JSS JOURNAL OF SPINE SURGERY
A QUARTERLY PEER-REVIEWED PUBLICATION, DEDICATED TO THE FIELD OF SPINE SURGERY, SCIENCE AND CLINICAL OUTCOMES

Peer Review File
Article Information: https://dx.doi.org/10.21037/jss-22-28

Reviewer A

The authors compared the 3D printing and freehand surgical techniques for adolescent idiopathic spinal deformity. It is interesting to evaluate the parameters of the surgery among residents, fellows and attending doctors, however, as authors mentioned, there are concerns about the sample size, and study design (such as the assessment of the accuracy).

Comment: How did the authors obtain 3D-printed guides? What is the slice thickness and pitch of CT slices? The material and printing method of the guides should also be included in "Methods". If the guides are commercial, name the product and the company. These basic data are needed to ensure the quality of the guides.
Reply: Thank you very much for this comment; we agree this information should be included. The slice thickness of CT scans was 0.625 mm and the pitch was 1.375. FIREFLY® Pedicle Screw Navigation Guides were obtained from Mighty Oak Medical®.
Changes in Text: The following text was added to the methods section as suggested, "FIREFLY® Pedicle Screw Navigation Guides were obtained from Mighty Oak Medical®. Preoperative computed topography (CT) scans were conducted with slice thickness of 0.625 mm and the pitch 1.375. The material used to manufacture patient-specific components is an epoxy resin indicated for use in stereolithography systems. Patient contacting materials used for non-patient-specific components are manufactured in accordance with ASTM F899 or F136[9]. In the pediatric population, surgery was to occur within six months of CT scanning for FIREFLY® compatibility." Lines, 73-79

Comment: Include the name the 3D fluoroscopy unit in "Methods".
Reply: Thank you; this has been addressed in the methods section.
Changes in Text: The following sentence was added to the methods, line 73-74, "The ZIEHM C-arm was utilized for intraoperative fluoroscopy."

Comment: The authors stated that "3D-guide failure" is documented when 3D guides could be placed and "freehand failure" is documented when screws are malpositioned. These two failures are completely different and cannot be compared; 3D failure is

related to extent of the exposure of the lamina/spinous process, but freehand failure is purely technical. Also, the data of these failures are not included in "Results".
Reply: Thank you for addressing this; it had been a point of discussion amongst the authors previously, and ultimately "failure" was a term utilized for its descriptive nature. It was placed in quotations because, as the reviewer astutely notes, it is not a true comparison, nor is it a true screw failure. Our intent had been to address any intraoperative conversions from 3D to freehand, or any freehand screw placement within 3D cases, and account for such changes within our study methodology. It was not included in the results as the "failure" rate was not compared between freehand and 3D for exactly the reasons the reviewer describes. To address these valid concerns, the language has been edited to reflect that this was not a side-by-side comparison, but rather a note on data collection.
Changes in Text: Lines 96-106 have been edited to reflect the above.

Comment: Even with less levels fused, 3D printing group showed much higher implant cost than that in freehand group. The difference is mainly due to the cost of the 3D guides? If so, it should be mentioned in "Discussion".
Reply: This is an important discussion point that, as the reviewer notes, we had not fully addressed. This paragraph has been expanded to expound upon this issue and clarify both our results and implications.
Changes in Text: The following text was added as lines 182-192 of the discussion to further discuss this important point, "The total cost of spinal surgery completed with 3D printed guides was significantly more expensive than surgeries completed with freehand techniques, primarily due to implant costs. The increased average cost noted in this study of approximately $7,500 in the 3D-printed group relative to the freehand group, is similar to that reported in prior studies[7,11]. Costs of 3D printed surgical planning models vary broadly from $175 for a 3D printed template model to $5400 for sophisticated 3D printed spinal phantom training[11] in addition to overall costs of pedicle screws and other permanent implant components. One potential solution to these costs could include the use of alternative materials to manufacture 3D printed guides, which may be less expensive than polymer-based 3D printed models[11]. Ultimately, further cost analyses, including cost-effectiveness analyses, may be warranted to determine if the increased cost of the 3D models is justified when similar perioperative outcomes have been demonstrated. It is possible that 3D guides may only be justified in academic training centers where surgical residents are regularly acting as first surgical assists."

Reviewer B

Comment: The authors compare the pedicle screws placement with a Three-dimensional printed guide technique versus a freehand technique in surgery for adolescent idiopathic scoliosis. Pedicle aiming techniques are of definite interest in spinal surgery and particularly, given the neurological risks, for adolescent thoracic scoliosis fusions. The objective is to assist the placement of pedicle screws and to reduce the rate of misplaced screws.
This problem is mentioned in the methodology: 3D guide failure (not using the guide) and Freehand screw failure (misplaced screws requiring repositioning or removal). It would be necessary to add screw failure with 3D guide (screws misplaced despite the guide). Unfortunately this does not appear in the results and that is a shame. The authors content themselves with analyzing the results only in terms of cost of the implants, operative blood loss and screw placement time.
Reply: This is an important point and we appreciate it being addressed. As the reviewer notes, two different types of pedicle screw placement are being assessed: freehand "failure" is a result technique, while 3D "failure" in our study was related to the extent of the exposure of the lamina/spinous process. As such, true comparisons between the "failure" rates are difficult to characterize. Furthermore, there were no non-exposure related failures of 3D guides; as in, if the guides were able to be adequately placed on the spinous processes, the pedicle screws remained. Even with a more extensive cohort, it would be difficult to fully remove the element of surgical technique entirely. We have clarified the language in the text so that it better reflects that our documentation of 3D transition to freehand was more a methodologic account of under what circumstances 3D had to be converted to freehand, rather than a comparison of "failure" rates between cohorts.
Changes in Text: Lines 96-106 have been edited to more accurately reflect these points.

Comment: The work is well presented, clear. Figures 1 and 2 clearly show the guide and its use. Despite the higher cost of the guide procedure, it is interesting to see a decrease in blood loss provided that the screws are well placed!
Reply: We appreciate your review and opportunity to present and improve this work.
Changes in Text: None.

Reviewer C

Abstract
Comment: Line 17–run-on sentence, fix for grammar.
Reply: Appreciate this note.

Changes in Text: This line now reads, “Three-dimensional (3D) printed guides are finding increasing applications in the field of orthopaedic surgery and more recently spine surgery.”

Comment: Line 26–you have not yet defined the 3D cohort, you need to define in parentheses at some point what you were referring to as the "3D"
Reply: The methods of the abstract have been adjusted to reflect the definitions of these cohorts.
Changes in Text: Lines 29-30 now read, “Intraoperative screw placement was conducted either with 3D printed guides (3D cohort) or traditional freehand technique (freehand cohort) for AIS patients undergoing spinal fusion at a single institution.”

Introduction

Comment: Line 45–this is a long run-on sentence, make it into 2 sentences.
Reply: Line 45 has been split into two sentences.
Changes in Text: Lines 49-51 “Three-dimensional (3D) printing technology was first developed in the 1980s (1,2). Through the printing of titanium hardware implants and in preoperative planning and patient education (3) 3D printing has found increasing application within the field of orthopaedic surgery.”

Comment: Line 68–I always like to include the hypothesis of my study in the introduction section
Reply: Thank you for this comment; our hypothesis has been added.
Changes in Text: Line 65-66 now reads, “Our hypothesis asked, if we utilize 3D printing technology in AIS operative fixation, will it change perioperative patient outcomes?”

Methods
Comment: Statistical methodology appears very sound, I commend you on this. The authors have utilized poison regression modeling to account for data heteroskedasticity, and have appropriately controlled for confounding factors through the multivariate regression. The issue I see with the methods, as I will allude to later, is the fact that the cohorts were defined by whether or not the hospital had access to a certain intraoperative fluoroscopy technology. I.e., the cohorts were not chosen in any sort of random, prospective manner, but were rather chosen as the group of patients that was treated prior and after the arrival of the intraoperative fluoroscopy machine. I would imagine this would introduce all kinds of bias to the results, but I do understand that within the confines of this single surgeon sample, this is more or less the data that we are working with.

Reply: Thank you for this insight and attention to both our analysis and design challenges. As you mention, within the confines of our single surgeon sample, the "pre/post" cohort design was utilized for its practicality. We were reassured, as demonstrated in Table 1, that no demographic or baseline features were significantly different between groups. We agree that in the future, a prospective randomized trial would certainly add value to the literature.
Changes in Text: None

Discussion
Comment: line 186– The authors here do allude to the fact that their sample size is relatively small, and thus while they performed a power analysis, they are probably not powered in an appropriate manner to draw conclusions beyond perhaps blood loss and 1 or 2 other metrics.
Reply: We agree; and have limited the scope of the analysis thusly. As with similar cited articles in the extant literature, there is precedent for analyzing pedicle screw placement individually by level, rather than by overall case. We included both; in addition to limited multivariate analysis as the reviewer describes.
Changes in Text: None

Comment: Line 216 --this is another good point. I have worked with a number of different surgeons, some that used 3D printed guides and some that used only intraoperative fluoroscopy. However, the surgeon that I have worked with that used 3D guides still use intraoperative fluoroscopy to check screw positioning. I do not have data to back this up, but I would guess that most surgeons are still checking their final construct with intraoperative fluoroscopy even when using 3D printed guides. This would of course add operative time while also ensuring more accurate placement of pedicle screws (i.e. inaccurately placed screws may be identified and corrected). While this may argue even more in support of these authors data, it still is a limitation in the study.
Reply: Thank you for this close read and commentary.
Changes in Text: None

Comment: While overall, I feel that this is a well written study, I have a number of concerns with it. The work is not particularly novel, as there have been a number of smaller sample size studies like this one already performed (they only had 18 patients in the 3D cohort and 11 in the freehand). A simple pub med search yields several. Still, I realize that it is always valuable to add to the literature regarding a relatively new and expensive technology, and for this reason I feel that the study does warrant consideration. The study is also limited given that it is a single institution and single surgeon study. Also, as I mentioned above, given that the study is retrospective in

nature and that the "selection" methodology as it were involved simply whether or not the surgeon had access to an intraoperative fluoroscopy machine, which is certainly not "randomization" or "prospective" in nature.

Reply: Thank you. We are grateful for the careful review and opportunities presented to improve the manuscript.

Changes in Text: None