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## Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 4: radiographic assessment of fusion

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### Recommendations

*Standards.* Static lumbar radiographs are not recommended as a stand-alone means to assess fusion status following lumbar arthrodesis surgery.

*Guidelines.* 1) Lateral flexion and extension radiography is recommended as an adjunct to determine the presence of lumbar fusion postoperatively. The lack of motion between vertebrae, in the absence of rigid instrumentation, is highly suggestive of successful fusion. 2) Technetium-99 bone scanning is not recommended as a means to assess lumbar fusion.

*Options.* Several radiographic techniques, including static radiography, lateral flexion–extension radiography, and/or CT scanning, often in combination, are recommended as assessment modality options for the noninvasive evaluation of symptomatic patients in whom failed lumbar fusion is suspected.

### Rationale

Lumbar fusion is performed in patients with pain due to lumbar degenerative disease. An outcome measure frequently cited in studies evaluating lumbar fusion techniques is the “radiographic fusion rate;” however, radio-

graphic fusion is not consistently defined throughout the literature. The purpose of this review is to examine the literature regarding the ability of various diagnostic techniques to assess fusion status after lumbar fusion is performed to treat degenerative disease.

### Search Criteria

A computerized search of the database of the National Library of Medicine between 1966 and July 2003 was conducted using the search terms “lumbar spine fusion assessment,” “lumbar spine pseudoarthrosis,” or “lumbar spine fusion outcome.” The search was restricted to references in the English language involving humans. This yielded a total of 1076 references. The titles and abstracts of each of these references were reviewed. Only papers concerned with the assessment of fusion status following arthrodesis procedures for degenerative lumbar disease were included. Additional articles were obtained from the bibliographies of the selected articles. Forty-five references were identified that provided either direct or supporting evidence relevant to the radiographic assessment of lumbar fusion status. Reports involving Class III or better medical evidence are listed in Table 1. Supportive data are provided by additional references listed in the bibliography.

### Scientific Foundation

Open surgical exploration is the only method that allows direct inspection of fusion integrity. This procedure

*Abbreviations used in this paper:* CT = computerized tomography; NPV = negative predictive value; PPV = positive predictive value; RSA = roentgen stereophotogrammetric analysis.

is considered the gold standard of lumbar fusion assessment.<sup>6,7</sup> It is, therefore, an appropriate benchmark to use in establishing the accuracy and predictive value of noninvasive radiographic studies for the assessment of fusion status following attempted lumbar fusion surgery.

#### *Plain Radiographs (static)*

Anteroposterior and lateral radiographs can demonstrate a continuous bone mass between adjacent vertebral segments following lumbar fusion. Because of their relatively low cost, widespread availability, and long history as a means of assessing fusion, plain spinal radiography remains a common method of assessment of lumbar fusion;<sup>6</sup> however, the limitations of static plain radiography as a reliable test for determining the presence or absence of a solid fusion have been well documented. Brodsky, et al.,<sup>3</sup> reported a 64% correlation between preoperative plain radiographs and surgical exploration in a retrospective study of 214 lumbar fusion exploration procedures in patients who had undergone prior posterolateral fusion. Plain radiography had an 89% sensitivity and 60% specificity for predicting solid fusion. Radiographs interpreted as demonstrating fusion had a PPV of 76%. Those predicting pseudarthrosis had an NPV of 78%. These data indicate a 0.18 likelihood ratio for a false-positive result (chance of a pseudarthrosis discovered at exploration when radiography indicates fusion), and a 2.25 likelihood ratio for a negative test result (chance of a fusion discovered at exploration when the radiography suggests pseudarthrosis).<sup>3</sup> The medical evidence provided by this review is considered Class II for the use of plain lumbar radiography compared with open surgical exploration to assess fusion because of the authors' selection bias for open exploration.

Similarly, in a retrospective study of 75 patients, Kant and coworkers<sup>11</sup> found a positive correlation between static radiography and surgical exploration of lumbar fusion in 68% of their patients (sensitivity 85%, specificity 62%, PPV 76%, and NPV 54%). The likelihood ratio for a positive result was 0.81, and the likelihood ratio for a negative result was 2.24. Finally, in a study of 49 patients treated with posterolateral and posterior interbody fusion with internal fixation, Blumenthal and Gill<sup>1</sup> compared findings on anteroposterior and lateral radiographs (interpreted by two surgeons and two radiologists) with surgical exploration of the fusion mass at the time of reoperation for hardware removal. They reported a 69% agreement between the radiographic diagnosis and surgical findings. The accuracy among the four physicians interpreting the radiographs ranged from 57 to 77% (false-positive rate 42%, false-negative rate 29%). These authors concluded that plain radiography has limited accuracy and validity for the assessment of lumbar fusion. Furthermore, they noted significant intra- and interobserver variation, indicating a lack of reliability ( $\kappa$  0.4–0.7). Their study provides Class I medical evidence indicating that static radiography is only accurate in determining fusion status in roughly two thirds of cases. Therefore, static anteroposterior and lateral radiographs are not recommended as a stand-alone assessment of the presence of an arthrodesis after lumbar fusion surgery for degenerative disease.

#### *Flexion–Extension Radiography*

In 1948 Cleveland, et al.,<sup>6</sup> advocated the use of dynam-

ic lumbar spinal radiography rather than static radiography, for the diagnosis of pseudarthrosis following attempted lumbar fusion surgery. Other authors have also suggested that lateral lumbar flexion–extension radiography allows for appropriate assessment of fusion status.<sup>4</sup> There has been disagreement, however, on the number of allowable degrees of motion at the treated (fused) levels for determining the presence or absence of successful bone fusion.<sup>16</sup>

Brodsky, et al.,<sup>3</sup> compared the findings of lumbar flexion–extension radiography to surgical exploration in a series of 175 patients who underwent reoperation for various indications following instrumented and noninstrumented lumbar fusion. They found a 62% correlation between preoperative flexion–extension radiography and intraoperative findings at exploration (specificity 37%, sensitivity 96%, PPV 70%, and NPV 86%). Their study provides Class II medical evidence that the absence of motion on flexion–extension x-ray films is highly suggestive of a solid fusion. The occurrence of some degree of motion at the treated levels, however, does not necessarily indicate a pseudarthrosis.

#### *Computerized Tomography Scanning*

Since the introduction of CT scanning in the 1970s, this modality has been used to assess lumbar fusion. Early studies involved axial sequences alone. Brodsky, et al.,<sup>3</sup> used 6-mm axial slice CT scans and demonstrated a 57% correlation between fusion assessment based on these scans compared with direct surgical exploration in a series of 214 operations on 175 patients. Computerized tomography scanning had a sensitivity of 63%, specificity of 86%, PPV of 72%, and an NPV of 81%. Laasonen and Soini<sup>12</sup> conducted a retrospective review of 20 patients who underwent CT scanning prior to surgical exploration and found an approximate 80% correlation between the CT study–based diagnosis of fusion and intraoperative diagnosis of fusion. Since the publication of these earlier studies, CT imaging technology has advanced. The use of thin-section axial sequences, improved resolution, and multiplanar imaging capability has enhanced the ability of CT scanning to assess lumbar fusion status. There have been no studies comparing these more advanced CT scanning capabilities with direct surgical exploration. Lang and colleagues<sup>14</sup> found that the addition of thin-slice and multiplanar CT scanning resulted in a higher rate of detection of pseudarthrosis compared with plain radiography. Similarly, Chafetz, et al.,<sup>5</sup> demonstrated that direct coronal CT scanning may be more sensitive than two-dimensional reconstructed coronal CT images for the detection of pseudarthrosis. Zinreich and colleagues<sup>21</sup> reported that three-dimensional CT reconstruction may be more sensitive than two-dimensional CT reconstruction for the detection of pseudarthrosis. Siambanes and Mather<sup>20</sup> demonstrated that multiplanar CT imaging detected pseudarthrosis in patients who had undergone posterior lumbar interbody fusion compared with plain radiography that had suggested a solid fusion. Santos and colleagues<sup>18</sup> examined 32 patients who underwent anterior lumbar interbody fusion with carbon fiber cages. Plain static radiographs were interpreted to demonstrate fusion at 86% of the assessed levels. Flexion–extension lumbar radiography suggested fusion rates ranging from 74 to 96% in this same group of patients, depending on the method used to analyze

TABLE 1  
Summary of studies involving radiographic assessment of fusion\*

Authors & Year	Class	Description	Comment
Blumenthal & Gill. 1993	I	Retrospective study of 49 patients instrumented lumbar fusion underwent exploration to remove instrumentation. AP & lat radiographs compared w/ op findings w/ 69% agreement. Accuracy ranged among the observers from 57–77%. False-positive rate 42%; false-negative rate 29%.	Limited accuracy of plain x-ray in assessing fusion status w/ low validity (large intra- & interobserver variation).
Bohnsack. et al.. 1999	II	Retrospective study of 42 patients (40 lumbar) on utility of planar bone scintigraphy ( <sup>99m</sup> Tc) to assess fusion just before admission for hardware removal. Based on scintigraphy data, pseudarthrosis was suspected in 5 (12%), & the condition was confirmed in 4 during op (10%), 2 diagnosed & 2 undiagnosed. The accuracy of the method was 88%; sensitivity, 50%; specificity, 93%; PPV, 40%; and NPV, 95%. The sensitivity & PPV of bone scintigraphy are low for possible instability after spinal fusion. The method is not sufficient to diagnose pseudarthrosis reliably after arthrodesis.	Based on low sensitivity, bone scan not adequate to diagnose nonunion.
Brodsky. et al.. 1991	II	Retrospective study of 214 explorations to remove of internal fixation devices, batteries, or for failed-back surgery in 175 patients w/ PLF. Plain x-rays, polytomography, bending films, &/or CT scans correlated w/ surgical findings. Significant inaccuracy found for all modalities: plain x-rays 36%, polytomograms 41%, bending films 38%, axial CT 43% noncorrelations. Axial CT had lowest inaccuracy (22%), whereas bending films had the highest (27%).	Significant inaccuracy of plain x-ray, polytomograph, bending films, & axial CT in assessing fusion status.
Kant. et al.. 1995	II	Retrospective study of 75 patients w/ instrumented lumbar fusions. Single-blinded examiner reviewed x-rays immediately before hardware removal & fusion exploration: 68% correlation btwn radiographic evaluation & intraop observation. Sensitivity 85%, specificity 62%, PPV 76%, & NPV 54%.	Limited accuracy of plain x-rays.
Laasonen & Scini. 1989	II	Retrospective study of 48 patients w/ persistent pain after lumbar fusion examined using CT (6-mm slices, selective sagittal recon). 157 findings observed including: fragmentation of the fusion mass (16), hair-line pseudarthrosis (9), & spinal stenoses (8). Reop in 20 patients: 21 of 27 main lesions detected by CT were confirmed; 6 CT findings were partially or totally incorrect. 16 (80%) of 20 correlations of CT & fusion assessments, 2 cases where CT suggested nonunion but fusion solid at op, 2 cases where CT suggested union w/ pseudarthrosis at op.	Moderate (80%) accuracy of CT in assessing fusion.
Larsen. et al.. 1996	II	Prospective study of 25 patients w/ lumbar fusion. All had hardware removal & fusion inspection. Studies to rule out pseudarthrosis included plain radiography, flexion–extension radiography, CT, & bone scintigraphy. Each study evaluated by blinded radiologist. At exploration, instrumentation removed & fusion inspected. No statistically significant correlation was found between radiographic & op findings.	Single-observer blinded study demonstrating no significant correlation btwn radiography & exploration.
Jacobson. et al.. 1997	III	Ultra evaluated in 10 patients after posterolat thoracic or lumbar fusion w/in 1 wk before second-look surgery. 20 sites evaluated for bone graft, solid fusion, clefts, fluid collections, & hardware visibility. Ultra & op findings compared. In 3 patients, standard radiographs were reviewed before ultra; blinded ultra evaluation was performed in the remaining 7. Ultra identified all 10 sites of pseudarthrosis seen intraop correctly. Of 10 sites w/ solid fusion at surgery, ultra depicted 6. At 4 sites (2 patients), fusion was mistaken for or obscured by hardware. Overall, sensitivity 100%, specificity 60%, & accuracy 80%.	Class III despite comparison w/ op because of lack of intraobserver reliability data.

\* PLF = posterolateral fusion; recon = reconstruction; ultra = ultrasonography.

the x-ray films. The addition of thin-section helical CT scanning reduced the radiographic fusion rate to 65%. The authors concluded that CT scanning is more sensitive than static or flexion–extension lumbar radiography for the detection of pseudarthrosis. Shah, et al.,<sup>19</sup> reached a similar conclusion in their study of 155 patients who underwent posterior lumbar interbody fusion procedures. They found that CT scanning was more sensitive for the detection of abnormalities than plain radiography. These papers are considered to provide Class III medical evidence on the utility of CT scanning for the diagnosis of pseudarthrosis following attempted lumbar fusion.

#### *Technetium-99m Bone Scan*

Technetium-99m bone scanning has also been used to assess the integrity of fusion following lumbar arthrodesis surgery. Bohnsack, et al.,<sup>2</sup> performed a retrospective study of 42 patients who underwent lumbar fusion and internal fixation. They obtained <sup>99m</sup>Tc bone scans before reoperation for hardware removal. This modality suggested pseudarthrosis in five patients (12%). Pseudarthrosis was found intraoperatively in four patients (10%). In two of these four patients pseudarthrosis was predicted based on the <sup>99m</sup>Tc scanning. The accuracy of <sup>99m</sup>Tc bone scanning was 88%, its sensitivity was 50%, its specificity was 93%, its PPV was 40%, and its NPV was 95%. This Class II medical evidence suggests that <sup>99m</sup>Tc bone scanning is not sufficiently reliable to diagnose pseudarthrosis following a lumbar arthrodesis procedure.<sup>2</sup>

#### *Roentgen Stereophotogrammetric Analysis*

Roentgen stereophotogrammetric analysis is a technique that uses radiopaque 0.8-mm tantalum markers implanted into each vertebral level incorporated in the fusion at the time of surgery. The details of the technique have been described elsewhere.<sup>10</sup> Postoperatively, the patient undergoes computerized radiographic assessment in which two 40° angled roentgen tubes are used. Evaluation is performed with the patient in different positions (for example, supine and upright) to detect movement. The technique assesses the amount of movement between the fused vertebral bodies in multiple planes. The amount of allowable movement that determines fusion compared with nonunion, however, is not well defined. This modality has been evaluated in patients at several centers. In a study of 11 patients treated with lumbar fusion, Johnsson and colleagues<sup>10</sup> compared the results of RSA with those of plain radiography at several postoperative time points. In eight patients in whom plain radiography demonstrated successful fusion, RSA revealed a progressive decrease in intervertebral movement over time with achievement of “rigid fusion” within 3 to 12 months. In a follow-up study, Johnsson, et al.,<sup>9</sup> conducted RSA in 12 lumbar fusion patients at multiple postoperative time points. Again, comparative plain radiographs were used and fusion was considered present in all patients. The authors found that in six patients in whom fusion was considered present negligible movement was observed after 1 month postoperatively, whereas in others in whom fusion eventually occurred gradual reduction in intervertebral movement was demonstrated over time. The fact that negligible movement was noted so soon after surgery, when fusion

presumably has not yet occurred, is an interesting observation. Pape and associates<sup>17</sup> undertook RSA in 10 patients following lumbar arthrodesis. Based on RSA criteria, fusion was thought to be present in all patients. This finding was confirmed with open surgical exploration in all cases. Although this report supports the accuracy of RSA, because fusion was present in all patients it is not possible to calculate the sensitivity, specificity, PPV, and NPV of RSA compared with exploration from their data.<sup>17</sup>

#### *Other Techniques*

Polytomography has been used to assess lumbar fusion status in the pre-CT scanning era, but it has been rarely used since the widespread introduction of CT scanning in the 1970s. In their retrospective study of 214 lumbar fusion exploration procedures in patients who had undergone posterolateral fusion, Brodsky, et al.,<sup>3</sup> found only a 59% correlation of fusion status between preoperative polytomographs and intraoperative findings (sensitivity 65%, specificity 84%, PPV 79%, and NPV 73%). This single study provides Class II medical evidence that polytomography cannot be reliably used to determine the presence of solid osseous arthrodesis following lumbar fusion procedures for degenerative disease.

The use of magnetic resonance imaging to assess for pseudarthrosis following lumbar fusion has been explored by several authors. Lang, et al.,<sup>13</sup> maintained that magnetic resonance imaging added unique information in cases involving lumbar fusion procedures. To date, the importance of this information remains unclear. A single report of the use of ultrasonography to evaluate fusion status was also reviewed.<sup>8</sup> Although the results of this study are promising, the ultrasonography technique has not been rigorously evaluated.

#### **Summary**

The assessment of fusion status with static plain radiography is accurate in approximately two thirds of patients treated with lumbar fusion when the radiographic results are compared with surgical exploration findings. Therefore, static plain radiography is not recommended as a stand-alone modality following lumbar fusion procedures. The addition of lateral flexion–extension radiography may improve accuracy because the lack of motion between fused lumbar segments on lateral views is highly suggestive of a solid fusion. Some degree of motion between segments may be present even when the spine has fused. The amount of motion allowable across fused segments is not clear, and the role of internal fixation in limiting motion has also not been adequately addressed. The addition of multiplanar CT scanning results in the detection of pseudarthrosis in some patients in whom fusion has been deemed successful based on plain radiographic criteria. Therefore, CT scanning may be more accurate in the determination of fusion status than plain radiography; however, a rigorous comparison of modern CT scanning and surgical exploration has not been performed. It appears that RSA is exquisitely sensitive for the detection of motion between vertebral bodies, and the loss of motion between treated vertebral segments does appear to indicate the presence of fusion. The modality, however, is invasive and not widely available. Furthermore, the only

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comparison of RSA with surgical exploration provided only Class III medical evidence supporting the accuracy of RSA. It is recommended that multiple modalities be used for the noninvasive evaluation of symptomatic patients with suspected fusion failure because no radiographic gold standard exists.

### Key Issues for Further Investigation

Modern CT scanning appears to have superior sensitivity compared with plain radiography for the detection of pseudarthrosis. A prospective study of CT scanning findings prior to surgical exploration for instrumentation removal would provide Class I evidence regarding the accuracy of the former compared with the gold standard of surgical exploration. If preoperative flexion–extension radiography is also used, then the influence of internal fixation on the accuracy of flexion–extension radiography could also be addressed.

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