A Novel Shear Reduction Insole Effect on the Thermal Response to Walking Stress, Balance, and Gait

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INTRODUCTION

Shear stresses have been implicated in the formation of diabetes-related foot ulcers. Our bench testing of a novel dynamic foot orthoses (DFO), found an average 270% reduction in shear stiffness at various regions of the DFO during the simulated gait cycle. The aim of this study was to evaluate the effect of DFO on thermal response to walking, balance, and gait in subjects with diabetes at risk for foot ulcer.

METHOD

Methods: Twenty-seven subjects with diabetes and peripheral neuropathy were enrolled. Subjects walked 200 steps in both DFO and standard insoles. Spatio-temporal gait and balance were assessed using a validated wearable sensors technology (LEGsys™, Biosensics. LLC, Cambridge, MA, USA). Thermal foot images were taken at

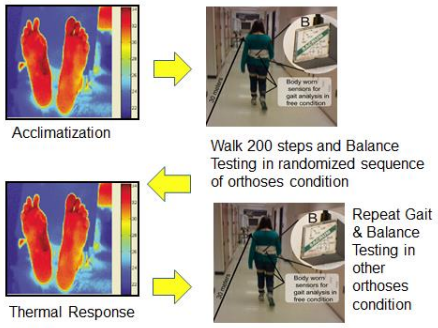

Figure 1. Gait & balance assessed using wearable sensors. Thermal imaging was conducted with Fluke Ti25 thermal imager.

baseline following five minute temperature acclimatization, and immediately after walking using Infra-red Camera (Fluke® T-i25). Testing order was randomized and a five minute washout period was used between trials. Sudomotor function was assessed by measuring electrochemical sweat conductance with a SudoscanTM,(Impeto Medical , Paris, France).

***Data Analysis*:** Comparison across walking task (single task and dual task) for each walking condition (type of footwear) was done with repeated measures ANOVA 2×2 test, and pairwise main effect or interaction comparisons were done using a Sidak adjustment. All calculations were made using SPSS® version 21 (SPSS, Chicago, IL, USA) or Matlab (MathWorks, v7.4).

RESULTS Walking in both insoles increased foot temperatures; however, significant ($p<0.05$) increases was observed in standard insoles only. The DFO significantly reduced forefoot (64.1%; $p=0.008$) and mid-foot (45%; $p=0.046$) temperature increases compared to standard insoles (SCI) (Figure 2). We also observed significant negative correlations with sudomotor function and baseline temperatures ($r=0.53$-0.57). For both single-task and dual-task conditions, there was a trend for improvement in all gait parameters. DFO demonstrated 10.4% less double support time during gait initiation compared to standard insoles ($p=0.05$). During dual-task, we observed a noteworthy 32% reduction in gait variability with DFO (p=N.S.).

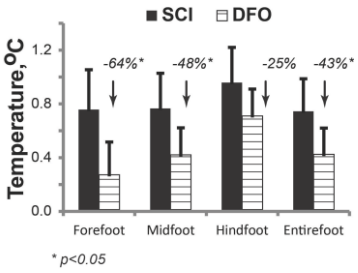

Figure 2. Depicts temperature changes in foot region using standard insoles (SCI) and dynamic foot orthosis (DFO) shear reducing insoles.

DISCUSSION

We found that a novel shear-reducing insole significantly reduced temperature increases over baseline in the forefoot (64%) and midfoot (48%) after walking 200 steps compared to standard insoles.

CONCLUSION

In conclusion, we found significant reductions in forefoot and midfoot temperature increases after known walking stress using a novel shear-reducing insole when compared to standard insoles. We also found sudomotor function demonstrated significant correlations with the thermal response after walking. Future work should focus on the efficacy of the DFO for reducing foot ulcers. Future footwear studies should also consider measuring thermal and sudomotor function changes.

CLINICAL APPLICATIONS

Shear stress-reducing insoles appear to hold the promise of preventing foot ulcers. In fact, studies have shown that shear-reducing insoles tend to prevent foot ulcers in high-risk patients with diabetes more effectively than traditional insoles

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American Academy of Orthotists & Prosthetists
41st Academy Annual Meeting & Scientific Symposium
February 18 - 21, 2015