Reviewer’s report

Title: The effect of customised and sham foot orthoses on plantar pressures

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Reviewer: Stephen Urry

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General
The paper is well structured and easy to follow and presents results that will be useful to both clinicians and researchers. The method is reasonably sound. With minor revisions this paper should progress to full publication.

Methods
(Minor essential) It might be important for some readers to know, in more detail, who the participants were and how they became involved in the study. Did they present at a clinic or were they recruited from the university staff? If from a clinic, were they deemed to be “patients” with “specific foot problems”? This has relevance to the issue of expectancy, and is important considering that a Credibility/Expectancy Questionnaire was used to derive some of the outcome measures. This aspect (the nature of the participants, their podiatric background, and the CEQ) should then receive a little extra attention in the discussion. While the major focus of the study clearly relates to the mechanical effects on plantar pressures, the inclusion of the CEQ really dictates the need for a short commentary.

(Minor essential) How were the orthoses initially presented to the participants? Was there an element of single-blinding (the provider knew the differences between orthoses but these were hidden from the participant)? Were the orthoses handled and seen, closely, by the participants or were they placed covertly in the shoes so that the expectation was based only on sensation from wearing them? Again, it could be expected that such factors could sway the expectations of the participant. Please expand this in the method and discussion sections, as appropriate.

Procedures
In paragraph 2:
The Pedar-X insole was placed on top of each orthotic condition and they were zeroed prior to…
Could be better phrased as:
In each test condition, the Pedar-X insole was placed on top of the orthosis and was zeroed prior to…

Results
When describing the plantar pressure results, the authors have tended to use phrases in the form, “The customized foot orthosis significantly increased maximum force compared to the contoured EVA sham orthosis…”. It would be preferable for such results to be phrased as, Maximum force was significantly greater with the customized foot orthosis compared with the contoured EVA sham orthosis. The second form is neutral and does not imply cause and effect.

Discussion

To state that polyethylene is "lacking compressibility" is technically incorrect. It would be better to say something such as, “under these loading conditions, the compressibility of polyethylene is insubstantial or negligible”, or even, “thin polyethylene appears to lack significant compressibility”.

It is preferable to state, “The contoured polyethylene sham orthosis was one-third the thickness of both EVA devices…” (thickness is the measurand, not thinness). This would also maintain continuity with the remainder of the sentence, “reduced material thickness…”.

(Compulsory revision)During their discussion regarding technical issues of in-shoe pressure measurement the authors indicate that the “resultant force is recorded” (because the sensors are insensitive to shear). I think the authors have made a mistake here – in a sensor which is capable of measuring both “vertical” and shear components, the resultant force can be calculated, whereas in a sensor which is insensitive to shear only the “vertical” component is known. In physics/mechanics/engineering etc, the “vertical” component is usually referred to as the “normal” component (“normal” indicating that the component is perpendicular to the contact surface – only when the contact surface is horizontal will the “normal” component be vertical (aligned with gravitational force). So, in an application like the one reported, the pressure sensors are modeled as indicating the discrete forces acting “normal” (perpendicular) to the contact surface. Because the contact surface on an orthosis is curvelinear but the sensors are usually calibrated when placed flat, it is possible that measurement error occurs, although the magnitude of any such error is currently unknown.

(Minor essential) The authors comment that “kinematic and kinetic effects associated with foot orthoses occur via changes in foot plantar pressures”, citing Redmond et al 2009, however this presents a rather narrow perspective. The authors should consider balancing this statement with a commentary regarding current interests in, for example, the “muscle tuning paradigm” (Nigg) which focuses more on transient impact forces. Like plantar pressures, transient impulses, are aspects of mechanical loading, but the method through which effects occur are substantially different and they should be considered separately.

Specific comments

Would the authors consider replacing the term “inert”, which they have used on several occasions through the report (with the good intention of indicating that the orthosis/orthoses under consideration was/were having minimal effect), since
it somewhat implies that the orthosis didn’t change? Also, it is rather close to “inertia” which, in mechanics and physics, indicates resistance to change. To do nothing, be inactive or resist change does not necessarily mean that there will be no effect! The term inert is, therefore, less than optimal. In paragraph 1 of the discussion, the authors state, “the contoured polyethylene sham orthosis was the only sham condition to have a minimal effect”, and this, in my opinion, is a far better phrase. (minimal, negligible, slight, small, nominal, marginal…).

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

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests