Author's response to reviews

Title: Rationale And Design Of The Plate Or Pin (POP) Study For Dislocated Midshaft Clavicular Fractures

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

Hereby we would like to submit our revision of the manuscript entitled: “Rationale en design of the Plate Or Pin (POP) study for dislocated midshaft clavicular fractures”. We have adjusted the manuscript accordingly to the reviewers comments.

First of all we would like to thank the reviewers for the time and effort they took for reviewing our manuscript.

1. Will the study design adequately address the hypothesis?
   Yes. Overall a well-designed study. Did the authors consider an additional non-operative comparison arm or is there now sufficient lack of equipoise to rule out conservative management in uncomplicated dislocated clavicular fractures.

   In recently reported prospective randomized studies, functional results after both plate fixation and intramedullary fixation with a Titanium Elastic Nail (TEN) proved to be superior compared to conservative treatment of dislocated midshaft clavicular fractures [1,2]. Therefore an additional non-operative comparison arm was not considered for this study.

2. Are sufficient details provided to allow replication of the work or comparison with related analyses? No. If not what is missing?
   A reviewer has requested that under Randomization, could the authors specifically state when the randomization occurs; is this prior to going to surgery, i.e. the doctor’s office, or is it in the operating room. (major compulsory revision)
   The same reviewer suggests that the pain diaries lack detail - they don’t really state how often they should fill it out. Could more details be provided. (minor essential revision)

   Patients are randomized prior to surgery in the doctor’s office by computerized block randomization.
   In the first two weeks after surgery, the patient is requested to fill out a diary that documents the experienced pain on a 10-point Likert scale (0 = no pain and 10 = extremely painful).
   Furthermore the type and amount of analgesics used is documented in the diary. This pain diary needs to be filled out daily. After 14 days the first outpatient department visit is scheduled and the pain diary is discussed with the patient and the researcher.

   We have adjusted the methods and design section accordingly.

3. Is the planned statistical analysis adequate? The powering of this trial is based on a difference of 6 points on the DASH between two operative arms. This is a relatively large effect size and given the comparison is of active treatments the result may fail to show a statistical significant difference if the effect size is small.
   Could the authors please comment. Are there other trials that have compared active operative treatments using the DASH? Is the DASH sufficiently sensitive to compare active treatments in clavicular fractures?
We started by considering a difference of 10 points in DASH score for the whole upper extremity as a clinically relevant margin [3]. For treatment of the affected shoulder we considered a lower DASH score margin of six points as clinically relevant, as stated in the protocol. We do understand the reviewer’s concern about the width of this margin, because it was derived from a comparison between the result of conservative treatment and the status of a normally functioning upper extremity, while the protocol describes the comparison of two operative techniques are compared. However, the margin of six points was decided upon not by taking the average DASH score of a normally functioning upper extremity, but by taking the worst possible status that may still be considered within the normal range. Hence, the smallest possible margin between the result of conservative treatment and a normal status was taken. If the two operative techniques would differ by that smallest margin, we would like to conclude that one of the techniques is superior to the other. If we would have considered an even smaller margin as clinically relevant, for instance a difference in DASH score of four points, then we may have to conclude that one technique is superior to the other, even if both result in outcomes within the normal range. That conclusion may be difficult to communicate to other surgeons.

We clarified the sample size section to further stress that the smallest margin between the result of conservative treatment and the normal range of DASH scores was taken as the clinically relevant margin.

Finally, we would like to state that we calculated the sample size and power of the study based on the margin that we consider clinically relevant instead of the difference we expect to find.

A study conducted by Liu et al.[4] also compared two active operative treatments for dislocated midshaft clavicular fractures and used the DASH score to compare the functional results after treatment. However a power calculation in this study is lacking.

We agree with the reviewers that the DASH score does not specifically focus on the clavicle. However, a score which solely assesses clavicular function is lacking. In our opinion the DASH score provides the most reliable result for rating upper extremity disability and symptoms. To provide a complete overview of shoulder function the Constant score is used as a secondary endpoint.

We added these comments in the discussion.

Furthermore we adjusted our primary endpoint according to our Medical Ethics Committee approval. Our primary endpoint is the DASH score after 6 months. The follow-up time of this study remains 1 year.

Secondary outcome parameters are listed in table 4.

4. Is the writing acceptable? The writing could be improved throughout. The statistical methods paragraph is not acceptable. Yes, however, they use the abbreviation, TEN, for Titanium Elastic Nail. Can this be modified? There are spelling errors (analgetics instead of analgesics, continuing variables instead of continuous variables).

The use of the abbreviation of TEN is modified: it is replaced by Elastic Stable Intramedullary Nailing (ESIN).

The statistical paragraph has been rewritten by specifying explicitly the type of analysis for each outcome parameter. The spelling errors have been corrected.
All authors agreed with the changes that were made. The authors hope these revisions are to your approval and the authors look forward hearing from you.

Yours sincerely, on behalf of all authors,

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References


