Reviewer's report

Title: Efficacy of customised functional foot orthoses in the treatment of Achilles tendinopathy: study protocol for a randomised trial

Version: 1 Date: 11 June 2009

Reviewer: Joshua Burns

Reviewer's report:

The study protocol is very well-written.

Major Compulsory Revisions

1. It is unclear how the authors expect custom foot orthoses to help Achilles tendinopathy. The literature is sparse and in some cases contradictory. The rationale for prescribing a custom device in light of contradictory evidence as to their mechanism of action needs expansion. For instance, if custom foot orthoses reduce pronation and realign the calcaneus, how are they expected to help people with ‘normal’ feet and ‘supinated’ feet which may not need realignment or mechanical support and who may end up being the majority of participants. Similarly, the modification of the device for the supinated foot type according to Burns et al (2006) was originally designed to reduce and redistribute plantar pressure. It is unclear how these properties will assist Achilles tendinopathy.

Allocating the most commonly prescribed device is pragmatic and understandable but the authors need to provide a rationale of how they expect it to help people with Achilles tendinopathy. If the mechanism of action is unclear and not mechanical, then simply prescribing footwear or a prefabricated intervention may be suitable.

It would be helpful to understand, at least in the authors’ experience, which of the design features of the custom device are expected to act on the complaint.

2. Did the authors consider controlling footwear? Treatment effect may relate to differences in footwear choices rather than differences in the device. For instance, the custom device requires deeper footwear and in many cases a fastening device for comfortable wear, but the sham can be worn in a wider variety of footwear due its highly compressible nature. Even though an inclusion criteria is accommodating footwear, the transient nature of footwear choices will depend on the device allocated for the 12-months study duration, especially for non-athletes.

3. Please clearly state which time-point and domain(s) of the VISA-A constitute the primary outcome. As it stands, there seems to be the potential for 16 comparisons as the primary endpoint (VISA-A Pain, Function, Activity or Total at 1, 3, 6, 12 months). Once selected, please justify the domain and time-point the
authors are most interested in improving in the context of natural history data of Achilles tendinopathy.

4. Did the authors consider stratification (or minimisation) for foot type and body mass to help balance the groups in case a particular foot type or weight category is prognostic of a treatment response?

Minor Essential Revisions
1. Reference no. 1 is not an epidemiological study as referred to in the opening sentence of the introduction (‘6-18%….‘). Please amend with the original source.

2. How will the custom orthoses be obtained: purchased, discounted, donated?

Discretionary Revisions
1. The word ‘functional’ in the title is meaningless, especially in light of our lack of understanding of how an orthosis produces its ‘function’.

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:

Non-financial competing interests: I have co-authored research papers with Dr. KB Landorf.