■ SPINE

Cement augmentation *versus* extended dorsal instrumentation in the treatment of osteoporotic vertebral fractures

A BIOMECHANICAL COMPARISON

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Aims

Loosening of pedicle screws is a major complication of posterior spinal stabilisation, especially in the osteoporotic spine. Our aim was to evaluate the effect of cement augmentation compared with extended dorsal instrumentation on the stability of posterior spinal fixation.

Materials and Methods

A total of 12 osteoporotic human cadaveric spines (T11-L3) were randomised by bone mineral density into two groups and instrumented with pedicle screws: group I (SHORT) separated T12 or L2 and group II (EXTENDED) specimen consisting of T11/12 to L2/3. Screws were augmented with cement unilaterally in each vertebra. Fatigue testing was performed using a cranial-caudal sinusoidal, cyclic (1.0 Hz) load with stepwise increasing peak force.

Results

Augmentation showed no significant increase in the mean cycles to failure and fatigue force (SHORT $p = 0.067$; EXTENDED $p = 0.239$). Extending the instrumentation resulted in a significantly increased number of cycles to failure and a significantly higher fatigue force compared with the SHORT instrumentation (EXTENDED non-augmented + 76%, $p < 0.001$; EXTENDED augmented + 87%, $p < 0.001$).

Conclusion

The stabilising effect of cement augmentation of pedicle screws might not be as beneficial as expected from biomechanical pull-out tests. Lengthening the dorsal instrumentation results in a much higher increase of stability during fatigue testing in the osteoporotic spine compared with cement augmentation.

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Osteoporosis commonly presents as vertebral fractures,[1] and posterior spinal stabilisation using pedicle screw fixation may be required.[2-4] However, loosening at the bone-screw interface is a common complication.[5-7]

Augmentation of pedicle screws with cement is widely used to improve stability in these patients.[8-10] An approximately twofold increase in pull-out-strength over non-augmented screws has been shown in biomechani cal studies.[6,11] The clinical significance of this has been questioned.[12] In pull-out tests, implanted screws are withdrawn posteriorly through the pedicle. However, this has rarely been reported clinically as a mechanism of failure.[13-15] Kueny et al[12] have shown a significantly increased strength of perforated, augmented pedicle screws compared with non-augmented screws in more physiological fatigue testing with a repeated, step-wise increasing force, leading to a more clinical failure pattern with cranio-caudal loosening of the screws in the vertebral bodies.

The length of the dorsal stabilisation that is required in the management of thoracolumbar fractures remains controversial.[16-18] Short instrumentation has been used, with pedicle screws inserted one level above and one level below the fractured vertebra, mainly because it is technically easy and involves a small incision and little blood loss.[16-19] Disadvantages include failure due to loosening of the screws and increasing kyphosis.[16,20,21] Pekmezci et al[22] showed that extending the instrumentation to two or three levels above or below an unstable three-column thoracolumbar fracture could restore stability, although they only measured initial stiffness and did not consider loosening.

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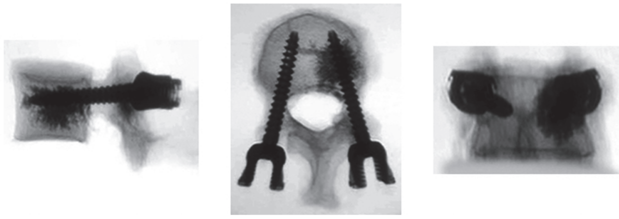

Fig. 1a

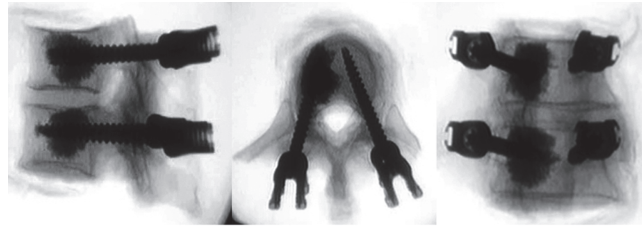

Fig. 1b

Radiographs (lateral/sagittal/antero-posterior) showing vertebral bodies after instrumentation and cement-augmentation of one side; a) SHORT instrumentation and b) EXTENDED group.

The question remains whether short instrumentation combined with using pedicle screws augmented with cement is sufficient to treat an osteoporotic fracture or is extended stabilisation required to provide adequate stability in these patients.

This study has two aims. One was to evaluate the effect of augmentation with cement in both a short and an extended stabilisation model using a fatigue test, to try to simulate *in vivo* loading with axial compression as well as flexion and extension moments. Fatigue failure of bone is believed to be more clinically relevant compared with failure due to pull-out.[12,13,23] The second goal was to investigate whether a short instrumentation with augmented screws or an extended stabilisation without cement augmentation, provides more stability during physiological fatigue testing.

Materials and Methods

A total of 12 (eight female, four male) cadaveric specimens of human thoracolumbar spines (T11 – L3) were collected from donors with expected osteoporotic bone mass, aged > 65 years (mean 76.3 years; standard deviation (SD) 8.9). After harvesting, the specimens were 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 fractures and to determine the volumetric bone mineral density (vBMD). This was determined by linearly converting the value in Hounsfield units from a defined voxel cube from the centre of each L1 vertebral body to the phantom's reference densities (Avizo 5.1, VSG Inc., Burlington, Massachusetts).

The specimens were allocated into two groups of six specimens with similar vBMD. Group I represented short instrumentation (SHORT). After defrosting the specimens overnight, the T12 and L2 vertebral bodies were separated from the thoracolumbar section. The specimens were sprayed with Ringer solution throughout preparation and wrapped in moist tissue prior to testing in order to preserve the constitution of the tissue. Commercially available 5.5 mm × 45 mm self-tapping, cannulated, augmentable, polyaxial screws (Mantis augmentable, Stryker, Duisburg, Germany) were introduced into both pedicles of each vertebra under fluoroscopic guidance followed by augmentation of one screw, also under fluoroscopic control. Each vertebral body was assessed radiologically to ensure that the cement did not cross the midline (Fig. 1). The specimens were then embedded in a custom-made fixture using a polyurethane resin (Ureol FC53, Gößl & Paff, Karlskron, Germany). The fixture was constructed so that the specimens were fixed to the posterior border of the vertebral body, but the pedicle remained free. In order to simulate an unstable L1 fracture, the L2 vertebral body was embedded with its inferior endplate downwards while the T12 vertebral body was embedded with its superior endplate downwards to simulate a loading from inferior (Fig. 2).

Group II underwent longer instrumentation (EXTENDED). These specimens consisted of two vertebrae (T11 and T12 or, L2 and L3, respectively) and were treated, instrumented and embedded in the same way as group I (Figs 1 and 2).

Mechanical testing-setup. The specimens were mounted on an x-y table in a servo-hydraulic testing machine (MTS 858.2, MTS Systems, Eden Prairie, Minnesota). Specimens in the EXTENDED group were loaded on the superior endplate with a weight of 25 kg for 15 minutes before mounting in the testing machine in order to achieve a more physiological compression. A 6 mm rod (XIA titanium, Stryker, Duisburg, Germany) was fixed to the screws using blockers (Mantis Redux, Stryker,). The rod was linked to a custom-made connector 8.3 cm above the upper screw, corresponding more or less to the bridged distance with a fractured vertebra. A joint in the connector allowed movement with 1° of freedom in the frontal plane of the vertebral body and was placed directly in line with the posterior border of the vertebral body. Load was introduced from above and acted as a moment on the screw (Fig. 3). The experimental setup was based on the ASTM F1616 norm, but in contrast to that loading, the inferior and superior parts of the fixations were tested separately.

Fatigue testing was performed by implementing a sinusoidal, cyclic (1.0 Hz) force. For the initial cycle it ranged from 50 N to 100 N, representing the physiological range of load during walking.[24] The maximum compressive force was increased step-wise by 0.05 N every cycle in order to accelerate failure by reducing the effects of degradation of the specimen (Locati test design).[12] Testing was stopped when the caudal displacement of the connector at the testing machine exceeded 20 mm.

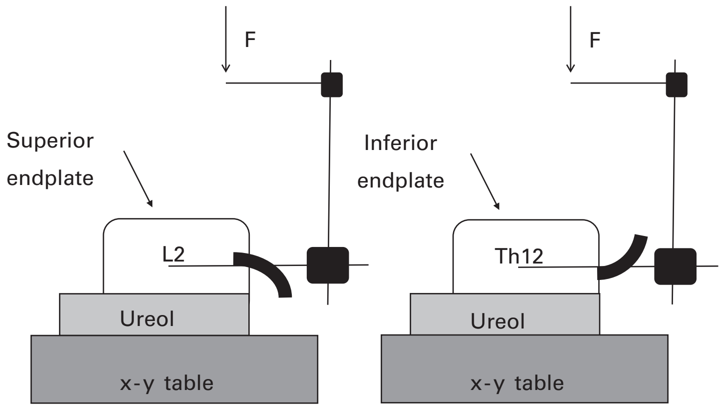

Fig. 2a

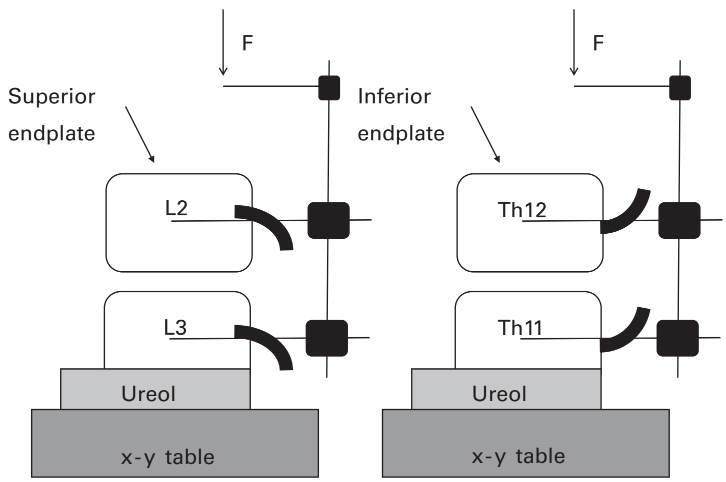

Fig. 2b

A schematic diagram showing the test setup for SHORT (a) and EXTENDED instrumentation; b) the thoracic vertebral bodies were embedded upside down in order to simulate a loading from inferior.

Testing was carried out separately for both sides (augmented or non-augmented). In both groups the augmented and non-augmented side were tested alternatively.

Measured parameters. The number of cycles until the end of the test was recorded, and this number was correlated with the fatigue force, which was defined as the maximum force applied to the implant before the test was terminated. Stiffness values were determined from a linear regression slope to the load displacement curves and were measured at the beginning of testing, after ten cycles of setting, and ten cycles before failure. After the mechanical testing, the specimens were screened for macroscopic loosening of the screws. Loosening was assumed if there was expansion of the entry point of the screw and if there was movement of the screw within the vertebral body as assessed by CT. However, no unified scoring system or quantification was used. The removal torque of each screw was measured using a Torsiometer 760 (Stahlwille, Wuppertal, Germany).

The study had ethical approval.

Statistical analysis. For statistical analysis using SPSS, Version 21 (IBM, Armonk, New York), the probability of a type I error was set to $\alpha = 0.05$. Normal distribution was investigated using the Shapiro-Wilk test. The homogeneity of variances was tested by Levene's test. The fatigue force and cycles to failure of the different testing groups were compared using parametric one- and two-way analysis of variance (ANOVA) with Tukey-HSD *post hoc* test. Non-parametric Mann-Whitney U test analyses were used to verify the homogeneity of vBMD and age of specimens as well as to compare the results of cycles with failure and fatigue force within the SHORT and EXTENDED groups separately. A univariate analysis was conducted to show the influence of vBMD on cycles to failure and fatigue force.

Results

The mean age and vBMD of the SHORT and EXTENDED groups were similar (p = 1.000 and p = 0.485, respectively, Table I).

The fatigue loading protocol led to a pattern of failure with caudal displacement of the tip of the screw and widening of the entrance point into the pedicle. Visual scanning of the specimens after testing showed loosening in all non-

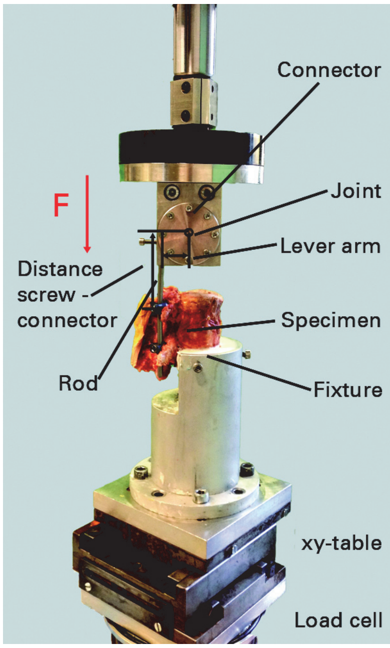

Fig. 3

Biomechanical test setup. Specimens were mounted in a servo-hydraulic testing machine. A rod was fixed to the screws and linked to a connector 8.3 cm superior to the upper screw. A joint in the connector allowed movement with one degree of freedom in the frontal plane of the vertebral body and was placed directly in line with the posterior border of the vertebral body. Load was introduced from superior and acted as a moment on the screw.

augmented screws, but not of the augmented screws. CT showed loosening of all non-augmented screws, with less loosening for the augmented screws (Fig. 4).

In the SHORT group, the mean removal torque was 0.85 Nm (SD 0.39) for augmented screws and 0.125 Nm (SD 0.11) for non-augmented screws ($p < 0.001$).

In the EXTENDED group, the mean removal torque was 1.04 Nm (SD 0.27) for augmented screws and 0.25 Nm (SD 0.33) for non-augmented screws ($p < 0.001$).

Table II shows the cycles to failure and fatigue load of both the augmented and non-augmented screws in the two groups. When comparing augmented and non-augmented screws for the SHORT group separately, there was a significant difference, with more cycles to failure ($p = 0.02$) and higher fatigue load ($p = 0.01$) for the augmented screws.

The cycles to failure ($p = 0.219$) and fatigue load ($p = 0.291$) were similar for augmented and non-augmented screws in the EXTENDED group.

When comparing the augmented and non-augmented screws in both groups, there was no significant effect of augmentation on cycles to failure and fatigue load for both the SHORT (cycles to failure, $p = 0.067$; fatigue load, $p = 0.077$) and EXTENDED (cycles to failure, $p = 0.239$; fatigue load, $p = 0.335$) groups.

The significant differences in the two groups for cycles to failure and fatigue force are shown in Tables II and III and Figure 5.

The significant differences in the two groups of stiffness at the beginning of fatigue testing and before failure in both groups can be found in Table IV.

There was no significant correlation between the cycles to failure and the vBMD ($r = 0.174$, $p = 0.237$) and the fatigue load and the vBMD ($r = 0.171$, $p = 0.245$).

Discussion

Several studies have shown good results after short instrumentation of thoracolumbar fractures[25,26] while additional instrumentation has been reported to increase stability.[18,27] However, most data do not relate to osteoporotic fractures and even in non-osteoporotic fractures, short instrumentation has a higher rate of implant failure and progression of symptomatic kyphosis.[25,26,28-31] Karami et al[32] showed that an increased length of screw, placed bicortically, improved fixation and decreased loosening in osteoporotic vertebrae, but there are risks of vascular damage using this technique. The results of the current study show that the effect of augmentation of a pedicle screw is not as great as has been suggested on pull-out tests.[6,11] Pooling all the test groups in our study we found that there was no significant difference between augmented and non-augmented screws. If just the SHORT group was considered, there were more cycles to failure and a significantly higher fatigue load. These findings are in agreement with those of Kueny et al,[12] indicating that there is a stabilising effect of augmentation with cement, but the relevance of this effect should not be overestimated.

Comparing the results of augmentation with cement and extending instrumentation in our study, we found that there was an increase in fatigue load of 16% with augmentation in the SHORT group and 76% in the non-augmented EXTENDED group. There was no significant difference regarding cycles to failure and fatigue load between non-augmented and augmented screws in the EXTENDED group. Furthermore, there was a significant decrease of stiffness during testing indicating a damage to the trabecular bone as shown by Kiner et al.[23] There were no significant differences between the augmented and non-augmented screws and between the SHORT and EXTENDED groups, but the decrease of stiffness occurred significantly earlier in the SHORT instrumentation group.

These results confirm the findings of Pekmezci et al,[22] that dorsal instrumentation of two levels above and below an unstable, three-column thoracolumbar fracture adequately restored stability, while short segment instrumentation did not.

In our study, augmented screws had a significantly higher removal torque and the CT-scans after testing showed a less significant loosening compared with non-augmented screws. This is probably due to various reasons. Augmentation leads to increased stability. However, the removal

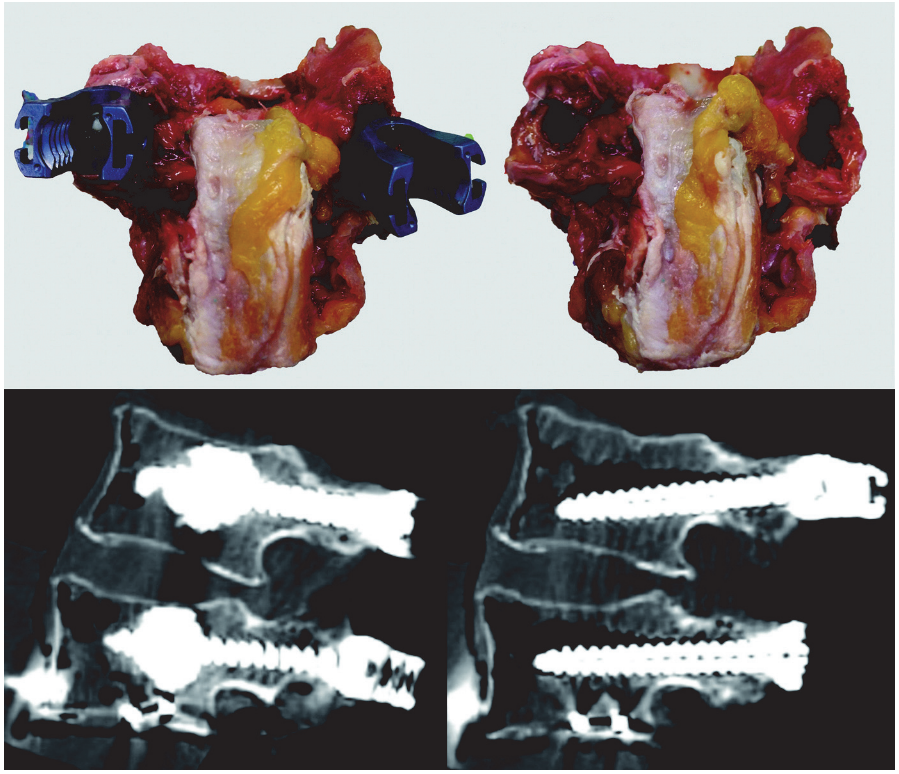

Fig. 4

A specimen after testing showing significant loosening of the right, non-augmented screw and widening of the entrance point into the pedicle. CT-scan demonstrating massive caudal dislocation of the non-augmented screw tips.

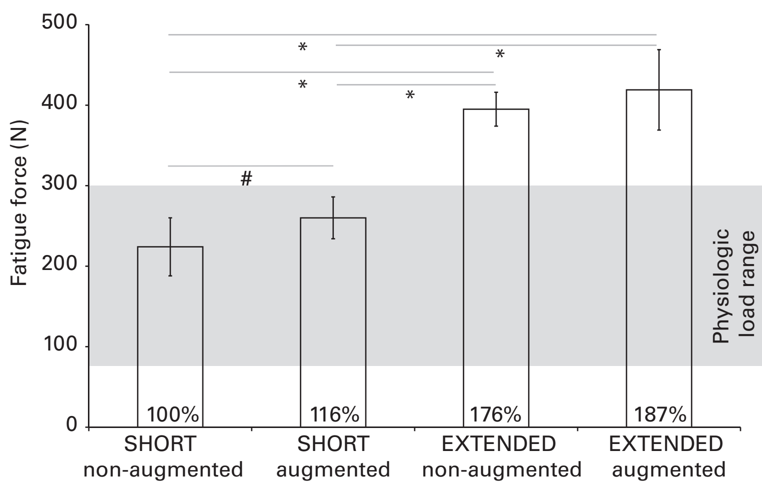

Fig. 5

Histogram showing the fatigue load of each group (error bars represent standard error). The grey box represents the range of forces measured *in vivo* during walking.[24] Significant difference (taking all results into account) is marked *. Significant difference of non-augmented and augmented screws in the SHORT group separately is marked #. Percentage values in each box indicate the increase of fatigue load starting from 100% in the SHORT non-augmented group.

torque might not be suitable for predicting loosening of augmented screws, since a loosened screw with adherent cement has a higher removal torque due to its higher volume and non-circular shape. In the SHORT group, the failure of the construct might be a combination of loosening of the pedicle screw and failure of the polyaxial screw head and bending of the rod. Polyaxial screws fail at a lower force than monoaxial screws.[33] There is a high risk of

Table I. Mean (standard deviation) age and volumetric bone mineral density (vBMD) of both groups

Group	N	Age (yrs)	vBMD (mg/cm^3)
SHORT	6	75.2 (7.4)	82.64 (19.3)
EXTENDED	6	76.8 (10.7)	86.76 (17.8)
		p = 1.000	p = 0.485

Table II. Output parameters for both groups (mean, standard deviation and p-values for SHORT and EXTENDED separately)

Group	Augmentation	Cycles to failure	Fatigue load (N)
SHORT	no	3171 (788)	224 (36)
	yes	3979 (656)	260 (26)
		p = 0.02	p = 0.01
EXTENDED	no	6752 (496)	395 (21)
	yes	7422 (1044)	419 (50)
		p = 0.219	p = 0.291

Table III. Comparison of cycles to failure and fatigue load between the groups (one-way analysis of variance with Tukey-HSD test)

Group		Group	Significance cycles to failure	Significance fatigue load
SHORT non-augmented	*vs*	SHORT augmented	p = 0.067	p = 0.077
		EXTENDED non-augmented	p < 0.001	p < 0.001
		EXTENDED augmented	p < 0.001	p < 0.001
SHORT augmented	*vs*	EXTENDED non-augmented	p < 0.001	p < 0.001
		EXTENDED augmented	p < 0.001	p < 0.001
EXTENDED non-augmented	*vs*	EXTENDED augmented	p = 0.239	p = 0.335

Table IV. Stiffness (mean and standard deviation) at the beginning of fatigue testing and before failure for both groups

Group	Augmentation	Stiffness start (N/mm)	Stiffness before failure (N/mm)	
SHORT	no	79.6 (11.4)	38.8 (10.3)	p < 0.001
	yes	82.3 (8.9)	43.5 (11.7)	p < 0.001
EXTENDED	no	86.2 (13.6)	40.2 (7.4)	p < 0.001
	yes	86.1 (10.9)	39.4 (6.7)	p < 0.001
		p = 0.194	p = 0.477	

failure when using polyaxial screws, particularly with short instrumentation, without direct instrumentation of the fractured vertebra, because of the high moment which is generated on the head of the screw due to the long lever arm, with the rod spanning one vertebra. For this reason, it might be better to use a monoaxial screw for augmented, short segment instrumentation of an osteoporotic vertebral fracture.

One of the limitations of this study is the relatively small sample size, due to the limited availability of cadavers. Furthermore, a biomechanical cadaver model does not replicate *in vivo* conditions. Another limitation is the variation of the dimensions of vertebral bodies in human specimens, which was not taken into account. Variations in the angle, direction and entry point of the introduction of the screws may also have influenced the results.

In summary, the stability of fixation in short dorsal instrumentation is improved by augmentation. However, the effect might not be as great as expected from biomechanical pull-out tests. Extending the instrumentation results in an increased stability during fatigue testing in the osteoporotic spine compared with augmentation and should be preferred in the treatment of unstable, osteoporotic, thoracolumbar fractures.

Take home message:

If the stability of short segment posterior instrumentations in osteoporotic vertebral fractures is insufficient, lengthening of the instrumentation results in a significantly higher increase of stability compared with cement augmentation of the pedicle screws.

Author contributions:

L. Weiser: Data collection, Data analysis, Contributed to method development, Performed surgeries, Writing the paper.
M. Dreimann: Data collection, Data analysis, Performed surgeries, Writing the paper.
G. Huber: Contributed to method development, Data analysis.
K. Sellenschloh: Data collection, Technical assistance.
K. Püschel: Preparation of the specimens.
M. M. Morlock: Data analysis, Contributed to method development.
J. M. Rueger: Data analysis, Writing the paper.
W. Lehmann: Supervision, Data analysis, Contributed to method development, Writing the paper.

The first two authors contributed equally to this work and therefore share first authorship.

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The author or one or more of the authors have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this article.

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