Reviewer's report

Title: A New Lumbar Posterior Fixation System, the Memory Metal Spinal System. An In-vitro Mechanical Evaluation.

Version: 1 Date: 3 April 2013

Reviewer: Job van Susante

Reviewer's report:

Review of manuscript “A new lumbar posterior fixation system, the Memory Metal Spinal System. An in-vitro mechanical evaluation” by Kok-D et al.

The authors performed a preclinical biomechanical testing of a new concept of pedicle screw augmented stabilization of the lumbar spine using a single rod. So far the golden standard for pedicle screw stabilization of spinal segments uses bilateral rounded titanium rods for inter-vertebral stabilization. The authors hypothesize that improvement of this concept may be obtained by changing to the use of a single square rod which can subsequently be placed longitudinally in the midline after attachment to the transverse connecting bars between pedicle screws. In addition, the titanium alloy has been changed to memory metal (nitinol) is assumed to have better biomechanical characteristics.

An important strength of the study is that testing of the new device has been performed in a controlled setting with comparison an established golden standard pedicle screw system.

In summery I can answer the questions for the reviewer guideline below

1. Is the question posed by the authors well defined?
The research question and hypothesis are well defined

2. Are the methods appropriate and well described?
The methods are appropriate and well described; the reader would benefit form a figure illustrating the testing device with both constructs.

3. Are the data sound?
The authors tested five constructs of each device. Given the relatively small standard deviation provided this appears to be an acceptable number.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?
Yes

5. Are the discussion and conclusions well balanced and adequately supported by the data?
The discussion is too short and should elaborate more on the authors view on the possible next step in clinical use, the fact whether there is literature available on single rod constructs or whether this is a true novelty.
6. Are limitations of the work clearly stated?
This is truly missing in the manuscript and should be added to the discussion.
7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished?
Maybe the authors can indeed provide us with some references of earlier/current work from their group on memory metal
8. Do the title and abstract accurately convey what has been found?
Yes
9. Is the writing acceptable?
I would suggest professional language editing before revision, there are some typographical and grammatical inconsistencies in the manuscript.

Apart from the (major) comments above I have some additional comments.

Major comments:
1. The abstract is good, however I find the mini abstract difficult to read. There is no clear summary of findings and conclusions. Please rephrase.
2. In the introduction, at the end of the first section, the authors state “instrumented spinal fusion plays a major part (suggestion: “an important role”) in the development of adjacent segments degeneration” and they hypothesize that the more flexible memory metal may decrease this chance. Please clarify this hypothesis from the point of view that all systems offer support until fusion after approximately one year is obtained; after fusion I do not see any hypothetical benefit. See also end of introduction (line 146-147) where again is stated that with the memory metal “there should also be less degeneration of adjacent segments.
3. Introduction, second section (line 130-131), the authors present the unilateral rod as an advantage to “facilitate a TLIF procedure, because the rod will not obstruct a TLIF cage”. In my hands I insert the cage prior to rod fixation and therefore I do not see this advantage.
4. M&M, first section on RODS. This is not entirely clear to me. Especially the first 6 sentences are hard to read or understand. Also the authors state “The A was set between…” Explain where A stands for.
5. M&M, last section. Not that pre-bent rods are in the meantime also available in the conventional systems with rounded titanium rods
6. M&M Connector Bridge. The first two sentences are difficult to understand. I would suggest that the authors presents an illustration of the new device in the corpectomy model for clarity purposes.
7. M&M, section The titanium Moss Miami components. Please elaborate on the potential difference in cross sectional thickness of the two rods studied (5.5 mm diameter titanium versus a 6.35mm square cross section (line 171) for the memory metal) and the consequence of influencing the parameters studied.
8. Results. All sub sections should elaborate more on encountered differences
between the two constructs and statistics should be included in the text.

9 Discussion. See earlier; the discussion is too short and should also deal with potential use in future, limitations of the study, other literature on single rod systems etc etc.

Minor comments:

10 As for Table 1 and table 2 I believe they do not add relevant information and I suggest to delete them.

11 Section on testing protocol. Mention in first sentence both spinal systems.

12 Please provide references from the literature behind the corpectomy model used in this study.

13 Results section. As for Table 3 and figure 2 I do believe that the figure does not add much information and can be deleted. The same accounts for table 4 and figure 3 respectively.

Sincerely,

Job van Susante, MD, PhD

**Level of interest:** An article whose findings are important to those with closely related research interests

**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 have no financial conflict whatsoever.