Lumbar interbody fusion

To the Editor: The undersigned authors have questioned the reported data in the study submitted by Marchi et al. (Marchi L, Oliveira L, Coutinho E, et al: Results and complications after 2-level axial lumbar interbody fusion with a minimum 2-year follow-up. Clinical article. J Neurosurg Spine 17:187–192, September 2012), as we were involved in the adjuvant evaluation of Dr. Pimenta’s initial patient series. Given the excellent results that Dr. Pimenta and coauthors presented at several meetings in 2008, with 100% fusion rates in the first 10 patients, it is not mathematically possible to achieve the results reported in this new article, even if treatment fails in every other patient (Pimenta L, Pesantez C, Oliveira L, et al., presentations to the AANS/CNS Annual Meeting and the Spine Arthroplasty Society, 2008).

Because of these concerns, we revisited the data collected independently on what we believe to be the first 19 of the 27 patients reported by Marchi et al. The study data presented in this letter were collected in July of 2008 as an outside, independent review of the clinical and radiographic data submitted by Dr. Pimenta on his prospective, nonrandomized study of 19 patients treated with a 2-level presacral axial lumbar interbody fusion (AxiaLIF) implant supplemented with posterior fixation, intended for regulatory submission.

Methods. The clinical data, plain radiographs, and multiplanar CT scans were submitted to each author in a blinded and independent fashion. Following our individual review, each case was then reviewed collectively over a 2-day period. There was consensus of our findings in all but one case, which was considered a minor difference in findings.

Results. At the 6-month follow-up, 4 of 19 subjects demonstrated radioluencies. Included among these were the patients in Cases 4 and 17, who are considered study outliers. The patient in Case 4, an 85-year-old woman, had dislodged her S-1 pedicle screws following multiple documented falls. Significant radioluencies were noted around the axial rod and the pedicle screws during revision surgery at 14 months. The patient in Case 17 had extensive osteolysis within the L-3 and L-4 vertebral bodies with perforation of the superior endplate of L-4. This was thought to be the result of infection or other pathological process. A sedimentation rate and white cell count were reported as normal. It was unknown to the reviewers if bone morphogenetic protein was used. At 6 months, the patients in Cases 15 and 16 exhibited minor radioluencies of 1 mm or less at the tip of the axial rod at L-4. The patient in Case 15 had fusion at both levels. The patient in Case 16, a 287-lb man with a body mass index of 37.2 had a nonunion at L4–5 with a solid fusion at L5–S1.

At 12 months, 4 of 14 patients (Cases 10, 11, 14, and 16) had radioluencies (29%) around the axial rod. These radioluencies were less than or equal to 1 mm in diameter and were observed along the L-4 portion of the rod. The patient in Case 11 underwent removal of pedicle screws to address complaints of pain after the 6-month follow-up. This may have contributed to the radiolucency noted at 12 months given that no radiolucency was observed at 6 months’ follow-up for this patient. In Cases 10, 11, and 14, fusion was, in fact, achieved at both levels at 12 months. In Case 16, fusion was achieved at L5–S1 but not at L4–L5. At 12 months, 19 (100%) of the patients had fusion at one level and 16 (84%) at both levels (Table 1).

Pedicle screws were placed at L-4 and S-1 bilaterally in 15 patients and at L-4, L-5, and S-1 bilaterally in 3 patients. One patient had dynamic fixation at L4–5 which failed prior to a revision done with a 2-level axial rod and facet screws at L5–S1. We did not find any dislodgment, breakage, or significant separation of the 2 components of the axial rod. On review of multiple CT scans there was a well-demarcated formation of dense bone surrounding the radiolucent region in the vicinity of the axial rod in Cases 10, 11, and 14, indicative of new bone formation.

Discussion of Marchi et al. It is difficult to comprehend the 22% fusion results reported by Marchi et al. in their 29 patients, when 16 of the first 19 of those patients had radiographically confirmed 2-level fusions at 12 months and the remaining 3 patients had radiographically confirmed fusions at 1 level (Table 1). It is also difficult to correlate the 50% improvement in visual analog scale scores and 40% improvement in the Oswestry Disability Index scores at 24 months in these 27 patients with the 22% fusion rate as reported by Marchi et al. Others have found significant improvement in pain scores and functional outcomes in conjunction with high rates of fusion using the presacral approach.2,5–7 It should be pointed out that some of the devices used in the study by Marchi et al. were early-generation implants that have not been marketed in the United States. However, the subsequent 2-level axial rod that is marketed in the United States has recommended surgical techniques for use from the manufacturer that include rigid posterior segmental fixation and interbody bone grafting with osteoinductive and osteoconductive material and preferably autograft bone. The authors reported that the grafting material used was only calcium phosphate and some bone marrow aspirate. On our review we noted less than optimal graft material seen on most of the postoperative CT scans, and only 3 patients had segmental posterior fixation.

Additional observations identified that the patients with radioluencies did not have segmental fixation at every level. A biomechanical study by Erkan et al. confirmed the need for segmental posterior fixation at L-4, L-5, and S-1 to provide uniform stability across each motion seg-
TABLE 1: Fusion status of 19 patients treated with 2-level AxiaLIF rod and supplemental posterior fixation

<table>
<thead>
<tr>
<th>Classification</th>
<th>6 Mos</th>
<th>12 Mos</th>
<th>24 Mos</th>
<th>Overall Fusion Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>no. of patients w/ at least 1-level fusion</td>
<td>18 (95%)</td>
<td>15 (100%)</td>
<td>2 (100%)</td>
<td>19 (100%)</td>
</tr>
<tr>
<td>no. of patients w/ fusion at both levels</td>
<td>15 (79%)</td>
<td>13 (87%)</td>
<td>2 (100%)</td>
<td>16 (84%)</td>
</tr>
<tr>
<td>1. fused: bridging bone advanced</td>
<td>14 (both levels); 2 (1 level)</td>
<td>12 (both levels); 2 (1 level)</td>
<td>1 (both levels); 1 (1 level)</td>
<td>15 (both levels); 3 (1 level)</td>
</tr>
<tr>
<td>2. fused: bridging bone</td>
<td>1 (both levels); 1 (1 level)</td>
<td>2 (1 level)</td>
<td>1 (1 level)</td>
<td>2 (1 level)</td>
</tr>
<tr>
<td>3. developing bone</td>
<td>1 (both levels); 1 (1 level)</td>
<td>1 (1 level)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. no early evidence of bone remodeling</td>
<td>1 (1 level)</td>
<td>2 (1 level)</td>
<td></td>
<td>2 (1 level)</td>
</tr>
<tr>
<td>5. no radiographic progress</td>
<td>1 (1 level)</td>
<td></td>
<td></td>
<td>2 (1 level)</td>
</tr>
</tbody>
</table>

In other words, greater points of fixation along the lumbar spine allow for greater distribution of the loads across the implant, resulting in lower loads distributed at each point of fixation. By skipping fixation at L-5, greater stresses and micromotion are transferred to the L-4 vertebra, possibly resulting in radiolucent areas around the axial rod at L-4. Lack of pedicle fixation at L-5 in all but 3 patients may have resulted in the loss of disc space height achieved at surgery, rod subsidence, and loss of lordosis, thus transferring greater stress to the fixation points which were at the terminal ends of the fusion construct.

A clinical review of 52 patients treated with AxiaLIF 2-level implants and supplemental posterior fixation with an average 29 months’ follow-up showed that 99 of 104 interspaces were fused. There was no implant subsidence, deep infection, neurological deficit, or rectal perforation.

In summary, we believe that additional review of the authors’ clinical and radiographic data pertaining to these 27 patients would be helpful in clarifying the conflicting clinical outcomes between such low fusion rates reported in the recent article and the 100% fusion rates and outcomes previously presented by the authors for the same patient set.

**Disclosure**

Dr. Nasca reports serving as a consultant for and being on the Scientific Advisory Board of Trans1.

**References**


**Response:** We thank Dr. Nasca and colleagues for giving their own analysis on a subset of patients from our cohort.

As cited above, short-term and partial results were presented by our group in international societies meeting during 2008. In such abstracts only 10 cases were analyzed. Before writing the article published in the *Journal of Neurosurgery: Spine* in 2012, other abstracts were presented during international meetings in 2009 (L Pimenta, E Coutinho, L Oliveira: Is radiolucency a signal of pseudarthrosis? Radiological evaluation after axiaLIF 2 levels. Presentation to EuroSpine, 2009; L Pimenta, J Lhamby, E Coutinho, et al: Is radiolucency a signal of pseudarthrosis? Presentation to IMAST, 2009) and 2012. At those opportunities we presented results based on 20 and 27 patients, respectively, in which 80% and 78% of the spine levels presented radiolucent lines around the axial rod.

Results presented after 2008 differ substantially in 3 important factors: first, experience based on 20 or 27...