Author's response to reviews

Title: The effect of taping versus semi-rigid bracing on patient outcome and satisfaction in ankle sprains: a prospective, randomized controlled trial

Authors:

Sacha Lardenoye (s.lardenoye@mumc.nl)
Ed Theunissen (e.theunissen@mumc.nl)
Berry Cleffken (bcl@mumc.nl)
Peter RG Brink (p.brink@mumc.nl)
Rob A de Bie (RA.debie@maastrichtuniversity.nl)
Martijn Poeze (m.poeze@mumc.nl)

Version: 3 Date: 5 January 2012

Author’s response to reviews: see over
Regarding: revised manuscript MS: 2016726115519559

Dear Ms Abigail Quiniquini,

Journal Editorial Office

Biomed Central

Thank you for offering us the opportunity to resubmit a revised version of our manuscript entitled ‘The effect of taping versus semi-rigid bracing on patient outcome and satisfaction in ankle sprains: a prospective, randomized clinical trial” We thank the reviewers for the valuable comments that enabled us to improve our manuscript. Please find enclosed a revised version of the manuscript and an itemized series of responses to the comments of reviewers.

Yours sincerely,

Martijn Poeze
Corresponding author
Department of Surgery, division of Traumatology
Maastricht University Medical Center+
P. Debyelaan 25
6202 AZ Maastricht
The Netherlands
Tel: +31-43-3871956
Fax: +31-43-3875473
Email: m.poeze@mumc.nl
Response to reviewer 1 (Eric Eils):

We thank the reviewer for his positive appraisal of our paper and for his constructive remarks.

1. The reviewer points out that 36 patients per group seem to be a low number and asked how we performed the analysis. We specified the analysis with the following sentence: `The minimum sample size is calculated for 90% power of testing and a 5% level of significance ($\alpha = 0.05$, $\beta = 0.10$) a minimum of 36 patients per group is required for this study. With a 20% drop-out and lost-to-follow up rate a minimum total number of 87 patients should be included in the study with complete follow-up to demonstrate an improved patient satisfaction of 15% (baseline values 2.6 (SD 0.5) (from pilot study (data not shown) compared to an expected value of 2.2 (SD 0.5) in the group of 72 patients with complete data.`

2. The reviewer asks to provide a figure showing an overview of the several data collection points and a hint how this data was statistically analyzed. We have created a table, but please advice if this should be included in the manuscript.

Additional table. Data collection points and parameters

<table>
<thead>
<tr>
<th>Follow-up time points</th>
<th>Outcomes and tests</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline, 5-7days post injury&lt;br&gt;out patient clinic</td>
<td>- patient satisfaction by VRS&lt;br&gt;- Karlsson scale&lt;br&gt;- complications&lt;br&gt;- hygiene by 5 point Likert scale&lt;br&gt;- anterior drawer test</td>
<td>repeated-measures analysis of variance</td>
</tr>
<tr>
<td>Week 2&lt;br&gt;out patient clinic</td>
<td>- patient satisfaction by VRS&lt;br&gt;- Karlsson scale&lt;br&gt;- complications&lt;br&gt;-hygiene by 5 point Likert scale</td>
<td>repeated-measures analysis of variance</td>
</tr>
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</table>
3. The reviewer asks which post hoc test was used. In case of significant interaction on repeated-measures analysis of variance post hoc analyses were performed in order to significant time or treatment interaction with Bonferroni adjustment for multiple comparisons. This is mentioned and presented in the revised manuscript.

4. The reviewer asks how range of motion was measured. We added additional information about the ROM: `The range of motion of the ankle joint covers the movement between maximum dorsal and maximum plantar flexion. The foot was placed in the neutral position, using the Neutral-0-method. The goniometer was aligned along metatarsal II, and then ROM was measured using an electronic goniometer (Hoggan Health Ind, West Jordan, UT, USA).

5. The reviewer asks how long it took to include 148 patients. We added: “Study design. Prospective, randomized controlled trial conducted in a trauma out patient clinic from February 2008 till July 2009”

6. The reviewer asks how the proprioceptive training was given and if both groups received training. We specified the proprioceptive training: “Supervised
proprioceptive exercises were given in both groups, starting one week after trauma. Verbal and written instructions for home exercises, focused on proprioceptive, range of motion training and strength exercises, were given by the attending nurse. During follow up additional instructions could be given. Follow up took place at week 3, 5, 9 and 13 post injury which was indicated in the study as week 2, 4, 8, and 12 after start of the study treatment” We did not analyse propriocepsis as it was not a outcome measure.

7. The reviewer asks to clarify the legend of table3. We added the text ‘Range of motion (ROM) is defined as the difference between injured and uninjured ankle when substracting the maximal dorsoflexion from plantairflexion. N is number of patients, SD standard deviation’ as legend to table 3.

8. Thank you for pointing out a error in figure 1. Lost to follow up should be N=5 and N=6. The new figure 1 is added to the revised manuscript.

9. The reviewer suggests to change figure 2 and 3 into tables. We would prefer to keep the graphics since graphic representation of the data provides a strong representation of the key message to the reader. Please advice.

Response to reviewer 2 (Eamon Delahunt) :

We thank the reviewer for the critical remarks which helped us to improve the manuscript and positive appraisal.

1. **LINE:** A meta-analysis comparing the different functional treatment options could not make definitive conclusions. The reviewer asks what is meant by functional treatment? We added: “A meta-analysis comparing the different functional treatment options (which included elastic bandage, tape, semi rigid ankle support, lace up ankle support) could not make definitive conclusions, because diversity of outcome results prohibited pooling of different studies [5,6,7]

2. **LINE:** In addition, tape treatment resulted in significantly more complications, the majority being skin irritations, when compared with treatment with an elastic bandage [5, 8]. The reviewer asks why not just conservative management with a well designed neuromuscular training protocol. Literature
indicates that functional treatment is preferable in ankle sprains (Kerkhoffs, Kannus and Renstrom, CBO guideline). They all compare functional treatment (early immobilisation with external support) with surgical treatment or immobilisation. No study is published comparing conservative (no external support) with functional treatment with tape or semi-rigid brace. A systematic review by van Rijn et al. in BMJ showed that there was limited evidence to suggest that the addition of supervised exercises to conventional treatment leads to faster and better recovery.

3. The reviewer believes that we excluded some important recent papers. We added some of these papers (Lin and Kemler) in the revised manuscript but they were all reviews which used the same studies and reviews that were already used in our manuscript.

4. LINE: Taping was performed by a select group of experienced and skilled healthcare professionals of the outpatient clinic. The reviewer asks for figures or description how the tape was applied. The description of applying tape is in our opinion too detailed to explain in the manuscript we therefore added a reference. We added the remark to the revised manuscript: ‘The tape was re-applied after two weeks’.

5. The reviewer asks for more details about proprioceptive training (what was the composition of these sessions. How frequently were participants to undertake these? Were the sessions supervised or done at home? If it is the case that they were undertaking a homogenous training protocol, then is the study more about the addition of bracing or taping to a supervised exercise protocol?)

We added in the manuscript: “Supervised proprioceptive exercises were given in both groups, starting one week after trauma. Verbal and written instructions for daily home exercises, focused on proprioceptive feedback, range of motion training and strength exercises were given by the attending nurse. During follow up additional instructions could be given”. They were given a homogenous protocol as addition to the functional treatment. A systematic review by van Rijn et al. (BMJ, 2010) showed that there was limited evidence to suggest that the addition of supervised exercises to conventional treatment leads to faster and better recovery.

6. LINE: As outcome measure patient satisfaction was assessed by verbal rating scale: poor (5), moderate (4), sufficient (3), good (2) and excellent (1) both at 2
and 4 weeks after start of the study treatment. The reviewer comments that it seems to be a very subjective scale and if this scale has been used in other studies. The evaluation of the patient satisfaction using a Likert-scale was used previously in other studies (Scholten, JBJS, 2008), although no formal validation study of this study item was performed.

7. **LINE:** In addition, the ankle joint function was assessed using the validated Karlsson scoring scale [11], range of motion and proprioception at 2, 4, 8 and 12 weeks after start of the study treatment. **COMMENT:** I don't think that the authors can say proprioception was measured: the quantification of this is through force-sense; threshold to detection of movement or joint position sense. The word proprioception should be deleted from the text. This has been deleted in the revised manuscript.

8. **The reviewer asks if the sample size is based on pilot data.**
   
   Yes.

9. **COMMENT:** The authors should report the statistics in more detail including there was a group*time interaction; a significant main effect for time; main effect for intervention. The values for Wilk’s Lambda; F values and partial eta squared values should be provided. As requested more details concerning the statistical outcomes are provided in the revised manuscript.

10. **LINE:** These results were also reflected by the experienced hygiene during treatment. At all measured time-points the reported hygiene was significantly higher in the patients treated with brace ($P_G<0.0001$, $P_T<0.0001$, $P_{TxG}<0.0001$). **COMMENT:** I may be mistaken but do not recall the authors mentioning the quantification of hygiene in the outcome measures section? This is indeed an omission in the text and has been changed in the revised version by adding the text: ‘The same 5-point Likert scale was used to assess patient-reported hygiene’.

11. **LINE:** The passive and active range of motion, expressed as the difference between the uninjured and injured ankle improved similarly in both the patients treated with a brace and the patients treated with taping (Table 4). **COMMENT:** Should this be Table 3? (Patient characteristics = Table 1; Karlsson Score = Table 2). Indeed, this should be table 3 and has been changed in the revised manuscript.

12. **The reviewer asks to provide a definition of functional treatment.**
We added: “Functional treatment (meaning non-operative and non-immobilizing therapy) is a commonly accepted treatment of ankle sprains” to the revised manuscript.

13. *The reviewer asks for a specification of the costs of the braces and tapes.*
   We added the specification in the revised manuscript.

13. As advised by the reviewer we adapted the conclusion: “In line with previous studies there is no difference regarding functional outcome and pain. Therefore using a semi-rigid brace should be considered for treatment of acute ankle sprains”