Title: Night-time splinting after fasciectomy or dermo-fasciectomy for Dupuytren's contracture: a pragmatic, multi-centre, randomised controlled trial

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Author's response to reviews: see over
Authors’ response to reviewers (in italics)

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Reviewer: Maria Kostaki

Reviewer’s report:

Major compulsory Revisions:

- In the secondary per protocol analysis, according to the analysis of methods, the no-splint group included individuals who did not use a splint or were given a splint once their extension loss exceeded the criterion agreed by the trial management group. In table 3, the number of patients listed to the no splint group is initially 68. However, according to the SCoRD Trial Flowchart in figure 1, among the 77 patients randomized to the no-splint group, 56 received the allocated intervention and hand therapy and 13 developed a contracture of the PIPJ and were given a splint as per protocol, which means that 69 patients should be listed to the no splint group in table 3. Was there another reason for excluding one more patient from the no-splint group in the secondary per protocol analysis?

  Thank you, this indeed looks inconsistent in the flowchart which has been amended to reflect that the 13 patients, who subsequently developed a contracture and were managed per protocol, did receive the allocated intervention so this number is now 69. This also is more consistent with the primary analysis methods – Intention-to-treat where these 13 patients were included in the group to which they were originally allocated.

  In Table 3 there are only 68 due to 1 patient being lost to follow-up at 3 months – this is clear in the flowchart (see analysis at 3/12)

- The trial shows no significant differences between the two groups. However, the no-splint group included patients that were given a splint during the trial, for different reasons. This means that the results referred to the no-splint group, contain data from patients that were finally given a splint. Couldn’t this have an influence to the evaluation of results?

  Yes this will influence the results, however the intention-to-treat (ITT) analysis is the most appropriate approach to the primary analysis in pragmatic trials.

  Should there be an additional result analysis excluding these patients from the no splint group? Additionally, it would be preferable to mention this point to the abstract.

  Additional analyses, such as that undertaken and presented in the secondary analysis (per protocol) have to be interpreted with caution. Multiple hypothesis testing increases the error rate and the overall risk of a type I error, therefore we have adhered to presenting the primary analysis (ITT) and one secondary analysis (per protocol). We feel that the inclusion of the 13 patients who developed a contracture and subsequently were splinted in the ‘no-splint’ group is justified as they were managed according to the study protocol which had allowed for these ‘deviations’ for ethical reasons. It also means that the results we present in this per protocol analysis allows conclusions to be drawn about two policies for managing patients - splinting everyone routinely after surgery versus keeping a watchful eye...
and only splinting patients who develop a contracture greater than 15° in the PIPJ or 20° in MCPJ.

We have added a sentence to the abstract about the secondary per protocol analysis

Minor essential revisions:
- It would be recommended to state once the whole term standing for the abbreviation PIPJ.
  Written out in full

- Some phrases need to be written more clearly. More specifically, the meaning in the last two phrases of the paragraph “interventions” and the second phrase of the paragraph “no splint group”, in page 6, is not very clear.
  Sentences have been amended as requested

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being Published

Reviewer: Tara Packham
Reviewer’s report:
General comments:
Appreciated seeing a pragmatic RCT design applied to a common practice in rehabilitation in an adequately powered study.

Discretionary Revisions:
1. Background section, paragraph 5: Study purpose stated clearly, but would like to see a clear statement of what the primary focus is (and how that ties to the outcome measures chosen)
   we have amended this to include more specific outcomes and hence the link to the chosen outcome measures should be clearer.

2. Methods section: Outcome assessment subsection 1st paragraph – suggest changing wording from “The questionnaire was posted to patients…” to “The questionnaire was mailed to patients…”
   this has been changed to ‘mailed’

3. Discussion section: paragraph 2 - consider using “representative” instead of “proximate”
   In this context we have used the term ‘proximate’ as opposed to ‘distal’ in relation to outcomes and therefore feel that the word ‘representative’ is not accurate

Minor Essential Revisions:
4. Discussion section: Results compared total active extension and total active flexion – need to address a) still unknown if differences in passive motion in splint vs. no splint group and b) composite measures do not allow examination of whether splints are more helpful for PIP contracture vs. MCP contracture vs. combined losses
yes we agree that this is a potential criticism, however we adhered to this analysis for 2 reasons: i) it was what we had specified in our protocol (previously published in BMC MSK Dis) ii) separate analysis of MCPJ, PIPJ and DIPJ results in multiplicity of tests and an increased risk of type I error. However we also agree that from clinical experience patients with PIPJ involvement vs MCPJ only respond differently and therefore agreed to conduct one subgroup analysis. The results concurred with the other analyses, that is, no differences between splint and no-splint group. This has been added to the discussion.

Major Compulsory Revisions:
none