Peer review file
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Reviewer A

Comment 1: The authors are to be congratulated for conducting a rct in cardiac surgery. Their study plan and reporting are well thought through. I have several comments. I am not at all familiar with this device and I am very familiar with this space. After reading the paper I still do not know what these pins look like or how they are used. How many are used. Are there different sizes, etc. this needs to be an integral part of the paper as I suspect no one that reads this will be familiar with this device. Pictures would be very helpful.

Reply 1:
We appreciate the reviewer's constructive comment. To answer these comments, we have added the details of the sternal pin in the revised manuscript as well as the picture of the sternal pin and other devices required in the revised figure.

Changes in the text:
Page 6, line 112 now reads,
'The PLLA sternal pins were inserted according to the manufacture instruction. Briefly, at the end of a cardiovascular surgery, six single stainless wires, two on the manubrium and four on the sternal body, are put through the sternum. After that, two holes for the sternal pins were made on the marrow of sternum using the specific reamer and sizer (Figure 1B) between 1st and 2nd wires and between 4th and 5th wires. Subsequently, the sternal pins were inserted into the holes and the sternum was approximated and closed in the usual fashion.'

We also have added new figures. Kindly see the figure 1 in the revised manuscript.

Comment 2: The study has power calculations but is not clear on how those were derived and from what pre-clinical or clinical data supports the power calculations.

Reply 2:
Our estimated power calculation is based on the previously published study (20). In the paper, the sternal dislocation which is defined as a gap of divided sternum in more than half depth of a sternal body occurred in approximately 20% of patients after sternotomy. The depth of a sternal body is reported as around 30 mm; thus, given that 20% of patients with the standard sternal closure have a 15 mm gap while 80% of patients do not have a gap (0 mm), the average difference of sternal gap could be estimated as minimal 3 mm. We also estimate the standard deviation as 1.5-2.5 in each group. As the result, the required sample size would be 40:40. We considered that some case might be deviated from inclusion criteria; thus, we surmised that 50:50 would be reasonable sample size based on the above estimation. To clarify this, we have added further details of power calculation in the revised manuscript.

Changes in the text:
Page 9, line 166 now reads,
'The sample size was determined based on the data from a previous report (20). Briefly, given that the sternal dislocation, defined as gaps between cut sternums in more than half of the sternum depth (the average depth of sternum is reported to be around 30 mm) will happen in 20% patients with the standard wire closure as reported (20) as well as given that sternal pins will negate this dislocation, the calculated required sample size was 40:40 (total 80), with 80% power and 5% type I error level.'

Comment 3: The groups are relative even however not perfect which is to be expected with only 50 pts in each arm. A more robust multivariant analysis should be performed rather than a propensity matched analysis to help glen more useful information.

Reply 3:
To answer this important comment, we further analyzed using simple and multiple regression analyses to examine the contribution of each variable to sternal gap (the maximal gap) and instability. As shown in new table 6 and 7, either simple and multiple regression analyses could not detect any significant variables affecting on the outcomes. We have added those data in a new section in the revised manuscript.

Changes in the text:
Page 11, line 206 now reads,
'*Regression analysis for the effects of sternal pin and variables to sternal gaps and*

stability

To further examine the effects of sternal pin as well as other variables on the sternal gaps and instability, we performed the simple and multiple regression analyses. To simplify, we set the maximal gap, either antero-lateral or cranial-caudal direction, and stability as outcomes. As the result, we found that there is no significant effect on sternal gaps/stability by either the existence of sternal pin or other variables, including age, sex, BSA and primary diagnosis (Table 6 and 7).

Also, we have added new table 6 and 7. Kindly find them in the revised manuscript.

Comment 4: Need more clarity as to what procedures were exactly done in each group.

Reply 4:

To answer this comment, we have added more details of device and procedure used in this study.

Changes in the text:

Page 6, line 112 now reads,

'The PLLA sternal pins were inserted according to the manufacture instruction. Briefly, at the end of a cardiovascular surgery, six single stainless wires, two on the manubrium and four on the sternal body, are put through the sternum. After that, two holes for the sternal pins were made on the marrow of sternum using the specific reamer and sizer (Figure 1B) between 1st and 2nd wires and between 4th and 5th wires. Subsequently, the sternal pins were inserted into the holes and the sternum was approximated and closed in the usual fashion.'

Comment 5: Also need to know if these were consecutive pts that were enrolled beyond the exclusion criteria.

Reply 5:

Essentially, the candidates of the study were determined during a preoperative meeting with careful consideration of inclusion and exclusion criteria by surgeons and the data manager. We had tried to enroll patients who are eligible for the study as consecutively as possible; however, we had several other clinical studies ongoing at the same time

which made it impossible to enroll all patients to this study. Furthermore, unfortunately, there were some patients who declined to participate the clinical study. As the result, they were not consecutive patients, which could be another potential limitation of this study. We sincerely hope that the reviewer understands the situation. We have added this limitation in the revised manuscript.

Changes in the text:
Page 16, line 298 now reads,
'Another limitation is that despite the small sample size targeted, the present study required a relatively long period, approximately 2.5 years, to enroll 100 patients since there were some other simultaneously running clinical studies and some eligible patients opted not to be enrolled.'

Comment 6: I was also struck by the ~5 day icu stay and 5-6 day length that the chest tubes were in. this seems excessively long by US standards.

Reply 6:
We understand the different standard in other countries. However, for some reasons, such as different health insurance system and hemorrhagic tendency of Japanese people, these ICU stay length and drain tube insertion period are deemed to be normal at least in our institute. We sincerely hope that the reviewer kindly understands this difference in the standard post-operative course.

Reviewer B

Comment 1: This is a really interesting study and well executed. It is disappointing I am sure that it is a negative study but I dont think this makes it any less valid. However, I think it need a major revision in one aspect - I have no idea what this poly lactide pin is. I notice that it is made in Japan so it is possible it is not available to any other countries. We need photos or figures explaining what the pin looks like and where you use it. How many do you use per patient. How do you insert it , does it require training, are there difficulties or hardware failures? I didnt see any reports of broken pins.

Reply 1:
We appreciate the reviewer's constructive comments. To answer this comment, we have added the detailed information about the sternal pin and device required in the revised

manuscript and figures. As to broken pins, fortunately, there was no report of broken pins in the present cohort.
Changes in the text:
Page 6, line 112 now reads,
'The PLLA sternal pins were inserted according to the manufacture instruction. Briefly, at the end of a cardiovascular surgery, six single stainless wires, two on the manubrium and four on the sternal body, are put through the sternum. After that, two holes for the sternal pins were made on the marrow of sternum using the specific reamer and sizer (Figure 1B) between 1st and 2nd wires and between 4th and 5th wires. Subsequently, the sternal pins were inserted into the holes and the sternum was approximated and closed in the usual fashion.'

Comment 2: I would also like to see some representative CT results - perhaps some axial slices through the sternum showing the gaps seen.

Reply 2:
We appreciate the relevant comments from the reviewer. Accordingly, we have added representative CT measurements in the two postures in the revised figures. Kindly see the figure in the revised manuscript.

Changes in the text:
We have added Figure 2 as representative images of CT.

Comment 3: Also, what about some figures or drawings showing the different body / arm movements you used to assess the patients.

Reply 3:
To address this, we have added visual images of the postures where we assessed the pain in the revised figure. Kindly see the revised figure 3.

Changes in the text:
We have added Figure 3 depicting postures that we assessed the postoperative pain.

Reviewer C

Comment 1: The authors present a study focused on the efficacy of sternal pins made of poly-L-lactide (PLLA) that are intended to stabilize sternal osteosynthesis after cardiac surgery.
They used -as criteria of stability- the movement of the two sternum parts under shear stress and analyzed it with thin 1mm CT-scan layers 3 weeks postoperatively. An additional aspect was post-operative pain assessed with numerical rating scoring system. The registered study was conducted with 100 patients randomized into two groups (with (group P) and w/o sternal pins (group N)) in a single institutional, prospective and randomized setting. A positive vote of the local ethical committee was obtained as well as patient informed consent.
The authors could demonstrate that sternal gaps occur in an anterior-posterior direction as well as in a cranio-caudal direction in both groups. These orientations are of interest in the special technical setting of putting sternal pins between the two sternal parts in order to prevent exactly these movements. An analysis of a potential movement within a sagittal level – in order to show a dehiscence between the sternal parts- is not shown.
The authors could not show differences between the two groups concerning the parameters ‘sternal gaps’ and ‘numerical rating scale of pain’. Even with advanced methods like propensity score matching, a significant difference could not be found.
They conclude that this method as an additional sternal fixation did not meet the defined criteria.

Question 1. Did you assess a movement of the sternal parts on the sagittal level in order to quantify a dehiscence (you have shown the cranio-caudal and anterior-posterior movement)?

Reply 1:
We appreciate the reviewer for the important questions. Unfortunately, we did not measure the dehiscence between the split sternums. As the reviewer pointed out here, although it appears that the sternal pin does not have any support effect to the inward direction, the dehiscence is an important factor which can cause post-operative complication. Thus, we have added descriptions about dehiscence as the limitation of this study.

Changes in the text:
Page 17, line 306 now reads,

‘Moreover, although we did not measure the sternal dehiscence between cut sternums as the sternal pin is deemed not to have any support in inward direction, the sternal dehiscence is an important factor leading to the sternal complication.’

Comment 2: Please correct some orthographic mistakes (p.25, Table 2, “Rigt upper limb”, “Numerical rating sclae”, same mistakes on p. 28, table 4; p. 29, p.30, Table 5, “Rigt”; “sclae”.

Reply 2:

We regret that we overlooked such mistakes. We have corrected the typos that the reviewer kindly pointed out.

Changes in the text:

Same typos in Table2, 4, 5 and 7 have also been corrected.

Reviewer D

I would like to congratulate the authors for their excellent work and well-written article. This article describes the efficacy of poly-L- lactide Sternal pin on sternal stability and post-operative pain. This is a prospective randomized clinical study.

I'm including few questions. Please consider making changes in the manuscript to increase the strength of the article.

Comment 1: How much time it takes for the sternal pin to completely absorb?

Reply 1: We appreciate the reviewer’s relevant comments. Unfortunately, there is no accurate data to show the duration for the ‘complete’ absorption of PLLA sternal pin at present time. According to the manufacture’s documentation, it is supposed to be absorbed up to a year. Clinically, it seems to take approximately two years until it is visually absorbed when examined at the time of redo sternotomy. However, it is known that the strength of the sternal pin will drop relatively fast due to hydrolysis, whereas the weight of the PLLA will remain for sustained period of time. We have added the description of this fact in the revised manuscript, and suppressed the tone of the description about long-term concern with this material. We sincerely hope that the reviewer agrees with the changes.

Changes in the text:

Page 16 line 287 now reads,
‘What makes this PLLA pins unique from other rigid sternal fixations is that the PLLA is bioabsorbable. In fact, the strength of the sternal pin drops relatively fast in 4-6 months due to degradation by hydrolysis, although the molecules itself remains until a couple of years later (26); thus, there is little long-term concern about infection on the material.’

Comment 2: Why authors chose three-week follow-up period?

Reply 2:
In our institute, a patient usually discharges about 3-4 weeks after a cardiovascular surgery, especially aortic surgery. Most our patients routinely undergo CT scan as a part of postoperative assessments; thus, we chose that time window. To clarify the rationale, we have added an explanation in the revised manuscript.

Changes in the text:
Page 7, line 130 now reads,
‘Sternal deviation was examined with computed tomography (CT) (1-mm thickness) approximately three weeks after surgery as we usually take a CT scan for patients who underwent a typical aortic surgery at this timing.’

Comment 3: Please consider including CT scan images with the two different postures demonstrating sternal gap if any.

Reply 3:
As requested by the reviewer, we have added representative CT images in the revised figure. Kindly see the figure.

Changes in the text:
We have added Figure 2 as the representative CT images.

Comment 4: Would the results differ if one patient who received the sternal pin in the N group is excluded?

Reply 4:

As the reviewer pointed out, one patient who received the sternal pin was included in the N group. We have analyzed all values with excluding this case; however, there was no significant changes from the original statistical analyses. The authors believe that the intention-to-treat method is the optimal approach for this type of study; thus, the case remains included in N group. We sincerely hope that the reviewer agrees with our approach.