

Reviewer 1 comments

General comments. The author should be congratulated for conducting an important study. The manuscript is well written and follows the CONSORT Statement recommendations for reporting randomized trials and was registered in Clinical trials.

We thank the reviewer for these kind comments

My main concern is that when the study was registered in Clinical trials the authors reported that a 20% difference in DASH scores was the primary outcome for the study and the secondary outcome was if the patient had return to work/ return to independency after 12 weeks. This should be mentioned in the manuscript

It is stated in the manuscript that a 20% difference in DASH was the primary outcome and the basis for the sample size calculation. It is now clarified that the ADLs were a secondary outcome measure

The number of patients who returns to work/return to independency after 12 weeks should be mentioned in the abstract. and in the result section.

We do not think this belongs in the abstract as this was a secondary outcome and there is insufficient room. We have now clearly stated the number of patients returning to work/ return to independence in the results section.

I would recommend the authors to highlight the both statistically significant and clinical significant difference in PRWE score between the groups which is much more interesting than the authors finding regarding their ADL-score.

We have put the absolute difference in the PRWE score in the result section. A difference of 11 – 14 points equates to clinical significance and we have also stated so in the manuscript with references.

Reviewer 2 comments

It is a random controlled study involving patients presenting with distal radial fractures. Based on better functional, clinical and radiological outcomes at short-term follow-up, the authors encourage the use of volar locking plates for the treatment of distal radius fractures. The study is well designed and the data is reliable. Therefore, the content of the manuscript have value for publication.

We thank the reviewer for these kind comments

Reviewer 3 comments

The reviewed study is relevant in the discussion on treatment of DRF's. The structure of the manuscript is complete. The aim and method are concise with details reported to "clinicaltrials.gov". The figures and tables are relevant. It is a well written manuscript.

We thank the reviewer for these kind comments

Method:

Authors could discuss the possible selection bias between the groups: In the control group 16/27 had closed reduction and cast immobilization. Were these fractures stable fractures? The remaining 11 fractures in control group received osteosynthesis. Were they unstable? All the fractures in the intervention group received osteosynthesis. It could be specified how they evaluated stability/indication for operation of the fractures, especially the conservative treated in control group.

We randomly assigned the patients to either osteosynthesis with a volar locking plate without postoperative mobilization or to a treatment which necessitates 6 weeks postoperative mobilization. It was up to the treating surgeon to choose between closed reduction and cast manipulation alone with or without K wire supplementation or stabilization with an external fixator. We are aware that there might be selection bias and that the sample size is too small to detect differences between treatments in the control group. Overall, the fracture distribution (AO A-C) was comparable between the groups. As stated in the manuscript, our main intent was to compare treatment with immediate mobilization to treatment with six weeks immobilization. We felt it would be more pragmatic allowing the surgeon to choose treatment in the control group.

PROM:

The reviewed study set the clinically relevant difference for DASH at 20. In more recent studies (1) the MCID for DASH is set at 10 and PRWE at 14. In 2008 these data might not have been available and therefore the authors set the MCID for DASH at 20. This could be discussed since the power calculation would have been different and more patients needed to show a difference.

We agree that if the sample size calculation had been based on a clinically significant difference of 10, this would have resulted in more patients being required in the trial. However we based our calculation on the instructions for the DASH scale in 2008. We have noted this in the manuscript

Discussion:

The authors could comment on the study by Karantana et al (2) where cost- effective analysis has been made. The reviewed study allows immediate use of movement in plating group, whereas Karantana et al immobilizes for two weeks in intervention group and six weeks in control group. Tubeuf et al (3) has also analyzed cost effectiveness and their results could be discussed.

Thank you for this comment. Cost effectiveness analysis is beyond the scope of our manuscript, and was not the focus of our study. We have cited these references.

References:

Are not up to date: three studies from 2013 and one from 2014. The two cost-effective studies could be included. Also more recent prospective studies could be referenced, for example Costa et al (4).

References:

1. Amelia Sorensen, Daniel Howard, Wen Hui Tan, Jeffrey Ketchersid, Ryan P. Calfee. Minimal Clinically Important Differences of Three Patient-Rated Outcomes Instruments
J Hand Surg Am. Author manuscript; available in PMC 2014 April 1.
Published in final edited form as: J Hand Surg Am. 2013 April; 38(4): 641–649
2. Karantana A¹, Scammell BE¹, Davis TR², Whynes DK³. Cost-effectiveness of volar locking plate versus percutaneous fixation for distal radial fractures: Economic evaluation alongside a randomised clinical trial. Bone Joint J. 2015 Sep;97-B(9):1264-70.
3. Tubeuf S¹, Yu G¹, Achten J², Parsons NR³, Rangan A⁴, Lamb SE⁵, Costa ML². Cost effectiveness of treatment with percutaneous Kirschner wires versus volar locking plate for adult patients with a dorsally displaced fracture of the distal radius: analysis from the DRAFFT trial. Bone Joint J. 2015 Aug;97-B(8):1082-9.
4. Costa ML¹, Achten J², Parsons NR³, Rangan A⁴, Griffin D², Tubeuf S⁵, Lamb SE⁶; DRAFFT Study Group. Percutaneous fixation with Kirschner wires versus volar locking plate fixation in adults with dorsally displaced fracture of distal radius: randomised controlled trial. BMJ. 2014 Aug 5;349:g4807.

All of the four suggested references have now been included.

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3 27368-Copyright assignment – Attached

4 27368-Audio core tip – Attached

5 27368-Institutional review board statement – Attached

- 6 27368-Clinical trial registration statement – Attached
- 7 27368-Informed consent statement – Included in the manuscript
- 8 27368-Biostatistics statement – Included in the manuscript
- 9 27368-Conflict-of-interest statement – Included in the manuscript
- 10 27368-Data sharing statement – This is included in the manuscript
- 11 27368-Google Scholar – Attached, see screenshot
- 12 27368-CrossCheck – N/A
- 13 27368-Grant application form(s) – N/a
- 14 27368-Language certificate – N/a

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