Author's response to reviews

Title: Relationship between distal radius fracture malunion and arm-related disability: A prospective population-based cohort study with 1-year follow-up

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

Thank you very much for reviewing our manuscript entitled “Relationship between distal radius fracture malunion and arm-related disability: A prospective population-based cohort study with 1-year follow-up”, and we thank the reviewers for their helpful comments. We have revised the manuscript addressing the reviewers’ comments as detailed in our response and we will be glad to address any other concerns.

We are looking forward to hearing more from you.

Sincerely,

Elisabeth Brogren and co-authors

Response to reviewers

Reviewer: Rita Patterson

1. Did the authors screen for injuries to the contralateral wrist? If this wrist is being used as a control injuries here could pose a problem.

We did not screen for injuries to the contralateral wrist. However, the mean and median values for the radiographic variables (ulnar variance, dorsal tilt and radial inclination) of the uninjured wrist are within normal range (Table 3) which suggests that the prevalence of prior distal radius fracture of the contralateral side ought to be low and would not substantially affect the results. We have now commented on this in the Discussion (P15, L13-17).

2. Statistical Analysis section: The paper states that the DASH has statistically significant effects as listed on Table 2. I only see only sex, dorsal tilt 1 year and ulnar variance 1 year as significant to 0.05 level. Please clarify and state what your criteria are for significance.

As stated in the Statistical Analysis section, we considered a p-value below 0.05 to indicate statistical significance (P5, L6-7). We performed linear regression analyses adjusting for age, sex, fracture AO type, treatment method and the corresponding radiographic variable in the contralateral wrist to investigate the relationship between the DASH score at one year and dorsal tilt, ulnar variance and radial inclination at one year, separately. Dorsal tilt, ulnar variance and sex (when adjusted for in the linear regression of dorsal tilt) showed significant effect on the DASH score, whereas radial inclination did not.

Reviewer: William Cooney

Concerns related to the method and materials related to

1. Lack of a classification of fractures on which treatment could be based or stratified. The more severe fractures likely had operating room treatment

It is correct that the patients who were treated with external fixation and/or percutaneous pinning had more severe fracture displacement at the initial
(pretreatment) radiographs than those treated non-surgically (Table 3). However, as stated in the manuscript, the main purpose was not to compare effectiveness of various treatments, but to determine the relationship between malunion and disability, irrespective of the treatment method used. The three malunion severity categories included patients from both treatment groups and the treatment method was adjusted for in all multivariate analyses. Although the findings involving differences between the treatment groups also are interesting the interpretation should take into consideration the non-randomized treatment allocation. We have commented on this issue in the Discussion (P13, L6-19).

2. Difference in anesthetic block. Hematoma does not provide muscle relaxation for ease of reduction

The difference in anesthetic block is part of the difference between the two treatment methods and as explained before, we are not primarily comparing the two treatment methods, but assessing the relationship between malunion and disability. We have now commented on the differences in anesthetic block mentioning the reviewer’s observation (P13, L13-15).

3. DASH Score was mailed to patients. Confusion on accurate completion of the DASH score could have occurred

Since the DASH is a self-administered questionnaire this issue is a potential problem with this and other similar outcome measures. The DASH has been widely used as a mailed questionnaire. Incomplete questionnaires (more than three questions left unanswered) were excluded. This has been commented on (P5, L1 and P16, L6-9).

4. Patients were not formally randomized

As explained above, the non-random allocation to the two treatment groups in this study is the reason why comparison of the treatment groups with regard to outcomes should be interpreted cautiously. The primary purpose of this study was rather to investigate how the three malunion severity categories affected the DASH score.

5. Why was the study results delayed in presentation for nearly 8 years; how was data stored over this time period.

This was a large research project and epidemiological data from the project about fracture incidence were the first to be analyzed and published. Because of several other simultaneous studies, clinical duties and workload there has not been capacity until now to present the present data. During this time the data were stored decoded in a database.

6. Patients were not separated into minor vs major trauma

As mentioned in the text (P3, L17-19), the injury trauma was moderate in 95 patients (67.4%), severe in 46 patients (32.6%), and unknown in two patients. In addition, the AO fracture type, which may represent initial severity of fracture, was determined (Table 1) and adjusted for in the Cox regression analysis.

Concerns related to the results were:

1. There was no wrist score utilized such as the Gartland Werley or Mayo or Krimmer wrist scores. A wrist score is suggested
The DASH score has been shown to be a reliable and valid evaluation tool of outcome after distal radius fracture (Macdermid et al, J Hand Ther 2004). The purpose was to assess the relationship between malunion and disability and considering that the DASH score is a widely used patient-reported outcome measure of upper-extremity related disability it was chosen as an appropriate outcome measure in this study. Although a wrist score also would be of interest we believe it represents a different type of outcome and would be more appropriately presented in a separate study. We have added a comment on this in the Discussion (P15, L19-24).

2. AO System of fracture assessment was used retrospectively rather than prospectively and therefore comparison of results between different treatment methods could be questions. This should be a stated limitation
AO fracture type was classified based on the initial fracture radiographs, before reduction was made. When assessing the relationship between the DASH score and malunion we included AO fracture type as a covariate in our multivariate analyses, in order to adjust for initial severity of fracture. We have stated that comparing the two treatment methods was not our primary purpose and that such comparison is limited by the non-randomized treatment allocation.

Discussion
Comparison of this study with others in the literature should be reported early, in particular studies that suggested that radiographic appearance and patient outcomes did not correlated. With the elderly patient, there are a number of studies that suggested that radiographic results (absence of malunion) did not affect outcome. The value of this study is that it shows the reverse. The results agree with this reviewers experience that anatomic reduction is important. Indeed, the better results with external fixation and open reduction and plate fixation demonstrate that function follows anatomy.
We agree with the suggestion that comparison with other studies should be reported early and have therefore changed the order (P12, L17-25 and P13, L1-4). We have commented on studies of elderly patients showing that radiographic results and functional outcome did not correlate (P13, L24-25 and P14, L1).

Concerns of Discussion
1. More discussion of the limitations of the study are needed
a. Prospective nature of the study is questioned since DASH was performed after treatment and mailed to patient. How was the DASH returned—by mail or during followup
We consider the study design to be prospective as we identified the patients at the emergency department and then followed them for one year with an outcome measure of arm function, radiographs and physical examination. The DASH score at one year was our primary outcome because we wanted to investigate the relationship between anatomy (i.e. malunion) and functional outcome after the fracture had healed. The DASH questionnaire was returned by mail.

b. Why was there such a long study reporting period
We have explained the reasons for delay in reporting in our response to point 5 above. Although rapid reporting of study results is desirable, it is not always possible and we do not believe this to be a limitation in terms of the relevance of the results.
c. Treatment was not based on fracture classification; how was intra-articular fractures considered in the study; Excluded??
When the study was carried out, closed reduction and cast or external fixation of extra- or intra-articular fractures were the standard treatments at the reported facility (as in many other facilities). About 28% of the fractures were AO type B or C. We have added a clarification on this issue (P10, L19-20). As stated earlier the type of fracture was shown and considered in the Cox regression analysis.

d. Clarify the fall out of patient followup
The reason to fall out of patients is unknown. They either did not respond to the DASH at all or had more than 3 unanswered questions or did not attend examination. This has been mentioned (P14, L22).

e. Review study by Macdermid related to the DASH and clinically important DASH score change of values
We could find one study, coauthored by Macdermid, a review that aimed at determining the minimal clinically important change for the DASH score and the authors proposed the same value that was reported in a previous study of patients with various hand and arm conditions cited in our manuscript; we have now added the reference (P5, L2-4 and P12, L6).