Peer Review File

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Review Comments

The authors present a small series of HA-coated screws for SIJ fusion. Overall, the manuscript is well written with simple methods. However, I have some comments regarding the manuscript that may need to be addressed prior to being acceptable for publication.

Comment 1: The title is rather misleading. It states 2-year clinical and 'radiographic' results, yet there is no mention or reporting of any radiographic results. To that extent, I am rather disappointed radiographic results were not included in a 24-mo f/u series. Adding HA to the screw design would imply to the readers that this is an improvement to previous designs in some manner. I believe one would like to see the outcomes from a radiographic standpoint in this regard. The challenge with evaluating patients postoperatively is radiographic f/u and determination of "fusion". As I do, I'm sure you see patients who do clinically well but radiographically demonstrate no evidence of bony fusion across the joint. I would be curious if the HA changes this challenge experienced with radiographic f/u.

Reply 1: Thank you for your comments; we hope to answer them sufficiently. In the current study, which utilized only standard of care interventions, the authors were unable to collect patient CTs throughout the follow-up process. As a result, we were impeded in our ability to make a reliable fusion assessment. In place of a fusion assessment, the authors assessed the mechanical stability of the implant, which is defined on line 90 to 93 of the Methods section as “absence of screw loosening and radiolucent gaps at the bone-screw interface, screw migration, and improvement in patient symptoms by 12 months postoperatively.” This outcome was assessed from plain film radiographs and is the radiographic outcome to which the title refers. Radiolucency was used as a major determinant of mechanical stability, and to reflect this, we have added additional data on the radiolucency scores that were collected.

Table 3.
RADIOLUCENCY

RATING	3 mo		6 mo		12 mo		24 mo	
	n	%	n	%	n	%	n	%
0	27	96.4	23	92	18	72	20	83.3
1	1	3.6	2	8	5	20	2	8.3
2	0	0	0	0	2	8	2	8.3

The radiolucency scores are based on the below criteria:

Table 1.

GRADE	CRITERIA
0	None: No evidence of radiolucent lines or halos
1	Mild: < 25% radiolucent lines along the implant interface
2	Moderate: 25% - 50% radiolucent lines along the implant interface
3	Severe: > 50% radiolucent lines along the implant interface
4	Indeterminate: A reliable determination cannot be made from the available imaging due to sub-optimal image quality, obscured fusion mass, obstructed view due to parallax effects or other imaging artifacts. The cause will be documented

Given this information the following has been added to the manuscript:

Lines 93-94:
Radiolucency was assessed using the criteria in Table 1, and these scores were used to inform decisions on mechanical stability.

Lines 128-131:
Radiolucency scores are located in Table 3. There were no severe cases of radiolucency at any time point. Of the 24 patients assessed at 24 months, 22 (91.6%) had mild or no evidence of radiolucency. At 12-month follow-up, 2 patients showed moderate signs of radiolucency, and the same number had moderate signs at 24-months.

Comment 2: On line 161-162, you state "This improvement in VAS pain and ODI scores is substantially greater than the minimally clinical important difference". It's important to keep in mind that those MCID values were validated for patients undergoing lumbar fusion. While using them as a benchmark to compare pre and postop disability scores for SI joint fusion is commonly done I would refrain from making any inferences regarding your results in comparison to those values as they were not validated to truly assess patient-reported outcomes following SI Joint fusion.

Reply 2: As the reviewer notes there is considerably less research done on validation of measures specifically for sacroiliac joint fusion. Taking the reviewers' point, the authors did further research and were able to find additional sources on the validity of these measures. A study by Copay and Cher (2016) investigated the use of ODI in sacroiliac patients and estimated the MCID for ODI to be 13 to 15 points. The authors were unable to find a validation source for VAS pain scores in sacroiliac patients specifically. However, an analysis by Myles et al. (2017) analyzed VAS pain scales use in postoperative patients after a wide range of surgeries and determined a change of 10

percentage points to be the MCID. The originally cited paper, Carreon 2013, notes an MCID of 11 to 13 percentage points. The authors believe that the MCID for VAS pain scores is therefore somewhere between 10 to 13 points.

The following sources have been cited to help establish the MCID as referenced in the text:

13. Carreon LY, Bratcher KR, Canan CE, Burke LO, Djurasovic M, Glassman SD. Differentiating minimum clinically important difference for primary and revision lumbar fusion surgeries. J Neurosurg Spine 2013;18:102-6.
14. Copay, A.G. and Cher, D.J., 2016. Is the Oswestry Disability Index a valid measure of response to sacroiliac joint treatment?. Quality of Life Research, 25(2), pp.283-292.
15. Myles, P.S., Myles, D.B., Galagher, W., Boyd, D., Chew, C., MacDonald, N. and Dennis, A., 2017. Measuring acute postoperative pain using the visual analog scale: the minimal clinically important difference and patient acceptable symptom state. BJA: British Journal of Anaesthesia, 118(3), pp.424-429.

Comment 3: Your outcome data table displays means with relatively large standard deviations which is likely due to the small sample. However, displaying the mean change/difference from baseline may present the data or effect better than simple means with standard deviation. The high variance does not give me confidence in concluding that patients on average see significant improvement following this procedure.

Reply 3: The reviewer makes a fair point about the high variances of the patient reported outcomes in this study. The authors believe this is due to the small sample size, as the reviewer mentioned, but also to the high variability in scores prior to surgery. Lower-back VAS pain preoperative time point scores ranged from 4.16 to 97.89. This large range indicates a wide variety in patient condition prior to surgery, and this variety also impacts the variance after surgery, as different patients have more room to improve. However, the standard deviations of VAS pain scores decreased from preoperative, indicating that the within-sample variability decreased. Furthermore, the statistical analysis to compare the repeated measure samples was done using Wilcoxon Signed Ranked tests, a nonparametric test which compared paired scores, analyzing the decrease within patient pain and disability scores. This test mitigates the within sample variation by comparing the difference between each timepoint within each subject. As each patient is compared to themselves, the high variability across the sample has considerably less impact on the outcome of the statistical test, as compared to an independent samples test. Therefore the authors strongly believe in the significance of the outcomes described by our statistical analyses.

Comment 4: -In addition, you mention MCID in the discussion but do not use MCID as an outcome measure. Although there are no validated MCID values for SI joint fusion, the literature appears to use VAS/ODI MCID values in the manner which you describe in your discussion. Using these values would be much more valuable given the small

sample then just simply reporting the mean values. Yes, on average it appears they have improvement but with such a small sample and large variation in the data I'm concerned the mean values are influenced by a handful of patients that have data skewing the mean and thus not representing the true mean outcome observed.

Reply 4: To address the reviewer's concerns, the authors have prepared the table below which describes the change from preoperative scores at each time point. The average decrease in lower back VAS pain scores was 33.05 points at 24 months postoperative. As for ODI, the average decrease was 27.59 points at 24 months postoperative, more than twice the MCID value of 13 points (Copay and Cher 2016).

The following table has been added to the manuscript:

Table 4. Change from preoperative scores.

Time point	VAS back		VAS left leg		VAS right leg		ODI		
	Mean	Stand Dev	Mean	Stand Dev	Mean	Stand Dev	Mean	Stand Dev	MCID
3 months	-26.19	29.53	-20.43	34.91	-21.14	27.99	-21.64	17.81	13
6 months	-21.36	35.46	-22.70	37.12	-14.38	38.07	-20.98	18.89	13
12 months	-23.23	28.44	-27.14	36.65	-27.01	38.03	-20.61	20.62	13
24 months	-33.05	31.89	-32.17	34.85	-30.69	41.40	-27.59	21.03	13