Author's response to reviews

Title: A randomized single blind crossover trial comparing leather and commercial wrist splints for treating chronic wrist pain in adults.

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Author's response to reviews: see over
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Dr Rikki Graham  
Senior Assistant Editor  
BMC-series journals

Dear Dr Graham

Re: A randomized single blind crossover trial comparing leather and commercial wrist splints for treating chronic wrist pain in adults. Jill Thiele, B AppSc; Rachel Nimmo, B Med Sci; Wendy Rowell, B AppSc; Stephen Quinn, PhD; Graeme Jones, M.D. MS: 1239671476257088.

Thank you for your email of 28th July. We have carefully considered the reviewers comments and have made adjustments accordingly. Changes to the manuscript are highlighted for your convenience. I confirm that this revision has been read and approved by all co-authors.

My co-authors and I look forward to hearing from you.

Yours sincerely,

Rachel Nimmo.  
Menzies Research Institute  
University of Tasmania  
Australia
Response to reviewers.

Re: A randomised single blind crossover trial comparing leather and commercial wrist splints for treating chronic wrist pain in adults. Jill Thiele, B AppSc; Rachel Nimmo, B Med Sci; Wendy Rowell, B AppSc; Stephen Quinn, PhD; Graeme Jones, M.D. MS: 1239671476257088.

Reviewer 1
1. The wash out period was based on our clinical observations, as there is no optimal wash out period supported by literature. Measurements should ideally have been repeated at the end of the washout period to ensure return to baseline. However, there was no order effect, i.e. the magnitude of benefit is similar in those receiving either intervention second as compared to first. This suggests that this is not a major problem. (pg 11, line 18)
2. The information regarding the level of significance between splints for the COPM measures are provided in the abstract and table 3. Qualitative statements regarding between splints results for both COPM and grip strength are also provided in the text.
3. Minor alterations have been made to text to address the remaining comments:
   - Consistency of use of terms wrist pain / OA / RA in discussion. (pg 11, line 6; pg 12 line 9)
   - Reworking of reference to Haskett in discussion. (pg 10, line 9)
   - Consistency of use of terms efficacy / effectiveness. (pg 10, line 1)
   - Comment regarding effectiveness of wash out period.

Reviewer 2
1. This trial was completed prior to the article by Haskett being published. There is significant benefit from more than one trial on a specific subject to provide consistency of results. Furthermore, this study demonstrates a significant improvement in patient perceived functional performance and satisfaction due to splint use, which was not demonstrated by Haskett.

Reviewer 3
1. We do not have data regarding medication use. However this is unlikely to bias the trial as participants were excluded from the trial if they were likely to require a change in pharmacological management during the trial (see materials and methods) and 5 patients were withdrawn after the first phase due to medication changes or inability to attend.
2. Our data does not support the concept that an exacerbation of wrist pain occurred with the splint was applied, nor that data could have been skewed due to the natural course of the disease. Our data demonstrates a decrease in measures from the first time point.
3. An assessment of differences in responses associated with different disease durations was not part of our original protocol, and we did not have sufficient sample size to examine the effect of disease duration. This is stated as a limitation (pg 12).
4. The Hawthorne effect is generally thought to be due to extra attention from the caregiver. This is unlikely to have occurred due to the fact that the off the shelf splints were also fitted for size to the patient by the therapist (although no modifications were made to the fabric splint), and that the same splint
instructions and education were provided so that subjects received the same amount of care.

5. The exact reason why leather splints are superior for short-term effects is uncertain, but supports our anecdotal observation of the functional benefit of leather splints as compared to fabric splints. We would postulate that the “skin like” fit and movement of the leather splint allows for functional wrist movement and also provides mechanical stability. (pg 10, lines 20 and 21)