Author's response to reviews

Title: Percutaneous pedicle screw reduction and axial presacral lumbar interbody fusion for treatment of lumbosacral spondylolisthesis: a case series

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Version: 2 Date: 21 July 2011

Author's response to reviews:

Referee #1

General Comment: In this paper, authors present three cases of grade 2 spondylolisthesis surgically treated by percutaneous pedicle screw reduction and axial presacral interbody fusion.

Comment #1: What type of bone graft was used for interbody fusion?

Authors' response: A mixture of INFUSE® recombinant human bone morphogenetic protein-2, tricalcium phosphate, and autograft harvested during the trajectory creation was used in all cases. This information has now been included in paragraph 7 under Surgical Technique.

Comment #2: All patients reported relief from back pain and resolution of radicular symptoms. Did you use any objective scale to document improvement?

Authors' response: A battery of standardized instruments was used to evaluate each patient with respect to the degree of symptom severity, functional impairment, and quality of life. All patients independently filled out a comprehensive questionnaire at each clinic visit that included an 11-point Likert scale for lower back and leg pain severity and the Oswestry Disability Index to quantify back function. Results of these instruments are now provided for each individual case.

Comment #3: Please mention the success criteria for fusion for your three cases?

Authors' response: Case 1 of the Case Presentation section now contains text that defines fusion success as no motion at the treated segment on flexion/extension radiographs and evidence of bone growth between the adjacent vertebral bodies on reconstructed computed tomography images.

Comment #4: For the reader's sake, please mention the important contraindications and complications of presacral interbody fusion in the discussion.
Authors’ response: The following text has been added as the final two paragraphs of the Discussion section: “The AxiaLIF System is not intended to treat severe scoliosis, severe spondylolisthesis (grade 3 or 4), tumor, or trauma. Contraindications for use include coagulopathy, bowel disease, pregnancy, and sacral agenesis. Usage of the AxiaLIF System is limited to anterior fusion of the lumbar spine at L5-S1 (2-LEVEL System for L4-S1) in conjunction with legally marketed posterior fixation systems. The AxiaLIF System should not be used with facet screws when spinal stenosis correction requires removal of significant portions of the lamina or any portion of the facets. The 2-LEVEL System is additionally contraindicated for patients with vertebral compression fractures or any other condition where the mechanical integrity of the vertebral body is compromised.

Preoperative imaging should be thoroughly evaluated with emphasis on perirectal fat pad thickness, identification of the rectum/sacrum interface, aberrant vasculature, and anticipated trajectory. Thus, relative contraindications for the presacral approach include insufficient presacral fat pad, previously explored presacral space, large vessels crossing the presacral space, and anatomic abnormalities that preclude placement of an axial rod through the lower lumbar segments.

Comment #5: Can grade 1 and 2 listhesis be managed by a standalone presacral interbody fusion augmented with posterior instrumentation?

Authors’ response: We believe that the combination of spondylolisthesis reduction by pedicle screws and presacral interbody fixation provides sufficient stability and indirect decompression for successful treatment in these cases. We have made no changes to the manuscript in response to this question.

Comment #6: Figure 6. Please provide lateral view as well.

Authors’ response: A reconstructed sagittal CT image has been provided in Figure 6 demonstrating fusion at 1-year follow-up.

Referee #2

Comment #1: There are many studies about percutaneous presacral axial screw placement for degenerative disc disease. The authors here describe these specifically for Grade 2 spondylolisthesis. Since the axial presacral screw placement is a newer technique, the authors need to describe the placement procedure in more detail. For example: where exactly was the initial entry point, the final point, any difficulties in reaching anterior aspect of sacrum while still maintaining the trajectory?

Authors’ response: We have included this requested information in Surgical Technique, paragraph 6. The text reads as follows: “The trajectory of the axial rod was planned preoperatively on sagittal MRI images. Based on preoperative imaging analysis and with the spondylolisthesis at least partially reduced, this anterior trajectory was deemed feasible in all cases. Therefore, a 2 cm
paracoccygeal skin incision was made and the presacral approach was performed to place the anterior axial rod as previously described [7]. Specifically, the entry point was selected under fluoroscopic guidance close to the S1-2 junction (on the lateral images) and close to the midline (on the antero-posterior images) so that the extension of a straight line from the entry point would cross the center of the L5-S1 disc (for the single level cases) or the center of the L5 vertebral body (for the two level case). The trajectory was further adjusted as the guide pin and/or hand drill were advanced through the bone by turning the bevel of the guide pin in the desired direction or controlling the back of the hand drill.”