Author's response to reviews

**Title:** ORCHID: Open reduction and internal fixation versus casting for highly comminuted intra-articular fractures of the distal radius in elderly patients - A randomized clinical multi-center trial

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**Author's response to reviews:**

Cover letter:

Dear ladies and gentlemen,

we thank the reviewers for their detailed comments.

We revised the manuscript according to the reviewer`s report.

Reviewer JAC:

Minor revisions:

1. The recruitment rate and number of centers are now mentioned;
2. The randomisation process is now explained in detail and also the involved persons
3. the data collection of the dash and sf 36 are now described in detail
4. the procedure is described in detail now: it is the surgeon , who delivers the operative and conservative procedure ; all surgeons performing the procedure are familiar with the techniques; house standard means, that every center is allowed to use the locking plate they are used to – there is no special plate due to the study (so no new learning curve is expected due to the study!); also the reduction and splinting techniques are made according to the used house standard – no special splinting technique is demanded by the study; - this part is revised in the manuscript

Table 1 is included to give an overview which scores are assessed at Visit 1-6

Discretionary revisions:

1. outcomes
the outcomes and the outcome assessment are described more detailed now
2. the walter mrcd is now incorporated

3. the ITT analysis is now described in more detail

Rev. comment:

“It would be preferably to state what is intended by ‘ITT’ when it is referred to. It would appear in the primary analysis it is often called a ‘complete case ITT analysis’. I think the protocol should be explicit about this with regards to the main (‘confirmatory’) analysis”

Orchid study group:

In this protocol, we adhere to the original meaning of the intent-to-treat analysis, namely analyzing patients according to their random assignment, regardless of the treatment actually applied.

We will explicitly state nominators and denominators in case of incomplete data, and attempts will be made for multiple imputation where sound and necessary.

Reviewer CL:

Major revisions

1. It is described in detail why the dash score is used as assessment tool and not the prwe

Rev. comment:

“The method or instrument of measuring wrist function is not stated. A validated instrument should be used/specified in the protocol and standardized across all 15 centres. An injury-specific assessment tool (Patient Rated Wrist Evaluation – PRWE) has been validated for the use in hand/wrist injuries specifically, distal radius fractures and should be considered as a specific instrument to be used.


Orchid study group:

The Disability of the Arm, Shoulder and Hand (DASH) questionnaire was selected as the preferred specific outcome tool because of the longer experience gained with this instrument in Germany. Cross-cultural validation started as early as in 2003 (see Ewert MT et al. Validation of a German version of the 'Disabilities of Arm, Shoulder and Hand' questionnaire (DASH-G). Z Rheumatol 2003;62:168-77). It is the recommended tool for outcome assessment in the national clinical guideline for managing fractures of the distal radius (http://www.uni-duesseldorf.de/AWMF/ll/012-015.htm) and shows comparable psychometric properties to the PRWE in evaluating recovery after a distal radius fracture (MacDermid JC et al. Responsiveness of the short form-36, disability of the arm, shoulder, and hand questionnaire, patient-rated wrist evaluation, and physical impairment measurements in evaluating recovery after a distal radius fracture. J Hand Surg Am 2000;25:330-40).
2. Blinding:
Options for blinding outcome-assessors were discussed extensively by the members of the trial steering committee and methodological advisory board. In case of a parallel-group comparison of two different, let’s say, conventional and minimally-invasive surgical interventions, blinding by coverage of access routes or scars is, of course, possible and may reduce observer bias.

The panel members consented that when comparing a non-operative with an operative treatment, blinding by sleeves or dressings is laborious and associated with an unfavorable ratio of expenditures and gains. We stress this is a pragmatic RCT, with physically measured wrist function used as a secondary endpoint.

However, the primary, patient-centered outcome, SF-36 health-related quality of life rating after one year, will be queried by phone, limiting the degree of observer bias for this endpoint.

Minor revisions:

1. Eligibility:
The term is replaced

2. obesity is described with use of the BMI

3. Evaluation:
As falls are associated with future falls and an increased risk of fractures this point is assessed.
The term “employment “ is replaced by independence and ability to cope with activities of daily living

Sincerely,
Christoph Bartl on behalf of the ORCHID Study group