

Insufficient stability of pedicle screws in osteoporotic vertebrae: biomechanical correlation of bone mineral density and pedicle screw fixation strength

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Abstract

Purpose Loosening of pedicle screws is one major complication of posterior spinal stabilisation, especially in the patients with osteoporosis. Augmentation of pedicle screws with cement or lengthening of the instrumentation is widely used to improve implant stability in these patients. However, it is still unclear from which value of bone mineral density (BMD) the stability of pedicle screws is insufficient and an additional stabilisation should be performed. The aim of this study was to investigate the correlation of bone mineral density and pedicle screw fatigue strength as well as to define a threshold value for BMD below which an additional stabilisation is recommended.

Methods Twenty-one human T12 vertebral bodies were collected from donors between 19 and 96 years of age and the BMD was measured using quantitative computed tomography. Each vertebral body was instrumented with one pedicle screw and mounted in a servo-hydraulic testing machine. Fatigue testing was performed by implementing a cranio-caudal sinusoidal, cyclic (0.5 Hz) load with step-wise increasing peak force.

Results A significant correlation between BMD and cycles to failure ($r = 0.862$, $r^2 = 0.743$, $p < 0.001$) as well as for the linearly related fatigue load was found. Specimens with BMD

below 80 mg/cm^3 only reached 45% of the cycles to failure and only 60% of the fatigue load compared to the specimens with adequate bone quality ($\text{BMD} > 120 \text{ mg/cm}^3$).

Conclusions There is a close correlation between BMD and pedicle screw stability. If the BMD of the thoracolumbar spine is less than 80 mg/cm^3 , stability of pedicle screws might be insufficient and an additional stabilisation should be considered.

Keywords Pedicle screw · Spine · Bone mineral density · BMD · Osteoporosis

Introduction

Vertebral fractures represent one of the most common manifestations of osteoporosis [1]. In cases of secondary kyphosis or unstable fractures as well as during deformity and tumour surgery, a posterior stabilisation is often necessary. In this regard, pedicle screw fixation is considered the gold standard [2–4]. However, loosening at the bone-screw interface is a common complication [5–7].

Several factors have been reported related to screw loosening. Stress shielding might lead to a remodelling of the bone surrounding the screw following lesser fixation [5]. Furthermore, wear debris, infections, and local high strains due to inadequate anterior support have been reported as risk factors for screw loosening [5, 8, 9]. A high incidence of loosening is reported for the elderly population [5, 10]. In this regard, osteoporosis is mentioned as a major risk factor [6, 10, 11], as the incidence of loosening ranges up to 60% in osteoporotic patients [12].

There are several biomechanical studies showing significantly reduced pull-out strength of pedicle screws in osteoporotic vertebrae [2, 6, 11, 13, 14]. However, the

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clinical significance of this testing method has been questioned, since withdrawing of the screws posteriorly through the pedicle has rarely been reported as a mechanism of failure in clinical reports [15–18]. Furthermore, there is rare evidence regarding a threshold of bone mineral density (BMD) which has to be assessed as being insufficient for stable screw fixation and an additional stabilisation, such as lengthening of the instrumentation or cement augmentation, should be performed. Only two studies focussed on this topic and showed that loosening might be expected at BMD measured less than 90 mg/cm^3 [19] and that vertebrae with an average BMD of $95 \pm 33.3 \text{ mg/cm}^3$ (QCT) could not be stabilised anatomically by pedicle screws [20].

The goals of this biomechanical cadaver study were to evaluate the correlation of bone mineral density and pedicle screw strength using a fatigue test, to try to simulate *in vivo* loading conditions. Fatigue failure of the bone is believed to be more clinically relevant compared with failure due to pull-out [15, 16, 18]. Based on this, a threshold of BMD was defined from which the stability of pedicle screws is insufficient and an additional stabilisation procedure should be recommended.

Methods

We hypothesized that there is a clear correlation between BMD and pedicle screw showing a threshold of BMD from which stability of pedicle screws is insufficient. A total of 21 (eleven female, ten male) cadaveric specimens of human T12 vertebral bodies were collected from donors between 19 and 96 years of age (mean 69 years, SD 19 years). After harvesting, the specimens were sealed in plastic bags and stored at -20°C .

Each specimen was scanned using a 16-row CT-scanner (Brilliance 16 CT; Philips Healthcare, Hamburg, Germany) with a solid calibration phantom (Bone Density Calibration Phantom; QRM, Moehrendorf, Germany) to screen for prior fractures, to measure the pedicle width, and to determine apparent volumetric trabecular bone mineral density (BMD). The BMD was determined by linearly converting the Hounsfield unit value from a defined voxel cube from the center of each T12 vertebral body to the phantom's reference densities (Avizo 5.1, VSG Inc., Burlington, Massachusetts, USA).

After defrosting of the specimens the night before testing, the T12 vertebral bodies were separated from the thoracolumbar spine. Specimens were sprayed with Ringer solution throughout preparation and wrapped in moist tissue prior to testing to preserve tissue constitution. Each T12 vertebral body was instrumented using commercially available $5.5 \times 45 \text{ mm}$ self-tapping, monoaxial screws (XIA3, Stryker Inc., Kalamazoo, MI, USA). Screws were inserted parallel to the vertebral end plate into one pedicle under

fluoroscopic guidance. The implantation was performed alternately in the left and the right pedicle while the remaining other pedicle was not instrumented and not used for further investigation. The specimens were then embedded in a custom-made fixture using a polyurethane resin (Ureol FC53, Gößl & Paff, Karlskron, Germany). Orientation of the vertebral body was parallel to the base plate. The fixture was constructed in such way that the specimens were fixed to the posterior border of the vertebral body, but the pedicle remained completely free (Fig. 1).

Mechanical setup

The specimens were mounted on an x - y table in a servo-hydraulic testing machine (MTS 858.2, MTS Systems, Eden Prairie, USA). A 6-mm rod (XIA titanium, Stryker Inc., Kalamazoo, MI, USA) was fixed to the screws using blockers (XIA Blockers, Stryker Inc., Kalamazoo, MI, USA) and linked to a custom-made connector of 8.3 cm superior to the screw. This distance corresponds approximately to the bridged distance of a fractured vertebra. A laterally orientated rotational joint in the connector allowed bending of the rod. Since the joint was positioned above the posterior border of the vertebral body, the axial actuator load from superior acted as a moment on the head of the screw (Fig. 1)—superpositioned by the axial loading. The loading of this experimental setup was similar to the loading in the ASTM F1717 norm.

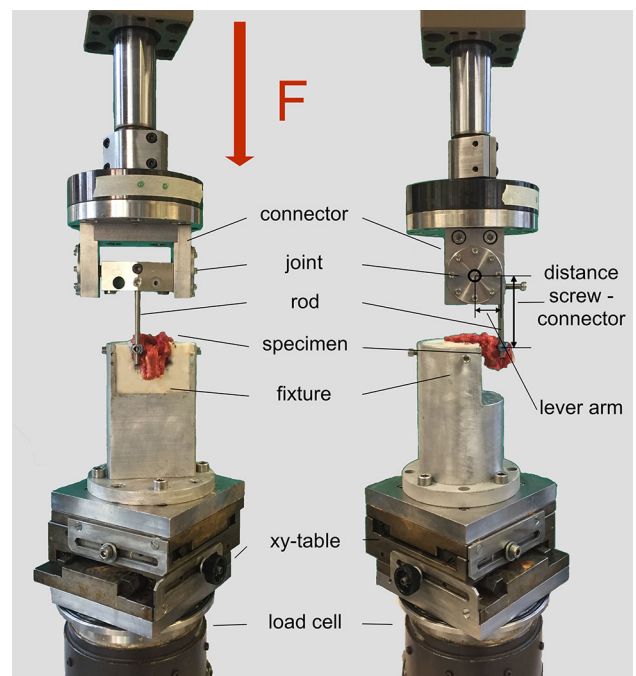


Fig. 1 Schematic diagram showing the test setup in the servo-hydraulic testing machine. The orientation of the rotational joint right above the posterior vertebral wall is visual

Fatigue testing was performed by implementing a sinusoidal, cyclic (0.5 Hz) force. For the initial cycle the axial load ranged from 50 to 100 N, which represents the load range during physiological walking [21]. The maximum compressive force was increased stepwise by 0.05 N every cycle to accelerate failure by reducing the effects of specimen degradation (Locati test design) [18]. Testing was stopped when the caudal displacement of the connector at the testing machine exceeded 15 mm.

Output parameters

The number of cycles and the linearly related maximum force (failure load) until the end of the test were recorded. Stiffness values were determined from a linear regression slope to the load displacement curves and were measured after ten cycles of setting as well as ten cycles before failure. After the mechanical testing, the specimens were manually screened for macroscopic loosening of the pedicle screws. Loosening was assumed if significant expansion of the entry point of the screw was observed and in case of a significant movement of the screw in the vertebral body. Furthermore, additional CT scans were made to evaluate loosening. The removal torque of each screw was measured (Torsiometer 760, Stahlwille, Wuppertal, Germany) to receive a quantitative measure.

Statistical analysis

For statistical analysis (SPSS, Version 21, IBM, Armonk, USA) the type I error probability was set to $\alpha = 0.05$. A linear regression analysis with stepwise reduction was performed to investigate the influence of the BMD as well as the age and pedicle width on the cycles to failure or fatigue load, respectively. Significance of the regression was tested using an ANOVA analysis. Nonparametric Kruskal–Wallis test analyses were performed to compare the cycles to failure and the fatigue force of different BMD groups. The threshold values of the different BMD groups were based on the guidelines of the American college of radiology which defined a QCT trabecular spine BMD range which is approximately equivalent to the World Health Organisation diagnostic category: normal: $\text{BMD} > 120 \text{ mg/cm}^3$; osteopenia: $80 \text{ mg/cm}^3 \leq \text{BMD} < 120 \text{ mg/cm}^3$; osteoporosis: $\text{BMD} < 80 \text{ mg/cm}^3$ [22].

Results

Specimen's age was between 19 and 96 years and the BMD ranged from 43.3 to 203.6 mg/cm^3 . BMD significantly decreased with age ($r = -0.724$, $p < 0.001$).

The fatigue testing produced a pattern of failure with caudal displacement of the tip of the screw as well as a widening of the entrance point into the pedicle (Fig. 2). The visual screening of the specimens after testing showed a loosening of 18 screws and the removal torque was less or equal to 0.30 Nm in these cases. In three cases ($\text{BMD} \geq 150.00 \text{ mg/cm}^3$), there was no visual loosening and the removal torque was higher than 2.0 Nm (Table 1). CT after testing confirmed these results. Additionally, there was a significantly decreased stiffness at the end of testing compared to the beginning, indicating failure (Start: $74.5 \pm 9.6 \text{ N/mm}$, End: $28.4 \pm 7.2 \text{ N/mm}$; $p < 0.001$).

Linear regression analyses were calculated for the dependent variables cycles to failure and fatigue load with the predictive variables BMD, age, and pedicle width. A stepwise reduction of parameters showed no significant influence of age ($p = 0.423$) or pedicle width ($p = 0.937$) on the coefficient of determination and therefore were omitted. There was a highly significant correlation between BMD and cycles to failure ($r = 0.862$, $r^2 = 0.743$, $p = 0.001$) and consequently also between BMD and fatigue load ($r = 0.854$, $r^2 = 0.73$, $p < 0.001$) (Fig. 3). Nevertheless, when the BMD is left out, there is a significant correlation between age and cycles to failure ($r = 0.662$, $r^2 = 0.438$, $p = 0.001$) as well as age and failure load ($r = 0.662$, $r^2 = 0.438$, $p = 0.001$).

Specimens with bone mineral density below 80 mg/cm^3 , which is defined as threshold value for osteoporosis [22, 23], only reached 45% of the cycles to failure and only 60% of the fatigue load compared to the specimens with adequate bone quality ($\text{BMD} > 120 \text{ mg/cm}^3$) and accordingly there was a significant difference regarding the cycles to failure ($p < 0.001$) as well as the fatigue load ($p < 0.001$) between these two groups (Table 1).

Discussion

Loosening of pedicle screws is a relevant complication in posterior spinal stabilisation, especially in osteoporotic patients [10–12]. There are different methods to improve screw stability in these cases. Augmentation of pedicle screws with bone cement is widely used and has shown good results in biomechanical as well as clinical studies [24]. Karius et al. showed that the use of radiofrequency-activated cement shows significantly increased pull-out forces in osteoporotic and non-osteoporotic vertebrae and concluded that this is a simple procedure with increased control and fewer complications like extravasation [25]. Wilke et al. investigated the biomechanical performance of a lamina hook system compared to a pedicle screw system. They showed that there are no obvious biomechanical disadvantages of the lamina hook system and inferred that

Fig. 2 Post-test-CT showing screw loosening with caudal displacement of the screw tip as well as widening of the entrance point into the pedicle sagittal (a) and coronal (b) orientation showing the loosened screw as well as sagittal (c) and coronal (d) orientation showing the extended screw canals

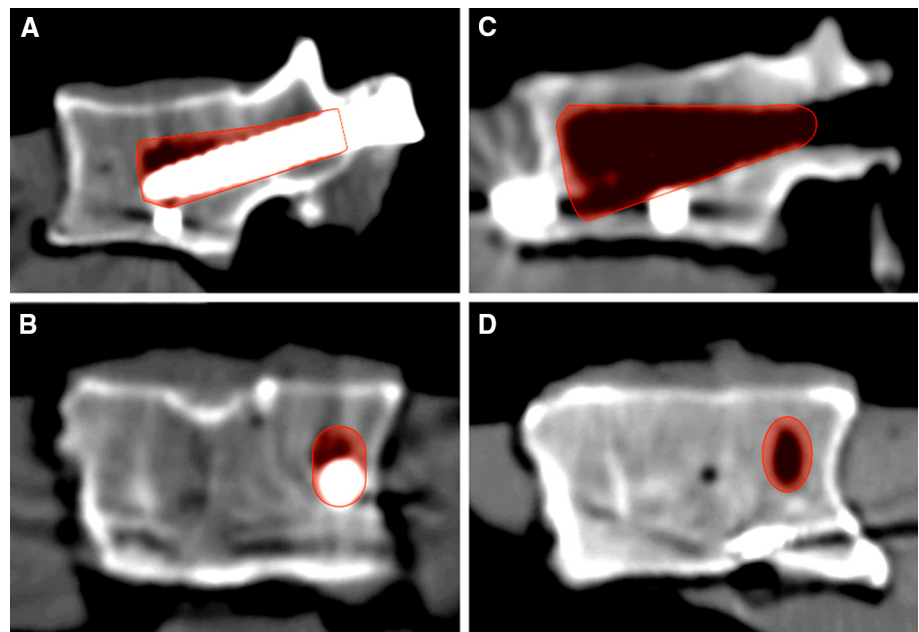


Table 1 The measured BMD, cycles to failure, fatigue load, stiffness at the start and end of testing, and removal torque for each specimen

Age	Gender	BMD T12 (mg/cm ³)	Cycles to failure	Fatigue load (N)	Stiffness start (N/mm)	Stiffness end (N/mm)	Removal torque (Nm)		
19	Male	200.0	5323	Mean 4765 SD 588	341.1	Mean 318 SD 26	86.4	29.9	3.2
66	Male	178.1	5501		375.0		71.0	26.9	2.4
51	Male	169.1	5173		332.7		80.8	25.5	2.6
54	Female	162.4	3958		266.2		66.0	20.6	0.3
39	Female	129.0	4304		289.6		73.1	22.5	0.1
78	Male	125.4	4328		305.0		74.3	25.9	0.3
89	Female	119.5	3035	Mean 3042 SD 1114	231.2	Mean 237 SD 51	69.6	29.0	0.1
70	Male	112.6	4354		297.7		76.6	25.0	0.3
46	Female	107.8	4745		317.1		95.7	32.8	0.2
58	Male	103.2	3399		258.2		72.4	37.7	0.3
68	Female	84.1	1396		162.1		66.5	43.1	0.1
61	Male	83.0	3264		242.8		79.4	26.8	0.1
84	Female	82.8	1551		170.7		79.9	23.4	0.1
67	Female	82.0	2597		214.9		84.3	43.5	0.2
90	Female	72.7	2695	Mean 2091 SD 655	222.8	Mean 192 SD 30	61.7	37.2	0.1
86	Male	69.8	2935		225.0		69.9	26.3	0.1
82	Female	69.4	2641		219.3		74.7	36.3	0.1
96	Male	63.9	1507		163.2		59.5	18.8	0.1
75	Female	59.7	1250		156.1		65.4	23.2	0.05
85	Male	57.5	2257		200.2		93.7	25.3	0.2
88	Male	51.5	1350		158.1		63.9	17.2	0.05

Means and standard deviations for three groups of BMD (T12: <80 mg/cm³, 80–120 mg/cm³, >120 mg/cm³)

it might be an alternative stabilisation method for the treatment of elderly spines [26]. Furthermore, Aycan et al. tested pedicle screws with expandable poly-ether-ether-

keton shells which might be an alternative method to increase pedicle screw stability omitting the disadvantages of cement augmentation [27].

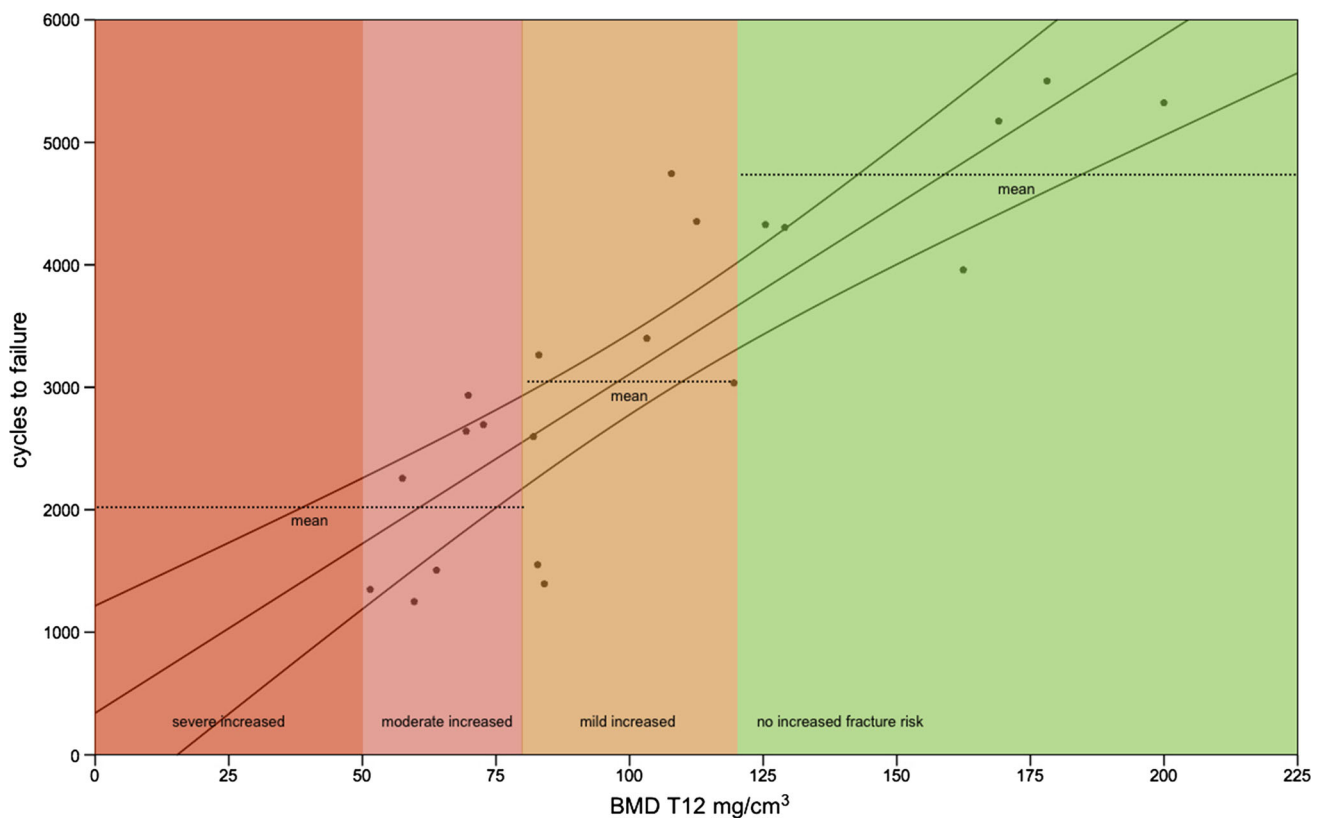


Fig. 3 Correlation between cycles to failure and BMD T12 shown with 95% confidence interval of the mean value. Different risks for osteoporotic fractures depending on the BMD are coloured according to Link [23] and mean cycles to failure of each group are marked

There are several factors influencing the stability of pedicle screws such as length, diameter, design, and particularly the BMD. Biomechanical pull-out tests have shown a high correlation between BMD and pedicle screw stability [7, 13, 19]. However, axial pull-out of the screw posteriorly through the pedicle is a very rare failure pattern (0.2–1%), and therefore the clinical relevance of these studies is very limited [15, 16, 28].

The current fatigue testing was utilised because of a series of forces within the physiological range [21] and an *in vivo* like failure pattern with cranio-caudal loosening of the screws in the vertebral bodies with a loosening zone expansion at the screw tip [29, 30]. It was based on the corpectomy model (ASTM 1717) which has been shown to be suitable to simulate a postoperative loading condition *in vitro* [16]. Although it has to be determined if a biomechanical fatigue testing setup is able to gather clinically relevant pedicle screw loosening parameters, this loading protocol is closer to the clinical situation compared with pull-out testing anyway. A stepwise increasing load accelerates failure to reduce specimen degradation. A significantly decreased stiffness during testing, indicating damage to the trabecular bone as shown by Kiner et al. [31], as well as a very low removal torque after testing is consistent with the loosening of the screws during testing.

The measurement of the BMD using QCT is a standard clinical method, and therefore the results of this study can be transferred into clinical routine [23, 32]. Bredow et al. measured the Hounsfield units in a preoperative CT scan and showed that determination of the bone density using this data can predict the risk of screw loosening [33]. Furthermore, Popp et al. showed that the vertebral trabecular bone score (TBS) alone or in addition to BMD predicted incident clinical fracture risk in a representative population-based sample of elderly postmenopausal women, which also highlights the importance of preoperative measurement of bone quality to assess the risk of screw loosening [34].

The existing evidence regarding the question from which BMD the fixation of pedicle screws in the vertebral body is insufficient is rare. Wittenberg et al. performed a biomechanical study with pull-out and cyclic loading in human and calf vertebral bodies. They concluded that loosening may be expected at BMD measured less than 90 mg/cm^3 (QCT) [19]. Furthermore, they described that under physiologic loads, screw loosening occurred in spines with BMD below 74 mg/cm^3 . Okuyama et al. investigated the pull-out force, tilting and cut-up of pedicle screws. They showed that vertebrae with an average BMD of $95 \pm 33.3 \text{ mg/cm}^3$ (QCT) could not be stabilised

anatomically by pedicle screws [20]. A clinical study by Okuyama et al. also showed a close relation between BMD and the stability of pedicle screws and the authors conclude that patients with a mean BMD less than $0.674 \pm 0.104 \text{ g/cm}^2$ (DEXA) have an increased risk for screw loosening [35]. Contrary, Kumano et al. described in their clinical study of patients with one level fusion, that the rate of non-union, screw loosening and screw breakage did not differ significantly between a group with a BMD more than 100 mg/cm^3 and a group with a BMD less than 100 mg/cm^3 . However, patients with severe osteoporosis were excluded from surgeries preoperatively [36].

Regarding the measurement of bone quality in vertebral bodies using qCT there are threshold values which are approximately equivalent to the World Health Organisation diagnostic categories. Osteoporosis is defined as a BMD below 80 mg/cm^3 while a BMD between 80 and 120 mg/cm^3 is defined as osteopenia [22, 23].

The results of this study showed a highly significant correlation between the BMD and the cycles to failure as well as the fatigue load during fatigue testing. This clearly supports the studies mentioned above, and shows that it is possible to predict the stability of pedicle screws by measuring the preoperative BMD. The osteoporotic specimens with a BMD below 80 mg/cm^3 finished significantly lesser cycles to failure (45%) and resisted a significantly lower fatigue load (60%) compared to the specimens with a BMD higher than 120 mg/cm^3 . Thus, due to a decrease of the cycles to failure by 55% and a decrease of the fatigue load by 40% it can be assumed that pedicle screw fixation is insufficient in osteoporotic vertebrae with a BMD below 80 mg/cm^3 .

Due to the use of human specimens, this study is limited with regard to sample size and the variation of the vertebral bodies. Variations in the angle, direction and entry point of the introduction of the screws may also have influenced the results. Furthermore, a biomechanical cadaver model is not able to simulate in vivo conditions. Reducing the individual variations by introducing the pedicle width did not show a significant influence. In three cases with very high BMD the implanted screws showed no loosening in the post-testing CT. Thus, the failure occurred at the rod or the fixation. Therefore, the values for fatigue load and cycles to failure would be even higher without this limitation. Due to the testing setup with stepwise increasing load, the measured failure loads are higher than loads occurring in patients during physiological activities.

In summary, there is a close correlation between BMD and pedicle screw stability and therefore the stability of pedicle screws might be insufficient in osteoporotic vertebrae. Accordingly, an additional stabilisation procedure, such as lengthening of the instrumentation or cement

augmentation, might be considered in patients with a BMD below 80 mg/cm^3 .

Compliance with ethical standards

Conflict of interest The authors declare that there is no conflict of interests regarding the publication of this paper.

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