Reviewer's report

**Title:** Pullout strength of pedicle screws with cement augmentation in severe osteoporosis: A comparative study between cannulated screws with cement injection and solid screws with cement pre-filling

**Version:** 1  **Date:** 17 August 2010

**Reviewer:** Alejandro Espinoza

**Reviewer's report:**

Major Compulsory Revisions

The authors did carry out a sequence of mechanical tests to evaluate the influence of cement augmentation on spinal screws. The choice of cellular foam is a good one to avoid the influence of biological tissue’s inherent variability. A major topic that this reviewer feels that needs to be addressed is the design of the experiment (DOE). The power of the study is not mentioned and there is no calculation regarding this very important topic. This work is a classic example where the Taguchi DOE or another robust statistical design method can be applied, to precisely find out what factors are the most influential and if interactions exist among them. This should be addressed because the conclusions drawn from the experimental results might change or not have enough credibility due to a low sample size number. Although the reviewer realizes that the experiments have already been carried out, it is advisable to confirm the statistical power and factor/level effects even as a calculation a posteriori.

The factors and levels for the experiment need to be explained in an easier to follow fashion. For example, instead of describing the experimental groups in a paragraph, a schematic flowchart would do a better job.

Minor Essential Revisions

**Background section**

- Third paragraph: “Recently, the expandable screw developed for Merck Corporation’s Omega 21 spinal system has increased the interfacial strength…”

The Omega 21 was marketed by a company called EBI, which was absorbed by Biomet-Merck, around 10 years ago. The publications mentioned (refs. 6 and 7) are from the turn of the century as well. Please update with newer references. The literature shows very few reports on this particular product.

- Fourth Paragraph: “Cylindrical screws are used in most implant systems”

Please cite a reference justifying this statement. Are there actual market share numbers? Why would surgeons prefer one type over another?

**Methods section**
- Density of the foam block is 88 kg/m3. A more recent reference by Bullmann et al (see end of this review for a citation) shows actual osteoporotic bone densities in a range almost half of that. Also the ASTM F1839 standard directs that the lowest grade should be (Grade 10, 160 kg/m3 and is higher than your chosen value. Would you care to comment how was this density value chosen?

- Describe the experimental design in detail. Include a statistical power calculation, six samples per experimental group seems a little low number. If needed, seek the help of a biostatistician.

- How was the insertion rate measured? Even though this is the recommendation from the ASTM standard, the method used in this work should be described.

- Continuing with the rate topic, was the flow rate of the cement slurry considered?

- What was the consistency of the slurry prior to injection? Was there a specific procedure to ensure that the cement had the same conditions in each case?

- Partial screw removal: Why was a 4 minute wait period chosen?

- Cement curing time: this is not mentioned in the manuscript. Would the authors consider this to be an influencing factor?

Minor typographic/writing errors:

• where it says “Carton” for Instron’s home address, it should be Canton.

• Please state the complete name and city of the bone biopsy needle manufacturer, as well as the diameter used (this would influence the flow rate).

Results Section

- Typographic error: Second paragraph, last sentence, where it reads: “no significant difference in pullout strength was found between conical and cylindrical screws (p < 0.05)” Shouldn’t the p value be larger than 0.05?

Discussion Section

Change the text in “Their results indicated that the failure force, failure stress and resistance force were highly linearly correlated with the pullout rate”. This sentence would read better like this:

“Their results indicated that the failure force, failure stress and resistance force showed a highly linear correlation with pullout strength”. “Pullout rate” should be pullout strength, because the authors only report one value for pullout rate (5 mm/min).

The authors mention a composite cement/bone structure in the area of cement infiltration. While this observation is correct, a little more detail should be offered in terms of what type of composite structure they refer to. A simple analysis of a law of mixtures would explain that the difference in density between trabecular
bone and bone cement occupying some of the voids (because the porosity will not be completely covered by the bone cement – due to a host of factors such as cement wettability, porosity considerations, flow rate, etc.), is the cause for a much stronger volume of interest leading to the pullout of the bone plus the cement. How would the authors relate this to potential adjacent level damage due to the mismatch of materials’ strength in the operated levels vs. the adjacent (intact) ones? Can the authors offer a way to ensure/measure that the intended amount is actually inside the bone (to account for all of it and avoid leaks)? This is related to the comment the authors make in the last paragraph of the Discussion section: “Third, only one volume (3 ml) of cement was tested. The amount of injected cement may play an important role in determining pullout strength…”. Three comments arise regarding this statement: first, this type of study is precisely what is needed to establish what factor has more influence. Second, the diameter of the screw with respect to the available bone region is important too, maybe more than the amount of injected volume. In cases of slim pedicles, this is crucial. And finally, the failure mode of these screws may not be necessarily a constant-rate pull-out. What are the comments of the authors to a more physiological-resembling failure method: fatigue testing to create loosening? Please address these comments in your discussion section.

Figure captions:
What are the error bars in the graphs? Please state Standard Deviation or Standard Error, where applicable. This should also be addressed in the Methods section.

Cited Literature:
Many works cited are more than five years old. Please review the latest literature for more up-to-date references and comparisons to your data. There are studies out there very similar to yours, even using the same screws, be sure to cite them. As it is, this paper would have been cutting-edge in 2000, not 2010. Are there any other expandable screws on the market? Do people use them? Also, please review the latest ASTM standard versions. At least one is already obsolete and has been superseded by a new version.

This paper was mentioned by the reviewer early in these comments:


Discretionary Revisions
- None

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