Reviewer’s report

Title: A Multi-center, Randomized, Clinical Study to Compare the Effect and Safety of Autologous Cultured Osteoblast Injection to Treat Fractures

Version: 4 Date: 2 August 2008

Reviewer: Peter Ebeling

Reviewer’s report:

Kim S-J et al have conducted a multi-center, randomized, clinical study to compare the effect and safety of autologous cultured osteoblast injections to promote fracture healing. Callus formation was accelerated by autologous osteoblast injections.

This reviewer suggests the following compulsory revisions:

1. More detail is required regarding the autologous osteoblast cultures. What was the duration and method of culture? How was sterility assured? This section on page 4 needs to be expanded considerably to include these and other details.

2. Does a callus formation score of < 3 at 6 weeks represent delayed fracture healing? This should be specified here on page 5.

3. What were the side effects of local fracture site injection of osteoblast cultures?

4. It is unclear why 77 patients were enrolled when 74 was the number originally planned (Page 7). Please clarify.

5. A Figure should be included to show the recruitment pathways and reasons for exclusion, drop-out, etc.

6. One decimal point is adequate for age and two orders of significance for p-values. These should be changed throughout, including the Tables.

7. The meaning of the comparisons at different time points is unclear. A table could be added for the comparisons between osteoblast injection and control groups at different time points.

8. Figure 2: What does sum of the difference in callus formation scores mean? The standard errors should be included in the Figure as well as the significance of the difference.

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 declare that I have no competing interests.