Author's response to reviews

Title: Evaluation of Implant Loosening Following Segmental Pedicle Screw Fixation in Adolescent Idiopathic Scoliosis: A 2 Year Follow-up with Low-Dose CT

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Author's response to reviews:

Author’s response to the comments and concerns of Referee no 2:
Author’s response is written in blue.

Reviewer's report

Title: Evaluation of Implant Loosening Following Segmental Pedicle Screw Fixation in Adolescent Idiopathic Scoliosis: A 2 Year Follow-up with Low-Dose CT

Version: 5
Date: 30 June 2014
Reviewer: Ian Stokes

Reviewer's report:

Re-review of this manuscript is again difficult since the authors have again not provided a cover letter addressing how they have addressed (or not) prior reviewer concerns and suggestions.

The main point raised by this reviewer, and not addressed in previous revisions, was the likelihood that the CT method is over-sensitive - i.e. identifies false-positive instances of screw loosening. In Table 3 there are 15 cases of loosening by CT, no loosening by plain x-ray. Also, in Table 2 there are 28% of cases of apparent loosening (by CT) but no pain, all suggestive of false positives by CT. This points to over-sensitivity of CT (i.e. false positive identification of loosening and thus low specificity).

The manuscript now provides a conclusion "Low-dose CT should be considered as the method of choice to evaluate the evidence of screw loosening" based on (1) evidence of greater sensitivity of the CT method and (2) the lower dose relative to plain radiography. This is a questionable conclusion of the present study, since high sensitivity but low specificity of CT is not a sound basis for recommending its use.

In the Discussion they mention that the artifacts around metallic pins might produce false positive evidence of loosening. However, this is the only mention of
the possibility that high sensitivity of CT might result from erroneous false positive results more sensitive than plain radiography in detecting evidence of implant loosening. The reader is left unclear as to whether this additional sensitivity provides greater accuracy, or whether it provides false positive information - therefore it is unclear which radiological method is preferable.

Dear Dr Stokes!

We are really sorry for the inconvenience. At all our revisions we have submitted a detailed description of what we have edited and how we reacted to your suggestions and concerns. We highlighted all changes in the body of manuscript in yellow and we responded to all comments writing in blue text. All changes suggested have been done. It seems that something went wrong during the submission process.

However, it seems that your present major concern is the discrepancy between CT and radiography detection of radiolucent zones, which we call throughout the manuscript as CT-evidence of loosening and we never call our finding as “hardware failure”.

Our study is an observational study describing our finding of the evidence of radiolucent zones on CT (which we call evidence of loosening as other workers previously did) among patients with AIS operated with segmental pedicle screw fixation (in our study, CT’s were done two years following surgery).

What is unique with this study is:
1- No previous report of CT-evidence of loosening in literature on this category of patients namely AIS.
2- All reports on evidence of screw loosening are reports among patients operated for degenerative diseases mainly lumbar spine.
3- Most / almost all reports are using plain radiography. And those reporting on CT use routine CT, which means high radiation dose exposure. Our low-dose CT means exposure of these young patients to extremely low- radiation dose, much lower that plain radiography.

It is very well known that CT is more sensitive than plain radiography with regard to screw loosening, hardware failure, evaluation of screw placement etc. CT is almost a gold standard in this respect. What so far has hampered the use of CT as a routine method to evaluate these findings is the concern for radiation exposure. In our institution, we have since 2005 adopted the low dose CT in the pre- and postoperative work-up of scoliosis, a project that rendered my doctoral theses (Adolescent idiopathic scoliosis. The role of low-dose computed tomography) and more than 10 scientific publications. The method is now widely used in Sweden in the work-up of scoliosis.

We understand your concern that our findings indicate higher sensitivity but not accuracy of CT. We do not agree that absence of pain among 28 % of patients with loosening indicate false positive results. Among patients with evidence of loosening there were 5 patients with pain, one patient with neurological deficit, one with PJK and 3 patients with slight pull out. No pain was reported among any
patient with no evidence of loosening, statistically significant difference. So the finding of CT-evidence of screw loosening was of importance. Röllinghoff et al showed that 35 out of 64 patients (54%) operated with pedicle screw fixation showed signs of pedicle screw loosening. However, only 7 of these 35 (20%) corresponding to 11% of the whole study cohort complained of back pain. This is the almost exactly the same rate of reported pain among patients with screw loosening in our cohort (5 out of 26, 19% had pain). In another study, Wu JC et al studied the incidence and the long term outcome of dynamic pedicle screw fixation among 126 patients and observed an incidence of loosening of 19.8%. None of the patients with loosening reported any symptom. Ohtori et al have also reported that CT helps to detect twice as many screw loosening as plain radiography. They reported that the rate of screw loosening 12 months following surgery was 7-15% evaluated on plain radiography compared to 13-26% when evaluated on CT. In conclusion, the higher sensitivity of CT is well-known in evaluating different aspects of postoperative follow-up of patients underwent spinal surgery.

We have clearly admitted the drawbacks of CT, the possible negative impact on accuracy of the method and the possibility of false positive and false negative evidence of loosening in the discussion section page 10 highlighted in yellow and grey.

As this is the first study reporting on CT-evidence of screw loosening among patients with AIS, we really do not know the clinical significance of this finding and whether this finding persist after e.g. 5, 10, 15 years or it might heal with osseous reintegration. From my personal experience (we have now clinically started to screen these patients with 5 years CT-control), I have noticed that some of these radiolucent zones have been filled with bone building/callus and integrated in the hosting bone. However, most of them persist.

All reports we have touched in discussion concern patients operated for their degenerative spinal diseases. To our knowledge, no reports in literature on evidence of screw loosening among AIS-patients, especially no report using CT.

We have adjusted the text in the body manuscript to clarify your concerns, highlighted in grey (previous revision is still highlighted in yellow). Other minor suggestions of changes have been done accordingly. Hope you find this third revision adequate and reasonable.

Minor Essential Revisions (from previous review, but not addressed in the revision):

Abstract, Results, Line 10: "1 patients" -> "1 patient"
Done

Introduction, paragraph 1, line 3: explain 'weight bearing forces' (with respect to failure of pedicle screw fixation). Probably the muscular forces are more important than gravitational forces.
Done
Page 5, penultimate paragraph, line 2: this would be reports of pain, not occurrence of pain in medical records, presumably.

Done

Page 7, first full paragraph: ‘Among patients with evidence of loosening,’ Authors should clarify that this is evidence of loosening by CT.

Done

Page 7, first full paragraph: ‘The misplacement rate for the whole amount of screw was 11.8 %’ - delete ‘for the whole amount of screw’.

Done

Throughout the manuscript use the abbreviation 'et al.' for 'et alia' as is the normal convention.

We use et al throughout the manuscript in accordance with the journal praxis.

Page 10, Conclusions, line 3: ‘Evidence of loosening *occurred* in one third of patients’.

Done. “Evidence of loosening on CT occurred”....

Other Minor Essential Revisions

(1) The Abstract should mention use of plain radiography (as well as CT) in the Methods.

Done.

(2) The Discussion provides comparisons between the present findings and those in the literature without adequate explanation of (1) whether comparisons are being made between CT and plain radiography (whose agreement is shown here to be poor), and (2) whether the clinical series referred to are for pedicle screw usage in adolescent patients with scoliosis (as in the present study) or adult patients with degenerative or other conditions.

(3) Page 4, line 10: 'evaluated by *an* experienced senior neuroradiologist'.

Done

(4) Page 9, line 5: ‘with lower *sensitivity* of plain radiography.’

Done.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests: I declare that I have no competing interests