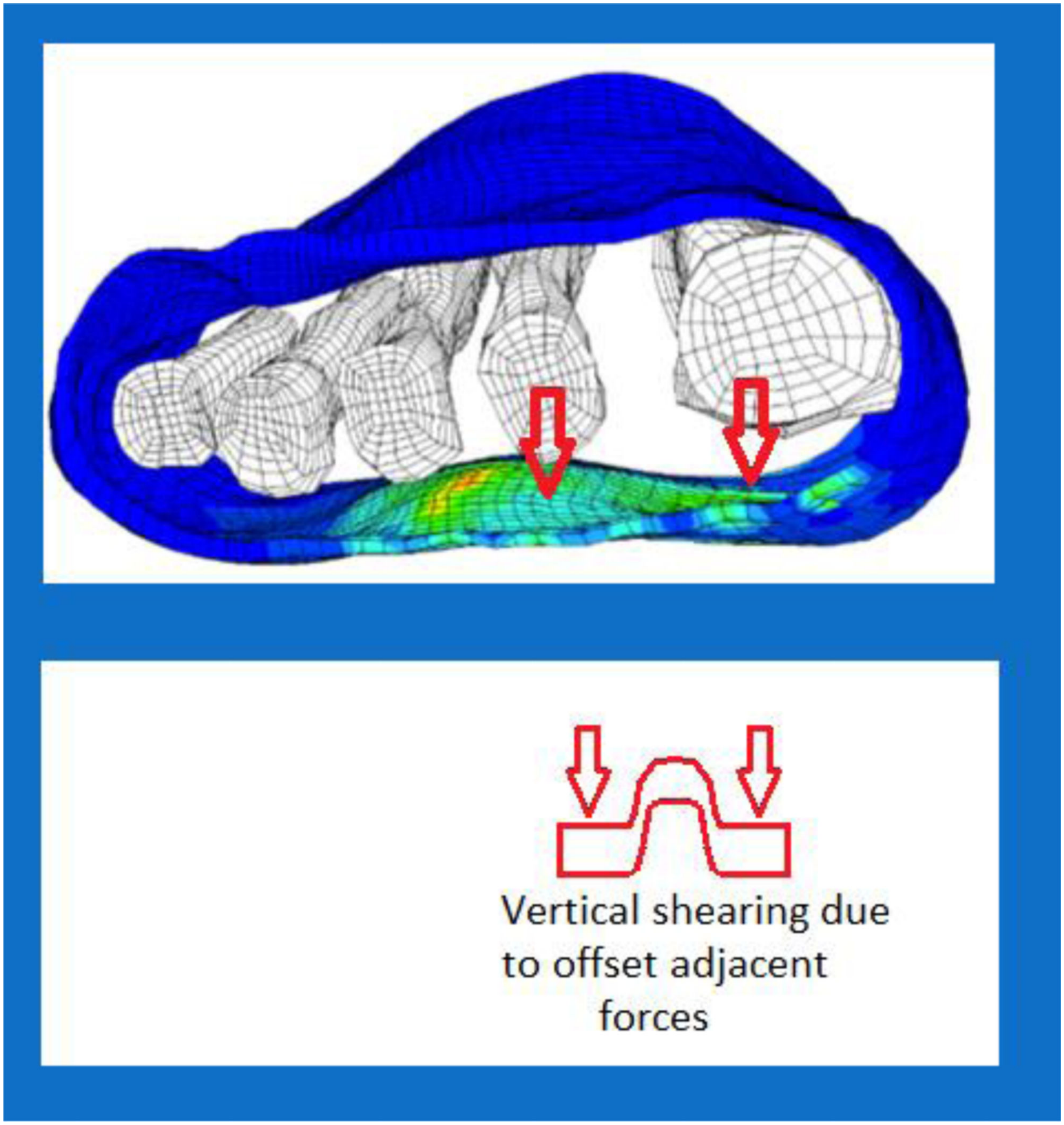

Figure 5.

Shear can occur in multiple planes besides acting on the plantarsurface of the foot. The illustration above shows the concept of vertical shear, caused by adjacent bony structures moving relative to interspersed tissue.

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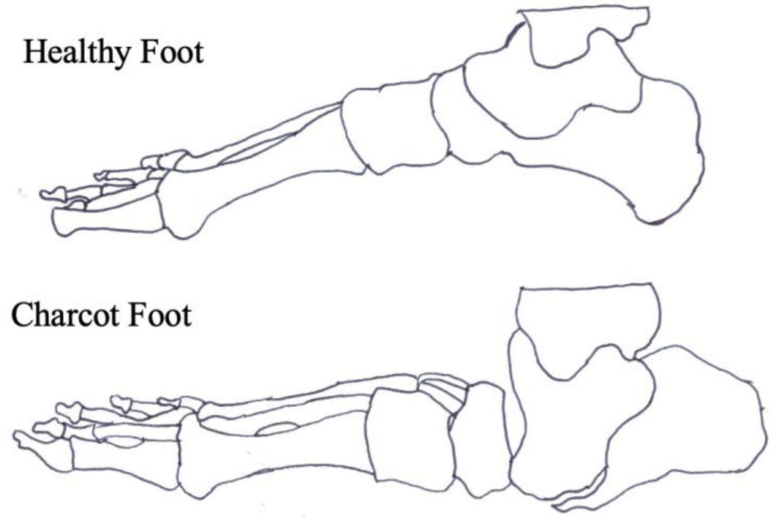

Figure 6.
Anatomical bone representation of a healthy foot structure compared to a Charcot foot structure.

Table 1.

Selection of companies with products used to monitor foot pressure and/or shear.

Company/ technology	Sensor principle	Options	Comments
Tekscan	Conductive ink	Both in-shoe (F-Scan®) and platform systems.	In-shoe sensor array can be trimmed to fit shoe. High resolution grid of sensors.
Paromed	Hydrocell sensors	Pressure platform and the Parotec® in-shoe system	Foot pressure measurements are used for automated insole fabrication.
Materialize Motion (formerly RSScan	Resistive sensors	The Footscan® system includes entry-level and advanced options.	Foot pressure measurements are coupled with foot shape data and used for automated insole fabrication.
Sensor Products Inc.	Piezo resistive elements	Tactilus High Performance Footplate	Data sampling can range from 200 to 400 Hz. Used for orthotics and ulcer studies.
Pressure Profile Systems (PPS)	Capacitance approach	Pressure systems for different body regions	The TactileMat has large pressure mapping surface area (220 mm x 450 mm)
XSENSOR Technology Corp.	Capacitance approach	Both in-shoe and platform systems	High-speed, high-resolution plantar pressure and gait measurement data.
Innovative Scientific Solutions	Optical approach	Platform allows for both pressure and shear measurements	Calibration challenges for shear sensors are overcome by measuring the relative change in the position of a polymer film.