Biomechanical Model for Testing Cage Subsidence in the Osteoporotic Spine Under Permanent Maximum Load

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Abstract

Background

Fusions in cases of reduced bone density are a tough challenge. As not only does bone quality have an influence on force transmission, these forces must be bridged for much longer time, as a fusion takes longer than in bone-healthy patients. However, cage subsidence or displacement results to loss of reposition and pain. From a biomechanical point of view, the majority of current studies have focussed on the range of motion or have shown test setups for single component tests. Definite setups for biomechanical testing of the primary stability of a 360° fusion using a screw rod system and cage on the osteoporotic spine are missing. The aim of this study is to develop a test stand to provide information about the bone-implant interface under reproducible conditions.

Methods

After pre-testing with artificial bone, human functional spine units were tested with 360° fusion in TLIF technique. The movement sequences was conducted in flexion, extension, right-left lateral bending and right-left axial rotation on an osteoporotic human model.

Results

During the testings of human cadavers, 4 vertebrae were fully tested and were inconspicuous even after radiological and macroscopic examination. 1 vertebra showed a subsidence of 2mm and 1 vertebra had a cage collapsed into the vertebra.

Conclusions

This setup is suitable for biomechanical testing of cyclical continuous loads on the osteoporotic spine. The embedding method is stable and ensures a purely monosegmental setup. The optical monitoring provides a very accurate indication of cage movement, which correlates with the macroscopic and radiological results.

Background

Increased life expectancy [1] and the associated demographic change in our society correlate with an increase in age-related diseases of the spinal column. In addition to constrictions of the spinal structures in the affected segment, the degenerative changes also cause instabilities and deformities in the coronary and sagittal plane. Depending on the severity of these diseases, they can lead to massive limitations in the quality of life for patients [2, 3]. For instabilities or deformities requiring surgery, lumbar intersomatic fusion has established itself as a stabilizing procedure over the last three decades.

Due to the high primary stability and fusion rates of over 90%, the use of interbody implants (cages) is a standard procedure in addition to posterior stabilization [4]. The additive stabilization offers high primary stability in the segment. However, it is possible to correct the deformities and to interlock the inserted cage by intersomatic compression via the pedicel-screw-rod system. It is not yet clarified how much preload is applied to the segment and to what extent this promotes cage subsidence. In review of the literature there are only a few publication focusing on intersomatic fusion techniques in patients with reduced bone density. Additionally, it has been described that an increased subsidence rate of the cages occurs in patients with low bone density [5].

Previous studies provide only limited information on cyclical primary stability. Most early studies, as well as current work, focus on measurements of the range of motion (ROM) of the spinal column being treated [6, 7]. Other studies focus on the component and material testing. Moreover, cages in testing setups are statically and dynamically loaded with pressure, shear and torsion until failure, independent of the motion segment [8, 9]. Some studies apply the bending moment using a lever arm and an axial testing machine [10]. In cyclical testing, sometimes only one direction of movement is tested [11, 12] usually craniocaudal. Another limitation of previous studies is the fixation of the vertebral bodies in a monosegmental structure. Screws [13, 14] or additional vertebral segments [15] are often used for embedding. The use of anchor bolts reveals an increased risk of possible damage the vertebral body integrity while embedding a complete vertebra could lead to increased mobility.

For these reasons, it is not possible to carry out cyclical, biomechanical testing of the primary stability of a 360° fusion using a screw rod system and cage in various directions of movement on the osteoporotic spine with established test setups. The purpose of this study was to develop and evaluate a test setup to carry out tests that provide information about the bone-implant interface under reproducible conditions. In particular, it should be possible to examine the subsidence behaviour of the cage and the movement of the screws relative to the vertebral body.

Methods

Ethics declarations

While alive all body donors gave their informed and written consent to the donation of their bodies for teaching and research purposes. Being part of the body donor program regulated by the Saxonian Death and Funeral Act of 1994 (third section, paragraph 18 item 8), institutional approval for the use of the post-mortem tissues of human body donors was obtained from the Institute of Anatomy, University of Leipzig. The authors declare that all experiments were conducted according to the principles of the Declaration of Helsinki.

Specimens

To evaluate the method for embedding the vertebral bodies, preliminary tests had to be carried out, as it was not clear whether the planned embedding would be sufficient without additional screws in the respective vertebral bodies. For this purpose, 3D-printed artificial vertebrae made of PLA were produced from CT scans.

For the main experiments, the TH12/L1 segment was taken from six cadavers aged 65-90 years (median: 75) and freshly frozen (-80°C). The mean bone density value (BMD) was 0.862±0.130 g/cm2.

Two artificial bone spinal columns (Sawbones, Pacific Research Laboratories, Vashon, WA, USA) were used for preliminary tests of the test set-up. These were supplied with a screw rod system in Cortical Bone Trajectory (CBT) technology using the freehand technique. The first test unit received a Banana PEEK Cage (DePuy Spine Inc, Raynham, MA, USA) and the second received an Oblique PEEK Cage (TiPEEK, Medacta, Castel San Pietro Switzerland).

Implantation

First, the soft tissue dissection was carefully performed at the human specimens. Afterwards, they were instrumented with a screw-rod system.

To ensure that the treatments can be reproduced for later comparative tests, the preload on the cage was set in a standardised way by a system developed in-house. In this system, the vertebral bodies are clamped between two plates and a defined preload force of 70 N is applied by a thread guide (Figure 1).

The pretension is measured by a force sensor (PCE-FM 1000, PCE Deutschland GmbH, Meschede, Germany). The rods are then locked in the screw heads according to the manufacturer's instructions. This procedure creates a defined initial situation of cage locking.

Embedding

For the preliminary tests, 3D-printed artificial bones were embedded in plaster (Boesner, Witten, Germany) with different configurations with and without additional fixation screws in the upper and lower vertebral plate as well as deep and flat (see Figure 2) according to our planned embedding technique. The different configurations of the embedding were investigated for the upper and lower surface of the vertebra.

Afterwards, the vertebral bodies were axially pulled out of the embedding by a testing machine (ZwickRoell, Ulm, Germany).

Alignment

The embedding in the embedding tubs of the sawbones and human specimens follows a defined protocol. Templates and markers were developed for this purpose, which ensures the exact alignment of the instrumented vertebral bodies (Figure 3).

For dorsal flat embedding of the vertebrae, an inclined plane is placed under the embedding tub. This compensates the cut-off plane of the embedding tub and thus ensures that the embedding is parallel to the table. The vertebrae are fixed to the spinous process by a multi-jointed stand. The vertebra is aligned using an embedding stencil and two thin Kirschner wires. One Kirschner wire is inserted translaterally and one with an angular offset of 90° to dorsal. This creates the plane in which the transverse plane of the cage should be located. The holder is then aligned so that the translateral wire is positioned on the pedicle and the ventral wire is positioned centrally between the two vertebral surfaces. Then, the embedding is carried out in the lower embedding tub with a resin-hardener mixture (Rencast FC52/53, Huntsman, Texas, USA).

For the embedding of the upper segment and to ensure the plane-parallelism of the embedding tubs to each other, the upper embedding tub must be suspended with the same slope angle as the inclined plane. Besides, a marking on the embedding tubs ensures that there is no rotation offset around the cylinder axis. The vortex is now aligned using the positioning template and is also embedded. After curing, it is installed in the test rig.

Test setup

The test set-up was designed in close accordance with the Wilke guidelines [16] for the biomechanical testing of spinal implants. It consists of a frame which is firmly anchored in the machine bed of the servo pneumatic testing

machine (DYNA-MESS Prüfsysteme GmbH, Stolberg, Germany). A servo motor with a transmission gear is attached to this frame. This generates the swivel movement of the construction. The motor is torque-controlled and can perform moves cyclically with predefined moments. The angles of the swivel movement are also detected. The construction allows a movement in a flexion-extension direction as well as a lateral bending of the segment by conversion and 90° rotation. To obtain information about the forces acting on the composite, a 6-DOF force sensor (ME-Meßsysteme GmbH, Hennigsdorf, Germany) is installed on the lower embedding (Figure 4).

The control and evaluation are achieved by a self-developed programme.

The embedded vertebral body implant composite was clamped into the test set-up for the examination of cage variants on an artificial bone. A template was used to ensure that the axis of rotation has a reproducible position. During the extension-flexion tests, the rotation axis of the motor should be in the posterior 2/3 area of the vertebral bodies [17]. During rotation for lateral flexion, the axis should be centrally in the vertebral body in the sagittal plane [18]. To ensure the position of the rotation axis, a pointer is used to extend the shaft close to the vertebrae. The pointer is placed on the steel shaft and is guided around the side plate of the swingarm. A telescopic mechanism is installed to guide the pointer close to the vertebrae. For correct positioning of the cage, a rod with an optical measuring cube is screwed firmly into the screw guide of the cage. Further optical markers are attached to the pedicle screw heads and the embedding tubs, as well as to the spinous processes of the vertebrae. After the vertebral bodies have been aligned for the planned direction of movement, the testing starts.

Test execution

For the tests, a compression force of 500 N was applied by the servo pneumatic testing machine. The swivel movement is moment controlled between 7.5 Nm and -7.5 Nm and a frequency of 1Hz. Each vertebral body was loaded with 10,000 cycles each for the two directions of movement. The movements were measured at defined points in time using optical image correlation (Limess Meßtechnik und Software GmbH, Krefeld, Germany; ISTRA 4D Dantec Dynamics A/S, Skovlunde, Denmark). The termination criterion of the fatigue strength test was the exceeding of the ROM of ±10° in one of the three directions of movement.

Evaluation

The data preparation was done by a self-written Matlab routine (MATLAB 2019b, The MathWorks, Natick, MA, USA). The data was evaluated using Excel (Excel 2013, Microsoft Corporation, WA, USA).

Results

Embedding

Pull-out tests of 3D-printed artificial vertebrae in plaster showed greater pull-out forces when using anchor bolts with at least 1676 N. However, pull-out forces of at least 110 N could also be achieved if anchor bolts were not used (see Figure 2).

Relative movement of the artificial bone to the embedding material

The relative movement between bone and embedding material was 0.5507 ± 0.0012 mm on average in the upper segment. In the lower segment, there was less relative movement between bone and embedding material. This amounts to 0.0052 mm ± 0.0005 mm on average.

Relative movement of the human specimens to the embedding tub

The measurements with donor preparations showed comparable behaviour. The upper vertebral body moved relative to the embedding tub in a range from 0.1636±0.0299 mm at the beginning of the measurement to 0.3852±0.0054 mm after 10,000 cycles of extension/flexion. In the lower segment, the range was from 0.0061±0.0075 mm to 0.0155±0.0136 mm.

Main experiments

During the testing of human cadavers, 4 of the 6 tested specimens could be fully tested. One sample showed a fracture of the vertebral body after extension/flexion loading. In two specimens, the ROM increased by more than 10° during lateral flexion, which is why the test was stopped.

Stiffness reduction of the specimens

Due to the applied load and the resulting movements, the stiffness of the preparations decreased during the experiment. This increased the ROM as illustrated by the curves of a KS02 specimen in figure 5.

The average increase in ROM of all successfully tested specimens after 5000 cycles of extension and flexion is 45% ± 20% and after 10000 cycles 68% ± 24%. Similar behaviour is observed for the subsequent lateral bending. In this case the ROM magnification is 98% ± 49% after 5000 cycles and 164% ± 49% after 10000 cycles. In the case of torsion, the ROM increased by 17% ± 9% after 5000 cycles and by 20% ± 10% after 10000 cycles.

Loosening of the pedicle screws

The specimens without excessive ROM magnification showed an even loosening of the upper and lower screws. Depending on the specimen, either the lower screws or the upper screws showed a greater relative movement in the bone than the screws in the other vertebra. The relative loosening rate of the upper screw in the case of extension-flexion movement is 52% ±10% and of the lower screw 56% ±24%. During subsequent lateral bending, the loosening rate was increased to an average of 96% ±41% for the upper screws and 173% ±158% for the lower screws. When the segment failed, the loosening was extremely either on the cranial screws or the caudal screws, but never equally on both screws. After rotation, loosening was 18% ± 19% for the caudal screws and 16% ± 27% for the cranial screws.

Displacement of the Cage

During the measurements, the relative movement between the cranial vertebra and the cage, at an average of 0.50 ± 0.43 mm, was much less than the movement of the cage to the caudal vertebra at 1.41 ± 1.55 mm. A diagram of the typical cage movement is shown in figure 6.

Average decrease of the Z-force

As the testing proceeds, there was an approximately logarithmic decrease in Fz force. This amounts to an average decrease of 50 ± 11 % (248 ± 54 N).

During the subsequent radiological inspection, one segment showed a collapse of the cage into the base plate. In another sample, subsidence of the cage of approximately 2 mm into the surface of the vertebral body was detected (see Figure 7).

The follow-up examinations of the disassembled preparations confirmed the results of the radiological analysis.

Discussion

We developed a test setup for biomechanical testing of primary stability in 360° instrumented vertebral body segments in accordance to the principles of Wilke et al. (1998). It allows examining the bone-implant-interface during a sequential permanent load of extension/flexion, lateral bending as well as axial rotation. After pre-testing on artificial bone, the main experiments were carried out on 6 osteoporotic vertebral segments. 4 of these successfully passed all testing setups.

The stable embedding of only half of a vertebra is achieved by a deeper ventral and a flatter dorsal embedding. This allows good visual access to the dorsal vertebral region and the inserted implants (cage and internal fixator) (see figure 4) while minimising the demands on human cadavers.

Due to the direct embedding of the tested segments, only two vertebral bodies are required per test. As the aim of this test method is to carry out fatigue strength tests, this modification was chosen to exclude the influence of other vertebrae. In their publication on test criteria for spinal implants, Wilke et al. (1998) planned to use an additional segment cranially and caudally. These test criteria are mainly developed for ROM measurements. By using this embedding method with only 2 vertebrae, it is possible to test three different heights (TH12/L1, L2/L3, L4/L5) per donor preparation, which would not be possible with other test setups [19, 20] or without possibly weakening the integrity of the vertebrae by inserting anchor screws [21]. The well-defined embedding procedure with the developed embedding guides ensures an exact alignment of the specimens. In combination with the standardisation of the cage clamping force, we could guarantee an exact reproducibility and comparability of the tests.

The preliminary tests with plaster showed that a sufficiently positive connection can be established between the embedding material and the vertebrae (see figure 2). These results were confirmed by the subsequent human preparation tests using a suitable casting resin [22, 23]. Even after the load of 10,000 cycles in extension/flexion, lateral bending and axial rotation, no loosening of the preparations in the embedding occurred. Therefore, the deviation from the test criteria according to Wilke et. al. [16] is permissible for us.

The measured relative movements between bone and embedding mass are the results of deformations of the vertebra due to the forces and moments introduced [24]. In this case, the displacement of the lower spinous process (measuring point of the lower vertebra) is smaller than that of the upper one, as this was also be partially embedded. Asymmetry along the transverse plane of the vertebrae prevents the spinous process of the cranial vertebra from being embedded. This has only a minor influence on biomechanical testing.

With the applied load of 7.5 Nm in each direction of movement and the superimposed compression force of 500 N, a loosening of the pedicle screws was achieved for all preparations. Furthermore, it was possible to measure the relative movement between bone and cage - see figure 4. As shown in figure 5, the effect of the cage subsidence into the surface of the vertebra as well as the collapse could be shown. Compared to the data from a study by Rohlmann et al. [25] the initiated moments we chose to represent a permanent maximum load and would be over-dimensioned for a real physiological endurance test [26]. The loads were chosen to ensure comparability with FE-based tests [27] and to test the performance of the test rig. or future testing, the reduction or adaptation of the load to the donor's body weight, as carried out in other studies [28, 29], is reasonable and would thus correspond more closely to the real loads on osteoporotic bones.

If the criterion for stopping the measurement with a ROM magnification of ±10° is exceeded, further biomechanical testing is not advisable for these specimens, as this must be evaluated as a failure of the implant system and as non-physiological ROM [30].

Since the compression force in the Z-direction was realised by a compression position set at the beginning of the test and was not permanently controlled, it also decreased during the test due to the decrease in stiffness of the specimen. Thus, an adaptation to the total body weight is recommended. Also, the compression force should be controlled during the entire process of the test.

The resulting loosening of the screws corresponds essentially to the behaviour already described in other biomechanical cyclic tests [11, 12]. While pullout-tests to investigate screw stability simulate a simple load case and can be carried out with relatively simple test setups. In contrast, this load is not in a physiological range of motion. Cranio-caudal-cyclical loads on the screw head correspond more to the real load occurring in humans [31]. However, these were usually carried out using one or two screws in artificial vertebrae or PE material [32, 33]. By using 4 screws in the screw-rod system in combination with a cage between the human vertebrae, the level of abstraction in biomechanical testing is further reduced and corresponds even more to the clinical circumstances in vivo.

The clinical evidence of cage subsidence or collapsing into the vertebral surfaces could correlate with the micro-movements between the cage and cortical bone. With the measurement method carried out, we were able to optically measure the movement between cage and bone during biomechanical permanent loading. Similar biomechanical tests determined the subsidence over the total height loss of the segment and without dorsal stabilisation [34]. The total height difference of the segment was postulated as subsidence. However, this could also be caused by deformations of soft tissue and/or bone in places other than the cage-bone interface. By directly measuring the relative movement between bone and cage, phenomena of subsidence can be measured more precisely and directly.

In the context of the macroscopic follow-up inspection, clear imprints of the cages on the vertebral body surfaces could be detected in some cases. These were found particularly caudally or cranially in the dorsal area of the cover plates. Because of the small number of test experiments, we were not able to make a reliable prediction of the

correlation between cage-bone movement and the presence of the imprints. However, it appears that the imprints are particularly clear on the vertebra, to which the relative movement was also particularly large.

Although the basic functionality of the test set-up could be confirmed by the preliminary tests, there is still potential for improvement. The physiological movement initiation on the lumbar vertebrae is cranial and is also implemented in this way by other test set-ups [35, 36]. In contrast to this, the current test stand concept is based on the swivel movement for flexion/extension and lateral bending initiated from caudal. However, this could be solved by installing the specimen rotated by 180°. Furthermore, it is not possible in this setup to introduce pure moments into the specimens. Up to now, this has been prevented by the fixed mounting of the upper embedding tub. By using an XY table, two degrees of freedom could be released, so that shearing forces would be reduced. In the pre-tests, these occurred due to asymmetrical stiffness of the specimens and the application of the Fz force. In the future, the test bench will be used for the examinations of spine segments with different configurations of screws and cages. The focus will be on fatigue strength tests with defined load direction.

Conclusion

With our experiments, we were able to show the functionality of the test setup and its advantages and disadvantages. This setup can be used for biomechanical analyses of primary stability in a 360° fusion using a screw rod system and cage in different directions of movement under cyclical permanent maximum load and also by adapting the parameters with realistic load scenarios. Effects of subsidence can be detected by optical imaging and correlated with the radiological and macroscopic examinations.

Abbreviations

FE: Flexion and Extension

LB: lateral bending

AR: axial rotation

TLIF: Transforaminal lumbar interbody fusion

CT: computed tomography

TH: thoracic

L: lumbar

PEEK: Polyether ether ketone

Declarations

Availability of data and materials

The datasets used and analysed during the current study are available from the corresponding author on reasonable request and were stored at the repository of the University Hospital Leipzig.

Ethics declarations

Ethics approval and consent to participate

While alive all body donors gave their informed and written consent to the donation of their bodies for teaching and research purposes. Being part of the body donor program regulated by the Saxonian Death and Funeral Act of 1994 (third section, paragraph 18 item 8), institutional approval for the use of the post-mortem tissues of human body donors was obtained from the Institute of Anatomy, University of Leipzig. The authors declare that all experiments were conducted according to the principles of the Declaration of Helsinki. Because of this we do not need an ethics approval.

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Competing interests

The author P Pieroh is member of the Editorial Board of the journal BMC Musculosceletal Disorders.

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All other authors declare that they have no competing interests.

Consent for publication

All authors consent to a publication in BMC Musculoskeletal Disorders as submitted here.

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Figures

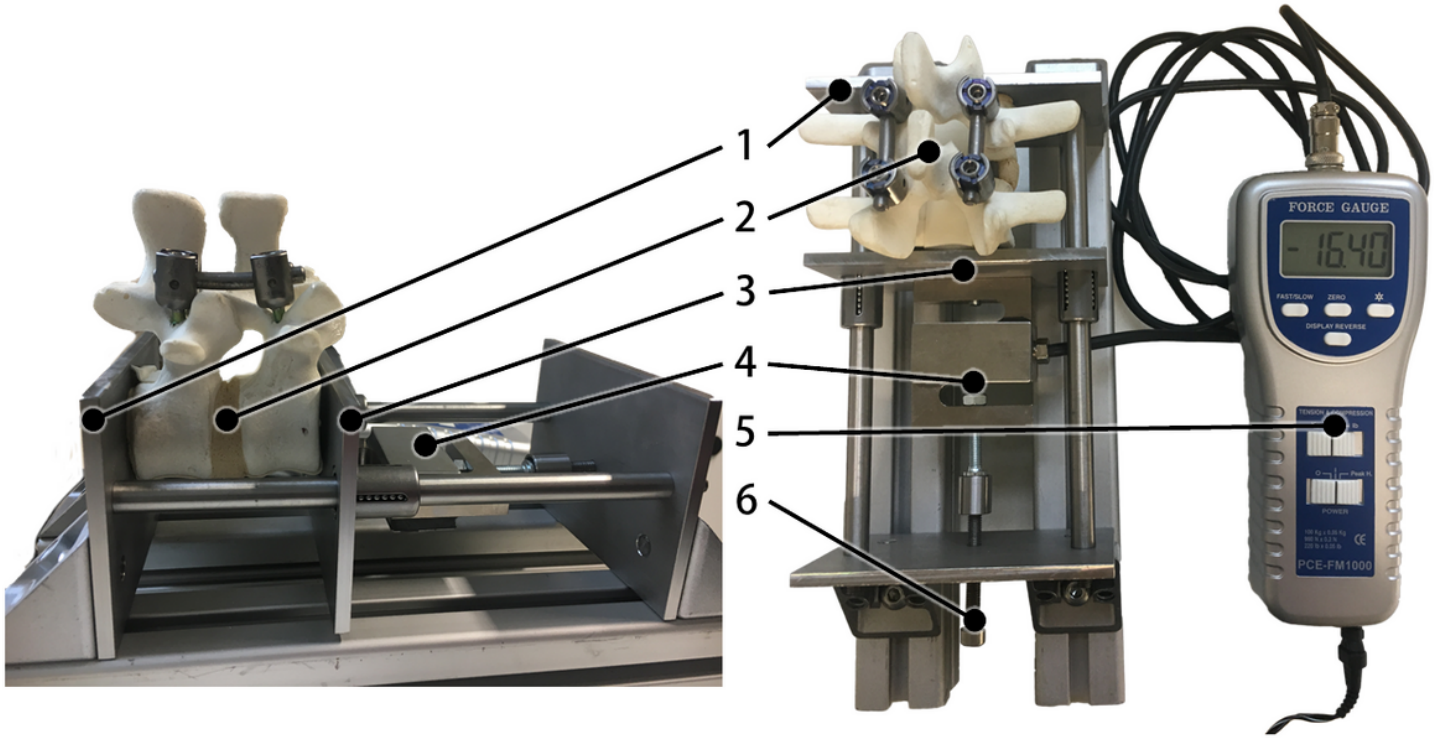

Figure 1

Setup for adjusting the cage compression force 1: Fixed clamping plate, 2: Vertebral segment, 3: adjustable clamping plate, 4: force sensor, 5: Measuring device, 6: Adjusting screw

configuration			pullout force
cranial	with anchor screws	low (L)	2100 N
		high (H)	2062 N
	without anchor screws	low (L)	239 N
		high (H)	110 N
caudal	with anchor screws	low (L)	2070 N
		high (H)	1676 N
	without anchor screws	low (L)	1961 N
		high (H)	720 N

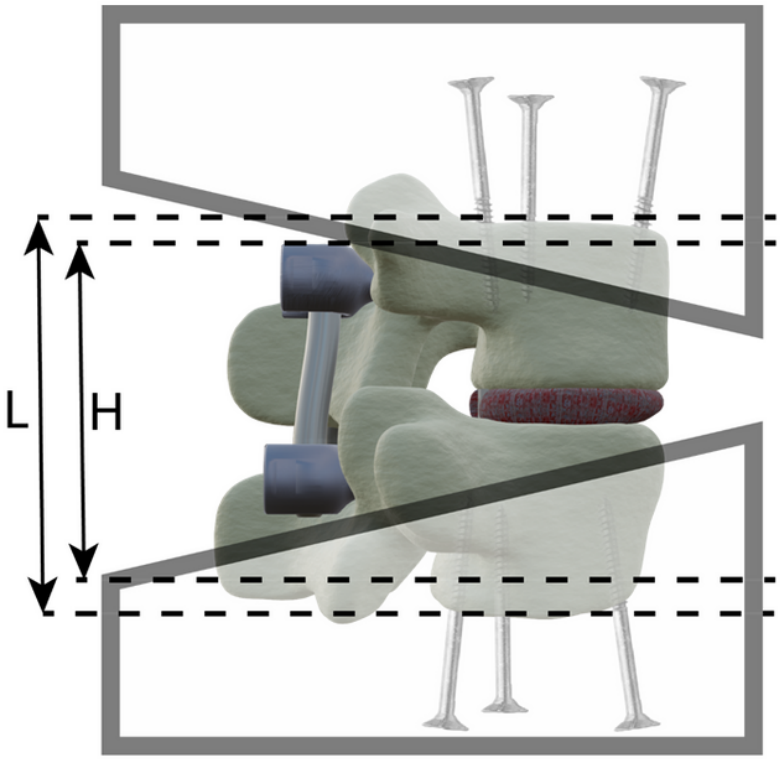

Figure 2

Configurations of the embedding pull-out tests and their achieved pull-out forces

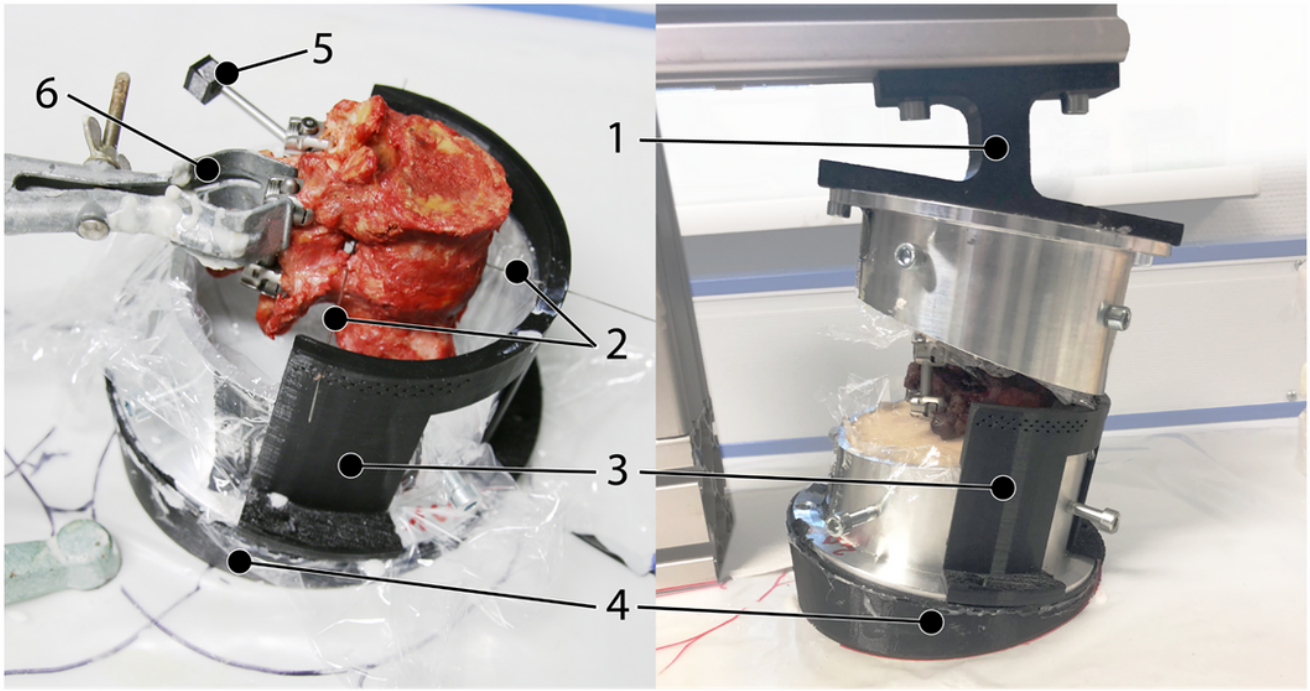

Figure 3

Embedding of the spinal segments 1: Angle bracket, 2: Kirschner wire, 3: Embedding stencil, 4: inclined plane, 5: Cage markers for the digital image correlation system, 6: multi-jointed stand bracket

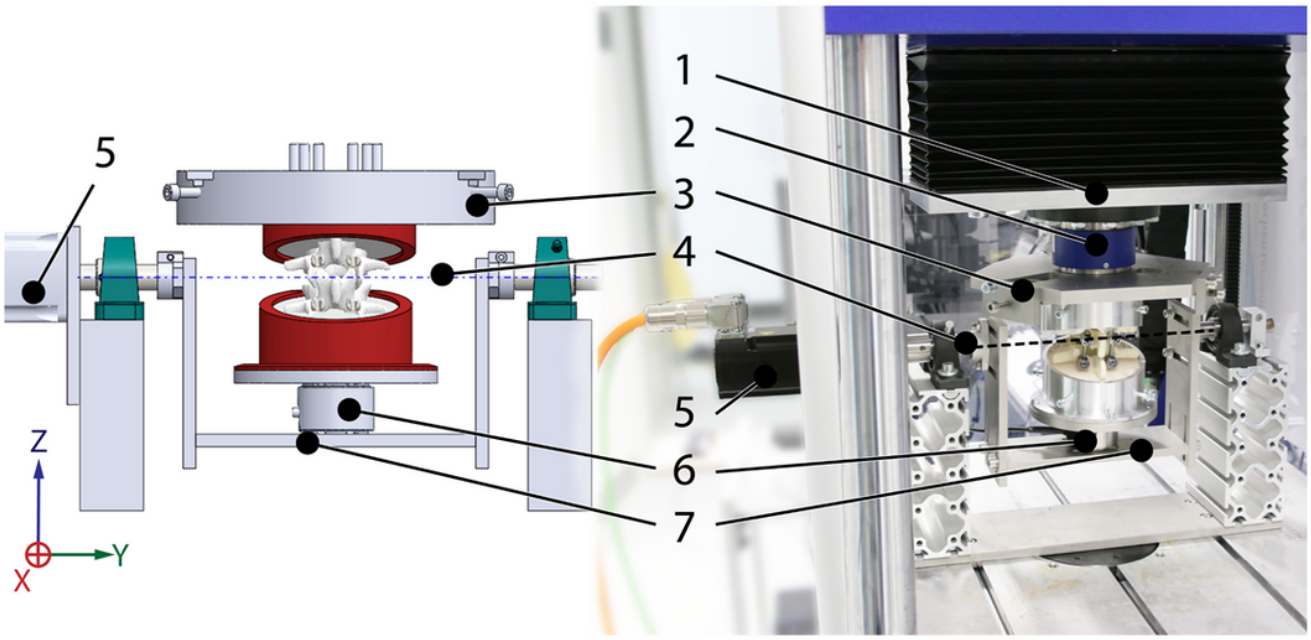

Figure 4

Test setup 1: Pneumatic cylinders for the Fz force, 2: Force sensor for the Fz force, 3: cranial clamping plate, 4: pivot axis, 5: servo motor with planetary gear, 6: 6-DOF force sensor, 7: swing arm

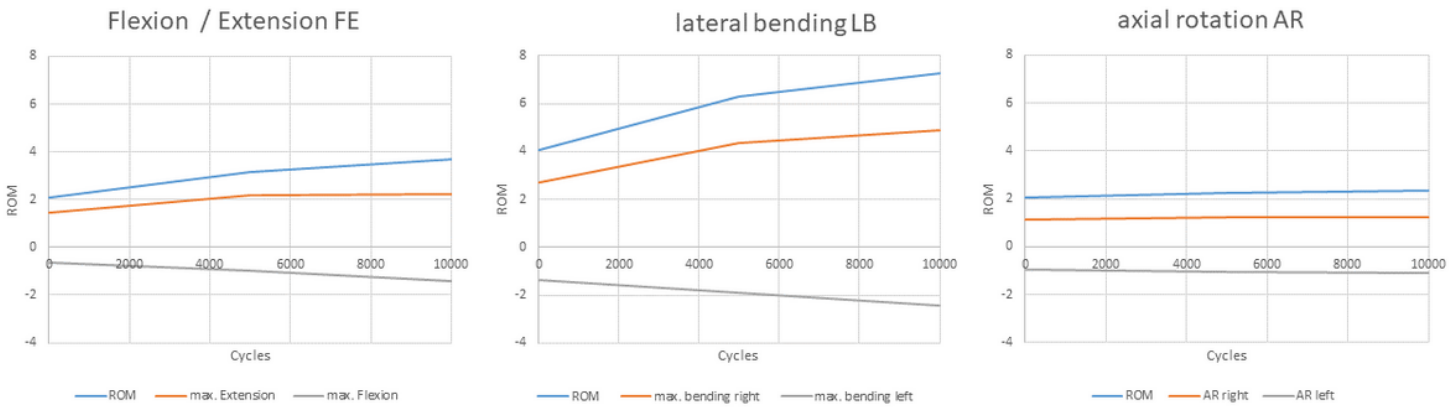

Figure 5

Exemplary representation of the Range of Motion (ROM) for a functional spinal unit at different cycles in the fatigue strength test for left: Flexion and Extension (FB), middle: lateral bending(LB) (middle) and right: axial rotation (AR).

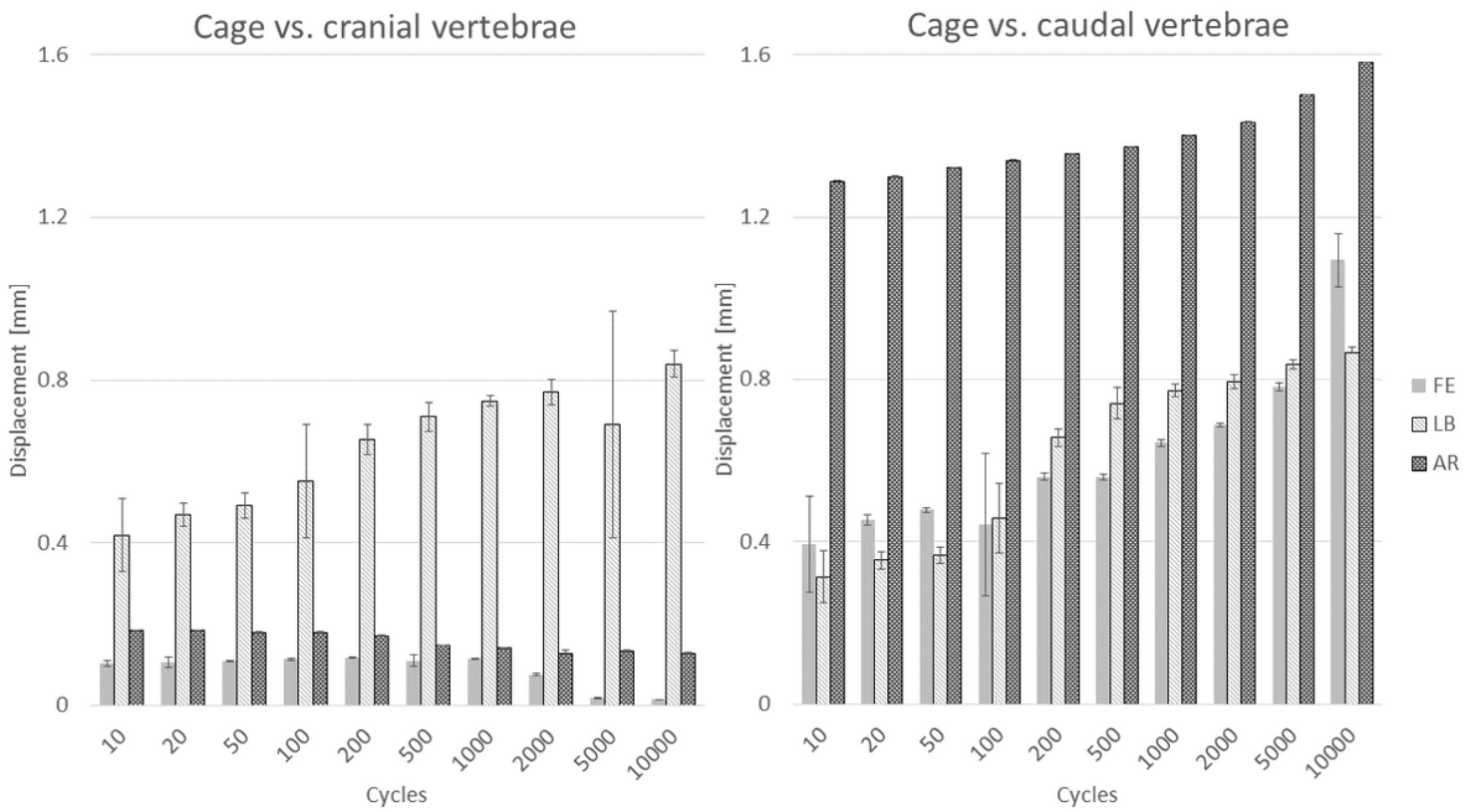

Figure 6

Exemplary relative movements of a cage to the cranial vertebra (left) and the caudal vertebra (right) for different cycles in the fatigue strength test. Abbreviations: Flexion and Extension (FB); lateral bending(LB); axial rotation (AR).

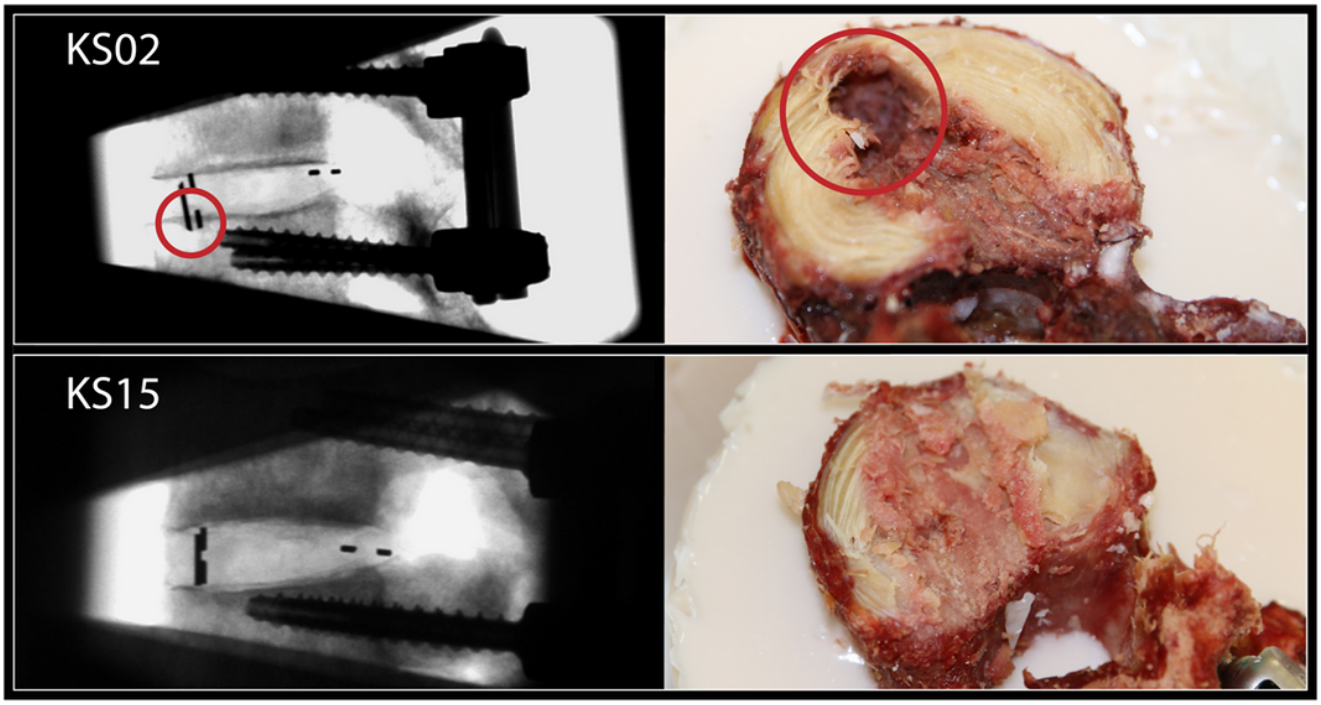

Figure 7

Comparison of a spinal segment with subsidence (above) and without subsidence (below) in radiological (left) and macroscopic (right) follow-up examination.