Reviewer’s report

**Title:** A comparison of customised and prefabricated insoles to reduce risk factors for neuropathic diabetic foot ulceration: a participant-blinded randomised controlled trial.

**Version:** 1  **Date:** 30 April 2011

**Reviewer:** Bijan Najafi

**Reviewer’s report:**

This study compared plantar pressure of 119 neuropathic participants randomized in two groups, one using custom made foot orthoses (CFO) and the other one using pre-fabricated foot orthoses (PFO). They assumed peak pressure is associated with diabetic foot ulcer (DFU) therefore further reduction in peak pressure could be beneficial in reducing the risk of DFU. Data were collected at issue and 6-month follow-up. Their results suggest that there is no any statistically significant difference between two groups in point of view of peak pressure reduction. Authors concluded that custom-made insoles are more expensive than prefabricated insoles and no better in reducing the typically measured peak pressure.

**Major Compulsory Revisions**

This study suffers from three major shortcomings that may make its conclusion invalid or misleading:

1) The majority of participants in this study do not have foot deformity or major foot posture abnormality. CFO may provide a better outcome for those who have abnormal foot posture or foot deformity. While its benefit for patients with normal foot posture or patients without deformity might be minimal. For example, according to Burns et al randomized controlled study (Burns, Crosbie et al. 2006), CFO in those patients with abnormal foot posture (e.g. Pes Cavus) will reduce significantly the peak pressure compared to PFO group. Thus, it stands to reason that in those patients with abnormal foot posture the benefit of CFO could be higher than PFO for reducing the risk of DFU. Therefore it is misleading to generalize the conclusion that CFO does not provide a better outcome than PFO in general DPN population. I strongly encourage authors to use a multivariable statistical analysis (e.g. multiple linear regression analysis) or consider foot posture index as a co-variant (e.g. using N-way ANOVA) to explore whether the benefit of CFO is improved by increasing the foot posture abnormality. Additionally, reporting the existence of foot deformity and consider them for statistical analysis as potential confounding factor could be very helpful.

2) This study does not address two important confounding parameters for measuring plantar pressure. Two main parameters may bias peak pressure measurement are 1) gait velocity, 2) body mass. Considering that this is a randomized study it may assume that there is no significant difference between
two groups in point of view of weight, height, age, and body mass. The data in the Table I also confirms this hypothesis. However, it would be interesting to consider body weight as confounding to explore whether in patients with higher BMI, the benefit is the same or different than those with lower BMI. Additionally, authors should control gait velocity of participants after wearing orthoses. Previous study suggests that peak pressure is significantly increased by increasing gait velocity. (Najafi, Crews et al. 2010) Subjects by wearing different orthoses may change their normal gait velocity that in turn may bias the results. According to Wrobel et al.(Wrobel, Edgar et al. 2010) and Najafi et al.(Najafi, Miller et al. 2010), gait velocity is changed as a type of footwear. Therefore it stands to reason that gait velocity increase due to wearing orthoses may be higher in CFO compared to PFO group. Therefore, a potential increase in gait velocity in CFO group may mask its benefit. If authors unable to estimate the gait velocity from the gathered data, they may measure the duration of stance time using F-scan data and examine whether there is a significant difference between two groups or consider the stance duration as co-variance for their statistical analysis.

3) There are many factors that may contribute in developing of diabetic foot ulcer in patients with diabetes. High plantar pressure could be one of them. Although some researchers suggested that those who developed foot ulcer had higher peak plantar pressure than non-ulcerated patients, there is no any evidence to indicate that ulcer happens on those spots where the pressure is high except other factors such as foot deformity, callus, joint motion limitation, or abnormal gait cause such pressure increase. Indeed, offloading is a very helpful technique to accelerate DFU healing but to me it is not a valid to hypothesize that reducing plantar pressure will necessary reduce the risk of DFU! On the other hand in those who have limited joint range of motion, abnormal posture, abnormal gait, etc designing appropriate CFO may reduce the risk of DFU since they may modify the biomechanical problem associated with abnormal gait one of the important risk factor associated with DFU. Therefore, it may not valid to conclude that since CFO does not reduce peak pressure further than PFO in general diabetes population therefore it cannot reduce the risk of DFU. But may be valid to conclude that additional gait examination is required to decide whether prescribing a CFO is beneficial.

Discretionary Revisions:

1. Page 7: Report the sample frequency of measurement.
2. Page 7- Were the initiation and termination phases excluded from data analysis? How many steps were averaged for the final results?
3. Page 7: Did subjects wear their own shoes or the type of shoe was standardized?
4. Page 7: A description about identifying different anatomical region of foot or the process of masking would be helpful
5. Page 10: Insoles v. no insoles – present the statistical values for each statement.
6. Page 11- Discussion – last paragraph. I am not sure this is a true claim that there is no any prior randomized study that explored the benefit of CFO in reducing peak pressure compared to PFO! For example, Burns et colleagues (Burns, Crosbie et al. 2006) in a randomized study of over 120 subjects demonstrated a significant reduction of plantar pressure in CFO group compared to PFO in Pes Cavus population.

References:


Najafi B, Miller D, Jarrett BD and Wrobel JS: Does footwear type impact the number of steps required to reach gait steady state? an innovative look at the impact of foot orthoses on gait initiation. Gait Posture 32:29-33, 2010


**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests' below