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Effect of Footwear and Orthotic Devices on Stress Reduction and Soft Tissue Strain of the Neuropathic Foot

Donovan J. Lott^{a,b,*}, Mary K. Hastings^b, Paul K. Commean^c, Kirk E. Smith^c, and Michael J. Mueller^{a,b}

^a Movement Science Program, Washington University, St. Louis, MO, USA

^b Applied Biomechanics Laboratory, Program in Physical Therapy, Washington University School of Medicine, St. Louis, MO, USA

^c Mallinckrodt Institute of Radiology, Washington University School of Medicine, St. Louis, MO, USA

Abstract

Background—Ground reaction forces from walking result in stress (pressure) and soft tissue strain at the plantar aspect of the foot. Excessive plantar pressure and tissue strain on the insensate foot may lead to ulceration. Our study investigated the effect of therapeutic footwear and custom-made orthotic inserts on pressure and tissue strain along the second ray of the plantar foot, and how these two variables are associated.

Methods—Twenty subjects (mean age 57.3 [SD 9.3], 12 male, 8 female, body mass index 32.5 [SD 7.4]) with diabetes mellitus, peripheral neuropathy, and a history of a plantar ulcer participated. Plantar pressure data were recorded during computed tomography scans for four conditions (barefoot, shoe, shoe+total contact insert, and shoe+total contact insert+metatarsal pad). For each condition tested, tissue strain and plantar pressure were determined at the second metatarsal head and at 15 other points along the second ray.

Findings—Differences were noted between the 4 conditions for pressure ($p < 0.004$) and soft tissue strain ($p < 0.042$) at the second metatarsal head. Correlation coefficients demonstrated an association between pressure and strain (Barefoot $r = 0.81$, Shoe $r = 0.75$, Shoe+total contact insert $r = 0.73$, and Shoe+total contact insert+metatarsal pad $r = 0.44$).

Interpretation—Footwear and orthotic devices tested in this study decreased pressure and soft tissue strain at the second ray of the foot, and these two variables were strongly related. A better understanding of the role tissue strain plays in distributing plantar forces may lead to improvements in the design of orthotic devices.

Keywords

Plantar ulceration; Diabetes mellitus; Metatarsal pad; Total contact insert

*Corresponding author: Donovan J. Lott, Address: Program in Physical Therapy, Washington University School of Medicine, 4444 Forest Park Blvd., Campus Box 8502, St. Louis, MO 63108, USA, Telephone: (314) 286-1439, Fax: (314) 286-1410, E-mail: djlott@artsci.wustl.edu.

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1. Introduction

The applied forces from the weight of the body and the push-off forces with walking cause pressure (stress) and soft tissue (ST) strain to the foot. ST strain is defined as the amount of ST deformation relative to the original ST thickness. Every material has a certain strength, expressed in terms of stress and strain, beyond which the material reaches failure or breakdown. Failure of a material may occur from absorption of a high amount of energy due to excessive stress or from excessive strain.

Stresses in the form of high peak pressures on the plantar aspect of the feet are highly associated with skin breakdown and ulceration in people with diabetes mellitus and peripheral neuropathy (Veves et al., 1992). These neuropathic ulcers frequently occur at the forefoot area beneath the metatarsal (MT) heads (Boulton et al., 1983).

While ST strain at the plantar aspect of the foot can be beneficial in distributing the forces from weight bearing and walking over a greater area of the foot to decrease localized stress, *excessive* ST strain under the MT heads is another mechanical factor related to peak pressures that potentially contributes to ST injury. The amount of research investigating the effect of ST strain is quite limited compared to the number of studies examining the effect of peak pressure (stress). However, some engineering theories of failure (the Maximum Distortion Energy Failure Theory or the von Mises' criterion) assume that strain can result in material failure when the magnitude of strain energy reaches a critical value (Hills et al., 1993; Ozkaya & Nordin, 1999). Limiting high magnitudes of ST strain at the areas of peak pressure on the plantar forefoot should also be effective in minimizing the potential trauma and injury to the ST in the MT head areas (Gefen, 2003; Gefen and Linder-Ganz, 2004).

An inherent problem with using ST strain to characterize tissue mechanics and potential tissue trauma to the foot is the lack of methods to measure ST strain in footwear. Ultrasonography has been utilized to measure ST strain of the foot with some success (Cavanagh, 1999; Wang et al., 1999; Hsu et al., 2005). Gefen et al. (2001) investigated ST strain of the heel pad with digital radiographic fluoroscopy in conjunction with an optical method to measure plantar pressures. More recently, Weijers et al. (2005) utilized a pressure measuring insole mounted on a plank upon which subjects stood during spiral computed tomography (CT) scans. These methods, however, only measured ST strain of the foot with the subjects barefoot and did not provide information regarding ST strain and plantar pressure in individuals wearing footwear. Investigating how ST strain and pressure are affected by footwear and orthotic devices would provide information that may prove useful towards design of accommodative footwear and orthotic devices to minimize the amount of energy the ST of the foot absorbs during weight bearing activities.

The purposes of this study were: 1) to investigate the effect of therapeutic footwear and orthotic devices on pressure distribution and ST strain at the second MT head and 2) to examine the association of pressure and ST strain along the second MT of the foot. We investigated the second MT head as this area is a frequent site for ulceration (Sinacore & Mueller, 1993), and researchers have demonstrated high peak plantar pressures at the second MT head relative to the other MT heads in subjects walking barefoot (Holmes and Timmerman, 1990), and with footwear (Hodge et al., 1999). Investigators have also recently demonstrated that stress and strain is highest at the second MT head during simulated terminal stance phase of barefoot walking (Weijers et al., 2005). We hypothesized the magnitudes of pressure and ST strain at the MT head area would be greatest with the subjects barefoot and would decrease as footwear and orthotic devices were added. We also hypothesized a strong association would exist between pressure and ST strain at the second MT for all conditions tested.

2. Methods

Twenty subjects (12 men, 8 women) with diabetes, peripheral neuropathy, and a history of a midfoot or forefoot plantar foot ulceration participated. See Table 1 for subject characteristics. Subjects were recruited from the Diabetic Foot Center, Volunteers for Health, and the Diabetes Research Training Center at Washington University School of Medicine, and BJC Health System in St. Louis, MO, USA. Sensation testing was done with Semmes Weinstein monofilaments and a vibratory threshold test using methods with established reliability (Diamond et al., 1989; Maluf and Mueller, 2003). All subjects were unable to sense the 5.07 Semmes Weinstein monofilament on at least two sites of the plantar surface of their foot. The vibratory threshold level was quantified with a biothesiometer (Biomedical Instrument, Newbury, OH, USA). The mean value for the group was 48.3 (4.1) volts indicating a severe degree of neuropathy (Maluf and Mueller, 2003; Caselli et al., 2002). Prior to testing, all subjects gave informed consent according to an approved Washington University School of Medicine Institutional Review Board protocol.

Subjects were tested for four different conditions during data collection: 1) Barefoot, 2) Shoe, 3) Shoe+total contact insert (TCI), and 4) shoe+TCI+metatarsal pad (MTP). For the Barefoot condition, a thin sock was used to hold the pressure sensor in place. For the Shoe condition, the subjects wore new therapeutic shoes with standard inserts (SoleTech shoes, Advanced Orthopedic footwear, style number E3010) that are commonly prescribed and are covered by the "Therapeutic Shoe Bill" for Medicare part B. The shoes were fitted by a certified pedorthist or orthotist. For the TCI condition, a new custom-made TCI replaced the standard insert from the Shoe condition. The custom insert was made from a base of 1.27 cm #2 plastizote with a shore value of 35. The MTP condition included a MTP in addition to the therapeutic shoe and the TCI. Each MTP was standardized according to foot size and included an adhesive backing to secure it in its appropriate location on the TCI (Mueller et al., 2006). The MTPs were made of cork with a shore value of 55. The pedorthist or orthotist attempted to position the MTP 1 cm proximal to the MT heads, and the average location of the MTP for the 20 subjects was 9.6 (6.4) mm proximal to the MT heads (Hastings et al., 2006).

Pressure and imaging data were collected simultaneously with the subjects seated in a custom-built loading device that has been described previously (Commean et al., 2002). Briefly, the subjects were seated and placed one foot against a vertically positioned plate. The subjects' ankles were manually positioned by a physical therapist and engineer to allow forefoot contact only against the plate to simulate the late stance phase of gait (~80% stance phase) when forefoot pressures are at their greatest magnitude (Kelly et al., 2000). Plantar pressure data were recorded with the F-Scan system (Tekscan, South Boston, MA, USA) during multi-slice CT foot scans (Somatom Sensation 16, Siemens Medical Systems, Inc, Iselin, NJ, USA). The parameters used for the eight CT scans were: 120kVp, 210 mAs, 0.75 mm collimation, 0.75 mm effective slice thickness, reconstruction slice thickness of 0.7 mm, a B30S medium smooth reconstruction kernel, and a 512 x 512 matrix. The feet were scanned from the plantar surface to the ankle (approximately 150 mm in 16 seconds). Three lead markers (1.5 mm in diameter) (Beekley Corporation, Bristol, CT, USA) were placed on the forefoot portion of the sensor for locating and identifying the sensor and footwear on the plantar surface of the foot during CT scanning. The pressure sensor was attached to the subject's foot with tape and a thin sock was placed over the foot to secure the sensor. The sensor was calibrated according to the manufacturer's guidelines and using standardized techniques (Hastings, 2003). Two CT images were collected for each of the four conditions: 1) a preloaded scan with the subjects applying a forefoot load of approximately 45 N and 2) a loaded scan with the subjects applying a load of approximately 50% body weight (mean load of 525 [147] N). Previous work has indicated that pressing with a load of 50% body weight through a single foot is a reasonable surrogate for the load that occurs at ~80% stance phase of walking (Mueller et al., 1999;

Commean et al., 2002). A scale with a digital readout was placed behind the plate that the forefoot contacted. The subjects were instructed to press against the plate (~45 N for the preloaded scan and 50% body weight for the loaded scan) for each of the eight scans using the digital readout as visual feedback, and the subjects also received feedback just prior to the initiation of scanning from a physical therapist who monitored the F-Scan qualitative pressure distribution. The testing order for the four conditions was determined randomly.

After data collection, the CT image data and the pressure sensor were aligned using methods with established reliability (Hastings et al., 2003). Data reduction included identifying the second MT head in the CT data using Analyze software (Biomedical Imaging Resource, Rochester, MN, USA) (Robb, 2001; Robb and Barillot, 1989; Robb et al., 1989), and the location of the MT head center was identified on the pressure sensor. Measurement locations were established from the CT data using bony structures and F-Scan sensels visible in the CT data. The centroid of the second MT head was determined in the corresponding projected sagittal view. The sensel directly below the centroid of the MT head was labeled as “0” and represented the center of the MT head as projected to the plantar skin surface. Lines were drawn in a radial fashion from the centroid of the MT head to corresponding F-Scan sensels (from five sensels distal to three sensels proximal to the MT head sensel) at the plantar aspect of the foot. For the MT shaft measurements, a line was drawn parallel to the MT shaft in the sagittal view of the second ray. Orthogonal lines were then drawn from the F-Scan sensels to the MT shaft line. The shaft measurements started with the fourth sensel proximal to the MT head center.

ST thickness measurements were taken under the MT shaft and MT head by measuring the distance from the inferior surface of the bone to the outer surface of the skin along the lines established as described above. These ST thickness measurements were taken for the 16 consecutive sensels (from 5 distal to the MT head sensel to 10 proximal from the MT head sensel) covering a distance of 8.13 cm for both the preloaded and loaded CT scans for all four conditions.

Because the methods we used for the preload conditions included a minimal forefoot load (~45 N), some ST strain had likely already occurred where the load was applied (Hsu et al., 1998). This preload was applied to a small area of the forefoot, and the portion of the forefoot bearing the preload differed between testing conditions (i.e. near the MT head for the Barefoot condition and more proximal for the MTP condition). To obtain the best estimate of the second ray's ST thickness with the forefoot unloaded (no ST strain), we used the ST thickness measurements for the preloaded conditions that had the lowest recorded pressure value at each measurement site (sensel) for any of the four conditions for each individual subject. The average magnitude of pressure for the preload across the 16 sensels with the lowest recorded pressure value for all four conditions was 1.1 (3.2) kPa.

ST strain was determined by the following formula: $ST\ strain = ([ST\ thickness\ preloaded - ST\ thickness\ loaded] / ST\ thickness\ preloaded) \times 100(\%)$. The applied pressure was calculated as the difference in pressure between the loaded scan and the preloaded scan at each of the corresponding ST thickness measurement locations defined by the 16 pressure sensels described above. The variables of interest for this study included the ST strain and pressure difference values at the 16 corresponding F-Scan sensor sensels along the second ray.

Repeated measures analysis of variance with post-hoc one-tailed paired t-tests (for a priori hypotheses) were used to test for differences between pressure and ST strain for the four different footwear conditions. Criterion for significance was set at $p = 0.05$. Pearson correlation coefficients were used to determine the relationship between ST strain and the applied pressure at the 16 adjacent points along the second MT.

3. Results

Pressure and ST strain at the second MT head were greatest in the Barefoot condition and least in the MTP condition. Differences were noted between all four testing conditions for applied pressure ($p < 0.004$) and ST strain ($p < 0.042$) at the second MT head. Mean (SD) applied pressure values were: Barefoot = 272 (148) kPa, Shoe = 173 (94) kPa, TCI = 140 (62) kPa, and MTP = 98 (51) kPa (see figure 1). The average (SD) ST strain values at the second MT head were: Barefoot = 38.2 (9.2)%, Shoe = 31.6 (9.4)%, TCI = 28.9 (10.9)%, and MTP = 24.1 (6.0)% (see figure 2). Table 2 contains the ST thickness and pressure data for the preloaded and loaded conditions.

Stress-strain (pressure-ST strain) data were plotted for the second MT head and for a location on the midshaft of the second MT 7 sensels proximal to the MT head (~3.5 cm proximal to the second MT head) for the four conditions (see figure 3). This location 7 sensels proximal to the MT head was chosen because it was the point where the greatest average ST strain occurred beneath the MTP for the MTP condition. The area under the curves in the graphs in figure 3 suggests the footwear and orthotic devices reduced the energy absorbed by the ST beneath the second MT head and shifted the energy absorption to the proximal foot under the MTP in the MTP condition.

Pearson correlation coefficients demonstrated a strong relationship between ST strain and applied pressure along the second ray for all four footwear conditions; however, the strength of this association decreased with the addition of a MTP (Barefoot $r = 0.81$, Shoe $r = 0.75$, TCI $r = 0.73$, and MTP $r = 0.44$) (see table 2). Figure 4 illustrates this relationship for the mean pressure and ST strain values for all four testing conditions.

4. Discussion

The results from this study demonstrate a reduction in pressure and ST strain at the second MT head with the inclusion of footwear and orthotic devices during the simulated terminal stance of gait. This finding supports results of other studies that have found a reduction in pressure with the use of therapeutic footwear (Lord and Hosein, 1994; Kato et al., 1996; Ashry et al., 1997; Chen et al., 2003; Bus et al., 2004; Tsung et al., 2004; Mueller et al., 2006). However, this is the first study to demonstrate a decrease in ST strain at the MT head from the use of therapeutic footwear and orthotic devices. Our results provide additional evidence to support the use of therapeutic footwear and orthotic devices to protect the plantar ST of the foot. As the footwear and orthotic devices tested in this study decreased what we consider excessive ST strain at the MT head in the Barefoot condition, we speculate that the ST under the MT head received less internal stress that could lead to tissue injury.

The stress-strain plots in figure 3 support this thought of reducing potential harm to the ST under the second MT head as they demonstrate reductions in stress (pressure) and ST strain under the second MT head with the inclusion of footwear and orthotic devices. As the stress and strain are successively reduced from the Barefoot, to the Shoe, to the TCI, to the MTP conditions, the energy absorbed by the ST at the second MT head is also reduced. These reductions in stress and strain suggest that the tissues are subjected to less energy that may be potentially harmful. Figure 3 also demonstrates the shifting of the stress and strain to the ST beneath the MTP at the midshaft of the MT and away from the ST beneath the second MT head where tissue injury and skin breakdown commonly occurs in individuals with diabetes and neuropathy (Boulton et al., 1983). It should be acknowledged that this transfer of stress and strain to the midshaft of the MT may potentially increase fracture risk of a MT in people with osteoporosis/osteopenia, although we have not observed this complication in clinical practice. A better understanding of ST strain of the plantar tissues of the foot in people with diabetes

and neuropathy is critical in developing more effective footwear and orthotic devices to minimize harmful stresses and potential skin breakdown.

In this study, ST strain at the second MT head was 38.2% and 31.6% in the Barefoot and Shoe conditions. Previous work investigating ST strain beneath the second MT head without footwear included subjects without any known medical conditions (no DM or PN) (Cavanagh, 1999; Wang et al., 1999; Hsu et al., 2005; Weijers et al., 2005) and who were younger (Cavanagh, 1999; Wang et al., 1999; Weijers et al., 2005) than the subjects in this study. The subjects in two of the studies were tested in non-weight bearing positions using an ultrasound transducer applied to the plantar surface of the foot, and the results demonstrated ST strain of 47.3 and 47.7% (Wang et al., 1999; Hsu et al., 2005). The small contact area of the ultrasound transducers (4.73–5.02 cm²) may have contributed to these greater magnitudes of ST strain relative to our finding. As the contact area for the applied force decreases, the ST is allowed to deform laterally to a greater extent than when the applied force has a contact area involving the entire forefoot or larger area. Weijers et al. (2005) utilized methods involving subjects standing on a plank during CT scans. During their toe-off posture which was similar to the testing position employed in our study, ST strain at the second MT head was 35%, consistent with our finding of 38.2%. Cavanagh (1999) used ultrasound for determining ST strain, but in contrast to Wang et al. (1999) and Hsu et al. (2005), Cavanagh mounted the transducer flush with the floor to allow the entire forefoot to be in contact during the terminal stance of actual gait. Given this dynamic loading with full weight bearing, his results for average maximum ST strain during the stance phase of gait were 45.7 (6.7)%.

This study is the first to examine pressure and ST strain in various footwear conditions at several consecutive points at the plantar foot. Our results demonstrate a strong relationship between pressure and ST strain that decreased with increased loading of the more proximal ST of the foot (Barefoot $r = 0.81$ to MTP $r = 0.44$) (see figure 4). The graphs in figure 4 demonstrate the pressure value relative to the magnitude of ST strain is greater in the Barefoot condition compared to the other three footwear conditions. The decrease in the association between stress and strain with more proximal loading of the foot from use of a MTP is an interesting finding. This result may be from the varying material properties of the ST between different regions of the foot. The material properties of the ST are key elements in understanding how the tissues of the diabetic foot respond to loading and deserve further investigation. (Chen et al., 03; Gefen, 03; Thomas et al., 04; Erdemir et al., 05) More research into ST strain may help to elucidate how the material properties of ST influence the foot's response to loading. Footwear and MTPs have the potential to distribute stresses and strains in all directions rather than the uniplanar slice investigated in this study. Future investigations should examine applied pressures and ST strain in a three dimensional manner. Finite element models are one means investigators are pursuing to examine the three dimensional effect of pressure on the ST of the foot (Lemmon et al., 1997; Gefen et al., 2000; Jacob and Patil, 1999; Cheung et al., 2005).

There are limitations to our study. ST strain and pressure data were determined from a static loading during CT imaging instead of during walking. We recognize that a static loading of the foot for data collection may not reproduce the ST strain that occurs during the dynamic activity of gait. However, we have reported previously that peak pressures collected during CT imaging using these methods are similar to pressures recorded during walking (Commean et al., 2002; Mueller et al., 2006). A second potential limitation in accurately measuring strain is that we used a preloaded condition rather than an unloaded condition for determining the ST strain. Since the average preload along the second ray was quite low (1.1 [3.2] kPa) we do not believe it represents a meaningful limitation. Another limitation to our study is that we only analyzed pressure and ST strain along the second ray of the foot. We analyzed the second ray because it represents a common site of skin breakdown and foot ulceration in people with DM and PN (Sinacore & Mueller, 1993), and the second MT head has been shown to be the area

with the greatest amount of stress and strain while subjects are barefoot during terminal stance (Weijers et al., 2005). In addition, pressures from a MTP often are applied along the second ray. While we examined the relationship between pressure and ST strain, it is important to recognize that plantar pressure is based on a normal force and the ST thickness measurements used to determine ST strain are measured obliquely (Commean et al., 2002). Therefore, pressure and ST strain are not exactly associated. Although the limitations of the study should be recognized for purposes of generalizability, we believe the results have important implications for understanding stress and strain on the neuropathic foot.

5. Conclusions

In summary, we found therapeutic footwear and orthotic devices to be effective in decreasing stress (pressure) and strain at the second MT head. These results support the use of therapeutic footwear and orthotic devices to help protect the neuropathic foot from injury by decreasing the amount of energy these tissues must absorb during gait. In addition, ST strain and applied pressure were highly correlated along the second ray of the neuropathic foot. We recommend further investigation into the mechanism of pressure reduction via therapeutic footwear and orthotic devices to better understand the role of pressure and ST strain in tissue injury. This understanding may facilitate new and better designs of orthotic devices to reduce the excessive localized pressures and internal stresses thought to be responsible for skin breakdown and ulceration in the neuropathic foot.

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Fig. 1.

Applied pressure at the second metatarsal head decreased relative to the barefoot (BF) condition with increasing use of therapeutic footwear (Shoe) and orthotic devices (TCI = Shoe + total contact insert; MTP = TCI + metatarsal pad). Differences noted between all four conditions (* $p < 0.004$).

Fig. 2.

Soft tissue strain (STS) at the second metatarsal head decreased relative to the barefoot (BF) condition with increasing use of therapeutic footwear (Shoe) and orthotic devices (TCI = Shoe + total contact insert; MTP = TCI + metatarsal pad). Differences found between all four conditions (* $p < 0.042$).

Fig. 3.

Stress-strain plots for the soft tissue beneath the second metatarsal head (2nd MTH) and the midshaft of the second metatarsal (MShaft) for the 20 subjects across four conditions: 1) Barefoot, 2) Shoe, 3) Total contact insert, and 4) Metatarsal pad.

Fig. 4.

Mean soft tissue strain (STS) in percentage of strain (solid line) and applied pressure difference in Pascals x 10⁴ (dashed line) shown at 16 consecutive points (total distance 8.13 cm) along the second metatarsal for the 20 participants for all four testing conditions. Note the high association between STS and the applied pressure for all four conditions.

Table 1

Subject characteristics

Number of subjects	20
Gender	12 M/8 F
Mean age (SD)	57.3 (9.3) years
Body Mass Index	32.5 (7.4) kg/m ²
Vibratory perception threshold	48.3 (4.1) volts
DM type	5 (Type 1) 15 (Type 2)
Duration of DM	16.1 (10.5) years
Mean number of prior ulcers	2.6 (±2.1)
Location of prior ulcers:	
Hallux	12
1 st MT head	7
3 rd MT head	2
5 th MT head	2
Midfoot	5

Table 2

Pressure and soft tissue thickness (STT) at the second metatarsal head (2nd MTH) and correlation coefficients for soft tissue strain (STS) and applied pressure along the second ray

Testing condition	Preloaded pressure @ 2 nd MTH (kPa)	Loaded pressure @ 2 nd MTH (kPa)	Preloaded STT @ 2 nd MTH (mm)	Loaded STT @ 2 nd MTH (mm)	r for 16 points along 2 nd ray	r ² for 16 points along 2 nd ray
BF mean (SD)	3 (4.8)	275 (150)	11.6 (1.9)	7.1 (1.7)	0.81	0.69
Shoe	3 (4.8)	176 (96)	11.6 (1.9)	8.0 (1.8)	0.75	0.60
TCI	3 (4.8)	143 (63)	11.6 (1.9)	8.2 (1.7)	0.73	0.60
MP	3 (4.8)	101 (53)	11.6 (1.9)	8.8 (1.7)	0.44	0.30