Reviewer's report

Title: Clinical investigation for displaced proximal humerus fractures in elderly. A randomized study of two surgical treatments: Reverse Total Prosthetic Replacement versus angular stable plate Philos (The DELPHI-trial).

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Reviewer: Guido A Wanner

Reviewer's report:

In the present manuscript, the authors describe a protocol for the investigation of two different options for the operative treatment of displaced proximal humerus fractures in elderly patients (age 65 to 85 years). The authors seek to compare reverse total shoulder arthroplasty (RTSA) to open reduction and fracture fixation with an angular stable plate (“Philos”; control group; n= 60/group) in patients with displaced three- or four-part fractures (AO types 11-B2 and 11-C2). The study is designed as a prospective, randomized multicenter trial with a follow-up of 5 years in accordance to the recommendations of the Consort statement. As the primary outcome parameter, the postoperative shoulder function assessed by the Constant Score has been defined. Secondary outcome measures comprise quality of life score, Oxford shoulder score, radiographic evaluations, and assessment of cost effectiveness.

The study addresses a relevant issue in the field of orthopaedic surgery, and other prospective randomized studies with the same objective are currently not available.

Comments as minor revisions:

1. According to the power calculation, the minimum number of patients to be included in the study is 51 patients/group, and the authors choose to include 60 patients/group. However, according to page 13 (‘Interventions’), only 55 patients in each group will undergo surgical treatment. This should be clarified. Likewise, there is a discrepancy regarding the time period of patient recruitment (until autumn 2015 [p. 17, line 550] vs. spring 2016 [p. 13, line 421]). Another question is if the age of the patient cohort as well as the rather long follow-up of 5 years has been taken into account in order to prevent the study to be underpowered.

2. The statements regarding the length of follow-up are inconsistent: 2 years (p. 7, line 215), 5 years (p. 7, line 225, p. 13, line 402, and abstract), or even 10 years (p. 19, line 631). Please clarify.

3. When are radiographic evaluations performed during follow-up? After 12 and 24 months only (p. 11, line 351)?

4. The number of participating surgeons (one surgeons per study center?) and their skill levels/experience with both treatment options should be specified.

5. How can the physiotherapists be blinded (semi-blind study design) if the time
line of physical therapy for both groups substantially differs?

6. Is the surgical approach standardized for both groups (p18, line 581)? The statements on page 14 (lines 443 and 465) are somewhat misleading. With respect to the surgical technique, occasional use of a medial buttress plate and/or bone grafting in the control group (Philos) might affect the outcome. This should be discussed.

7. Although the study design can be regarded as state of the art, the question remains if it keeps its informative value by the time it will be published due to improvements/changes of implants (given the follow-up of 5 years). Another concern with these types of studies is if conditions can be identified, in which patients benefit from either treatment, and, thus, the study can provide help for decision-making in the individual patient situation. This should be also addressed in the Discussion section.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests