Chapter 7

A FAST AND ACCURATE TECHNIQUE TO EVALUATE SURGICAL LUMBAR FUSION

7.1 INTRODUCTION

In evaluating fusion status after lumbar interbody fusion, plain radiographs - often with additional bending films - are widely used. However, the accuracy of predicting solid arthrodesis by radiographs is limited as illustrated by Brodsky. In that study, 175 patients were included who either had internal fixation devices removed after lumbar spinal fusion or who were re-operated for failed back surgery. The pre-operative radiological assessment was compared to the surgical findings. Noncorrelations were present in 36% of plain radiographs, in 41% of polytomographs, in 38% of bending films and in 43% of CT-scans. Other investigators have confirmed the inaccuracy of imaging techniques in evaluating spinal fusion. Although progress in computed tomography and magnetic resonance imaging is being made, one generally assumes that the only way to be sure about fusion status is surgical exposure.

Whatsoever, since routine surgical exploration after posterolateral or interbody fusion is not feasible, non-invasive techniques are required that at least can accurately determine whether the vertebrae are rigidly connected or not. Roentgen Stereophotogrammetric Analysis (RSA) enables this assessment. Up to the 1970’s, the development of RSA was slow and it was not generally used. In 1974 Selvik introduced a complete RSA-system that included instrumentation for implantation of tantalum landmarks, devices for calibration of the roentgen set-up, and comprehensive software. RSA can be applied to assess growth, volume changes, and movement of bony structures. The main application of RSA is to assess the micromotion of orthopaedic implants with respect to the surrounding bone.

RSA has been used in only a few studies assessing the mobility of the lumbar spine after fusion. In these studies anteroposterior radiographs of the spine in supine and erect positions were made. The so far limited application of the RSA-technique is probably explained by the need for specific hardware and specially educated investigators. RSA is also time-consuming since manual detection, labeling of markers and the RSA-calculations of each radiograph take approximately one hour.

In order to reduce the total analysis time of RSA-radiographs, a software package has been developed that is able to perform the measurements of the coordinates automatically in digital RSA-images (RSA-CMS, MEDIS, Leiden, The Netherlands). The software package runs on a PC with the Windows NT operating system. RSA-CMS can handle scanned conventional radiographs (Vrooman et al.) or direct radiographs in DICOM-format. The use of Digital Roentgen Stereophotogrammetric Analysis (D-RSA) with direct radiographs in DICOM-format has not been reported previously.

In this study, D-RSA was tested for its applicability in the assessment of fusion after lumbar spinal arthrodesis (posterolateral or interbody) using lateral bending films.
7.2 MATERIALS AND METHODS

The validity and variability of D-RSA were tested by rotating a standardized cylinder with tantalum markers in relation to a calibration box. The cylinder was rotated in the y-direction (see figure 7.1). By changing the position of the roentgen tubes, the sensitivity of D-RSA on differences in the external parameters was tested.

D-RSA

To determine lumbar spinal fusion status by D-RSA from digital lateral bending images the following was needed: 1) well placed tantalum bone-markers; 2) a biplanar radiographic system and a calibration box, and 3) a computer and calibrated D-RSA software. Since D-RSA provides a fully automatic analysis of digitally acquired lateral bending images, no specially trained investigators were needed.

1) Insertion of bone-markers

For the kinematic analysis, at least three tantalum markers with a diameter of 0.5-1.0 mm had to be inserted in a non-linear manner and well separated in at least two dimensions in each of the L4, L5, and S1 lumbar vertebrae. We used six bone-markers (Ø 1.0 mm) in each vertebra to make sure that enough markers could be detected automatically and no interactively correction by an observer was needed. The bone-markers of the lumbar vertebrae were placed into the vertebral body through each pedicle screw hole in a standardized manner. The first marker was introduced at the ending ventral of the pedicle screw hole, the second in a caudal-lateral direction and the third in a caudal medial direction (Fig. 7.2A). We also standardized the insertion of the bone-markers in the sacral vertebrae. The first marker of the sacral vertebra was inserted through the hole of the pedicle screw in a cranial-lateral direction, the second 1 cm lateral of the S1 foramen, and the third in the middle of the S1 and S2 foramen (Fig 7.2B). The markers were placed on each side of the S1 vertebra resulting in a total of 6 markers within the sacrum. The bone-marker positions were accessible for both posterolateral- and interbody fusion techniques. The tantalum markers were placed on a piece of bone wax (Ethicon bone wax, Johnson & Johnson), then each marker was scooped on the top of a simple biopsy needle (Ø 1.2-1.5 mm) and the marker was pushed into place by a mandarin. No specially designed implantation device was needed. We tested stainless steel and titanium hardware (pedicle screws, spinal rods and straight slotted connectors, ISOLA System AcroMed®, Cleveland, Ohio, USA) for fixation of the L4-5 and L5-S1 levels.

2) Radiographic examination

A calibrated reference cage with tantalum markers was placed under the soft-bone and radiographed simultaneously by two roentgen tubes at 1.0-1.5 meter distance at a 20- 30° angle from a lateral position (Fig. 7.3). When a scattergrid was applied, a more precise distance and angle of the roentgen tubes had to be used due to the specified grid focus. Flexion and extension from a neutral position were recorded in relation to the axes with a standardized orientation in relation to the soft-bone. For the experiments, normal radiation exposures were used (80-90 kV, 7-8 mAs). The acquisition of all the images was based on storage phosphor technology.
Figure 7.1 Testing validity and variability of D-RSA using a standardized cylinder and cube with tantalum markers

The cylinder was rotated along the y-axis (A) (see table 7.1), and the distance of the roentgen tubes was changed from 1.0 to 1.5 meters while the cylinder was not rotated (B) (see table 7.2). Finally, the angle of the roentgen tubes was increased from 20º to 30º without rotation of the cylinder (C) (see table 7.2).
Figure 7.2 Placement of tantalum markers in the L4, L5 and S1 vertebrae.

A: lateral view of L3-sacrum. The markers of the lumbar vertebrae were placed through each pedicle screw hole: the first marker was placed ventrally of the pedicle screw hole, the second in a caudal-lateral direction in the corpus just beyond the pedicle, and the third in a caudal-medial direction to the caudal end-plate. The markers were placed in each pedicle screw hole so totally 6 markers were inserted in each vertebra.

B: posterior-anterior view of sacrum. The first marker of the sacral vertebra was inserted through the hole of the pedicle screw in a cranial-lateral direction, the second 1 cm lateral of the S1 foramen, and the third in the middle of the S1 and S2 foramen. A total of 6 markers was also inserted in the sacrum.
Figure 7.3 Biplanar radiographic system
The biplanar radiographic system consisted of two roentgen tubes positioned at a distance of 1.0-1.5m in a 20-30° angle from the object. A calibration box with tantalum markers was placed under the object. The lumbar spine was radiographed in flexion and extension from a lateral position.
3) Computation of movements

The digital roentgen data were transferred to a computer with RSA-CMS software. The software identified and numbered the tantalum markers of the calibration box and the soft-bone in a standardized manner (Fig. 7.4). Thereafter, the three dimensional (3-D) coordinates of each bone-marker were determined in flexion and extension. From the 3-D coordinates, the ranges of motion (ROM’s) consisting of three translational components (Tx-lateral; Ty-axial or vertical; Tz-anteroposterior) and three rotational angles (Rx, Ry, and Rz representing flexion/extension, axial rotation, and lateral bending, respectively), were computed.

Figure 7.4 Stereopair of the L4-5 level in extension
The tantalum markers of the calibration box and the soft-bone were identified and numbered in a fully automatic manner.
7.3 RESULTS

7.3.1 Standardized cylinder rotation

The standardized cylinder was rotated by hand over approximately 15º and 30º. The D-RSA measurements are shown in Table 7.1. Subsequently, the position of the roentgen tubes in relation to the cylinder was changed. The main concern in positioning the tubes was to get an image including all the markers of the calibration box. First, the distance of the roentgen tubes to the cylinder was changed from 1.0 to 1.5 meters and the range of motion (ROM) was calculated. Then the angle of the roentgen tubes in relation to the cylinder was changed from 20º to 30º. These differences in the position of the roentgen tubes had a minimal effect on the translation and rotation (<0.4 mm and < 0.4º; Table 7.2).

7.3.2 Soft-bone experiments

By placing the tantalum markers in the described positions in the soft-bone, the computer could easily identify and number the markers. The translational and rotational changes during flexion and extension could be determined in about four minutes. Translations of the fixated lumbar soft-bones during flexion and extension were in a range of 0.04-0.3 millimeters and rotations in the range of 0.04-0.7º (Table 7.3).

Table 7.1 Accuracy of D-RSA measurements.

<table>
<thead>
<tr>
<th></th>
<th>T-x (mm)</th>
<th>T-y (mm)</th>
<th>T-z (mm)</th>
<th>R-x (º)</th>
<th>R-y (º)</th>
<th>R-z (º)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rot-0º</td>
<td>-0.07</td>
<td>-0.01</td>
<td>0.06</td>
<td>-0.11</td>
<td>-0.11</td>
<td>-0.01</td>
</tr>
<tr>
<td>Rot-15º</td>
<td>-0.19</td>
<td>0.01</td>
<td>-0.48</td>
<td>-0.11</td>
<td>16.19</td>
<td>-0.05</td>
</tr>
<tr>
<td>Rot-30º</td>
<td>0.15</td>
<td>0.01</td>
<td>-0.26</td>
<td>-0.414</td>
<td>32.20</td>
<td>-0.22</td>
</tr>
</tbody>
</table>

T = translation  R = rotation
A standardized cylinder was rotated by hand in the y-direction over approximately 0º, 15º and 30º. The rotational changes measured by D-RSA are shown in the table. See also figure 7.1A.

Table 7.2 Translational and rotational changes with differences in the external parameters.

<table>
<thead>
<tr>
<th></th>
<th>T-x (mm)</th>
<th>T-y (mm)</th>
<th>T-z (mm)</th>
<th>R-x (º)</th>
<th>R-y (º)</th>
<th>R-z (º)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distance</td>
<td>-0.11</td>
<td>-0.08</td>
<td>-0.37</td>
<td>0.34</td>
<td>0.05</td>
<td>-0.05</td>
</tr>
<tr>
<td>Angle</td>
<td>-0.11</td>
<td>-0.13</td>
<td>0.01</td>
<td>-0.04</td>
<td>0.28</td>
<td>-0.02</td>
</tr>
</tbody>
</table>

T = translation  R = rotation
The distance from the roentgen tubes to the cylinder was changed from 1.0 to 1.5 meters (see also figure 7.1B). The angle of the roentgen tubes varied between 20º and 30º (see also figure 7.1C).

Table 7.3 Range of motion of the fixated lumbar spine during flexion and extension.

<table>
<thead>
<tr>
<th></th>
<th>T-x (mm)</th>
<th>T-y (mm)</th>
<th>T-z (mm)</th>
<th>R-x (º)</th>
<th>R-y (º)</th>
<th>R-z (º)</th>
</tr>
</thead>
<tbody>
<tr>
<td>L4-L5</td>
<td>-0.28</td>
<td>-0.11</td>
<td>0.15</td>
<td>0.12</td>
<td>-0.18</td>
<td>-0.72</td>
</tr>
</tbody>
</table>
L5-S1 0.08 -0.15 -0.04 0.04 -0.34 -0.07

T = translation  R = rotation

Once the tantalum markers were well placed and visible between the hardware it did not matter what type of hardware (stainless steel or titanium) was used to fixate the lumbar vertebrae. However, since tantalum has a higher density on radiographs than titanium, markers positioned in the projection of the titanium hardware could easily be detected with increased radiation exposure or with the use of a scattergrid (Fig. 7.5). The tantalum markers in the projection of stainless steel hardware could not be detected.

Figure 7.5 Visualization of malpositioned markers
When titanium hardware was used to fixate the lumbar vertebrae, using a higher voltage or a scatter grid could easily detect tantalum markers in the projection of the hardware.

7.4 DISCUSSION AND CONCLUSIONS

The classical goal in performing lumbar spinal fusion is to obtain a solid fusion. Many reports claim fusion rates up to 90% or more using a posterolateral- or interbody fusion technique with or without hardware. In these studies fusion results are assessed either by conventional radiographs, bending films or computed tomography (CT). We question these outcomes since it appears that radiological findings have a positive correlation with the surgical observations during re-operation in only 57-69 % of the cases depending on the imaging technique used.\(^1\)\(^2\)\(^6\) In addition to the findings by Brodsky\(^2\)\(^,\) Kant\(^6\) compared the plain radiographs with the surgical findings in 75 patients who had persistent low back pain after lumbar fusion and found a positive correlation in only 68% of the patients. The noncorrelates included false positive as well as false negative findings. Blumenthal\(^1\) found an overall agreement between radiological and surgical findings of 69% in a study of 49 patients.
The high rate of inaccuracy of different imaging techniques possibly explains the poor correlation between radiological findings and clinical outcomes after lumbar fusion. In our previous study (Ch 5) on 157 highly selected patients with severely disabling chronic low back pain treated by lumbar interbody fusion 91 patients showed solid fusion on bending films. Out of these 91 patients, 73 (80%) had a satisfying clinical outcome. However, of the 66 patients with radiological pseudoarthrosis, 32 (48%) also had a good clinical result. A false-positive correlation between radiological findings and clinical outcome might explain the persisting of low back pain symptoms after radiological solid fusion while a false-negative correlation could lead to a successful clinical outcome without radiological fusion.

In evaluating spinal fusion, a special problem arises with the widely used interbody cages. The function of these cages is to stabilize spinal segments by distraction as well as by allowing bone ingrowth and fusion. A prerequisite for spinal fusion is the formation of bone tissue. Cages that allow as minimal end-plate destruction as possible are proposed to prevent postoperative loosening of the cage during spinal motion. However, there is no imaging modality by which the status and vitality of graft material inside a cage can reliably be assessed. Kuslich et al.\textsuperscript{7} reported that radiolucency around the cage and/or angulation greater than 5 degrees on bending films are signs of lack of fusion. This may be true, but it is not allowed to turn this statement around since absence of radiolucency around the cage or angulation less than 5 degrees does not necessary indicate that fusion has occurred. Although D-RSA measures motion rather than fusion we believe that the ranges of motions (ROM’s) detectable by D-RSA are so small that it reliably indicates whether or not fusion has occurred.

In this study, the established RSA technique is modified into a digital and fully automatic method for determining three-dimensional lumbar spinal motion in a highly accurate manner. With the current version of the software, total analysis time of one stereo radiograph is about 4 minutes, which is less than, for example, a CT-reconstruction of the lumbar spine. Since routine surgical exploration of spinal fusion is not preferable, a reliable technique to confirm fusion or pseudarthrosis such as D-RSA is needed. We conclude that the D-RSA-technique enables accurate assessment of the stabilizing effect induced by lumbar fusion.
REFERENCES
