Reviewer’s report

Title: Medical Grade Footwear: The impact of fit and comfort

Version: 0 Date: 24 Oct 2016

Reviewer: Emma Cowley

Reviewer's report:

A clear opening to the abstract - minor amendment is in the results 'their' not 'the' perceived comfort

Please also change the line about the medial border of the 1st metatarsal being statistically 'different' to 'higher or lower (p<0.05)'

P4

In the introduction, please change 'The forefoot has been highlighted as the most frequent area of pain related to footwear [1]. Forefoot pain is commonly associated with wearing ill-fitting footwear [2,3]; causing pressure over bony prominences on the dorsum of the lesser toes, the medial aspect of the first metatarsal head or the lateral aspect of the fifth metatarsal' to:

'The forefoot has been highlighted as the most frequent area of pain related to footwear [1] and is commonly associated with wearing ill-fitting footwear [2,3] with associated pressure over bony prominences on the dorsum of the lesser toes, the medial aspect of the first metatarsal head or the lateral aspect of the fifth metatarsal.'

Line 9 seems to relate to shoe length with assumption that footwear has led to lesser toe deformities - Coughlin's 1984 article postulates the reason for deformity and Menz' et al.'s footwear characteristics study describe common findings and is not a prospective study of the development of lesser toe deformities. Neither should really be used as a citation to imply without doubt that this is the way toes deform - be a little more speculative.

By contrast you are citing an experimental study in the line about shod feet being stiffer and downgrade this to 'shod feet are thought to be' when actually you could upgrade this by critiquing the study and noting the findings - how was stiffness measured, was it a large study etc.

Line 25 in the introduction needs to be reworded with some explanation of the 'recent studies' cited and avoid the word 'cramping' unless you mean muscle cramp rather than confinement of the toes in a small space.
Line 32 - avoid the use of 'it is thought' and 'transverse metatarsal arch' when referring to the spread of the distal parts of metatarsals (the transverse arch is at the proximal end). Instead cite the reasons that one might think this eg study findings.

Metatarsal splay is better described as horizontal splay not coronal splay when the foot is plantigrade.

This line is supposition - Poorly fitting footwear compresses the digits and alters function, eventually leading to structural changes - please be less 'sure!!'. Try and postulate in the absence of prospective study or where cause and effect has been demonstrated in controlled trials.

Line 36 again is too black and white - try and add nuance eg: This subsequently subjects the toes to increased pressure from the upper of the shoe and, in some people, could lead to tissue breakdown/ulceration.

Line 36: ill-fitting footwear 'is' not 'are'

Line 40 This is the real 'so what' line - the impact of why your study has value building on the findings of previous studies investigating the effects of footwear on foot ulceration rates. Rather than saying footwear is a 'major' cause of anything, be more specific. Please add more detail here eg a large, randomised controlled trial (or whatever is relevant here!) showed an x reduction in re-ulceration rates. Make your point with more analysis and you'll have a springboard for your study.

The same is needed in the penultimate line of the introduction - you are citing percentages which are not very meaningful until you cite the numbers in a study - if the study of robberies in a quiet street reported a 100% increase in a decade it would sound alarming until you realise that there was only 1 robbery last decade and 2 this. If you are citing percentages from studies add the numbers in brackets eg 25% (10 out of 40) to ensure the percentage is interpreted correctly.

Line 55: recommended by NICE not just recommended (as opposed to a Trust or charity etc - NICE is the gold standard so tell the reader who recommends it)

Again, you are losing the significance of your argument saying 'studies suggest' in line 55. Which studies, how big, which patient group, what did the studies look at?

Overall, you need to add more critical depth to your literature review.
Methods:

Line 21: add spaces between the = signs

Did you do a power calculation? If so please it here or add a reason why n=30 was your chosen sample size

Line 24: NHS or private?

Line 25: which university ethics committee?

General note: the font is changing throughout - this should be uniform across the document

Line 30: change pathologies to deformities

Line 53: change pathologies to deformities

P6

More detail on the condition of the participants' own footwear would be useful to help compare the data eg age / condition, size, heel heights etc

Line 57: validated against what? Please add more in the literature review about how pressure is measured and how this system was validated rather than discussing the validity of a tool in the methodology

P7

Line 22: (IBM SPSS, Version 24, USA)

Please add what alpha was set at

P8

Comfort scale values need absolutes - values of change eg 3 points on the VAS.

Line 17: name the statistical tests

P9:

Line 28: add cycle after gait
References need to be tidied and standardised - there are changes in font and odd parentheses by author initials

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