Author's response to reviews

Title: Effects of Soft Bracing or Taping on a Lateral Ankle Sprain in a Controlled Trial: Recurrence Rates and Residual Symptoms at one year

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Author's response to reviews: see over
Rebuttal concerning Reviewers Comments to Author:

Reviewer’s report:
Thank you for your interesting and well written study.

Major Compulsory Revisions
1. In the introduction, line 76 tot 85, you could be more concise on why this study was needed. Is it only skin irritation with tape use and loss of tape stability? Or maybe the associated costs with taping are higher than with bracing? Did you expect a difference in recurrences and residual symptoms?

We thank the reviewer for the positive feedback. As the ankle brace seems to be more user friendly (easier to apply by patients themselves and less skin irritation) and is based on the principles of ankle tape treatment, we started from the assumption that the ankle brace is a reliable replacement for ankle tape treatment in case of an acute lateral ankle ligamentous sprain (ALALS). Therefore we hypothesized that the risk for ALALS recurrences and residual symptoms were similar in both treatment groups. This was mentioned in the method section (statistical analyses) en is now mentioned in the introduction as well.

2. Line 78: ‘The stability of the taped ankle decreases approximately 14% after 30 minutes of exercise.’, while the referenced article describes: ‘there was a loss of tape stability < or =14% after 30 min of athletic exercise’. Therefore, please adjust to: ‘The tape stability decreases approximately 14% after 30 minutes of exercise’.

We have adjusted the sentence according the fair comment.

3. Line 90: ‘Patients aged 18 years and older and diagnosed with a n ALALS caused by an inversion trauma were recruited from 20 family practices and nine physical therapy practices in the Utrecht region, in which is located in the center of the Netherlands, and from the emergency.’

Difficult sentence to read, please change to: ‘Patients aged 18 years and older and diagnosed with an ALALS caused by an inversion trauma were recruited from 20 family practices, nine physical therapy practices, and from the emergency departments of a regional hospital and a university hospital located in the central part of the Netherlands.’

After re-reading the sentence, we agree with the reviewer and chanced the sentence as suggested.

4. Line 89: Participants
Please mention if an age limit was followed for inclusion.

Indeed, an age limit was followed for inclusion. The exclusion of participants aged younger than 18 is now mentioned explicitly in the section about the participants.

5. Line 109: Please describe what 'independent' means. Does is it mean for example: 'blinded for the severity of the inclusion injury'?

The research assistant was the first to contact the patients and did the first screening of the inclusion and exclusion criteria (age, multiple trauma, complicated trauma, history of surgery). When the patients seem to be eligible for participation in the study the research assistant assigned the patients to the brace or tape group in order of presentation. The research assistant was not aware of the severity of the ALALS. We have described the procedure in more detail in the method section of the article, in which we used the reviewer’s suggestion and adjusted the sentence.

6. Line 111: Treatment
Please describe if a pain medication protocol was used at initial treatment.

In this study no specific pain medication protocol was prescribed. This is now mentioned additionally in the treatment section.
7. Line 126: Control group
I am surprised that skin problems were not registered in your study, as you mention this to be an important complication of tape use. Please describe why this side effect was not reported in your study in the discussion.

We do have information about skin irritation/allergic reactions from those patients who did not complete their prescribed four week treatment. We have added a sentence about this subject in the paragraph about compliance.

8. Line 146: 'A recurrence of ALALS was defined as a new inversion trauma of the same ankle...', does this mean you did not use a time-loss definition of ankle sprain recurrence? Please describe exactly how this question was formulated in your questionnaire.

To be more precise we have added the two questions (and the corresponding answers) we used to register re-injuries. ‘Patients had to answer the following questions: “Did you re-injure your ankle after the start of this study (Answer Yes or No)? And “What was the nature of the injury (Response options: Sprain, Broken ankle, Overuse injury, I don’t know, Other).”

9. Line 162: 'Being able to stand on one leg for 15 seconds was classified as having successfully accomplished a one-leg stance test.' Please describe the cut-off point for a successful test in more detail.

We did describe the cut-off point for a successful one-leg stance test in more detail.

10. Line 166: 'Pain during walking, running, pivoting, and jumping was reported by the patient. Patients were classified as having pain (Yes/No) when they reported pain during at least one of these activities.' I assume you mean pain in the ankle joint. Please describe.

We did indeed mean pain in the ankle joint, and adjusted the sentence.

11. Line 170: 'In addition, data on the compliance of wearing the soft brace or tape, and the use of medication and other therapy were collected during the five-week online questionnaire. This means these data were self-reported, please mention this when you refer to these data.

The data are self-reported by the patients. We now have mentioned this explicitly in the sentence.

12. Line 174: 'The incidences of the primary outcome (ALALS recurrence) were expected to be similar in both treatment groups.' For readability please change to: 'The incidences of ALALS recurrences were expected to be similar in both treatment groups.'

No problem at all; We changed the sentence.

13. Line 191: RESULTS
In Figure 2 you mention Lost to follow-up in the brace group: 'Preferred brace over tape' I assume this should be changed to: 'Preferred tape over brace use.' Please change if my assumption is right., otherwise delete.

You were right, we changed the sentence in “Preferred tape over brace use”.

You mention an intention-to-treat analysis, but in figure 2 you show that participants that were lost to follow-up were not included in the analysis. Therefore you applied an 'efficacy subset analysis'. Although the numbers lost to follow-up are low, this sort of analysis might introduce some bias. Please report the use of 'efficacy subset analysis'.
We did perform an intention-to-treat-analysis. After checking the Consort statement regarding this intention-to-treat-principle (www.consort-statement.org), we came to the conclusion that this principle is no longer in use and is replaced by a more explicit request for information about retaining patients in their original assigned groups. We have described the groups used for the different analyses in more detail now. We hope the reviewer does agree.

14. Line 156 ‘The dynamic anterior ankle test was used to measure ligament stability.’ In a recent study (Clinical evaluation of a dynamic test for lateral ankle ligament laxity by J. S. de Vries, 2009) this test has been shown to have a low reliability in effectively testing lateral ankle ligament laxity in a clinical setting. Please describe this in the discussion.

After reading the suggested article we have adjusted the sentence in the method section and have rewritten the paragraph in the discussion.

15. Line 245 You discuss the relationship of mechanical ankle instability with functional instability. A recent study by Hiller et al proposes a new model which describes this relationship. The proposed new model of chronic ankle instability is supported by data from previous studies and their own study. More subgroups are identified than in previous models, with perceived instability as a common link. Please consider to discuss your findings with respect to this new model.

We have rewritten the paragraph about the relationship between mechanical ankle instability and functional ankle instability and discussed our findings with respect to the model of Hiller et al.

16. Line 271 ‘A re-injury was not assessed by a medical professional, so no detailed information about the severity of these new injuries was available.’, while in the Methods section you describe: ‘Ankle fractures or overload of the affected ankle were not regarded as recurrences of ALALS.’ This implies that someone assessed the re-injury on several criteria. Please describe the criteria, and the person that interpreted them, in the methods section. Please also describe or discuss if this person was blinded for the intervention group.

The re-injuries were not assessed by a medical professional. In response to your comment No. 8 we mentioned the two questions (and the corresponding answers) we used to register re-injuries. We hope this section is clearer now.

17. Line 280 ‘We do not expect that this has influenced our results.’ Please explain why not.

Our explanation was written in the next sentence. We have complemented this sentence.

18. Line 293 ‘Additional research on the treatment of ALALS needs to be conducted, focusing on effectiveness, cost-effectiveness, and the patient’s preference.’ This advise is not supported by your research. Please add a statement why you provide this advice, or delete the advice.

We have deleted the statement about cost-effectiveness and replaced it with an advice and statement to perform an economic evaluation.

19. Line 300 ‘with the possible exception of the anterior drawing sign test.’ This added information does not seem appropriate in your conclusion, as you question the relevance of this finding in the discussion. Consider deleting this sentence or provide more support for making this statement.

We have deleted this sentence.

20. Line 301 ‘These findings should be confirmed in larger randomized trials.’ Do you expect that a larger RCT will find different results? And should this trial focus on primary treatment or secondary treatment of ankle sprains? Please be more
concise in your advice.

We have deleted this recommendation in the conclusion section.

21. Line 442 Table 1. Please group baseline characteristics for readability of the table if other than N, for example years, days, etc.

We have rearranged the table to improve the readability.

Minor Essential Revisions
1. Line 116: 'Only in case of very severe ankle swelling was the ICE treatment continued and the allocated intervention was postponed for a few additional days (average 3-4, with a maximum of six days).’ For readability please change to: 'Only in case of very severe ankle swelling the ICE treatment was continued and the allocated intervention was postponed for a few additional days (average 3-4, with a maximum of six days).

We improved the sentence.

2. Line 198: 'A total of 57 patients (36%) of which 30 in the brace and 27 in the tape group, visited a physical or manual therapist during the treatment period after the initial trauma.' Do you know how many treatment sessions were followed in each group? If so, please describe as this might influence ankle function.

We do have gathered this information. It is now included in the results section of the article.

3. Line 214: 'Seventeen patients underwent no physical examination after one year of follow-up,...' For readability please change to: 'Seventeen patients were lost to follow-up and therefore did not have a physical examination after one year.'

We did change the sentence.

I wish you success in adjusting this study for publication!
Thank you very much for the valuable advices.

Reviewer’s report:
This is an interesting study of the effects of a 4 week taping or soft brace program on recurrent ankle sprain rates and residual symptoms one year post acute lateral ankle sprain. Overall the study is clearly written but some points need clarification. The discussion was unable to be fully reviewed due to missing information in the methods that may affect interpretation of the results.

Major compulsory revisions
1. Material and methods
Please describe in more detail how an ALALS was diagnosed.

We thank the reviewer for the constructive feedback. Patients with a possible ALALS in this pragmatic controlled trial were referred to the Department of Sports Medicine as soon as possible. To check if the patients were eligible for inclusion, a sports physician conducted a baseline assessment. The sports physician diagnosed an ALALS based on the following items: swelling of the injured ankle; any discoloration by hematoma; limited dorsiflexion in the injured ankle; clear tenderness at at least one of the anatomical locations of the injured ankle, difference in the anterior drawer sign between the injured and heterolateral ankle and difference in the talar tilt test between the injured and heterolateral ankle. We have added this information to the method section. The results of the talar tilt test after one year of follow-up are included in table 2.

2. Line 113: What sort of compression was used and did all participants receive the same type of compression?
In this pragmatic trial the sort and type of compression was not specified, but a part of usual care. As goes for the athletic tape used, the health care professional decided on the most appropriate sort and type of compression for the patient.

3. Line 121: Did all participants receive the same brace? What brand/s and manufacturer/s?

The soft brace all patients in this study received was the Push Med ankle brace (Nea International bv). It is now mentioned in Figure 1 as well as in the article itself.

4. Line 129: What type of athletic tape was used and did all participants have the same type? Was any underwrap used?

In this trial we tried to stay as close as possible to the current treatment methods (usual care) in the Netherlands. Therefore the type of tape and application technique used was not specified. The health care provider who treated the patients chose the type of athletic tape used and whether any under wrap was needed (e.g. in cases of known skin problems).

5. State whether the outcome assessors were blinded or not in the data collection section.

The sports physicians were not blinded for the treatment method used. We have mentioned this in the data collection section.

6. Line 148: Please provide the questionnaires used for determining recurrences as an appendix.

After a comment from reviewer one we have mentioned the questions used to define a recurrence in the method section data collection and outcomes. We hope the reviewer does agree with this adjustment.

7. Was any information gathered after the end of the intervention period, about whether participants used bracing or taping during activities? This may have had more effect on the long-term results than the intervention.

We did indeed gather information about the use of brace and tape during activities after the intervention period. We do however have reasons to believe that the question used to measure the use of tape and brace during activities was not understood by all patients. More than half of the patients did not answer this question. Since we question the reliability of this question, we chose not to report the results in this study.

8. Line 152: Please provide more information about the secondary outcome measures: how was the level of swelling determined, how was the amount of dorsiflexion determined, what is a dynamic anterior ankle test and how was it scored?

The determination of the secondary outcome measures was based on clinical interpretation of the sports physicians. We used the anterior ankle test as described by Van Dijk et al. (1996). This reference is now included in the article.

9. Line 171: Please provide more information about how you collected the compliance data. Was this a once only questionnaire at 5 weeks, or a daily/weekly questionnaire over 5 weeks?

The compliance data were once collected at week 5. We have adjusted the sentence in the methods section.
10. Line 181 ff Statistical analyses.
11. This section is quite difficult to follow. From the results it appears you compared the baseline characteristics of the groups but it is unclear how this was done. Were your data tested for normality of distribution? A number of different test outcomes are reported in the results sections and it would be useful to have them placed within the stats section with the appropriate statistical method employed i.e. RR, HR, OR. Was Chi-Square used to compare the RR between groups or another method? Was the logistic regression performed to adjust for potential confounders, given there were none reported to be different at baseline? How were the statistical results for compliance determined?

We did indeed compare baseline characteristics and have added this information to the statistical analyses section. We also mentioned which statistical method was used to determine the RR, HR for the different analyses. As no baseline differences between the two groups occurred, multivariable regression analyses (logistic regression for the one year incidence and Cox regression) were not performed.

12. Line 268: The statement 'multivariate analysis did not change the effect estimates' is difficult to assess as these have not been reported in the paper.

We apologize for this mistake. We have deleted the sentence.

Minor essential revisions
1. Line 103: Which medical ethics committee approved the protocol?

The METC of the University Medical Centre Utrecht approved the protocol. This is now mentioned in the article.

2. Line 107: What do you mean by 'on the order of presentation'?

If the patient was eligible for inclusion, the research assistant allocated the patient to the brace or tape group based on the order of registration to participate in this study. The recruitment and selection of patients is now better described in the methods section.

3. Line 274: What is a 'power approach paradox'?

This paradox means that if you do not find a significant difference in your study and you do perform a sample size calculation afterwards you automatically will find your study to be underpowered. It is however possible that there is truly no significant difference between the two treatments. That both treatments are in fact equal to each other.

4. Line 276: Can you say your study lacked power when you have just stated that a power analysis was not performed?

In line with the answer to comment 3, we can’t just say that our study lacked power. It is possible that soft brace treatment and athletic tape treatment are equal to each other.

5. Line 234ff. Consider comparing your results with others that examined ligament laxity prospectively following an ankle sprain eg Hubbard Tj and Cordova M 2009 Mechanical Instability After an Acute Lateral Ankle Sprain Arch Phys Med Rehabil 90: 1142–1146

We thank the reviewer for the literature suggestion. We have rewritten the specific paragraph in our discussion section and chose to use the studies from Hertel (2002) and Hillier (2011).

6. Line 246ff. For the paragraph comparing the results of the soft brace with other braces, there should be more discussion around whether the soft brace fits more with other functional treatment types rather than other braces. From the figure there does not appear to be any rigidity in the soft brace and its difficult to
To our knowledge the brace has not been compared to other brace types. One of the first prototypes of the brace was compared with ankle tape as well (Twellaar, 1993). This design of this brace was based on the principles of functional tape bandage (Coumans bandage). The brace was therefore compared with ankle tape.

Discretionary revisions

1. Line 59: Place the references by the relevant country.

   We did place the references by the relevant countries.

2. Line 59: Reword to ‘Ankle injury rates are high in both....’

   We reworded the sentence.

3. Line 92: Delete ‘in’ before ‘which’

   We have rewritten this sentence.

4. Line 138: Replace ‘anamnesis’ with ‘clinical history’

   We have replaced anamnesis with clinical history.

5. Line 182: Change risk ratio to relative risk (RR)

   We have changed risk ratio to relative risk.

Thank you very much for the valuable advices.