Reviewer's report

Title: Assessment of a Novel Biomechanical Fracture Model for Distal Radius Fractures

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Reviewer: Andrew R. Thoreson

Reviewer's report:

The study is well-designed and well-executed. A strength of the study is that their model geometry is directly supported by actual clinical observations. A weakness however is the supposition that these observations are inclusive of all comminuted extraarticular distal radius fracture geometries. A stronger conclusion would be that data from such models is sensitive to fracture location/geometry. Minor weaknesses of the current manuscript include omission of some details of test method and statistical analysis, which could be easily addressed.

1. Use of the 1027 Sawbone is likely appropriate for this study of a model of fracture commonly occurring in osteoporotic patients. Perhaps the authors could comment on the selection of this particular bone surrogate, and why it was selected over others that were available. (Discretionary Revision)

2. The authors state that there were no plate/screw interface failures for Sawbone model testing. While similar in stiffness to bone, the shearing/fracture toughness of these models are quite different. Are observations of hardware failure really as relevant for this portion of the testing? (Discretionary Revision)

3. The results of the preliminary Sawbone study seem counter-intuitive: the longer lever arm in the new model under high loading did not result in lower stiffness compared to the standard model. While lack of a statistically significant difference could simply be a matter of sample size and statistical power, the authors should comment on the how these results matched their predictions, in both the preliminary study and the main experiment. (Major Compulsory Revision)

4. Was the wedge osteotomy for both types of models made with a jig or fixture for consistency? Were the landmarks used to reference the position of the osteotomy easy to identify consistently? If not, how does this impact the repeatability of the measurements? (Major Compulsory Revision)

5. Was there a gap between the bone at the apex of the wedge in the model? Either way, the authors should comment on how creation or omission of such a gap affects biomechanical properties and how this compares to other studies. (Major Compulsory Revision)

6. Load was distributed to the radial head from the actuator with a negative
imprint mold. The amount the distal fragment is constrained will depend on how deeply the bone is seated in such an impression; what was its depth and how was it consistently created? The different models may be differentially sensitive to distal fragment constraint as well. (Major Compulsory Revision)

7. The load protocol reference from Wolfram et al. was used for a study of vertebral body loading. How did the authors determine that this protocol was relevant to distal radius loading? During early rehabilitation, essentially all of the load will be supported by the fracture fixation device and loads will generally be smaller ~100 to 200N. (Major Compulsory Revision)

8. Biomechanical setup and Statistics, paragraph 1: One of the failure criteria was a displacement of 3 mm, which must be the displacement of the actuator and not necessarily that of the fragment. Other studies have directly measured fragment displacement (Willis et al. JBJS 2006). Use of actuator displacement vs. fragment displacement is a limitation that the authors should include in their discussion. (Discretionary Revision)

9. Biomechanical setup and Statistics, paragraph 3: The significance level (P-value) for the t-tests needs to be stated? Also, was an analysis conducted to assure that 11 pairs will provide adequate statistical power? If not describe how sample size was determined. (Major Compulsory Revision)

10. Results, paragraph 2: What is meant by “residual displacement was subtracted from measured displacement”? Does this accommodate for settling the fixtures during loading? Describe why this was done. (Major Compulsory Revision)

11. Results, paragraph 1: Since comminuted extraarticular distal radius fracture is often associated with an osteoporotic population and since BMD was evaluated in this study, can the authors comment on whether these specimens would be representative of this population? (Discretionary Revision)

12. Results, paragraph 2: What is meant by the phrase “Failure in 11 specimens equally distributed in two groups”?

13. Results: Please include a statement regarding the failure mode for all specimens tested. (Discretionary Revision)

14. Discussion, paragraph 1: The model is described as “improved” but no justification for improvement is provided. Clearly the results are different and the authors make a case that the model geometry matches some clinically observed fractures, but that alone does not improve this model over others proposed. The statement should be supported or altered. (Major Compulsory Revision)

15. Discussion, paragraph 2: A limitation discussed is that only axial loading and no torsional loading was applied in this study. Additionally, other important
loading modes should be discussed, included bending moments, or compound eccentric loading (bending and axial compression). (Discretionary Revision)

16. Discussion, paragraph 4: Use of an established loading protocol is cited as a strength of the study, but is application of a loading protocol designed for vertebral body loading applied to distal radius actually a strength when so many other papers exist describing loading on distal radius models. Does this make comparing results to other studies more challenging? (Major Compulsory Revision)

17. Discussion, paragraph 6: It is stated that “the new fracture model resembles more closely the in vivo situation”. This is not entirely accurate as has been said, distal radius fractures can take on near infinite patterns. It may be a closer match to fractures in studies cited, but that study alone is not all-inclusive and this needs to be recognized. (Major Compulsory Revision)

18. Conclusion: The sentence indicating that previous research suggests the previous model of distal radius fracture does not mimic the in vivo situation is not strongly supported; the previous literature suggests that the fracture model did not match in vivo situations in one particular study. The outcomes of this paper much more strongly suggest that biomechanical properties are sensitive to the position of the extraarticular comminuted fracture, which can occur along a continuum. The degree of sensitivity is also likely dependent on the type of fracture fixation device applied. The reviewers should modify their conclusions to focus on the more important contribution of this study in pointing out sensitivity of the model until a more exhaustive study of fracture location frequency is completed. (Major Compulsory Revision)

19. There are a few spelling/grammatical errors throughout. (Minor Essential Revision)

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I work for a laboratory that has performed test work for hire for a manufacturing of distal radius fracture fixation devices, namely Conventus Orthopaedics, Inc. This testing was completed in September 2010.