Reviewer’s report

Title: What is the Difference in Morphologic Features of the Lumbar Vertebrae Between Caucasian and Taiwanese Subjects? A CT-based Study: Implication of Pedicle Screws Placement via Roy-Camille or Weinstein Methods

Version: 5 Date: 28 Nov 2018

Reviewer: Harvinder Singh Chhabra

Reviewer’s report:

Reviewer #2 (Comments to the Author): General Comments

1. The authors should describe the method of estimating the sample size. An epidemiological study with 52 males and 38 females seems less convincing without detailed statistical data. It will be helpful to know the detailed statistics of the study and adding it to the manuscript before coming to the conclusion. Thank you for the detailed reply. As per the calculations by the authors, at least 95 subjects must be recruited in each group. However, study does not have (95*2=190) 190 subjects. The authors have mentioned that they have included 78 patients for L1, 81 for L2, 77 for L3, 78 for L4 and 73 for L5 measurements. Authors may provide sample distribution for both the groups.

Due to different distribution of mean, standard deviation and numbers for each radiographic parameter, the effective sample sizes were also different based on the G*Power website (Heinrich-Heine Universit´at D’usseldorf, D’usseldorf, Germany). Accordingly, not all effective sample sizes were 95 in our radiographic parameters.

Regarding L1 measurements, 5 patients did not have symmetrical distribution on the axial planes, and 7 patients did not have the cutting planes parallel to the inferior endplates. Accordingly, 12 patients were excluded based on our exclusion criteria (lines 17 to 20, page 7, in the material section), and 78 subjects were included for L1 measurements. Two sides of the pedicle angle (PA), midline axis distance (MAD), pedicle axis distance (PAD) and pedicle diameter (PD) in one vertebra were taken as independent sets of data. The numbers for L1 measurement was 156 (78*2=156) (table 1).

Regarding L2 measurement, 5 patients did not have symmetrical distribution on the axial planes, and 4 patients did not have the cutting planes parallel to the inferior endplates. So 9 patients were excluded based on our exclusion criteria (lines 17 to 20, page 7, in the material section), and 81 subjects were included for L2 measurements. Two sides of the pedicle angle (PA), midline axis distance (MAD), pedicle axis distance (PAD) and pedicle diameter (PD) in one vertebra were taken as independent sets of data. The numbers for L2 measurement was 162 (81*2=162) (table 1).

Regarding L3 measurement, 6 patients did not have symmetrical distribution on the axial planes, and 7 patients did not have the cutting planes parallel to the inferior endplates. So 13 patients
were excluded based on our exclusion criteria (lines 17 to 20, page 7, in the material section), and 77 subjects were included for L3 measurements. Two sides of the pedicle angle (PA), midline axis distance (MAD), pedicle axis distance (PAD) and pedicle diameter (PD) in one vertebra were taken as independent sets of data. The numbers for L3 measurement was 154 (77*2=154) (table 1).

Regarding L4 measurement, 7 patients did not have symmetrical distribution on the axial planes, and 5 patients did not have the cutting planes parallel to the inferior endplates. So 12 patients were excluded based on our exclusion criteria (lines 17 to 20, page 7, in the material section), and 78 subjects were included for L4 measurements. Two sides of the pedicle angle (PA), midline axis distance (MAD), pedicle axis distance (PAD) and pedicle diameter (PD) in one vertebra were taken as independent sets of data. The numbers for L4 measurement was 156 (78*2=156) (table 1).

Regarding L5 measurement, 5 patients did not have symmetrical distribution on the axial planes, and 12 patients did not have the cutting planes parallel to the inferior endplates. So 17 patients were excluded based on our exclusion criteria (lines 17 to 20, page 7, in the material section), and 73 subjects were included for L5 measurements. Two sides of the pedicle angle (PA), midline axis distance (MAD), pedicle axis distance (PAD) and pedicle diameter (PD) in one vertebra were taken as independent sets of data. The numbers for L5 measurement was 146 (73*2=146) (table 1).

For the comparative data, the Zindrick MR et als (reference 1) did not provide detailed samples distribution of their subjects. For our study, there were 52 males and 38 females with mean age at 34.5±5.8 (range, 22 to 46). The numbers for age between 22 to 29 were 14 (male: 10, female: 4). The numbers for age between 30 to 39 were 54 (male:30, female:24). The numbers for age between 40 to 46 were 22 (male:12, female:10).

References:


Reviewers Fresh Comments- Thanks for the reply. The reviewers query has still not been addressed at all. Author has not justified the sample size.

2. The authors have not made it clear about the place where the study has been conducted. If the study has been carried out at a single centre in Taiwan, unless the patients had came from all over Taiwan, is difficult to understand that how a single centre could represent the entire Taiwanese population. We agree with the authors' belief that since their centre is a referral medical centre, some patients from middle and Southern Taiwan may be transferred to them. However, this does not justify that the sample size represents the
complete Taiwanese population. Also authors may provide the sampling frame and sampling method to chose the representative population.

We just merely represented the radiographic measurements from our institute. We added this as one of our major weaknesses in the lines 16 to 18 in the page 12 based on reviewer's recommendation at the last version.

We summarized our sampling frame and sampling method in the following figure based on reviewer's recommendations.

Reviewers Fresh Comments- Thanks for the reply. We agree that the author has mentioned this as a major weakness of their study. Still for 97 population of around 3 crores, 90 subjects does not justify sample size. Authors may also give details of sampling method. The flow chart provided depicts the methods how patients are included in the study. Author should give details about sampling method. Authors may clarify which patients have been randomised (as depicted in flow chart).

3. An epidemiological study with 52 males and 38 females seems less convincing without detailed statistical data. We understand that the authors have mentioned this as a weakness of their study, however this is an important aspect which needs to be justified before making a conclusion about the Taiwanese population and their comparison with Caucasians. 3. Thanks for your comments. The raw statistic data regarding mean, standard deviation (SD) and sample sizes in all radiographic parameters were revealed in the table 1 and 2 and in the results section. With the mean, SD and sample sizes, we might conduct the comparison between two groups (Taiwanese and Caucasians populations). Moreover, the references (reference 1, 2) for the Caucasian population were also revealed the mean, standard deviation (SD) and sample sizes in the table 1 and 2 in our manuscript based on the original papers. For similar manuscripts mentioned in the below, the authors also conducted the measurements in the authors' hospital or institute and make some comparison between different races. The authors revealed mean, standard deviation (SD) and sample sizes in each radiographic parameters in these manuscript (References 3 and 4). Mitra SR et als investigated the lumbar pedicle morphology in the 20 Indian cadavers and compared their results to westerners (Reference 3). Kim NH et als investigated thoracic and lumbar pedicles morphology in the Korean population with 73 dried columns and compared their results to westerners (Reference 4). In these two references, the authors provided statistical data regarding mean, SD and sample sizes to compare their results to western populations. We also provided statistical data regarding mean, SD and sample sizes in the table 1 and 2, which might be enough for comparison with the Caucasian population. It is difficult to understand the analysis as group wise data has not been provided. Also author must provide p-value for each calculation. Include all comments for the authors in this box rather than uploading your report as an attachment. Please only upload as attachments annotated versions of manuscripts, graphs, supporting materials or other aspects of your report which cannot be included in a text format. Please overwrite this text when adding your comments to the authors.
We provided P value and 95% CI in each comparative parameter and revealed in the following tables based on reviewer's recommendations.

For L1 measurements:

For L2 measurements:

For L3 measurements:

For L3 Transverse Intertangential Angle (TITA) measurement:

For L4 measurements:

For L4 Transverse Intertangential Angle (TITA) measurement:

For L5 measurements:

For L5 Transverse Intertangential Angle (TITA) measurement:

Reviewers Fresh Comments- Thanks for detailed reply. Data regarding L3 TITA and L5 TITA seems to be incorrect.

Reviewer's New Comment-

1. Page no12 line 10-19, "Based on the G*power software, the parameters were set up as follows: $\alpha = 0.05$, equal sample sizes ($N2/N1 = 1$), power =0.8 and two tails in the formula. With the given results between Taiwanese (mean:-10.1, SD: 8.1) and Caucasian populations (mean:-14.3, SD:12), the effective sample size for TITA at L3 was 95".

Authors should explain N2, N1 in his study and how their ratio is taken as one. Authors have not provided sufficient information to back (calculate) the sample size.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No
Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

Declaration of competing interests
Please complete a declaration of competing interests, considering the following questions:

1. Have you in the past five years received reimbursements, fees, funding, or salary from an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

2. Do you hold any stocks or shares in an organisation that may in any way gain or lose financially from the publication of this manuscript, either now or in the future?

3. Do you hold or are you currently applying for any patents relating to the content of the manuscript?

4. Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript?

5. Do you have any other financial competing interests?

6. Do you have any non-financial competing interests in relation to this paper?

If you can answer no to all of the above, write 'I declare that I have no competing interests' below. If your reply is yes to any, please give details below.

I declare that I have no competing interests
I agree to the open peer review policy of the journal. I understand that my name will be included on my report to the authors and, if the manuscript is accepted for publication, my named report including any attachments I upload will be posted on the website along with the authors' responses. I agree for my report to be made available under an Open Access Creative Commons CC-BY license (http://creativecommons.org/licenses/by/4.0/). I understand that any comments which I do not wish to be included in my named report can be included as confidential comments to the editors, which will not be published.

I agree to the open peer review policy of the journal

Do you want to get recognition for reviewing this manuscript? Add a record of this review to Publons to track and showcase your reviewing expertise across the world's journals. Signing up is quick, easy and free!

Yes