Author’s response to reviews

Title: Feasibility of designing, manufacturing and delivering 3D printed ankle-foot orthoses: a systematic review

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Handling Editors comments:

Please ensure that this systematic review is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (see Liberati A, Altman DG, Tetzlaff J, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. BMJ (Clinical research ed) 2009;339). Once this has been performed, please provide a statement that this has been done in the 'methods' section of the manuscript.

- The systematic review has been reported in accordance with the Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) guidelines. This has been added to the methods sections on page 5, line 92.

Reviewer #1
Method' section:

Line 93 - comma required before 'EMBASE'
- Amended (page 5, line 96)

Line 94 - 'and' required before 'ProQuest'
- Amended (page 5, line 98)

Line 96 - 'manufacture' spelling error
- Amended (page 5, line 99)

'Study selection, data extraction and study quality' section:

Line 122 - no comma required after 'title'
- Amended (page 7, line 126)

'Orthotic details' section:

Line 199 - readability of this sentence may be improved by separating it into two sentences:

Three studies used Nylon 12 (PA2201, DuraForm PA, PA2200) [10, 11, 15]. A range of materials were used in the remaining studies including Rilsan D80 (Nylon 11) [11], DuraForm GF (Glass filled Nylon 12) [11], Accura 40 resin [12], DSM Somos 9120 Exposy Photopolymer [12], DuraFrom Ex [13], medical-grade polycarbonate [14], acrylonitrile butadiene styrene (ABS) [16, 17], polylamide 12 (PA12) [18], polyurethane [19] and polylactide (PLA) [20].
- Amended (page 10, line 205)

'Outcomes' section:

Line 209 - 'The reported outcomes included…..'
- Amended (page 10, line 215)

Line 213 - 'The reported mechanical properties included…..'
The material displacement of the AFO model was higher when mechanical properties were derived from test specimens compared to when mechanical properties were supplied from FEA software (SolidWorks 2016). This illustrates the need to use mechanical properties from 3D printed test specimens rather than default material properties.

‘Conclusion’ section:

I have some concerns that the conclusion of this review firmly states that 3D printing of AFOs is ‘feasible’ despite earlier discussion around mechanical failures of AFOs whilst being used by clients and structural issues when AFOs are exposed to UV light in some manufacturing techniques.

Considering this, I think the conclusion needs to highlight the current limitations of 3D printed AFOs, and to highlight that although feasible, 3D printed AFOs are not yet ready to be integrated in current clinical practice. The conclusion in the abstract is more nuanced in its report of feasibility with its mention of ‘potential benefits’.

We agree that the 3D printed AFOs is not ready to be integrated into clinical practice. We have added the sentence ‘The feasibility of using 3D printing to manufacture AFOs is dependent on the AFO design and printing method and therefore additional research is needed before 3D printed AFOs can be integrated into clinical practice.’ to the conclusion on page 17, line 379.

Electronic databases were searched from January 1985 to June 2018. This has been added to page 2, line 34 in the abstract.
Line 42: The use of the word 'unimpaired' is not consistent with the term 'healthy' used in the methods of the abstract or through the manuscript, please consider changing.

- The word unimpaired has been changed to healthy page 2, line 42.

Background:

Lines 71-72: Please provide a reference or rephrase using 'clinical experience informs us…'

- The reference for Ramdharry GM et al. 2012 has been added (page 4, line 72).

Method:

Line 102: Please state the date the searches were concluded.

- The searches were performed in June 2018. Added to page 5, line 96

Line 133: Please write GRADE in full first.

- Amended (page 7, line 137)

Results:

Line 144: Please consider replacing orthotic with AFO.

- Amended (page 8, line 149)

Line 152: Reference to Line 114 I understood that CAD manufacturing techniques were excluded, therefore is it possible to assess this outcome?

- Manufacturing techniques such as CAD/CAM where the machine carves a block to form an orthosis based on digital model milling were excluded. This method was not included as an outcome measure. However, CAD models are required for 3D printing and the dimensional accuracy between the computer models and printed AFOs was assessed as an outcome.

Discussion:

You aim (Lines 86-89) states that you will investigate the feasibility of 3D printing for the design, manufacture and delivery of AFOs by evaluating biomechanical effects, mechanical
properties and fit of 3D printed compared to traditionally manufactured AFOs. However, only 5 of the 11 studies make this comparison. You have acknowledged the low numbers in sample sizes but it would be useful to highlight in the first paragraph of the Discussion that not all 11 studies made this comparison.

- We have added the line ‘However, only five of the 11 studies compared 3D printed AFOs to traditionally manufactured AFOs.’ to page 15, line 309.

Line 334: Please consider revising the term 'some sort of'.

- The term 'some sort of' has been removed.

Table 1: Please include the reference number to the references listed in column

- Amended (Table 1, page 25)