Author's response to reviews

Title: Tendon lengthening and fascia release for healing and preventing diabetic foot ulcers: a systematic review and meta-analysis

Authors:

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Author's response to reviews: see over
Dear Prof. Menz,

Please find attached our revised manuscript entitled, ‘Tendon lengthening and fascia release for healing and preventing diabetic foot ulcers: a systematic review and meta-analysis’ for consideration for publication in the *Journal of Foot and Ankle Research*.

We thank the reviewers for their valuable comments and the opportunity to improve our manuscript. Below is a detailed outline of the changes to our manuscript based on the reviewers’ comments.

**Reviewer 1**

**Reviewer's report:**

A well defined aim, clearly described (and appropriately selected) method make this a highly readable review. The reporting of results is succinct and includes relevant discussion. The Tables (1, 2 and 3) are used with good effect and present relevant information.

**Author response:**

Thank you for reviewing our manuscript. We are glad that you found it insightful and enjoyable to read.

**Reviewer 2**

**Reviewer comment:**

There were only 2 RCTs identified, one of which had sub optimum power and only one prospective cohort study which unfortunately included a wider range of procedures. The variability in the studies raises significant questions as to the value of the results.
Author response:

Thank you for your valuable comment. Accordingly, we have eliminated all non-RCTs from the meta-analysis. Within the discussion, we have commented on the variability in quality of the studies and hence the need for caution when interpreting the results.

- Page 15, paragraph 3, lines 1 to 5: “The main limitation of this review was that the majority of studies were not RCTs and ranged in the level of quality. The results of studies (i.e. those that weren’t RCT’s) were reported descriptively as we believe that these data add to the overall literature on this topic and are important from a clinical perspective. However, based on quality assessment, the results of these studies should be interpreted with caution.”

We have also high-lighted the need for further high quality RCTs in this area.

- Page 17, lines 1 to 2: “Further rigorous RCTs with longer follow-up are required to determine the long-term effectiveness and safety of these procedures.”

Reviewer comment:

For instance, in outcomes, time to healing of the ulcer, page 10, paragraph 2, the authors note a range of papers that could not be included in the meta-analysis due to different study designs and they produce a range of results. One of the studies included subjects without diabetes. It is difficult to see how this range of results provides any particular guidance / have any value.

Author response:

Thank you for your valuable comment. The results for the study which included participants without diabetes have been removed from the analysis.

We listed the results of studies (i.e. those that weren’t RCTs) individually as there is limited data available from RCTs. Although these studies may be of lesser quality, we believe that these data add to the overall literature on this topic and are important from a clinical perspective. As discussed in the previous author response, we have acknowledged the lack of quality studies in the discussion section of the manuscript (page 15, paragraph 3, lines 1 to 5).

Reviewer comment:

Perhaps of more concern is the pooling of the rates for ulcers healed and the rate of ulcer recurrence. In the latter, the pooled rate of recurrence was 11%. However, in the RCT with adequate power the rate was 38.5% and 20% in the other RCT. In my opinion, the 11% value is misleading due to the nature of the papers included.

Author response:

Thank you for your feedback. Accordingly, we have repeated the meta-analysis to include only RCTs. In addition, we have reported the individual study results for all non RCTs descriptively for all outcomes.
I accept that there is limited information available but do not feel all of the papers selected can be included. At the very least, I would recommend the following considerations:

a. The RCT results are reported separately to the other studies. However, in the paper by Allam (2006) the intervention group had either a gastrocnemius recession or Achilles tendon lengthening. The authors should describe how the decision was made as to which procedure was chosen, whether the rates actually varied between the procedure (if reported although note if not reported) and certainly consider if the complications were different as the Achilles tendon lengthening would provide a theoretically higher risk of rupture for example. The numbers of complications in the summary indicate these are small but they may all occur with one procedure.

Author response:

Thank you for your suggestion. We have updated the results section of the manuscript to report on the results of the two RCTs separately for all outcomes.

In addition, we have added a comment explaining how Allam (2006) made the decision to perform an Achilles tendon lengthening or a gastrocnemius recession procedure.

- Page 10, paragraph 1, lines 2 to 5: “Participants in the intervention group of one study [21] had either ATL or GR, which was determined based on dorsiflexion measurement at the ankle joint with the knee straight and flexed.”

For each of the applicable outcomes, it has been noted whether the results were reported separately for the Achilles tendon lengthening and gastrocnemius recession groups in the study by Allam (2006). The changes to the manuscript are outlined below.

- Page 10, paragraph 1, lines 9 to 11: “As the results were not separated for the ATL and GR participants in the study by Allam (2006) [21], comparisons between the two procedures cannot be made.”

- Page 10, paragraph 2, line 6: “The reported rate of ulcers healed in the intervention groups was 100%.”

- Page 11, paragraph 1, lines 6 to 8: “In the study by Allam (2006) [21] ulcer recurrence rates for the ATL and GR groups were 16.7% and 22.2% respectively.”

- Page 11, paragraph 2, lines 3 to 4: “The results were not separated for the ATL and GR groups in the study by Allam (2006) [21].”

- Page 12, paragraph 1, lines 9 to 12: “In the study by Allam (2006) [21], early complications from surgery were reported separately for the ATL and GR groups, which included: wound haematoma (16.7% and 22.2% respectively), ruptured Achilles tendon (16.7% and 11.1% respectively), and calcaneal gait (16.7% and 0% respectively).”

The need for further research into the complications associated with each of these procedures is highlighted in the discussion.

- Page 14, paragraph 2, lines 2 to 4: “Further high-quality RCTs are needed to determine which of these methods may be associated with fewer complications and improved patient outcomes.”

Reviewer comment:
b. The papers by Laborde (2009) and La Fontaine et al (2008) could be reported separately with the weaknesses in the study design acknowledged but they do cover specific procedures and therefore give an indication towards outcomes.

Author response:

Thank you for your suggestion. As previously described, the results of all studies (i.e. non-RCTs) have been reported separately. Due to the limited available data, we decided to include and report the results of all papers (excluding those with multiple procedures) that investigated the specific procedures of interest (i.e. Achilles tendon lengthening and gastrocnemius recession). As such, we included the studies by Batista et al. (2011) and Lin et al. (1996), in conjunction with the above mentioned studies by Laborde (2009) and La Fontaine et al. (2008). We have acknowledged the quality of these studies in the discussion section of our manuscript (page 15, paragraph 3, lines 1 to 5).

Reviewer comment:

c. Similarly, the paper by Kim et al (2012) could be reported separately. This is the only paper to include selective plantar fascia release and is at least prospective. This highlights a potential option for management but would be qualified by the need for further research.

Author response:

We agree with your comment. Accordingly, we have reported the results of the study by Kim et al. (2012) separately, and have commented on the quality of the study in the discussion section.

- Page 16, paragraph 1, lines 8 to 11: “As there was only one study investigating SPFR, results were unable to be pooled in a meta-analysis. Furthermore, the study was not a RCT, and therefore the findings should be interpreted with caution.”

Reviewer comment:

d. All of the remaining papers (26, 27, 28, 29, 30, 33) should be excluded as they either score very low on the quality assessment or include multiple procedures. The authors should justify why they would include papers with a low quality assessment given the other limitations.

Author response:

Thank you for your suggestion. As such, we have removed these studies from our meta-analysis, and have only included RCTs. Results of studies with multiple procedures are no longer listed separately in the results section of the manuscript, however, can be obtained from Table 2 (Characteristics of included studies) and Additional File 2 (Data extraction table).

As discussed in a previous author response (i.e. to comment ‘b’ from reviewer), we reported the results of all papers (excluding those with multiple procedures) that investigated the specific procedures of interest (i.e. Achilles tendon lengthening and gastrocnemius recession) due to the lack of available data. To clarify, these lower quality papers were not included in our meta-analysis, however were reported separately. Justification for the inclusion of these papers with lower quality is discussed in the manuscript (page 15, paragraph 3, lines 2 to 5).
Reviewer comment:

In the discussion (page 12 last paragraph) the authors state that the rate of healing for the procedures is comparable to current evidence on total contact casts. However, they reference papers that have not been included in the selected papers /results reported and suggest these papers were used for comparison. Were these included in the statistical analysis? At the very least, they should document the papers that have been used, evaluate the quality of the papers and incorporate the appropriate results. However, given the comments above, the RCTs provide their own control and analysis and thus it would only be relevant for the other 3 papers. One option would be to compare the results reported from the papers on total contact cast alone (assuming appropriate quality) against the results for the total contact control groups in the RCTs. They could then report whether these are comparable and this data can be used for the remaining 3 studies.

Author response:

Thank you for your valuable comment. We have no longer made comparisons between the results of our meta-analysis to previous research papers on the effectiveness of total contact casting. Comparisons between the surgical procedures and total contact casting are now only based on the results of our meta-analysis (i.e. pooled data of two RCTs).

- Page 13, paragraph 2, lines 2 to 9: “Interestingly, there was no statistically significant difference between these procedures and the current gold standard treatment of TCC for time to healing of the ulcer and the rate of ulcers healed. In addition, the rate of ulcer recurrence was found to be lower in participants who had undergone ATL or GR procedures compared to those treated with TCC alone. One RCT [15] included in this review also found that re-ulceration occurred significantly earlier in those managed with TCC alone compared to those who underwent ATL in conjunction with TCC (P = 0.03).”

Reviewer comment:

The authors state that they modified the scoring for item 27 relating to study power. Could they clarify whether or not this changed the possible overall score for this item and thus the total achievable school? I assume not as additional file 3 indicates a maximum score of 32 which is the same total score. As a result, I feel the authors should qualify the difference in the modification and the reasoning.

Author response:

We apologise if this was unclear in the manuscript. To clarify, we have now stated in the methods section of the manuscript, that “Scoring for item 27 relating to study power was modified in this review for easier application and analysis by the assessors”. . . . “While modification altered the total achievable score for this individual item (i.e. studies were not able to score a one, two or four), all studies were rated using the same scale and therefore comparability between the studies was not affected” (page 7, paragraph 1, lines 6 to 16).

Reviewer comment:

When the authors describe the outcomes and provide the references, it is difficult for the reader to cross-reference against the tables. In the tables the first column lists authors/year publication but not the reference number. I would recommend that the reference number is provided in the tables after the authors to facilitate quick reference between the text and the tables.
Author response:

Thank you for your suggestion. To make it easier for readers we have added reference numbers to all tables.

This manuscript describes original work and is not under consideration for publication by any other journal. Both authors approved the revised manuscript and this submission.

We appreciate your consideration of our revised manuscript for publication in the Journal of Foot and Ankle Research. We look forward to hearing from you at your earliest convenience.

Yours sincerely,

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