Author's response to reviews

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

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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

Dear Editor-in-Chief,

Thank you for your letter on Dec. 24. The authors have read the comments and suggestions made by the reviewers/editors with care. We have rewritten the manuscript and directly incorporated the suggestions to address each of their concerns. All changes in the revised manuscript are highlighted in bold. Our responses to the referees’ comments are listed below, and we deal with each issue in a point-by-point manner. We hope that with these changes our manuscript will meet the criteria for publication in *BMC Musculoskeletal Disorders*.

We look forward to hearing from you soon. Thank you very much again.

Sincerely,

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Response for reviewer #1:

Thank you for your review.

The authors would like to express our respect for your effort in reviewing this manuscript. We have carefully read the comments and suggestions. Below we list your comments and deal with each issue in a point-by-point manner.

Reviewer's comments:

General Comments:
1. Although the manufacturer claims that the product is suitable for a variety of applications this does not mean that it is suitable for your particular investigation.

Reply:
(1). We completely agree although the manufacturer claims that the test block is suitable for a variety of applications, this does not mean that the block is definitely suitable for investigation of screw pullout strength.

(2). The authors are aware that human cadaveric spines will be of more clinical relevance than will test blocks. Unfortunately, we do not have access to human cadaveric spine with severe osteoporosis in our hospital. Although the mechanical/physical properties such as density, porosity, strength and modulus of the test blocks are somewhat different from those of human cadaveric spines, however, the test blocks are the most convenient platform on which to perform the experiment in the circumstance that human cadaveric spines cannot be obtained.

2. Based on the provided reference, the density of the synthetic material used in this investigation seems to be appropriate. However, we believe that in addition to matching the density, it is important that the test model match the strength and modulus of osteoporotic bone. Based on the strength and modulus information provided by the manufacturer, it seems that it is well below what has previously been reported for osteoporotic cancellous bone.

Reply:
(1). The authors agree that in addition to matching the density, it is important that the test model match the strength and modulus of osteoporotic bone. In our opinion, although the pullout test did not measure the actual screw/bone interfacial strength, the test blocks, however, it provided a uniform platform on which to compare the mechanical behavior of pedicle screws with various designs.

(2). The compressive and tensile strengths of cancellous bone have been shown to be related to apparent density and thus vary by more than two orders of magnitude over a typical range of densities (Carter and Hayes, 1976).

3. I agree that for the purposes of this comparative study, using synthetic bone is appropriate. However, the discussion should note that the test material may not match the material properties of osteoporotic cancellous bone and that extrapolation of these findings to clinical utilization should be done with caution.

Reply:
(1). This concern has been incorporated into the limitations/discussion in the revised manuscript.
(2). A statement “Although the synthetic bone provides a platform for comparison of pullout strength, the material properties of the test block are somewhat different from those of actual osteoporotic cancellous bone; the extrapolation of our results to clinical utilization should be performed with caution.” has been added to the limitations/discussion in the revised manuscript. (Page 17, Line 13)
**Response for reviewer #2:**

Thank you for your review.

The authors would like to express our respect for your effort in reviewing this manuscript. We have carefully read the comments and suggestions. Below we list your comments and deal with each issue in a point-by-point manner.

**Reviewer's comments:**

**Minor Essential Revisions**

1. The addition of a Taguchi methodology did enhance the paper. However a couple of important details were left out:
   a) To keep the flow of the Materials and Methods section consistent, please put the Taguchi DOE section at the beginning before any sample preparation description. This will tell the readers what kind of experiments were carried out.

   **Reply:**
   As per the reviewer’s suggestion, the description of Taguchi DOE has been moved to the first paragraph in the “Methods” section.  

   **(Page 6, 1st Paragraph)**

   b) The Taguchi results showed that the factor “cement augmentation technique” was the most influential. Were there any interactions seen in the other factors or among factors? There is no mention of what type of array was used, if any interactions were sought and what type of optimization was carried out (a maximization seems the case here). This data is still missing. A short paragraph describing this should suffice.

   **Reply:**
   The following statements had been added in the revised manuscript:
   The Taguchi's L₈ array analysis revealed the design factor “cement augmentation technique” was the main influential factor, whereas “screw shape” was the least influential factor affecting the pullout strength. In addition, the highest pullout strength was found in combination of cylindrical-solid-fully insertion. The results of Taguchi analysis were consistent with our conclusion that the PMMA augmentation technique for solid screws with retrograde cement pre-filling offers improved initial fixation strength.  

   **(Page 17, Line 4)**

   c) The reference of Hsu’s paper (ref. 34) does not seem the most adequate to describe the Taguchi method. It is ok to leave it as an application of the Taguchi method, but the overall theory is better explained elsewhere, and that is the type of reference that should be added.

   **Reply:**
   As per the reviewer’s suggestion, two references explaining the Taguchi method were added.  

   **(Ref. 35 and 36)**
2. In several places, the grammar is incorrect and typos still exist. Please make sure that a proper proof-reading is conducted. Some of the confusing phrases this reviewer found are listed next in their corrected form (corrections in bold & underlined text):

   Reply:
   Thank you for correcting the grammatical errors and typos. To ensure a proper proof-reading, this revised manuscript had been edited by the editorial company American Journal Experts for correction of any remaining grammatical errors. (See the certificate attached as the last page)

Abstract Results
Pg 2 Last sentence, should read: “that of cannulated screws…”

   Reply: Thank you for noting this problem. This error was corrected accordingly. (Page 3, the last Paragraph)

Background section
Pg 4, 2nd Paragraph: “osteoporotic bone decreases”; “screw holding power have”;

   Reply: These two errors were corrected accordingly. (Page 4, 2nd Paragraph)

Pg 4 3rd Paragraph: “Our review of the literature found that most…”

   Reply: This error was corrected accordingly. (Page 4, 3rd Paragraph)

Methods section
Pg 8 Last sentence “…pilot hole accompanied with progressive needle retraction out of the test block…”

   Reply: This error was corrected accordingly. (Page 9, Line 8)

Pg 9 Second sentence “the screws were randomly…”

   Reply: This error was corrected accordingly. (Page 9, Line 12)
Pg 9 Biomechanical tests paragraph, 3rd sentence: “…was attached to the testing machine…”

Reply:
This error was corrected accordingly. (Page 9, Biomechanical tests paragraph, 3rd sentence)

Pg 9 Biomechanical tests paragraph, 5th sentence: “The force acting on the screw during testing was continuously recorded in 0.1 mm increments (sampling rate: 0.83 Hz) until the peak pullout resistance was reached, displacing the screw outwards.”

Reply:
This sentence has been revised accordingly. (Page 9, Biomechanical tests paragraph, 5th sentence)

Results Section
Pg 11, 2nd Paragraph “…higher pullout strength than that of the cannulated screws with…”
Same paragraph: is the increase 23% or 24%? (previous manuscript showed 24%)

Reply:
1. This sentence has been revised accordingly. (Page 11, 2nd Paragraph)
2. It should be 23%. (The figure of 24% in previous manuscript was a mistake)

Discussion Section
Pg 13, Second paragraph, sentences 6-8 and 9-10, essentially say the same. Condense into one or two to avoid redundancy.

Reply:
As per the review’s comment, the statement “It is suitable for a variety of applications requiring the open celled structure, such as cement injection and modeling osteoporotic cancellous bone” had been deleted to avoid redundancy. (Page 13, Second paragraph)

Pg 16 2nd sentence: “pre-filing for the cannulated screws”

Reply:
The erroneous “screwa” had been corrected to read “screws”. (Page 16, Line 1)

Pg 16 5th sentence: “would enormously reduce”

Reply:
The erroneous “reduces” had been corrected to read “reduce”. (Page 16, Line 5)
Pg 16 9th sentence: “…bone was thought to induce…”

Reply:
The erroneous “though” had been corrected to read “thought”.  (Page 16, Line 12)

Pg 16, sentences 10 to 13

Reply:
These sentences have been rewritten in the revised manuscript. (Page 16, Line 13 to 17)

Table 3. Please clarify where do the p values correspond to.

Reply:
The following two statements reading p-values for corresponding groups had been added in Table 3:

- $p = 0.0129$ (Solid Screw with PMMA prefilling vs. Cannulated Screw with PMMA injection, Conical Screw)
- $p = 0.005$ (Solid Screw with PMMA prefilling vs. Cannulated Screw with PMMA injection, Cylindrical Screw)

3. In the last paragraph of the Discussion section (3rd, 4th, 7th and 8th sentences), the text is the same as the authors’ previous paper conclusions (Chen et al. Ref # 4). It is odd to find that two different publications will arrive to the very same conclusions. Please reword so that they are not exactly the same.

Reply:
1. The statement “First, a test block was used rather than cadaveric vertebrae. Although physiological factors, such as the geometry of the vertebrae, density distribution, and blood perfusion were not considered, artificial osteoporotic bones were the most convenient choice to perform the experiment with reliably comparable results when human cadaveric spines could not be obtained.” has been rewritten as follows:

“First, a test block was used as a substitute for human osteoporotic vertebrae. Although the synthetic bone provides a platform for comparison of pullout strength, the material properties of the test block are somewhat different from those of actual osteoporotic cancellous bone; the extrapolation of our results to clinical utilization should be performed with caution.”  (Page 17, Line 12 to 17)

2. The statement “Third, only one volume (3 ml) of cement was tested. The amount of injected cement may play an important role in determining the pullout strength. Subsequent experiments with various cement volumes deserved to be conducted.” has been rewritten as follows:
“Third, the volume of injected cement tested was constant (3 ml). The amount of injected cement might be an important influential factor in determining the screw holding power. The effects of the amount of injected cement on bone/screw interfacial strength deserved to be conducted in the future.” (Page 17, Line 22 to 25)

3. The statement “Last, the only mechanical measurement was the pullout strength without considering other physiological loadings. In actual physiological situations, the screw/bone interface is subjected to complex multi-directional loading; however, as described in the ASTM F543-07 standard, the screw’s pullout strength is the best way to quantify the holding power of a bone screw and enables comparison with other studies.” has been rewritten as follows:

“Last, the present work is limited to static loading (pullout in test block) without considering of other physiological loadings. In actual physiological situations, the screw/bone interface is subjected to complex dynamic multi-directional loading. Our results cannot be used to predict the biomechanical performance of screw fixation under cyclic loading in the long term. Therefore, the possible future work could be to investigate the fatigue properties of pullout strength of the solid vs. cannulated pedicle screws in animal models.” (Page 18, Line 1 to 6)

Response for reviewer #3:

Thank you for your review.
The authors would like to express our respect for your effort in reviewing this manuscript. We have carefully read the comments and suggestions. Below we list your comments and deal with each issue in a point-by-point manner.

Reviewer's comments:

General Comments:
Manuscript is in general well designed.

Minor Essential Revisions
1. Several spelling and context errors were noted throughout the manuscript. Please be aware that 'data' is plural and thus should be paired with the appropriate plural verb (e.g. "the data were shown", not "the data was shown")

Reply: Thank you for pointing out these grammatical errors and typographical errors. To ensure a proper proof-reading, this revised manuscript had been edited by the editorial company American Journal Experts for correction of any remaining grammatical errors. (See the certificate attached as the last page).

2. Table 3: This table needs to express units (Newtons).

Reply: The unit (Newtons) had been added in Table 3.

3. Table 3: P-values demonstrate a comparison between which specific groups? may be beneficial to highlight statistical differences. Not sure you need data from each sample. The averages with SD are sufficient, if statistical differences are highlighted for all comparisons of interest.

Reply: The following two statements reading p-values for corresponding groups were added in Table 3:

- $p = 0.0129$ (Solid Screw with PMMA prefilling vs. Cannulated Screw with PMMA injection, Conical Screw)
- $p = 0.005$ (Solid Screw with PMMA prefilling vs. Cannulated Screw with PMMA injection, Cylindrical Screw)
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