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Which postures are most suitable in assessing spinal fusion using radiostereometric analysis?

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ABSTRACT

Background: Up to now, plain radiographs are not well suited to assess spinal fusion. Radiostereometric analysis performed for two postures may deliver more reliable results. However, it is unknown, which postures are most suitable for this procedure.
Methods: In a finite element study, spinal fusion at the level L4–5 was simulated assuming a posterior approach and the implantation of two cages and a spinal fixation device. The change of the distance between markers in vertebrae adjacent to the cages was calculated for moving from one of the following postures standing, flexion, extension, axial rotation, lying, and extension in a lying position to another. The changes of marker distances were calculated for the intact model, as well as for the situations: directly after surgery before fusion started, in the early-fusion-phase and in the late-fusion-phase. Differences in the marker motion between two postoperative situations were also calculated.
Findings: The most anteriorly placed markers showed the greatest motion between two postures. The greatest differences in marker motions between the two situations before-fusion and early-fusion-phase (0.54 mm) as well as between early-fusion-phase and late-fusion-phase (0.34 mm) were found for the two postures flexion while standing and extension in a lying position.
Interpretation: Pairs of X-rays taken while standing with maximum flexed upper body and while lying with maximum extended trunk are most suited for the assessment of spinal fusion when using radiostereometric analysis.

1. Introduction

Spinal fusion is a common treatment for severely degenerated, symptomatic spines. It is estimated that several 100,000 lumbar spine fusion procedures are performed per year (Williams et al., 2005). Fusion rates are reported to be between 86% and 100% (Hashimoto et al., 2002; Ito et al., 2010; Kuslich et al., 2000; Schiffman et al., 2003). The most reliable, yet potentially harmful, method to determine whether fusion was successful is a secondary operation in which the patient's back is reopened and the spinal segments are manually moved (Hilibrand and Dina, 1998). Because of the morbidity and costs involved, this is not recommended as a standard practice (Pape et al., 2004). Therefore, radiographs are usually used for the assessment of the outcome of spinal fusion. According to the Food and Drug Administration (FDA), the criteria for successful radiographic fusion are as follow: presence of bridging trabecular bone between the involved motion segments, translation motion less than 3 mm and angular motion less than 5° (Guidance Document for the Preparation of IDEs for Spinal System, Jan. 2000). But this seems to be a weak criterion when evaluating, for example, new implant concepts. Furthermore, plain radiographs are very difficult to interpret and are therefore not an ideal solution (Christensen, 2004).

Radiostereometric analysis (RSA) may offer an alternative for the assessment of spinal fusion (Pape et al., 2004). RSA is non-invasive once fusion surgery has been performed. For this method, spherical tantalum markers with a diameter of 0.8–1.0 mm are implanted into the vertebrae and a pair of X-rays of the vertebrae together with a RSA calibration cage is taken simultaneously from two different directions. This allows the precise determination of the locations of the markers relative to each other. The measuring accuracy is approximately 0.1 mm (Glyn-Jones et al., 2004). Johnsson et al. (1990) determined the mobility of the lumbar spine after posterolateral fusion without osteosynthesis in 11 patients. They acquired paired X-rays in supine and erect position. According to their measurements, translations between the fused vertebral segments began to decrease after 3 to 6 months. In three patients with radiographically poor fusion, no rigid fusion as defined by RSA was obtained. Recently, dynamic RSA has been employed to measure in vivo 3D motion of lumbar segments (Anderst et al., 2008). Using a high-speed biplane radiographic system, the motions between fused and adjacent vertebrae were measured in five subjects. The authors

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found that the vertebral rotation was not necessarily linearly related to trunk rotation and that some movements indicated fusion was completed, whereas others indicated incomplete fusion. RSA has also already been used to study the outcomes of intervertebral disc replacements (Park et al., 2009).

Directly after fusion surgery, no tensile force can be transferred by the implanted intervertebral cage and the added bone mass. This changes when fusion starts and the intervertebral motion depends then on the stiffness of the added bone. To assess the fusion state at a certain point in time, paired X-rays can be taken for two different body positions. The changes of the distances of the markers in the vertebrae adjacent to the cage describe the motion of the two vertebrae relative to each other when moving from one position to the other. The intersegmental motion is very small when a cage has been implanted. It is unknown which two postures cause the largest difference in intersegmental motion for the two situations before and after fusion. These postures would be best suited for assessing spinal fusion. If the measured intersegmental motion between two postures is below a certain value, fusion can be assumed. If it is above another threshold value, then fusion as defined by RSA has not yet occurred. These threshold values, however, depend on the posture combination and are not exactly known yet. For the evaluation of the fusion state itself, the two postures are best suited, for which the changes of marker distances between the early and the late phase of fusion is greatest. It is still unknown, which postures should be examined by RSA to determine whether fusion has started and which ones to estimate the fusion state. The finite element method is well suited to calculate intersegmental motion for different postures and to determine the changes in marker distances in a model since there are no physical measuring errors and the effects of single parameters can be determined precisely. Thus, the finite element method allows numerical simulation of RSA for spinal fusion assessment.

The aims of this study were (1) to identify the two postures where the largest difference of intersegmental motion occurs between the situations before and after fusion when moving from one posture to the other, and (2) to identify the two postures where the difference in intersegmental motion is largest between the early-fusion-phase and late-fusion-phase. The first two postures may be used to answer the question whether fusion has started or not and the second two to assess the fusion state itself by quantifying the motion between the markers.

2. Methods

2.1. Finite element model of the lumbosacral spine

A part of an existing osseoligamentous finite element model of the lumbosacral spine ranging from L3 vertebra to the sacrum was used (Fig. 1). The complete model was extensively validated using experimentally determined data (Rohlmann et al., 2006a; Zander et al., 2001; Zander et al., 2009). Solid hexahedral elements represented the vertebrae, the sacrum and the ground substance of the intervertebral discs. The geometry of the bones was taken from CTs. The curved facet joints were only able to transmit compressive forces, had a thin cartilaginous layer and a gap of 0.5 mm in the unloaded neutral position. Contact stiffness was a nonlinear function of the distance between the contact pairs (Sharma et al., 1995). The annulus fibrosus of the intervertebral discs was simulated as a fibre-reinforced hyperelastic composite (Eberlein et al., 2000). The nucleus pulposus of the intervertebral discs was modelled as an incompressible fluid-filled cavity. All eight major ligaments of the lumbosacral spine were included into the model and were represented by tension-only spring elements (Nolte et al., 1990; Zander et al., 2001). The material properties of the different tissues were taken from the literature (Table 1).

For modelling fusion surgery at level L4–5, the nucleus, cartilaginous layer of the endplates and parts of the annulus were removed (Fig. 1). To simulate a posterior approach, parts of the lamina at level L4 were also taken away. Then two wedge shaped porous TM-500 cages (Zimmer Inc., Warsaw, USA) with an opening and a height of 12 mm were symmetrically inserted between the two vertebrae (Fig. 2). The remaining free space was filled with bone graft. The pedicle screws and longitudinal rods of the posterior instrumentation at level L4-5 were simulated using beam elements. They had a shaft diameter of 5 mm and 6 mm, respectively. A rigid bond was simulated between pedicle screws and longitudinal rods and between pedicle screws and vertebrae.

Besides the intact situation, three states of fusion were considered: directly after surgery (hereafter referred to as before-fusion), when fusion has just started (early-fusion-phase), and after fusion has occurred and the added bone mass already has a high stiffness (late-fusion-phase). In the case before-fusion, no tensile forces could be transmitted between vertebral body, bone graft and cages. For the two cases after fusion, a perfect bond between bone graft, cage and vertebral body was

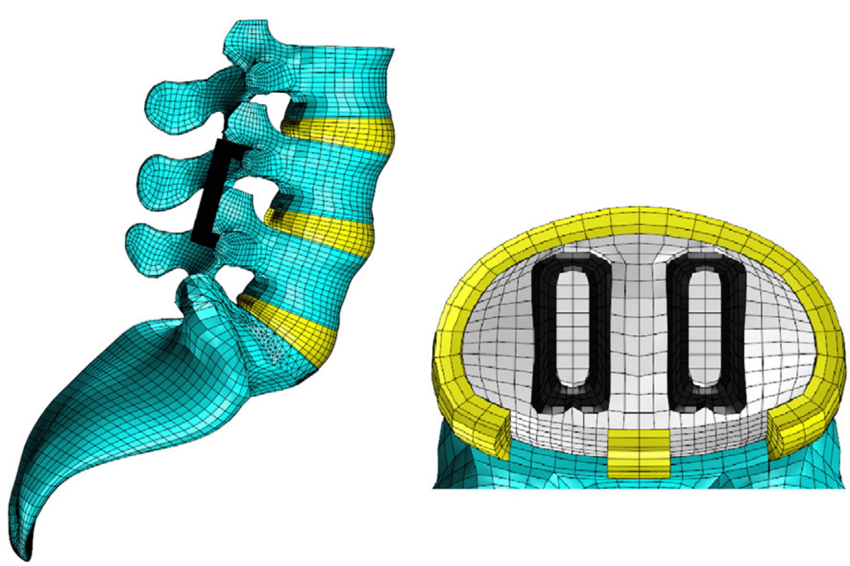

Fig. 1. Mesh of the finite element model (left) and positions of the cages (right).

Table 1
Material properties and element types used for the different tissues and the implant of the spine model.

Component	Elastic modulus	Poisson ratio	Element type	References
Cortical bone	10,000 MPa	0.3	8-node hex	(Rohlmann et al., 2006c)
Cancellous bone (transverse isotropic)	200/140 MPa	0.45/0.315	8-node hex	(Ueno and Liu, 1987)
Posterior bony elements	3,500 MPa	0.25	8-node hex	(Shirazi-Adl et al., 1986)
Ground substance of annulus fibrosus	Hyperelastic, neo-Hookean C10 = 0.3448, D1 = 0.3		8-node hex	(Eberlein et al., 2000)
Fibres of annulus fibrosus	Non-linear and dependent on the distance from the disc centre		Spring	(Shirazi-Adl et al., 1986)
Ligaments	Non-linear		Spring	(Nolte et al., 1990)
Cartilage of facet joint	Soft contact			(Sharma et al., 1995)
Cage	3,000 MPa	0.3	8-node hex	(Koutsostathis et al., 2009)
Rods	110,000 MPa	0.3	Beam	
Screws	110,000 MPa	0.3	Beam	
Added bone material, early-fusion-phase	50 MPa	0.3	8-node hex	(Rohlmann et al., 2006b)
Added bone material, late-fusion-phase	1000 MPa	0.3	8-node hex	(Rohlmann et al., 2006b)

assumed. The added bone material fuses with the adjacent vertebrae and it grows into the porous cage, allowing also the transfer of tensile and shear forces at the interface between cage and vertebral body. However, the stiffness of the added bone material differed for the early-fusion-phase and the late-fusion-phase. Based on a previous study (Rohlmann et al., 2006b), elastic moduli of 50 MPa and 1000 MPa were assumed for the added bone material, in the early-fusion-phase and in the late-fusion-phase, respectively.

The finite element programme ABAQUS, version 6.8 (SIMULIA Inc. Providence, Rhode Island, USA) has been used.

2.2. Loading

For the upright body position, the loading cases standing, flexion, extension, and left axial rotation were investigated. In addition, the postures 'lying on a lateral side' and 'extension-while-lying' were studied. The applied loads for the simulation of the different postures are given in Table 2. Standing was simulated by applying a follower load of 500 N (Rohlmann et al., 2009a) and lying by a follower load of 100 N. For the simulation of the other loading cases, these loads were applied in a first step. In a second step, the follower load was increased and, simultaneously, a moment was applied.

Table 2
Investigated loading cases.

Loading case	Follower load	Moment	Reference
Lying	100 N		(Wilke et al., 1999)
Standing	500 N		(Rohlmann et al., 2009a)
Flexion	1175 N	7.5 Nm	(Rohlmann et al., 2009b)
Extension	500 N	7.5 Nm	(Rohlmann et al., 2009b)
Axial Rotation	720 N	5.5 Nm	(Dreischarf et al., 2011)
Extension in lying position	100 N	7.5 Nm	

2.3. Evaluation

Twelve points representing the locations of the markers were defined in each of the vertebrae L4 and L5 (Fig. 2). In each pedicle screw two of these marker points were defined, one at the tip and one in the shaft. Two markers each were located in the anterior, middle and posterior part of the vertebrae. All these markers were symmetrically arranged in the mid-cross-section of the vertebra. The remaining two markers were located in the geometrical centre of the vertebral body, but shifted 5 mm cranially and caudally, respectively.

First, changes of the distances between corresponding points in the two vertebrae were calculated for each loading case to determine their range of motion (Fig. 3A). For these calculations, the standing posture provided the reference marker distance. The distance changes were determined for the intact model as well as for the three fusion states described. The largest motion of all markers was found in most cases at the two markers located in the anterior part of the vertebral body. This is especially true for the situations after surgery. Therefore, only the results for these points are presented here. The change of distance between two corresponding markers for a posture is hereafter called 'posture motion'.

Next, the maximum distance changes between two corresponding markers determined for two postures were calculated (Fig. 3B). These are hereafter called 'motion between two postures'. For the three situations after surgery, the 'motion between two postures' was calculated. Finally, the differences of 'motion between two postures' between two postoperative situations were determined (Fig. 3C). These differences allow best to discriminate between fusion and non-fusion and to assess the fusion state. In addition, the ranges of motion (ROM) in the loading plane at level L4–5 were calculated for the motion between the two postures with the highest motion and for the two postures usually taken when determining ROM from plain X-rays.

3. Results

3.1. Marker motions related to standing for different postures

In the intact situation, the change of the distance between the anterior markers adjacent to the cage was −1.5 mm for flexion and 0.9 mm

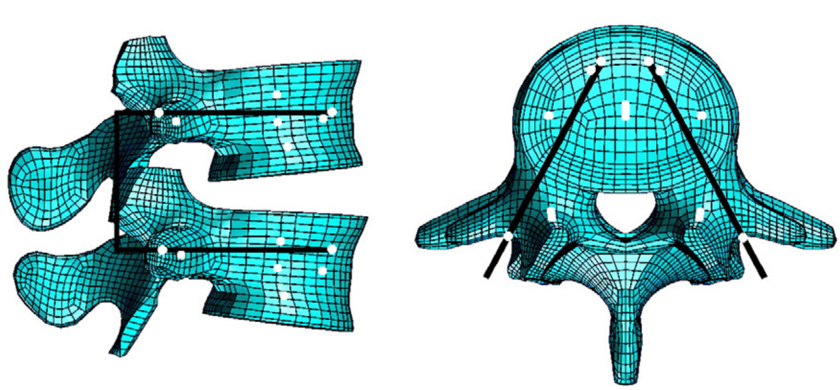

Fig. 2. Location of the markers in the vertebrae L4 and L5.

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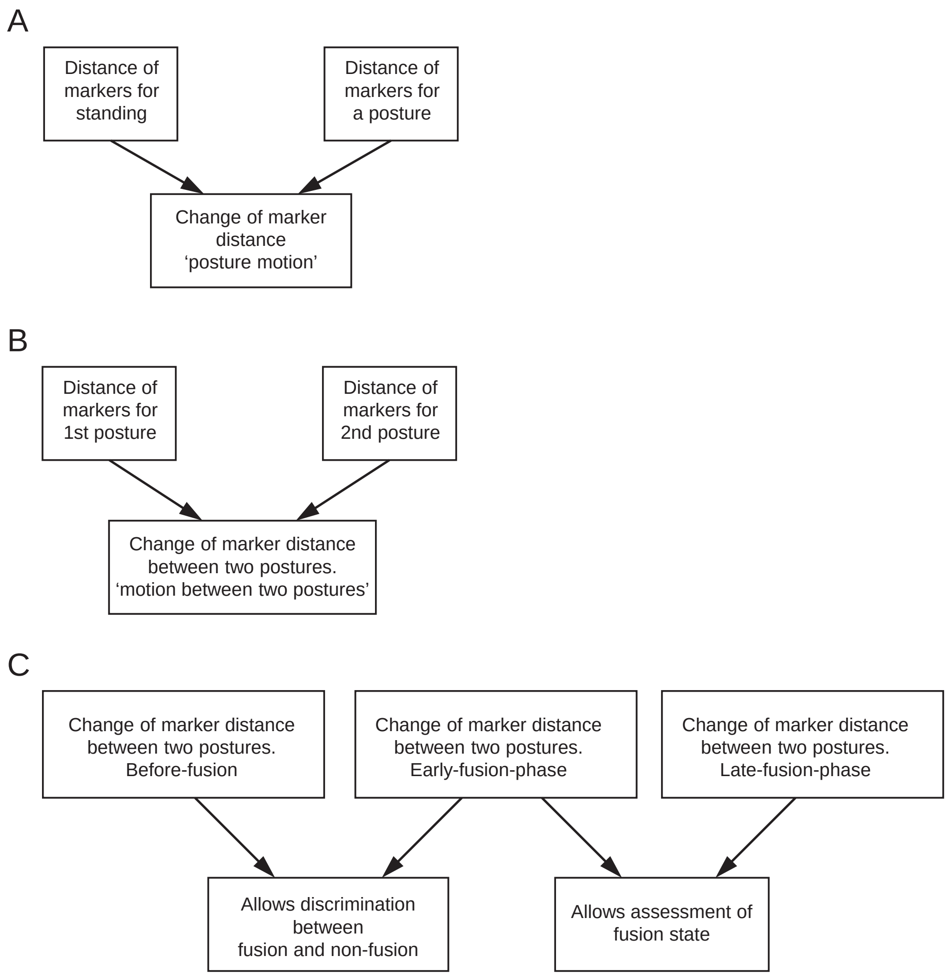

Fig. 3. Schematic sketch of the procedures for determining posture motion (A), changes of marker distances between two postures (B), and differences of marker distance changes between different fusion states (C).

for extension-while-lying (Fig. 4). For axial rotation the value was very small. After surgery, 'posture motions' was usually much smaller than for the intact spine. Before-fusion, the maximum change in marker distance was 0.8 mm for extension-while-lying. For the other postures the change in marker distance was less than 0.23 mm. In the early-fusion-phase, the magnitudes of the maximum 'posture motion' differed only slightly from the situation before-fusion, except for extension-while-lying which showed 0.31 mm. In the late-fusion-phase, the 'posture motion' was less than 0.1 mm for all loading cases.

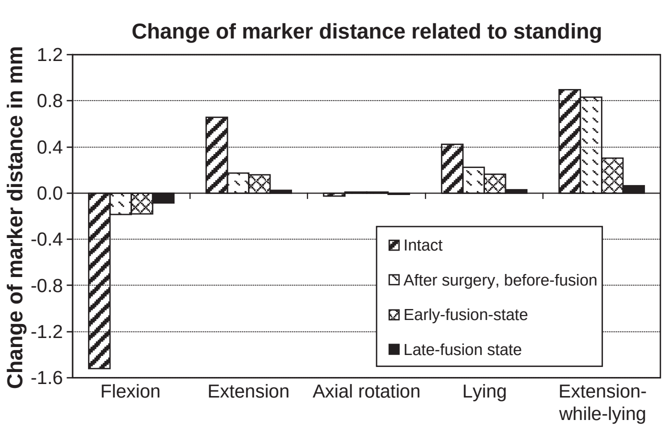

Fig. 4. Change of anterior marker distances related to standing for different postures and fusion states.

3.2. Marker motions between two postures

Before fusion, the greatest change in marker distance (1.05 mm) was found between the postures flexion and extension-while-lying (Fig. 5). The motions between extension-while-lying and rotation as well as between extension-while-lying and standing were also higher than 0.8 mm. For all postures combined with extension-while-lying, 'motion between two postures' was much smaller in the early-fusion-phase than before-fusion. The smallest change in marker distance was always in the late-fusion-state.

The differences in 'motion between two postures' between the situation before-fusion and early-fusion-phase as well as early-fusion-phase and late-fusion-phase are shown in Fig. 6. Between the situations before-fusion and early-fusion-state similar differences in marker distance changes (around 0.5 mm) were found for all combinations where the posture extension-while-lying is involved. Thus any of these combinations may be used for the discrimination between fusion and non-fusion. However, the difference between the situations early-fusion-state and late-fusion-state was largest for the posture combination flexion and extension-while-lying (0.34 mm). Hence, this posture combination is best suited to assess the fusion state itself. The load combination flexion and extension also showed a large difference between early-fusion-state and late-fusion-state (0.23 mm), however, only a very small difference between before-fusion and early-fusion-state (0.02 mm). Our results suggest that the two postures flexion and extension-while-lying are best suited for both discriminating between fusion and non-fusion and assessing the fusion

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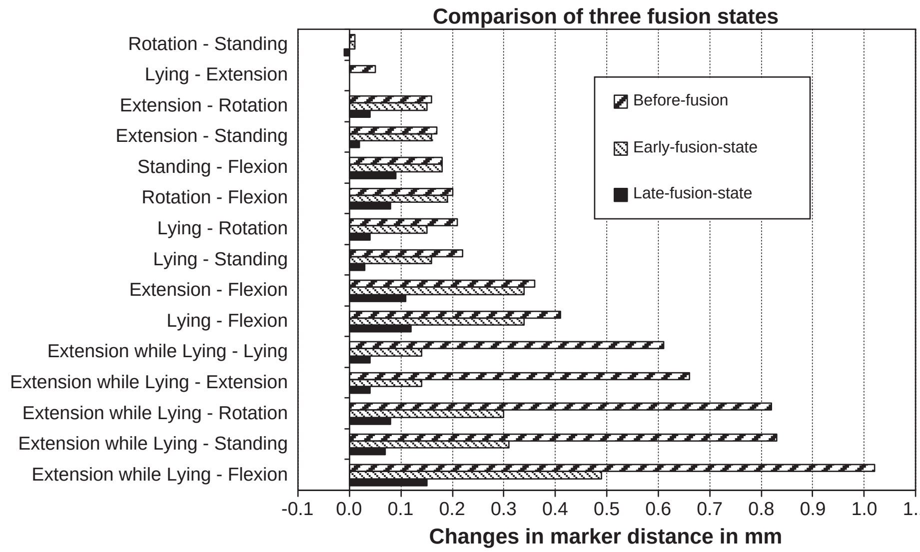

Fig. 5. Comparison of marker distance changes between postures for different fusion states.

state. They also suggest that a change of marker distance between these two postures of more than 0.5 mm indicates that fusion has not yet started while a value less than 0.2 mm indicates the late-fusion-state.

3.3. Range of motion in the sagittal plane

The calculated ROM between the two postures extension-while-lying and flexion was about 10° for the intact model, less than 1.5° before fusion and less than 0.3° after fusion. Between all other two postures the ROM values were even smaller. For the two standing postures flexion and extension the ROM was about 10° for intact model, less than 0.6° before fusion and less than 0.2° after fusion.

4. Discussion

In order to determine the two postures of which a pair of X-rays should be taken when using RSA, the changes in the distances of markers in the vertebrae adjacent to the cage were calculated for six postures. The intervertebral motions between two postures were then calculated for the situations before-fusion, early-fusion-phase, and late-fusion-phase. The differences of the 'motion between two postures' calculated for the situations before-fusion and early-fusion-phase as well as for the situations early-fusion-phase and late-fusion-phase led to the postures flexion and extension-while-lying which allow best to discriminate between fusion and non-fusion and to assess the fusion state.

This study has the following limitations: Only one spine geometry and set of material properties were assumed. Simplified loading cases were applied. However, these loading cases simulate the intervertebral rotation of an average person quite well (Dreischarf et al., 2011; Rohlmann et al., 2009a; 2009b). Fusion was studied only monosegmentally at level L4–5. Only one type of fusion implant was studied. This implant has a relatively low elastic modulus (3000 MPa), but this value is still 15 times higher than the value for cancellous bone. The average deformations of the implant before fusion started were for standing and flexion 0.006 and 0.015 mm, respectively, and thus negligible. These simplifications and assumptions affect the absolute values calculated. However, they should not affect the main result of this study. The real reliable threshold values for the discrimination between fusion and non-fusion have to be determined in a clinical study.

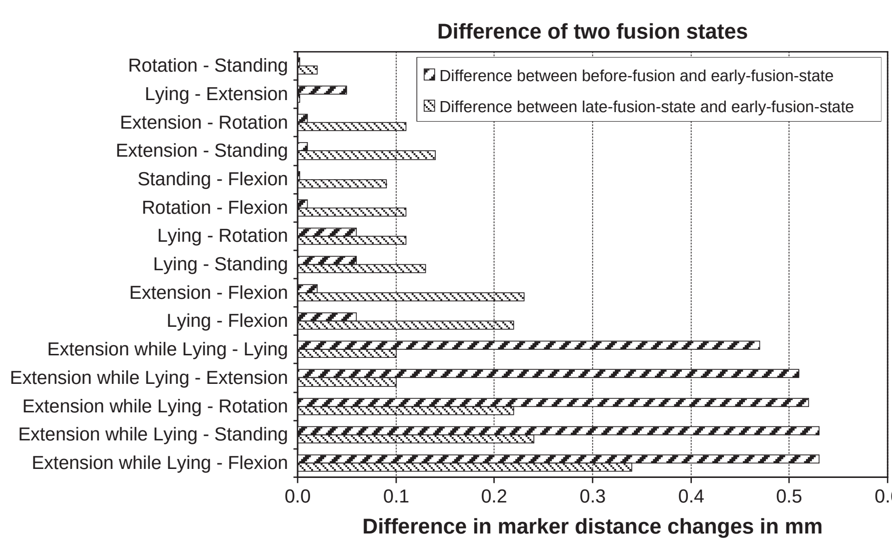

Fig. 6. Differences of marker distance changes between postures and two fusion states.

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The positions of the tantalum markers are well-determined in a simulation but may be difficult to determine in the X-rays due to the pedicle screws and the cages. They should therefore be placed as anteriorly as possible and in a different plane than the pedicle screws.

For the situations after surgery, the largest motion occurred in the most anterior markers. This is due to the posterior implant which shifts the centre of rotation towards its longitudinal rod. The most anterior markers have the largest distance of the centre of rotation and thus experience the largest motion.

In a numerical parameter study, the motion of single points can be determined very precisely. The uncertainty of marker motion is higher using RSA. Typically, RSA takes multiple markers into consideration in order to reduce inaccuracies and computes the transformation matrix to determine bone segment motion (Valstar et al., 2002).

The calculated ROM in the treated segment for the early-fusion-phase and the late-fusion-phase were always much lower (<1.5°) than the threshold value for fusion (5°) recommend by the FDA. The precision in determining the ROM is much higher using RSA than plain X-rays (Glyn-Jones et al., 2004). Thus, for RSA a new threshold value for ROM should be agreed on. Clinical studies using RSA are required to determine this value; the present study may just provide a theoretical optimal value.

In an upright body position, the intervertebral discs are compressed. During extension, this compression must first be compensated before a distraction occurs. This is the reason, why the marker motion differences between standing and extension are very small. In a lying position, however, the compression of the intervertebral discs is low. Consequently, only this small compression must first be compensated during extension-while-lying. This explains why large differences in marker motion are calculated between a lying and a standing posture.

The difference between the two situations before-fusion and after-fusion is that the bone graft is connected to the vertebrae after fusion. Therefore, a distractive load would cause a gap between the vertebra and the bone graft, if fusion didn't occur. Taking the posterior instrumentation into consideration which shifts the centre of rotation posteriorly, an extension in a lying position would cause a distraction in the segment. All other investigated loading cases cause a compression in the segment.

Effective fusion can be verified radiologically in many cases, however, it is sometimes critical. These critical cases are usually not known in advance. In a clinical study, markers could be inserted during surgery and RSA could be performed in all cases which are doubtful concerning fusion. In the future it will be possible to send the RSA images to an institute where the measurements of the marker motions will be performed automatically. The probability of fusion for this specific case will then be sent back.

5. Conclusions

In conclusion, discrimination between monosegmental fusion and non-fusion as well as the fusion state is best assessed using RSA in the positions flexion of the upper body while standing and extension-while-lying. If the difference of the distance of the most anterior markers in adjacent vertebrae for these two postures is above a threshold value, fusion has most probably not yet occurred.

Conflict of interest

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