Author’s response to reviews

Title: The Swedish version of OMAS is a reliable and valid outcome measure for patients with ankle fractures

Authors:

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Version: 2 Date: 7 March 2013

Author’s response to reviews: see over
Dear Dr Timothy Shipley,

Thank you for your e-mail of February 7. We are pleased that our manuscript finally has been reviewed and we would like to express our sincere thanks to the reviewers. Areas have been identified that need correction or modification. Although, as Dr Nauck comments the translation process we think there has been a misunderstanding. We have now expressed clearer that it is the Swedish version that is the issue for our study.

We have now revised the manuscript in the light of the reviewer’s comments. Attached, please find our responses. We hereby submit the revised manuscript for your reconsideration for publication in *BMC Musculoskeletal Disorders*.

Kind regards,
Gertrud Nilsson
REVIEWERS' COMMENTS AND OUR REPLY

Reviewer: Tanja Nauck

Reviewer’s comments
Major Compulsory Revisions:
The authors did not care about the general accepted guidelines for translation, cross cultural adaption and validation process of the OMAS questionnaire. It is not sufficient to translate the OMAS questionnaire to the preferred language und change some words. It needs a more complex validation process. The authors try to validate the OMAS questionnaire with a non-validated instrument. The FAOS instrument has not been validated for ankle fractures.

Reply
The original version of OMAS was created by two Swedish orthopedic surgeons Professor Claes Olerud and Med Dr Håkan Molander in the Swedish language and has been used in several studies in Sweden. This original version has been evaluated in the present study although with the small changes that have been described and with permission from Professor Claes Olerud. However, an English version of OMAS has been applied by several other authors in many studies, also by the originators of the questionnaire. To our knowledge the English version has neither been validated to another questionnaire. As the English version is the one being mostly read we thought it might be of interest to the readers to provide the information that the two versions were compatible. Obviously here might be misunderstandings and we have now revised the manuscript in the Title and in the Method section/Outcome measures/OMAS and made clear that it is the Swedish version that has been evaluated.

Indeed FAOS has not been validated in a group of patients only with ankle fractures. Instead the questionnaire has been validated in patients that were surgically treated with ankle ligament reconstruction (Roos et al.) and we think this group could be closely comparable to ankle surgery due to fracture. In another study, the questionnaire was validated in a group with different ankle injuries also including ankle fractures (Negahban et al.). We thereby think that the FAOS can be used as validating instrument in the present study. Furthermore, it was necessary for us to have a disease specific instrument in the Swedish language and to our knowledge no others already validated were available.

Reviewer’s comments
Minor Essential Revisions:

Abstract
-Results:
Please insert “Test-retest reliability correlation coefficient obtained was rho=0.95.” Also “the correlations coefficient versus the five subscales of FAOS ranged from rho=0.80-0.86.”

Reply
The rho has been inserted as suggested
Background
Page 2, Line 1-2: please delete word “now”

Reply
The text has been changed as suggested

Reviewer’s comments
Did the OMAS score have been proven for responsiveness in patients with ankle fractures?

Reply
We have now calculated the effect size using the values of OMAS at six-month and 12-month follow-up. The effect size was found to be 0.44. At the end of the Background section information about effect size has been shortly inserted, Statistics has been completed as well as Results and Discussion sections.

Reviewer’s comments
The author’s state: “few methodological studies regarding OMAS have been performed. Please specify and include the results or main outcomes.

Reply
The results from a few methodological studies have been described in the paper and one more new study has been published in 2012 (Wees et al.) and has now been included and referred to. The references have been written once more and hopefully this makes it clearer.

Methods
Reviewer’s comments
The authors described the results (tables) with median and range, so they also have to do in the methods section, describing the anthropometrics. Where the authors did recruit the patients? Are they all from the same cohort? Explain the different numbers of subjects included in the different reliability and validity steps. Please also insert the inclusion and exclusion criteria’s.

Reply
As OMAS is a non-parametric instrument, the points go from 0-5-10-15-20-25 (ordinal scale), and to our knowledge it should therefore be more correct to use median and range. Age and number of days in plaster cast should be regarded as parametric data (ratio scale) and by then the mean value and the standard deviation should be used.

The patients were all recruited at the University Hospital of Lund, Sweden (ref 29) as now has been described in the section Design/Participants and were from the same cohort. This has now been clarified. We have also described that this validity and reliability study was a part of an intervention study (ref 29). At six-month follow-up, all 106 subjects filled in OMAS and global self-rated function and of those 99 showed up at 12-month and by then filled in the same questionnaires. However, we also wanted to study the validity and reliability of OMAS as this had not been done before. Therefore a part of the cohort was asked to fill in OMAS once more and FAOS at the clinic as described. There were no particular inclusion- or exclusion criteria (age, gender, fracture types and surgical techniques and immobilization routines were all the
same as we have described) and we estimated that about 40 individuals should be enough. From ethical point of view no more subjects than necessary should be involved in studies.

**Reviewer’s comments**
Test-retest reliability of the OMAS
- Participants -> 19 had a bi-or trimalleolar fracture. Please implement also how many patients had a bimalleolar fracture and how many patients had an trimalleolar fracture.

- Please implement how many patients were treated with a non-rigid surgical technique and how many patients underwent a rigid surgical technique

- Did the kind of fracture influence the convalescence? Are they differences regarding the length of convalescence? If yes, it would be influence the results at 6 month post-surgery

**Reply**
Fracture types and surgical techniques that were used have been described in detail elsewhere (29). This information has now been added to the text as suggested.

As the aim of this study was to evaluate the reliability and validity of OMAS the convalescence or recovery in relation to fracture type was not focused on this time. Furthermore, all questionnaires were filled in at the same time and each person was compared to him/herself so the length of convalescence should not be assumed to influence the results.

**Reviewer’s comments**
Validity of OMAS using global self –rated function
- Please implement how many patients had a bimalleolar fracture and how many patients a trimalleolar fracture.

Validity of OMAS using the FAOS
- Please implement how many patients had a bimalleolar fracture and how many patients a trimalleolar fracture.

**Reply**
Fracture types and surgical techniques that were used are described in detail elsewhere (29). This information has now been added as described above and is now referred to.

**Reviewer’s comments**
Statistics
Did the variables been tested for normal distribution?

**Reply**
The OMAS was almost normal distributed at six-month. At twelve-month the distribution was slightly shifted which means some more subjects scored higher at that time. This could be expected as more individuals improve over time. Of the same reason we found it relevant to evaluate the validity of OMAS both at six-and 12 month follow-up. The distribution curves did not differ between the two measurements at 12-month.
**Reviewer’s comments**
Further statistical analyses are wanted to demonstrate the reliability of the OMAS questionnaire. Please implement the Intraclass coefficient and calculate the minimal detectable change as well as the SEM.

**Reply**
The ICC as well as SEM, SEM% and SRD, 95%SRD and SRD% has now been calculated. Statistics has been completed and the figures have been added in the Results and discussed in the Discussion section.

**Reviewer’s comments**
Results
Test retest reliability
Please insert significance range (e.g: “no significant differences were found between the two tests (p= xx-xx)

**Reply**
The p-value has now been added as suggested

**Reviewer’s comments**
Discussion
Page 6, line 7 #Please implement the kind of ankle fractures, were the OMAS questionnaire seems to be a reliable and valid tool.

**Reply**
The sentence has now been revised as suggested: The results of this study showed that the test-retest reliability and concurrent validity of the OMAS were good for patients surgically treated due to an uni- bi or trimalleolar ankle fracture.

We thank the reviewer for the comments and for the time spent reviewing our work.