Author's response to reviews

Title: Validation of the Western Ontario Rotator Cuff Index in patients with Arthroscopic Rotator Cuff Repair: A study protocol

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Author's response to reviews: see over
Dear Editor,

We want to thank you for the extensive and detailed review of our protocol ‘Validation of the Western Ontario Rotator Cuff Index in patients with Arthroscopic Rotator Cuff Repair: A Study Protocol’. The comments are multiple and of great help.

We will discuss your remarks consecutively:

1. It is true that the studies we refer to are based on case series. Unfortunately Randomized Controlled Trials comparing open vs arthroscopic rotator cuff repair do not exist. We feel that to conduct valid RCTs we need good measuring instruments. We believe that a disease specific quality of life questionnaire should be one of the outcomes when measuring the result of a rotator cuff repair. Therefore we adjusted the text. Actually, MacDermid [1] Published a protocol in BMC Musculoskeletal Disorders comparing arthroscopic versus open cuff repair in which the WORC is used. According to international comparison UCLA and Constant Score are much more frequently used, but are not free from valid criticisms.. Therefore, we added a disease specific quality of life questionnaire. When deciding which questionnaire we wanted to translate, the already existing multiple translations of the WORC was a very important argument for us.

2. We choose WORC, since it is a disease specific QoL questionnaire. It is composed by and for patients with rotator cuff disease (Kirkley). Many quality of life questionnaires concerning the shoulder exist. They can be divided into system-specific outcome instruments and disease-specific instruments. Poolman et al. encouraged the use of a disease-specific instrument, when available, to improve sensitivity to change.[2] This excludes OSS.

As far as we know two disease-specific QoL-questionnaires concerning the rotator cuff exist, The Rotator Cuff Quality-of-Life Measure (RC-QOL) and The Western Ontario Rotator Cuff Index (WORC). We choose WORC, because of the available translations in many languages and broad use in literature. We explained this in the Discussion section. In the WORC article in 2003 by Kirkley et al., the instrument is validated by correlating the questionnaire to various shoulder measures and the SF-36 in a group of 50 patients. However, none of them underwent arthroscopic rotator cuff repair.[3] Nonetheless, the WORC is used for measuring the result rotator cuff repair.[1, 4-7]

We believe WORC is a good outcome domain in rotator cuff repair, despite it has not been proved, yet. The difference between cuff disease and tendonitis is the discontinuity of the tendon, which elucidates an essential difference. A tendon with tendonitis can function, but with pain, and the process is reversible. A ruptured tendon lacks function. This deficit can be compensated, because of the construction of the rotator cuff. One can imagine that this compensation might not be entirely. Therefore it is important to measure the remaining deficit in a disease-specific QoL-questionnaire.

3. We specified validity to construct validity, because there is no gold standard. We worked this up in the Background and in the Discussion.
4. In this study we decided not to incorporate the WOSI because too many questionnaires can be too great of a burden for the patients and therefore create more drop-outs or incomplete reporting resulting in bias. Nonetheless, the suggestion is a good one, and will be used in future research from our study group.

5. We decided not to change the title because the term validation implies reliability (test-retest), construct validity and responsiveness.

6. Since this is a design article, we can not give numbers. The suggestion will be elaborated upon in studies with the results. In the section concerning patient routine in M&M we explain that the patients are invited to the study by telephone prior to their first visit at the outpatient clinic.

7. The word ‘failed’ has been removed.

8. We introduced the article by Constant et al.[8] in the appendix.

9. Indeed, it is not the purpose of the study to compare results of surgery and conservative treatment. The goal in this study is among others to measure the responsiveness of WORC. We believe patients will have a better shoulder function after the given time intervals. The result of conservative treatment can be measured after 6 weeks. If the shoulder function does not improve, therapy will be modified. We believe that it will be too great of a burden for them to intervene after 3 months instead of 6 weeks.

10. Responsiveness will be calculated at group level. Group findings cannot be translated to individual patients (ecologic fallacy). The suggestion concerning the main complaint score in order to judge minimal clinical important differences is a valid one, but is not our research aim at this moment.

11. In the question concerning shoulder hindrance we ask for general shoulder function, just like the WORC is meant to be.

12. This study is a first explorative study, in which power is not so important.

13. No, not really, but the letter of approval is attached.

14. Your suggestions have been incorporated. Besides, after incorporating the above mentioned suggestions some of the repetitions already disappeared. A few repetitions between Background, Discussion and Appendix still exist for clarity purposes.

15. Sharon Griffin (native speaker) controlled the translation process and gave final approval. Now, we indicate this briefly in Background.

16. The references are managed by Endnote X, with the BMC protocol. References are checked again, and corrected if necessary. Besides references 16, 34 and 46 have been added.
17. Thanks

18. References have been created

19. In the patient routine section we clarified that all patients were examined by the second author (T.E.L.)

20. The text has been adjusted

21. This is why we use the severity of symptoms scale. We moved the description of the test upward.

22. We include these commonly used group-characteristics, because we are comparing groups. If power permits we will control for age, sex and duration of complaints.

23. As far as we know, unfortunately, references regarding missing rules do not exist for WORC and Constant Score. Considering the SF-36, at least 50% of the questions should be answered for each domain[9], to be able to calculate a summary score. However, we will collect the data ourselves and will try to warrant complete reporting on WORC, Constant score and SF-36.

24. The word before has been removed

25. After discussing thoroughly your suggestion we decided to leave the description of the tests as it is, because it shows the extent of standardisation in this protocol since quite some tests can be interpreted in different ways. Moreover, we suggest the appendix to be published as an internet document, which will not detract form the article itself. Besides, as an internet document the tests are more accessible compared to a reference list.

26. The reference has been completed

27. Thanks

28. We have not taken over your suggestion, because the complete article is in the present tense

29. We believe the table is important. In orthopaedic research surgeons take it for granted that a high Constant Score or UCLA score equals a good result. Arthroscopic rotatorcuff repair is becoming more popular every year. This tendency is ‘scientifically’ supported by the literature mentioned in table 1. We say that this support is questionable.


