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ORIGINAL ARTICLE

An Apparatus to Quantify Anteroposterior and Mediolateral Shear Reduction in Shoe Insoles

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Abstract

Background:

Many of the physiological changes that lead to diabetic foot ulceration, such as muscle atrophy and skin hardening, are manifested at the foot–ground interface via pressure and shear points. Novel shear-reducing insoles have been developed, but their magnitude of shear stiffness has not yet been compared with regular insoles. The aim of this study was to develop an apparatus that would apply shear force and displacement to an insole's forefoot region, reliably measure deformation, and calculate insole shear stiffness.

Methods:

An apparatus consisting of suspended weights was designed to test the forefoot region of insoles. Three separate regions representing the hallux; the first and second metatarsals; and the third, fourth, and fifth metatarsals were sheared at 20 mm/min for displacements from 0.1 to 1.0 mm in both the anteroposterior and mediolateral directions for two types of insoles (regular and shear reducing).

Results:

Shear reduction was found to be significant for the intervention insoles under all testing conditions. The ratio of a regular insole's effective stiffness and the experimental insole's effective stiffness across forefoot position versus shear direction, gait instance versus shear direction, and forefoot position versus gait instance was 270% ± 79%, 270% ± 96%, and 270% ± 86%, respectively. The apparatus was reliable with an average measured coefficient of variation of 0.034 and 0.069 for the regular and shear-reducing insole, respectively.

Conclusion:

An apparatus consisting of suspended weights resting atop three locations of interest sheared across an insole was demonstrated to be capable of measuring the insole shear stiffness accurately, thus quantifying shear-reducing effects of a new type of insole.

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Abbreviations: (AP) anteroposterior, (CV) coefficient of variation, (DFO) dynamic foot orthosis, (DFU) diabetic foot ulceration, (ML) mediolateral

Keywords: diabetic foot, diabetic foot ulceration, orthotic devices, shear, shear stiffness

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Introduction

Diabetic foot ulceration (DFU) is a common and largely preventable complication accounting for a significant amount of avoidable contemporary medical amputations.[1–4] A technical review published by the American Diabetes Association showed that "preventive foot care"—a multidisciplinary field that utilizes risk assessment tools and methodologies, therapeutic footwear, and patient education—decreases the risk of DFU-associated amputation by as much 85%.[2] While some studies have described high-pressure areas in the plantar aspect of the diabetic foot as being predictive of foot ulceration,[3–7] identifying peak pressure alone is not adequate in determining the subsequent development of these ulcers.[3,6] In a case control study of more than 200 patients with diabetes, Armstrong and coauthors[3] found that there was no predictive cutoff for peak pressures in patients that ulcerated. Veves and coauthors[7] reported that only 38% of ulcer locations matched the peak pressure location. These results indicate that factors other than vertical compressive forces may play a significant role in ulceration.

Investigations have revealed a possible link between shear and the development of foot ulcers.[4,8–12] Additional evidence has also shown the correspondence of peak shear and peak pressure occurrence along the feet of patients with diabetes mellitus peripheral neuropathy to be of significant clinical importance.[9]

Clinical investigation of such matters cannot be overemphasized. Yavuz and coauthors[10] found that mathematical modeling alone could not accurately describe many instances of pressure loads and stresses on the foot, citing location errors of considerable magnitude in comparison with actual measurements of shear. This emphasizes the importance of developing a robust, reproducible means to accurately quantify the shear stiffness of various types of insoles for the purpose of alleviating diabetes-related lower-limb pathologies.

There are a few commercially available insoles that are being marketed or tested for their ability to reduce shear stress, that is, stress resulting from a force applied in parallel to the cross-sectional area of the insole. Those that have been tested in laboratory settings include Plastazote, Pelite, Poron, PPT®, Spenco, and Sorbothane; nylon-reinforced silicone; and NickelPlast.[13,14] Despite the inherent promise to reduce amputations, a systematic review concluded that many contemporary DFU prevention efforts, particularly therapeutic shoes and vertical stress reducing insoles, have thus far fallen short.[1] This same study, however, emphasized that shear stress-reducing insoles appear to hold the promise of preventing foot ulcers. In fact, Lavery and coauthors[15] have shown that shear-reducing insoles tend to prevent foot ulcers in high-risk patients with diabetes more effectively than traditional insoles, further emphasizing the necessity of a standardized method of quantifying shear reduction effects. The shear-reducing insole used in the work of Lavery and coauthors[15] utilized an insole currently on the market by Vasyli using GlideSoft® technology and composed of the following layers: Outlast® constant temperature material cover, Plastazote, a shock-absorbing layer, Teflon®, and ethyl vinyl acetate all sewn together with elastic.[15,16] This is similar in nature to the dynamic foot orthosis (DFO) insole under consideration within this study, which has the free-floating distal segment consisting a silicone layer at the metatarsal head with the remainder of the anterior section made of two separated orthotic layers (nylon fabric lining on the bottom) that slide over each other, as shown in **Figure 1**, to reduce the shear strength on the insole and shear stress on the foot. The DFO was developed by the University of Michigan Orthotics and Prosthetics Center to reduce sliding friction, compressive forces, and torque at the metatarsal heads. Though DFO insoles have anecdotally been shown to prevent and treat DFUs, the field currently has a dearth of replicable quantifiable data. To remedy this situation, an apparatus was developed in this study to measure shear stiffness at three locations in the forefoot region of shoe insoles, allowing for the quantification of the effectiveness of novel insoles as compared with regular insoles in reducing the shear forces under the foot. The apparatus was designed to mimic the forces experienced during various phases of the traditional gait cycle,[10–12] thus going beyond similar methods that only used single weights[16] to examine possible gait-related effects. Differences in shear stiffness—the ratio of applied shear force to the corresponding shear deformation—between a DFO insole and a regular insole were examined, and the reliability of the testing apparatus was performed.

In this study, a simple insole shear stiffness measurement system was developed to measure shear and quantify the performance of the DFO insoles. The design, setup, and working procedure for the apparatus are presented. Then the

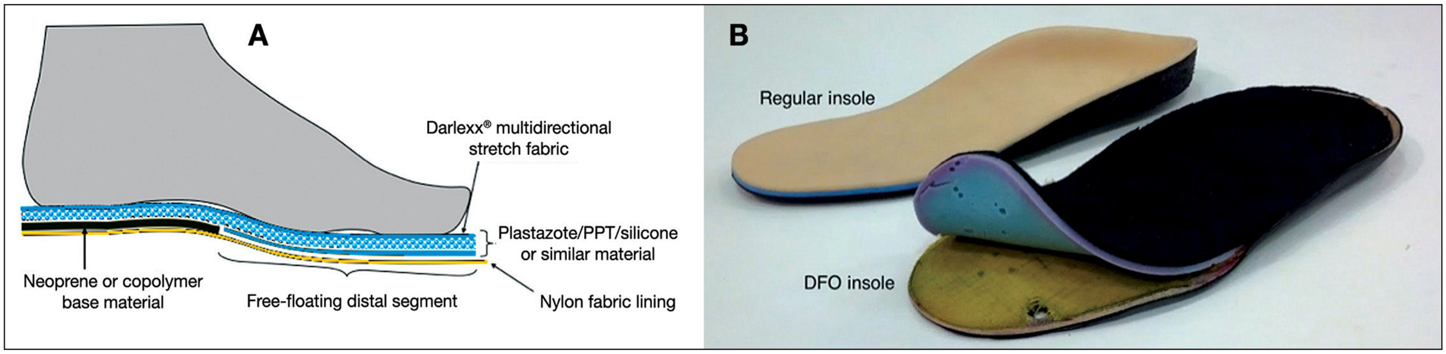

Figure 1. (A) Schematic diagram of the DFO showing the combination of special materials and a free-floating distal segment, which are responsible for shear reduction, and **(B)** picture of the regular insole and the DFO insole, with the free-floating distal segment of the DFO shown peeled by back from the base material.

shear stiffness measure experiments involving the regular and DFO insoles are described. The results demonstrated that the developed apparatus can reliably measure the shear stiffness of the insoles accurately. Compared with the regular insoles, the DFO insole reduced shear stiffness greatly.

Methods

The insole's shear stiffness in the anteroposterior (AP) and mediolateral (ML) directions at areas of interest in the forefoot (the metatarsal heads, toes) under a simulated gait cycle and the associated deformation under steady-state conditions is important to characterize the insole performance. To measure the insole's shear stiffness, an apparatus was developed, as shown in **Figure 2A**. The apparatus consists of six major components: (i) a Kistler 9255-A piezoelectric force dynamometer to measure the force in both AP and ML directions, (ii) an electric actuator (Siskiyou Model 200cri) to generate the shear motion and shear force across the shoe insole, (iii) individual weights suspended atop points of a suitable area (5.07–11.4 cm^2) held in place on the insole via a ridged adapter to prevent slippage and moved by an actuator to apply a compressive force during shear testing to simulate forces during gait cycle and allow for minimal displacement, (iv) a foot-shaped adaptor bolted to the flat plate meant to hold the insole firmly, (v) a flat plate between the foot-shaped adaptor and the dynamometer to approximate ground conditions, and (vi) the shoe insole under examination. **Figure 2C** shows the configuration and direction of the test and the weight imposed on the insole. A foot-shaped adaptor was connected to the shoe insole and linear stage with individual weights suspended atop points of a suitable area to simulate the gait cycle. The electric actuator's motion generates the shear motion and shear force across the insole. The induced shear force was measured by force dynamometer in both AP and ML directions on the shoe insole.

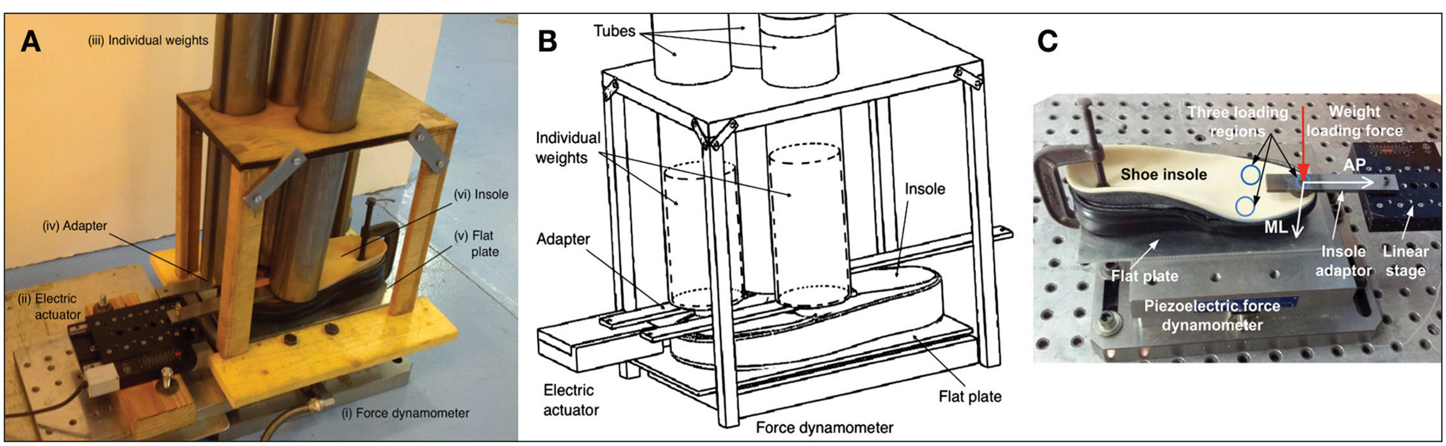

Figure 2. (A) Picture of the apparatus used during tests of the insoles, **(B)** a simplified schematic representation of the apparatus, and **(C)** the configuration and directions of tests.

The forefoot region was broken down into three regions for testing as seen in **Figure 3** consisting of (i) the first and second metatarsal heads (medial metatarsals); (ii) the third, fourth, and fifth metatarsal heads (lateral metatarsals); and (iii) the big toe (hallux). These regions were chosen based on their ability to approximate the positions of highest shear and pressure points. Values of peak shear stress for the regions of the foot were ascertained from existing literature[11,17] and informed the weight placement for each instance of the simulated gait cycle.

Testing was done on 20%, 40%, 60%, and 80% instance of the gait cycle for the three chosen regions in both the AP and ML directions for the shear reduction shoe sole from the DFO and regular insoles. Several instances of the gait cycle were chosen to measure a broad range of forefoot loading, enabling any possible nonlinear tendencies of the insoles to become apparent, a fact that might not otherwise have been possible to ascertain. Additionally, force measurements were made while shearing displacements ascending and descending to observe any hysteretic effects. To replicate the forces at given gait instance, the testing regions' position, shear direction, gait cycle, and weights applied are as shown in **Table 1**. The actuator generates the displacement in pairs that increased from 0.1 to 1.0 mm in 0.1 mm increments (the first displacement pair travels from 0.0–0.1 mm, the second 0.0–0.2 mm, and so on) and then decreased in the same manner from 1.0 to 0.1 mm with a speed of 20 mm/min. This pattern was chosen so that each single displacement could be compared with both its matching pair and across ascending and descending displacement increments to observe any hysteresis. No difference was observed between single displacement versus force measurements and this shear pattern. No slippage was observed between the ridged adapter on top of which the weights rest and the insoles tested within this range of displacement. **Figure 4** shows the typical measured force curve of the AP direction on the toe position with 80% gait cycle loading. The same procedure was carried out for the three regions (**Figure 3**) in the AP and ML directions, respectively. For each testing forefoot position with given gait instance and shear direction, the tests were repeated three times. Signal drift from the force dynamometer was removed and postprocessing peak detection software reported the values of maximum shear force at each level of displacement for every run.

Table 1.
Approximate Values of the Masses Applied to the High-Pressure Regions During Testing[a]

Instance of gait cycle (%)	Toe (kg)	First and second metatarsals (kg)	Third, fourth, and fifth metatarsals (kg)
20	0	5	3
40	4	10	7
60	10	13	9
80	18	17	10

[a] These values were chosen based on existing literature values.[11,17]

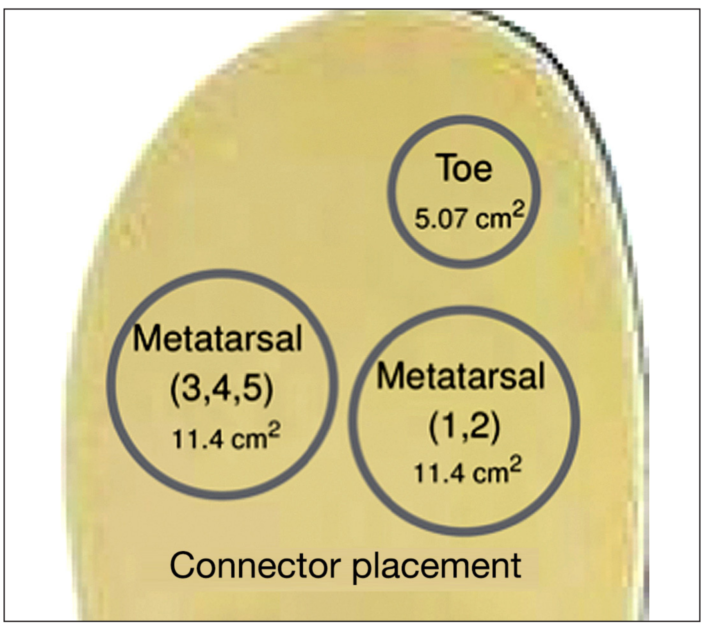

Figure 3. Approximate position of the three loading-point locations on the insole and their representative areas for shear stress analysis in the forefoot region.

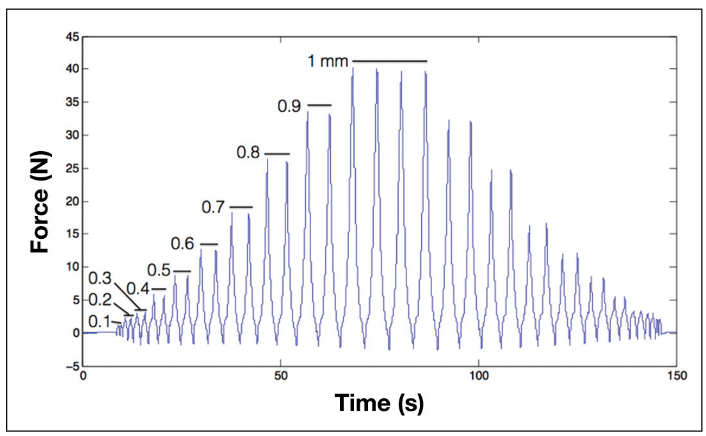

Figure 4. A representative measurement of force as a function of time. The run seen here is a regular insole sheared at the first and second metatarsal heads in the AP direction during 80% of the gait instance. The pairs of shear displacement are shown on the ascending path when displacements are increased from 0.1 to 1 mm in 0.1 mm increments. This pattern was chosen so that each single displacement could be compared with both its matching pair and across ascending and descending displacement increments to observe any hysteresis.

Shear stiffness is a critical parameter to characterize insole performance, found via simple least squares linear regression of the displacement versus peak shear force relationship for each insole—over the experimental range of displacements at each of the three designated forefoot regions, as shown in **Figure 5**. The shear stiffness reduction is used to compare the difference between the two insoles and can be calculated by taking the ratio of the averaged slopes. These parameters were chosen for their replicability, broadness of scope, ease of implementation, possible elucidation of nonlinear trends at higher displacements, and conservative estimation of shear reduction. Furthermore, it permits comparison within and between insoles, shear direction, and gait instances. By fitting a linear slope to displacement versus peak shear slope through linear regression, the effective stiffness of a particular trial can be estimated. The average effective stiffness was calculated over the range of displacements for both types of insoles at each point of interest for all gait instances.

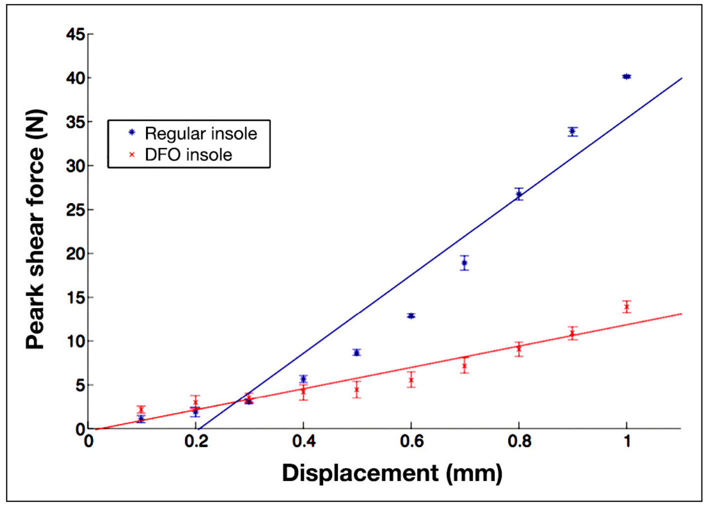

Figure 5. Displacement versus force graph of a typical experimental run. The results presented here are for both regular and DFO insoles sheared at the first and second metatarsal heads in the AP direction during 80% of the gait instance. The slopes of the fitted lines represent the effective stiffness of the insole.

For statistical analysis, one-tailed, two-sample *t*-tests assuming unequal variance (Welch's *t*-test, via the statistical software package R) at $p < .05$ across the subsets of position versus shear direction, gait instance versus shear direction, and forefoot position versus gait (H_0 shear reduction = 0% and H_a shear reduction > 0%) were performed. Ninety-five percent confidence intervals were calculated using pooled intertrial variance. Reliability was measured through the unbiased sample coefficient of variation (CV) for each insole at every direction, position, and gait instance combination (with $n = 6$).

Results

A typical result from the measured displacement versus force curve can be seen in **Figure 5** (this particular trial is for both a regular and DFO insole at the first and second metatarsal heads in the AP direction during 80% of gait instance). The peak shear force increased as shear displacement increased, with the DFO insole on the whole generating much lower peak shear forces than the regular insole. No significant hysteresis was seen in the tests.

Figures 6 to **8** show the measured shear stiffness of the regular and DFO insoles versus the four instances of gait loading (20%, 40%, 60%, and 80%) for the three regions. For the regular shoe insole in the AP and ML directions for the first and second metatarsal heads region, the measured shear stiffness increases as the increasing of the instance of gait cycle (%). Intratrial pooled standard deviations (that is, all trials performed at a specific region in a single direction at a particular gait instance) of stiffness measures were found to be within 15% of the average stiffness value in all cases and, in most cases, were approximately 5% (see **Figures 6–8**).

In **Figure 6**, for the regular shoe insoles in the AP and ML directions at the first and second metatarsal heads region, the measured shear stiffness generally increased with increasing gait cycle instance (%). The range of the measured shear stiffness was at approximately the same level in the AP and ML directions, with the same trends observed in the DFO insole. The DFO featured much lower shear stiffness on the first and second metatarsal heads region compared with the regular insole. **Figures 7A** and **7B** show the measured shear stiffness for the regular and DFO insoles versus the four instances of gait cycle at the third, fourth, and fifth metatarsal heads region in AP and ML directions, respectively. In the AP direction, the shear stiffness for the third, fourth, and fifth metatarsal heads region is much lower than that in the ML direction. While at the toe region as shown in **Figure 8**, the shear stiffness in the AP direction is approximately triple that of the value in the ML direction. The DFO also features much lower shear stiffness on the three testing regions compared with the regular insole in the AP and ML directions.

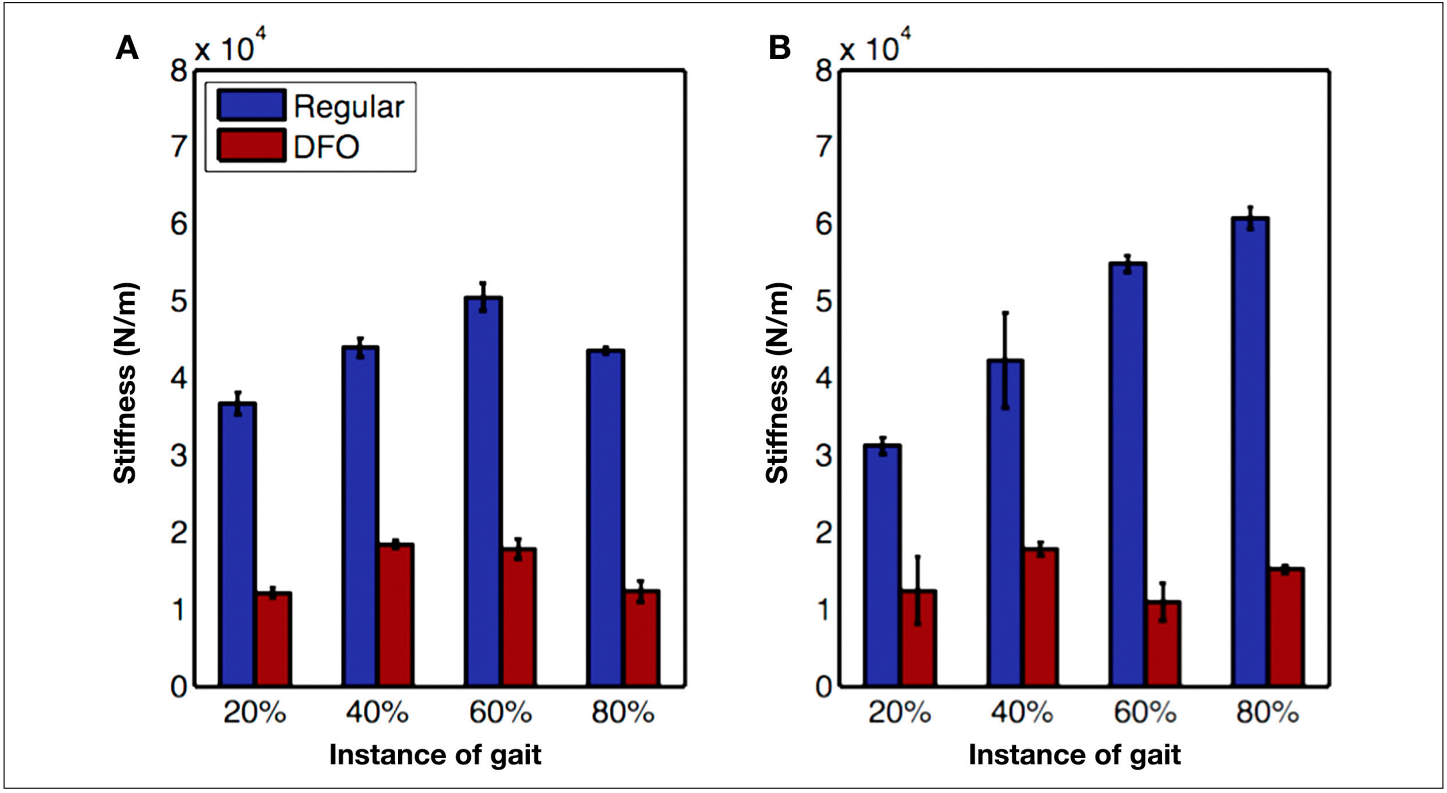

Figure 6. Shear stiffness comparison of a regular (blue) and DFO (red) insoles in the **(A)** AP and **(B)** ML directions for the first and second metatarsal heads region. The averages of six runs (a total of 240 peak shear versus displacement evaluations) for each gait instance (%) are shown along with the corresponding standard deviations.

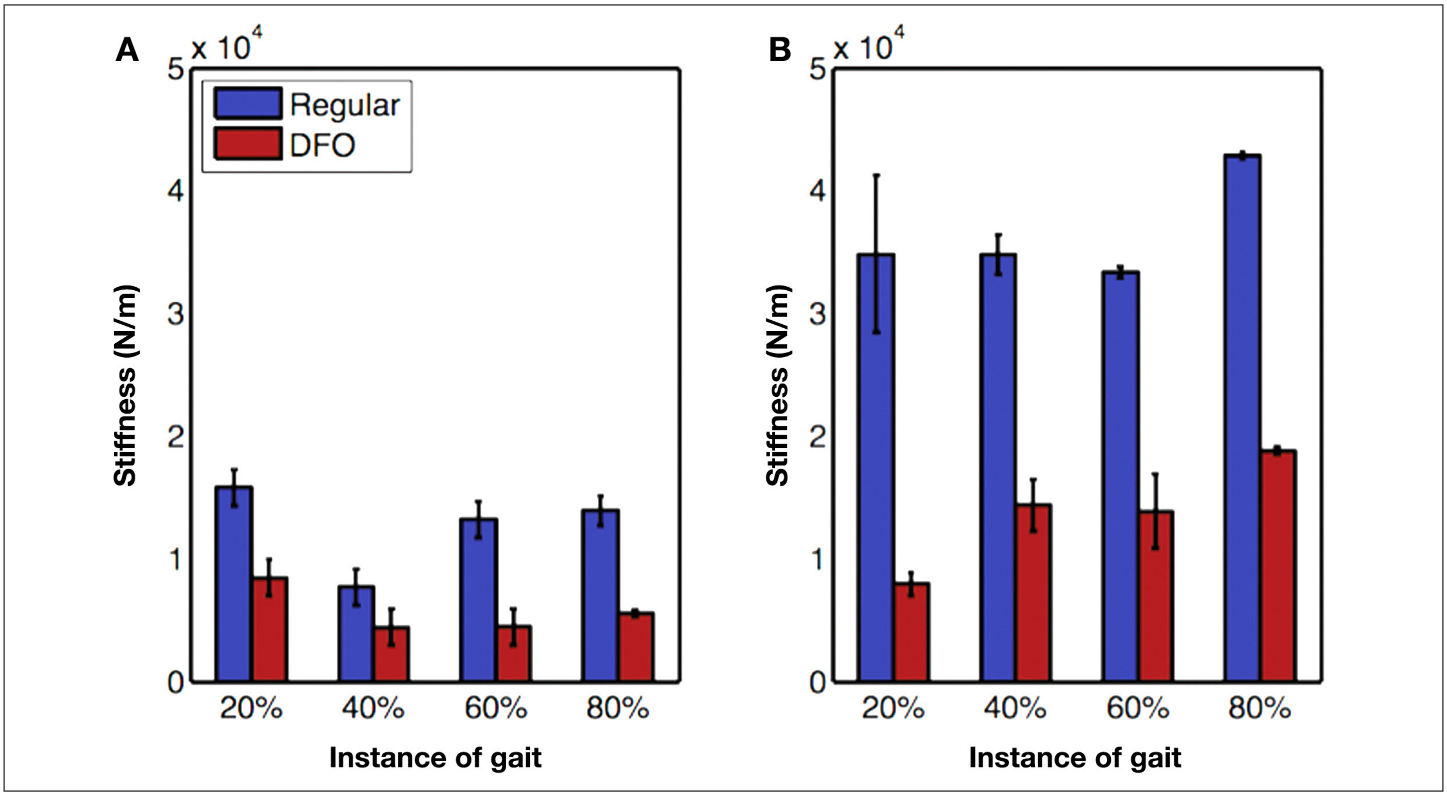

Figure 7. Shear stiffness comparison of a regular (blue) and DFO (red) insoles in the **(A)** AP and **(B)** ML directions for the third, fourth, and fifth metatarsal heads region. The averages of six runs (a total of 240 peak shear versus displacement evaluations) for each gait instance (%) are shown along with the corresponding standard deviations.

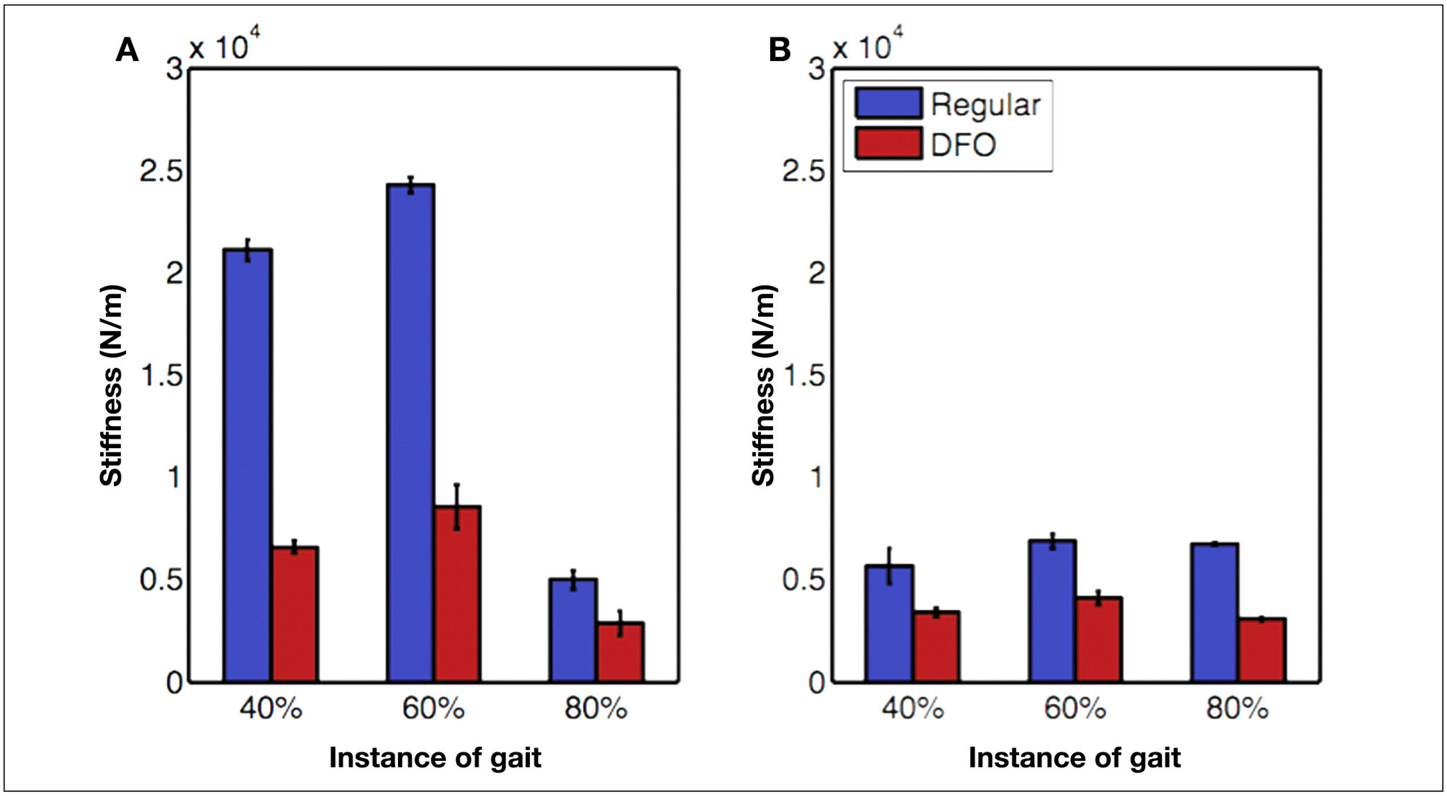

Figure 8. Shear stiffness comparison of a regular (blue) and DFO (red) insoles in the **(A)** AP and **(B)** ML directions for toe region. The averages of six runs (a total of 240 peak shear versus displacement evaluations) for each gait instance (%) are shown along with the corresponding standard deviations.

Compared with the regular insole, the shear reduction of the DFO insole was statistically significant in all cases, as shown in **Figures 6** to **8**. Shear reduction in terms of the ratio of regular insole effective stiffness and DFO insole effective stiffness were also significant across all testing conditions: (1) forefoot position versus shear direction (270% ± 79%), (2) gait instance versus shear direction (270% ± 96%), and (3) forefoot position versus gait instance (270% ± 86%; **Table 2**, **Table 3**, and **Table 4**, respectively). In each of these tables, the confidence intervals are presented in three distinct ways. The first representation is in terms of individual correlations and represented by single cells (for instance, shear reduction at the toe position in the AP direction). The second type of relationship is seen through variable correlations that sum across either rows or columns (for instance, all the AP shears across every forefoot position or the shear reduction at the toe region for all gait instances). Lastly, relational correlations sum across all fields in a particular table (giving us the correlations of forefoot position versus shear direction, gait instance versus shear direction, and forefoot position versus gait instance, seen in grey).

Table 2.
Shear Reduction of the Dynamic Foot Orthosis Insole Compared with a Regular Insole in Terms of the Ratio of the Regular Insole's and the Dynamic Foot Orthosis's Average Effective Stiffness as a Function of Forefoot Position and Direction of Shear[a]

	Toe	First and second metatarsals	Third, fourth, and fifth metatarsals	
AP	260% ± 77%	294% ± 41%	227% ± 57%	260% ± 58%
ML	184% ± 30%	347% ± 126%	287% ± 100%	281% ± 99%
	222% ± 58%	321% ± 94%	257% ± 81%	270% ± 79%

[a] A confidence interval of 95% is shown.

Table 3.
Shear Reduction of the Dynamic Foot Orthosis Insole Compared with a Regular Insole in Terms of the Ratio of Their Average Effective Stiffness as a Function of Gait Instance and Direction of Shear[a]

	Gait instance (%)				
	20	40	60	80	
AP	245% ± 81%	244% ± 74%	288% ± 72%	259% ± 90%	260% ± 70%
ML	344% ± 131%	215% ± 42%	303% ± 175%	282% ± 102%	281% ± 121%
	294% ± 109%	230% ± 60%	296% ± 124%	270% ± 96%	270% ± 96%

[a] A confidence interval of 95% is shown.

Table 4.
Shear Reduction of the Dynamic Foot Orthosis Insole Compared with a Regular Insole in Terms of the Ratio of the Regular Insole's and the Dynamic Foot Orthosis's Average Effective Stiffness as a Function of Forefoot Position and Gait Instance[a]

		Toe	First and second metatarsals	Third, fourth, and fifth metatarsals	
Gait instance (%)	20	—	277% ± 36%	312% ± 176%	294% ± 127%
	40	244% ± 109%	238% ± 10%	208% ± 48%	230% ± 69%
	60	226% ± 82%	392% ± 153%	268% ± 39%	296% ± 103%
	80	196% ± 33%	377% ± 33%	238% ± 16%	270% ± 28%
		222% ± 81%	321% ± 80%	257% ± 94%	270% ± 86%

[a] A confidence interval of 95% is shown. No trial is shown for the toe region at 20% gait instance, because there is negligible loading (see **Table 1**).

The average CV for each trial in every direction, position, and gait instance combination was 0.034 and 0.069 for the regular insole and DFO insole, respectively. An outlier existed for both insoles in the AP direction at the third, fourth, and fifth metatarsals forefoot region at the 60% gait instance (**Figure 7**), giving a CV of 0.106 for the regular insole and 0.185 for the DFO insole. Another outlier (CV = 0.194) existed in the ML direction and the first and second metatarsals position at the 20% gait instance for the DFO insole (**Figure 6**) but is likely attributable to a low gait instance and unique forefoot position (toward the base of the arch of the insole).

Discussions

We successfully demonstrated proof-of-concept in developing an apparatus capable of applying shear force and displacement to the insole forefoot region and calculating insole shear stiffness. The apparatus demonstrated good reliability with an intratrial variation of approximately 5% (CV_{Reg} = 0.034 and CV_{DFO} = 0.069) as seen in **Figures 6–8**. We also quantified the DFO insole's shear reduction in terms of the ratio of a regular insole's effective stiffness and the DFO insole's effective stiffness across forefoot position versus shear direction, gait instance versus shear direction, and forefoot position versus gait instance (270% ± 79%, 270% ± 96%, and 270% ± 86%, respectively). These results compare favorably with Lavery and coauthors[16] wherein GlideSoft insoles (with a thin low-friction region between two materials that acts analogously to the free-floating region as the DFO insole) were found to experience half the peak shear force as regular insoles. The designed apparatus has not only shown that the DFO insole can reduce shear significantly, but more generally has been proven capable of accurately measuring insole shear force and stiffness. Thus it is able to quantify shear reduction performance across different insole types.

Having established a reliable apparatus to quantify shear stress for insoles, we are now in a position to measure the effectiveness of several shear-reducing insoles, including those currently available on the market.

To further synthesize the realms of the theoretical and the clinical, the next step would be replication of results within finite element stress analysis software. This would anchor the empirical evidence obtained via clinical analysis of shear reduction and our own presented data with that of viscoelastic modeling of shoe insole material, equipping engineers with the tools necessary to refine and design these types of insoles to reduce shear in the appropriate regions of the forefoot.

There are limitations to this study. Our unit of analysis of three forefoot regions may not correlate empirically with compartmental motion of the healthy foot.[18] However, it does correlate well with data derived from diabetes patients with peripheral neuropathy and the location of peak pressure and shear points.[11] Similarly, we have reported here only the stiffness derived from strain-rate-controlled shears and not stress-rate-controlled strains, introducing the possibility of underloading and overloading insoles tangentially. We are currently working to extend the apparatus to provide both experimental conditions.

Future work should investigate the quantification of other mitigating foot-insole shear factors such as the effects of friction and slip. By accounting for such factors, additional avenues of real-world analysis are opened, including mimicking patient-specific wear patterns, mimicking time-varying shear patterns, and measuring thermal effects of body heat and friction on insole materials. Taking an even broader perspective, investigations that implant strain, heat, and bioimpedance sensors within insoles to quantify several of the discussed effects in conjunction with clinical examinations could then be used to grasp what factors of insoles significantly impart risk of DFU at the foot–ground interface.

Conclusions

We demonstrated the development of an apparatus consisting of suspended weights resting atop three points of interest sheared across an insole to measure the shear force. The experimental results demonstrated that the developed apparatus can measure the insole shear force and shear stiffness accurately. Using the apparatus, the shear-reducing (DFO) insole demonstrated significantly less shear stiffness (270%) in regions of clinical importance in the forefoot compared with regular insoles. Results from this research open the opportunity of using such a system with relative ease to quantify shoe insole shear stiffness performance and therefore more accurately correlate the effects of shear to the incidence of DFU.

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