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

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Author's response to reviews:

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 reviewer for the valuable comments that enabled us to hopefully 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,

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Itemized series of responses to the comments of reviewer 3 (Phillip Gribble):

General comments
We thank the reviewer for his constructive remarks and positive appraisal of our paper. We have the impression that our revised manuscript crossed the comments of reviewer 3 though. We have implemented most of his comments in the second revision of the manuscript, while some comments were similar to those of the other reviewers and were previously altered in the earlier revision.

More details on the classification of the patients in the different categories is provided in the revised manuscript (page 4 line 15-19). In the previous revision of the manuscript we have explained in detail the underlying calculation for the power analysis (page 7 line 10-19). Indeed no description of support therapy was given. In the new revision we have explained this; after the 4 week period no standard ankle support was given, but physiotherapy was continued in both groups until 12 weeks (page 6 line 8-12). This 4 week treatment period was chosen as standard treatment period based upon consensus in the Netherlands (Guideline Acute Lateral Ankle Ligament Injury, Dutch Institute for Healthcare Improvement CBO). Previous treatment period was set at 6 weeks. No other support was provided after the first week. After one week full-weight bearing was encouraged (page 6 line 8).

Specific comments
Page 3 line 2-3: The reviewer asks for a reference; we added the reference.
Page 3 line 8: ‘with’ is inserted in the revised manuscript.
Page 3 line 7-11: in the revised version we provided more details about different functional treatment options:
“Functional treatment (meaning non-operative and non-immobilizing therapy) is a commonly accepted treatment of ankle sprains. Functional treatment includes a wide variety of options. The most common functional treatment methods used in the Netherlands are taping or bracing which have superior functional results compared to plaster immobilization and elastic bandage [4,5]. 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”. In addition we agree that the term functional outcome may be confusing in relation to the term functional treatment. Therefore, throughout the text the word functional is deleted from the outcome terminology. We have revised the terminology into ‘functional treatment’ (as this is general accepted terminology) and ‘outcome’.
Page 3 line 19: The reviewer asks to define local complications, we added: “a semi-rigid brace leads to less local complications [allergic contact dermatitis, bullae, skin pressure abnormalities]” (Page 4 line 4-5).
Page 4 line 2: We have switched the hypothesis and aim sequence in our revised manuscript (page 4).
Page 4 line 9: The PA or junior resident examined the patient at the initial contact.
on the ED, while a supervised senior resident or treating physician assessed the final classification. This has been clarified in the revised manuscript (Page 4 line16 and page 5 line16).

Page 4 line15-17 In our study patients were classified having a grade II when having anterior lateral ankle pain without anterior drawer laxity or as grade III ankle sprain when anterior lateral ankle pain was accompanied with anterior drawer laxity. This has been clarified in the revised manuscript. (page4 line17-21)

Page 5 line 5: Pain medication and crutches were not standardized, but monitored at the first control visit before inclusion. Similar baseline parameters at inclusion between the groups indicate that no significant difference between these two groups is likely to be present. (Page 5, line14-15).

Page 5 line 14-19: Indeed the tape was re-applied in the outpatient clinic at least once after two weeks or when patients indicated that stability was lost from the tape or for hygiene purposes or skin related problems. This has been added in the revised manuscript. (Page5 line22-23)

Page 6 line 1: In the revised version more details about the exercises are provided “Supervised proprioceptive exercises were given in both groups, starting one week after trauma. Verbal and written instructions for daily 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” (Page6, line11-15).

Page 6 line 8: We have added more information about the pain scale “the level of pain was evaluated using a 5 point pain scale: no pain (1) mild pain (2) moderate pain (3) severe pain (4) overwhelming pain/worst ever (5)” (Page7 line3-5).

Page 6 line 13: Stability was defined as a positive laxity in ventral movement of more than one centimetre when the contralateral uninjured side did not have similar laxity (Page6 line20-21)

Page 6 line 18: The reviewer asks to provide more information about the goniometer. We added: “then ROM was measured using an electronic goniometer (Hoggan Health Ind, West Jordan, UT, USA)” (Page7,line 10-11)

Page 7 line 9: In 7.4 % of data points missing data interpolation was used.

Page 8 line 6-12. 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 (\( # = 0.05, \# = 0.10 \)) 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 primary outcome data (Page7 line 13-21)
From figure 1 it is clear that 100 patients were randomized of which two patients in both groups did not fulfil the inclusion criteria. Due to loss from follow-up 81 patients were analysed for the primary outcome parameter. Due to further loss from follow-up secondary outcome parameter could be evaluated in 70 patients. A priori sample size calculation was performed on the primary outcome parameter.

The presence of cross-over in two patients occurred after randomization was effectuated and patients were primarily allocated in the brace immobilization group. This is a frequently occurring phenomenon in longitudinal randomized controlled trials and the most common way of dealing with this is to apply the intention-to-treat principle as was done in our study. According to a calculation presented by Weinstein et al (Ann Thorac Surg 1989;48:49&5) a 4% cross-over does not threaten the power of the study.

A semi-rigid ankle support provided more stability and a quicker return to work and sport than an elastic bandage [5].

The reviewer has some concerns about the percentage of loss to follow up. This has been commented in the discussion as suggested by the reviewer.

In the revised version we have provided specific data relating to the individual cost of the braces as well as the costs of the tape. The costs are in euros. “the costs of treatment with a semi-rigid brace are higher than the treatment with a tape. Diercks et al. [18] described the effectiveness and costs in relation to the patient satisfaction in a small study on the treatment of acute ankle sprain with tape and treatment with a brace and found higher patient satisfaction, but also higher costs of the treatment with a semi-rigid brace (€183 versus €238) Specification of the costs are illustrated in the article by Diercks et al. The treatment of tape in our study was also cheaper mainly due to material costs than treatment with a semi-rigid brace (total costs: €167 versus €204, respectively)”.

We have added the suggested reference by Olmsted et al.