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The effect of cement augmentation on pedicle screw fixation under various load cases

RESULTS FROM A COMBINED EXPERIMENTAL, MICRO-CT, AND MICRO-FINITE ELEMENT ANALYSIS

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Aims

Anchorage of pedicle screw rod instrumentation in the elderly spine with poor bone quality remains challenging. Our study aims to evaluate how the screw bone anchorage is affected by screw design, bone quality, loading conditions, and cementing techniques.

Methods

Micro-finite element (µFE) models were created from micro-CT (µCT) scans of vertebrae implanted with two types of pedicle screws (L: Ennovate and R: S^4). Simulations were conducted for a 10 mm radius region of interest (ROI) around each screw and for a full vertebra (FV) where different cementing scenarios were simulated around the screw tips. Stiffness was calculated in pull-out and anterior bending loads.

Results

Experimental pull-out strengths were excellently correlated to the µFE pull-out stiffness of the ROI ($R^2 > 0.87$) and FV ($R^2 > 0.84$) models. No significant difference due to screw design was observed. Cement augmentation increased pull-out stiffness by up to 94% and 48% for L and R screws, respectively, but only increased bending stiffness by up to 6.9% and 1.5%, respectively. Cementing involving only one screw tip resulted in lower stiffness increases in all tested screw designs and loading cases. The stiffening effect of cement augmentation on pull-out and bending stiffness was strongly and negatively correlated to local bone density around the screw (correlation coefficient (R) = -0.95).

Conclusion

This combined experimental, µCT and µFE study showed that regional analyses may be sufficient to predict fixation strength in pull-out and that full analyses could show that cement augmentation around pedicle screws increased fixation stiffness in both pull-out and bending, especially for low-density bone.

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Keywords: Pedicle screw, Micro-CT, Micro-finite element analysis, Cement augmentation

Article focus

- Pedicle screw fixation in the osteoporotic spine remains difficult.
- The effects of screw design, bone quality, and cement augmentation were evaluated using micro-finite element (µFE) models.

Key messages

- µFE models of simulated cement augmentation around pedicle screws showed increased fixation stiffness in both pull-out and bending.
- This increase was more pronounced for low-density bone.
- No statistically significant effect of screw design was predicted.

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Strengths and limitations

- μFE calculations and bone volume fraction (BV/TV) did not account for bone debris and damage resulting from screw insertion.
- Excellent correlations with measured experimental fixation strength for both screw designs in pull-out served as validation for the modelling approach.
- This is the first μFE study of pedicle screw fixation to demonstrate the effects of cementing in different loading modes.

Introduction

Anchorage of pedicle screw rod instrumentation in the elderly spine with poor bone quality is still challenging.[1] Success of pedicle screw rod instrumentation depends on implant design as well as surrounding bone quality in the vertebral body, with the aim to provide adequate compression between screw threads and surrounding bone, as this was shown to be a critical aspect of fixation stability. With limited cortical support in the pedicle region, such compression relates primarily with cancellous bone density.[2]

Low peri-implant bone density, common in the elderly spine, can compromise stability.[3] To strengthen the mechanical interface between screws and bone, several studies suggested deviations from the common transpedicular trajectory,[4] or design changes in ratio between core and outer diameters, thread geometry and pitch, as well as improved osseointegration with coatings.[5] Fixation augmentation using bone cement might also improve fixation.[65]

While most studies of pedicle screw fixation are typically conducted with standardized tests involving pull-out and torsional and bending loads,[7-11] these are limited in their assessment of the role of bone quality. Experimental tests have shown that bone density, a predominant factor in bone strength,[12] is critical to maintaining mechanical stability of pedicle screws in pull-out,[13] but lacked a detailed analysis of the role of regional bone around the pedicle screws.

The use of high-resolution numerical models can help in the evaluation of fixation performance of implanted devices such as screws and anchors in trabecular bone.[14-18] Recently at the spine, such approaches suggested the specific influence of regional bone quality and screw design parameters at the pedicle-screw-bone interface that closely match experimental observations.[19] However, these methods have been so far limited to small portions of the vertebral bone around screws, which limits the loading scenarios that can be investigated or the simulated use of cementing to strengthen fixation. Detailed structural analysis of the instrumented spine involving a variety of loading cases for the pedicle screws might therefore better reflect the loads reported for daily activities to which these implants are subjected,[20] but require larger portions of the bone stock around implants. In this study, we used a combination of mechanical testing, micro-CT (μCT) imaging, and microfinite element (μFE) modelling to investigate how regional bone quality and cement augmentation can influence the fixation of pedicle screws in axial pull-out and forward bending loads. Our hypotheses were two-fold: 1) that regional bone quality around the pedicle screw can affect the fixation strength in pull-out and bending; and 2) that cement augmentation affects the fixation stiffness of screws in both loading scenarios and depends on bone density.

Methods

Specimen preparation, implantation, and scanning. Vertebrae were used from the thoracolumbar spines of six patients (aged 75 to 90 years), scanned with calibrated quantitative CT, and images cropped to remove posterior elements and then segmented using morphological steps with a global threshold. Bone mineral density (BMD, in Houndsfield units) was then calculated in the inner trabecular core. Three vertebrae were then selected, extracted, and cleaned based on higher mean BMD (358 Houndsfield units (standard deviation (SD) 26) to represent a non-osteoporotic group. These specimens were then implanted without pre-drilling by an experienced surgeon (MR) with both an Ennovate screw (L) and an S^4 screw (R) (Aesculap AG, Germany) of the same core diameter and length through the left and right pedicles, respectively. The R screw has a typical conical core shape, while the L screw consists of a pentagonal core design close to the tip of the screw.

Following implantation, the samples were scanned at an isometric resolution of 105 μm using a μCT scanner (v|tome|x s 240, 160kV, 580μA; General Electric, USA) (Figure 1).

Experimental tests. After scanning, specimens were embedded (Ureol FC 53; Vantico GmbH, Germany) and tested in pull-out (n = 6) until failure. The first tested was alternated. Pull-out stiffness (kN/mm) was defined as the slope of the first linear portion of the load-displacement curve, while pull-out strength was calculated for each screw as the maximum measured load (kN).

Apparent bone density analysis. μCT images were segmented with carefully selected, specimen-specific thresholds to generate a composite binarized image with separated bone tissue and pedicle screws (Figure 1). Subregions including each separate pedicle screw and bone structures within a 10 mm radius around each screw axis were cropped and the resulting images defined as the basis for a region of interest (ROI) analysis of pedicle screw fixation.[19] Bone volume fraction (BV/TV) was calculated for each screw within these ROIs.

μFE models. The two series of binarized images representing the full vertebra (FV) and subregions (ROI) were converted to μFE models (Figure 1),[17] consisting of approximately 10 million and 33 million eight-noded hexahedral elements, respectively. Pedicle screws were assigned linear elastic isotropic properties of Young's modulus of

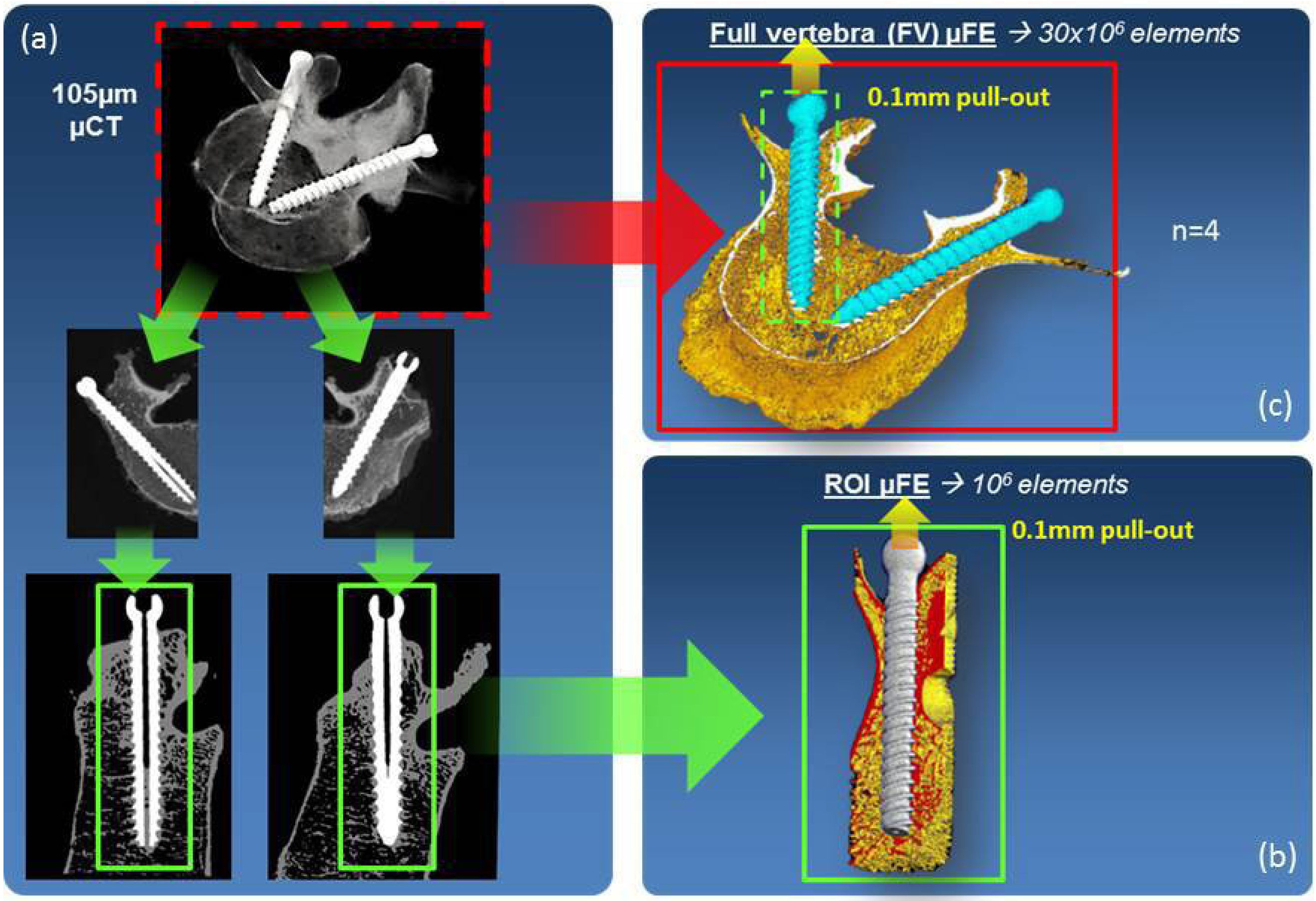

Fig. 1

a) Cadaveric vertebrae implanted with pedicle screws were scanned at 105 µm resolution with micro-CT (µCT). These images were segmented to separate bone tissue and implants and then cropped to a final 10 mm radius region of interest (ROI) around the screw axis, where apparent bone density bone volume fraction (BV/TV) was calculated. b) These ROI regions were converted to ROI microfinite element (µFE) models, which were then constrained at the bottom bone nodes while the upper nodes at the screw were displaced by 0.1 mm. c) In a parallel step, the full vertebral body with pedicle screws was also similarly segmented and converted directly to full vertebra (FV) µFE models.

110 GPa and Poisson's ratio of 0.3, typical of titanium; bone elements were attributed properties at the tissue scale, with Young's modulus of 12,000 MPa and Poisson's ratio of 0.3, based on nanoindentation measurements on vertebral bone in literature, after accounting for the dry state of the tested bone tissue.[19]

Virtual cement augmentation. The initial binary images of the FV models were adapted to simulate cement augmentation around the left, right, or the two screw tips. To do this, idealized spherical regions of 5 mm radius centred either at each screw tip or midway between the two screw tips were created around the tips of each screw (Figure 2). In total for the set of three specimens, this resulted in four image versions: 1) one where no cement was present (non-augmented); 2) one where the left screw tip was cemented; 3) one with the right screw tip cemented; and 4) a final image with cement embedding both screw tips. The corresponding regions in these FV models were then attributed Young's modulus and Poisson's ratio of bone cement from literature,[21] 3 GPa and 0.35, respectively.

Simulated load cases. For the ROI models, axial pull-out was simulated with a 0.1 mm axial displacement applied to the top nodes of the screw while bottom nodes were fully constrained. For the FV models, boundary conditions were defined so that bone surface nodes at the outer surface of the vertebra until the posterior elements were fully constrained, mimicking embedding used in experimental tests. Each FV model was then used to simulate two different loading schemes (Figure 3): 1) to simulate axial screw pull-out, a 0.1 mm axial displacement was assigned to the top nodes of the tested screw; and 2) to simulate forward bending, a 0.1 mm vertical displacement was applied at the superior nodes of the screw head, with the vertebral body aligned axially.

Pre- and post-processing and solving was performed with custom codes on a 10 dual core, 2.30 GHz Intel Xeon E5-2650 workstation with 128 GB of RAM. Models

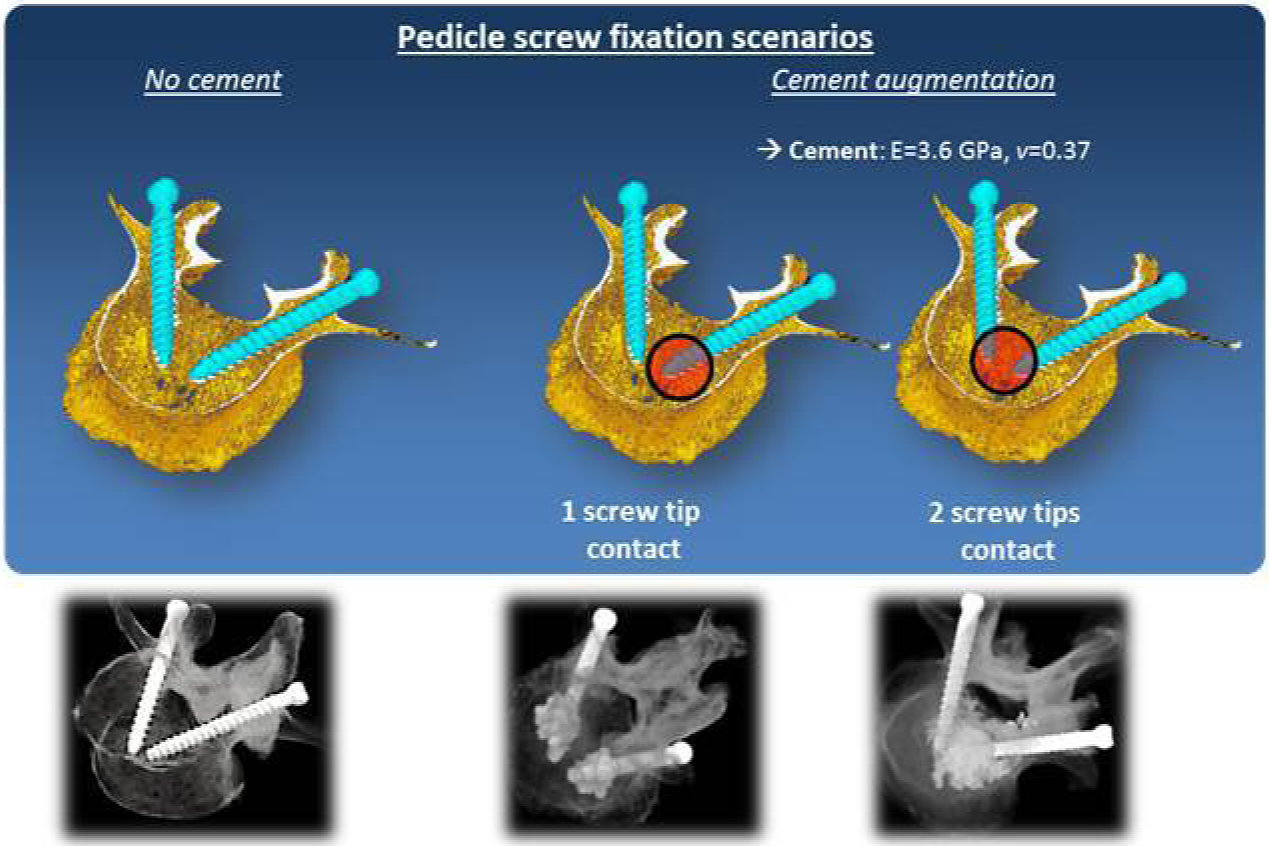

Fig. 2

The microfinite element models were used for testing cementing scenarios: non-augmented case; a case where cement zones were localized around each screw tip without contact; and a final case where cement zones were in contact with both screw tips.

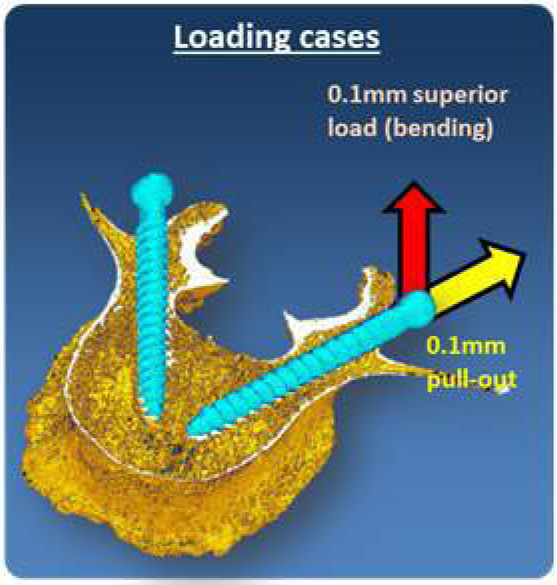

Fig. 3

Full vertebra microfinite element models were tested in axial pull-out and bending load for each screw.

were an open-source parallel solver (parFE; ETH Zürich, Switzerland).[22] For each model, von Mises stresses were visualized and structural stiffness of the pedicle screw-bone structure was calculated as the ratio of resulting force on the bottom bone nodes to the applied displacements. The modelling approach and limitations of the solver implied bonding at all interfaces.

Statistical analysis. To test our first hypothesis, linear regression correlations (including correlation coefficients (*R*)) were established between measured experimental properties and predictions of pull-out stiffness for each type of model (ROI and non-augmented FV), and compared to the ones derived between experimental properties and regional BV/TV. Linear regressions were tested for significance using a paired *t*-test. A Mann-Whitney U test was used to compare the experimental measurements and regional BV/TV for the different screw designs, and to compare the predicted stiffness between screw designs and between axial sub-models, as well as between the different augmentation scenarios for the FV models. Data are presented as means and standard deviations (SDs). Statistical significance was set at a level of $p < 0.05$.

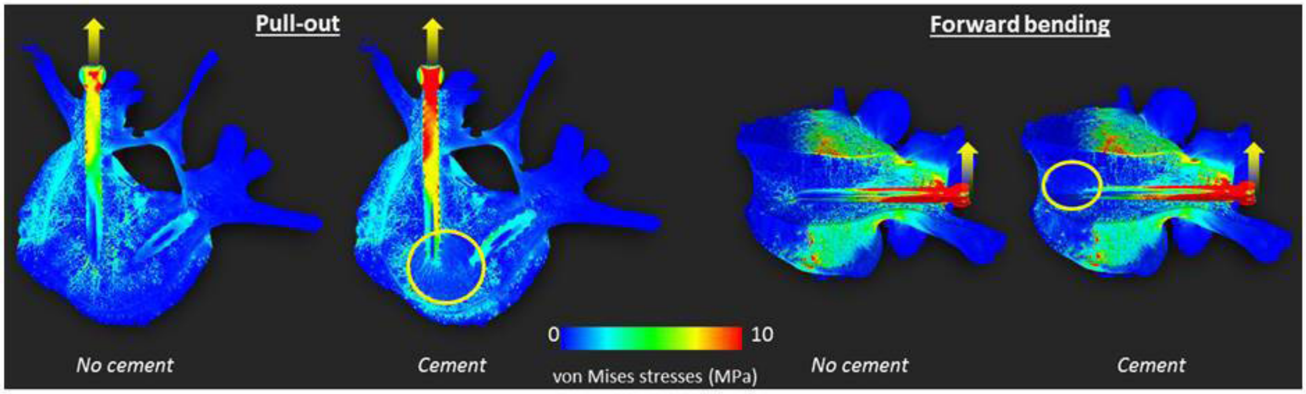

Fig. 4

Stress distributions in pull-out and bending within a typical full vertebra microfinite element model with and without cement augmentation (here shown for cement bridging both screw tips).

Table I. Regression parameters (slope and intercept), correlation coefficients (R^2), and p-values of linear regressions between experimentally measured pull-out strength and bone volume fraction around the screws, as well as with the predicted pull-out stiffness from the region of interest and full vertebra models.

Screw	BV/TV				μFE ROI pull-out stiffness				μFE FV pull-out stiffness			
	Slope	Intercept	R^2	p-value*	Slope	Intercept	R^2	p-value*	Slope	Intercept	R^2	p-value*
L	7,964.6	-1,699.6	0.8941	0.054	5.4589	-762.37	0.9165	0.020	1.0566	-335.55	0.9556	0.0124
R	4,781	-622.65	0.7485	0.135	5.4678	-778.6	0.9769	0.042	0.8892	-144.8	0.9177	0.040
L + R	6,133.8	-1,064.8	0.7884	0.003	5.4697	-772.75	0.94	9.03E-05	0.9845	-251.64	0.9344	6.4E-05

*Linear regression correlation.

BV/TV, bone volume fraction; μFE, micro-finite element; FV, full vertebra; L, Ennovate screw; R, S^4 screw; ROI, region of interest.

Results

Experimental test results and μCT-based BV/TV in the ROI. The mean experimental pull-out stiffness and strength were 624.95 N/mm (SD 75.99) for screw L and 690.89 N/mm (SD 121.94) for screw R (no significant difference due to screw design; p = 0.331, Mann-Whitney U test), and 1,180.24 N (SD 747.55) for screw L and 1,035.84 N (SD 580.96) for screw R (no significant difference due to design; p = 0.335, Mann-Whitney U test), respectively. The mean μCT-based BV/TV was 0.362 (SD 0.096) and 0.347 (SD 0.124) around screws L and R, respectively. No significant difference of BV/TV in the ROI due to screw design could be observed (p = 0.443, Mann-Whitney U test).

μFE predictions without cement augmentation. ROI simulations completed in under 33 minutes, while FV models were solved within 120 minutes. The stress distributions around screws for the FV are shown in Figure 4 for one typical specimen under both loading schemes, with and without cement augmentation.

The predictions of mean non-augmented pull-out stiffness for the ROI and FV models were 355.86 N/mm (SD 131.10) and 1,434.59 N/mm (SD 691.61) for the L screw, and 331.84 N/mm (SD 105.02) and 1,327.69 N/mm (SD 625.87) for the R screw, respectively. No significant differences due to screw design could be observed (p = 0.235 and p = 0.443 for the ROI and the FV models, respectively, Mann-Whitney U test). The predictions of mean bending stiffness for the non-augmented FV models were 88.70 Nmm/° (SD 50.80) and 95.68 Nmm/° (SD 48.93) for the L and R screws, respectively, without significant difference due to screw design (p = 0.235, Mann-Whitney U test).

Correlations between experimental pull-out strength and BV/TV and with μFE stiffness. Experimental pull-out strength was moderately correlated to BV/TV in the ROI around the screws for the pooled screw types (L + R: R^2 = 0.788, p = 0.003) as well as for each screw design (L: R^2 = 0.8941, p = 0.054; R: R^2 = 0.7485, p = 0.135, all linear regression correlation) (Table I). On the other hand, pull-out strength was strongly and significantly correlated with all μFE predictions, both pooled and for each screw type, of the ROI models and non-augmented FV models (R^2 > 0.91, p < 0.043, Mann-Whitney U test).

Furthermore, μFE-predicted stiffness generally significantly increased with increasing BV/TV around the screw, both in pull-out (L: R^2 = 0.956, p = 0.022; R: R^2 = 0.941, p = 0.030; L + R: R^2 = 0.931, p < 0.001, linear regression correlation) (Figure 5a) and in bending (L: R^2 = 0.837, p = 0.085; R: R^2 = 0.943, p = 0.029; L + R: R^2 = 0.883, p < 0.001, linear regression correlation) (Figure 5b).

Predictive stiffening effect of cement augmentation in pull-out and bending loads. Compared to the non-augmented scenario, pull-out stiffness was predicted to increase by mean 89.81% (SD 65.51%) and 89.87% (SD 76.48%) for L and R screws, respectively, when the cement was

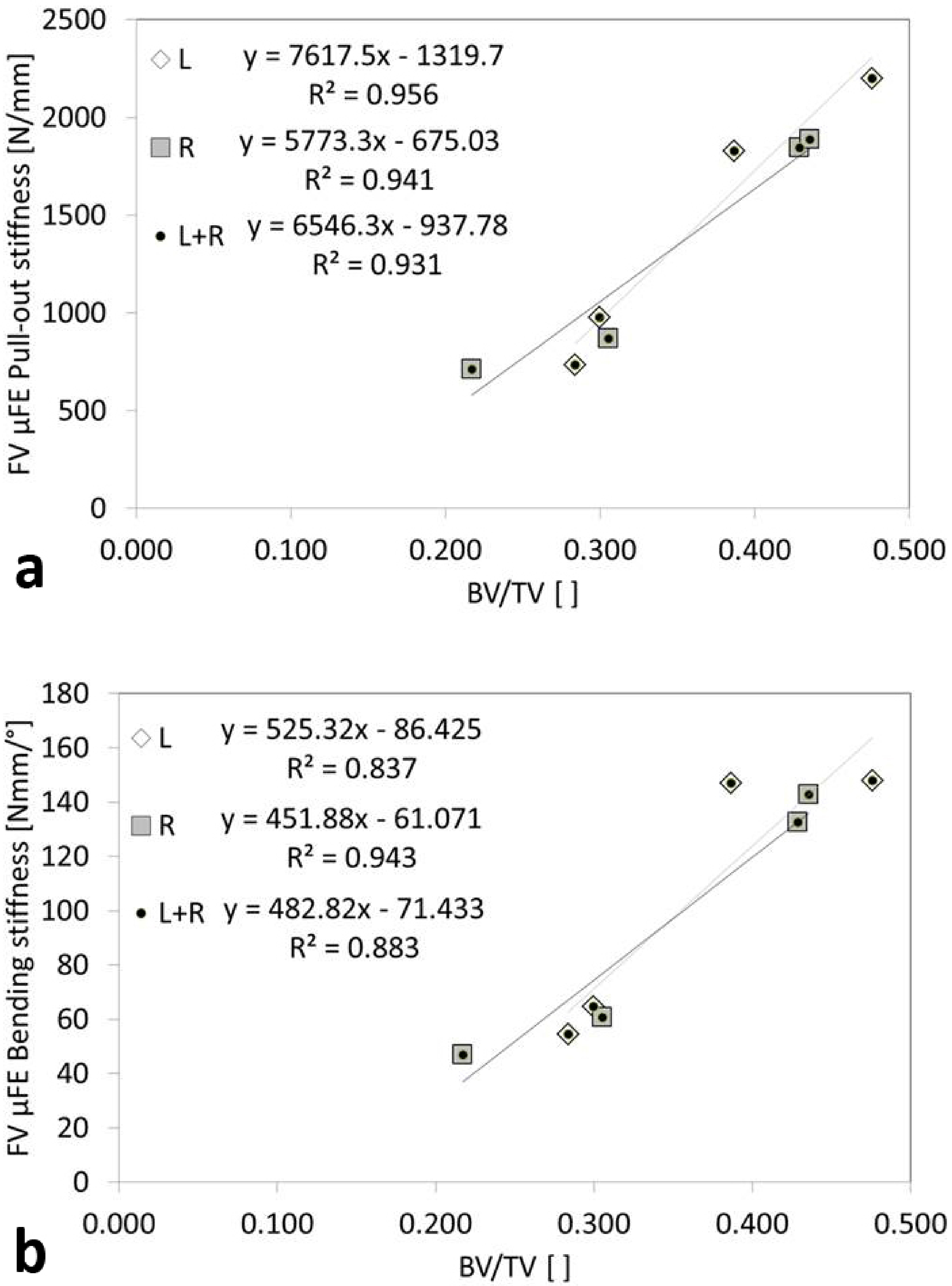

Fig. 5

Correlations between bone volume fraction (BV/TV) and the predicted stiffness in a) pull-out and b) bending. FV, full vertebra; L screw, Ennovate screw; R screw, S^4 screw; µFE, microfinite element.

isolated around the tested screw tip (Figure 6a). When the cement bridged both screw tips, these increased by mean 106.59% (SD 78.57%) (L screw) and 114.19% (SD 83.52%) (R screw). No significant difference due to screw design was observed in either cementing case ($p > 0.235$, Mann-Whitney U test).

The predictions of bending stiffness increases were mean 1.15% (SD 0.33%) (L screw) and 1.14% (SD 0.37%) (R screw) for cementing around one screw tip, and to mean 2.06% (SD 0.53%) (L screw) and 2.27% (SD 0.54%) (R screw) for cementing bridging both screw tips (Figure 6b). No significant difference due to screw design was observed in either cementing scenario ($p > 0.332$, Mann-Whitney U test).

Role of BV/TV on cement induced stiffening. For cementing involving only one screw tip, the stiffening effect of augmentation significantly increased with decreasing BV/TV around the screw in both pull-out (L + R: $R^2 = 0.831$, $p = 0.002$) and bending (L: $R^2 = 0.922$, $p = 0.040$; L + R: $R^2 = 0.847$, $p = 0.001$) (Figure 7). Significant trends were also predicted and more pronounced for samples with cement bridging both screw tips both in pull-out (L + R: $R^2 = 0.816$, $p = 0.002$) and bending (L: $R^2 = 0.990$, $p = 0.005$, linear regression correlation; R: $R^2 = 0.956$, $p = 0.022$, linear regression correlation; L + R: $R^2 = 0.949$, $p < 0.001$, linear regression correlation). Overall, the stiffening effect of cement augmentation on pull-out and bending stiffness was strongly and negatively correlated to local bone density around the screw ($R = -0.95$). None of these correlations were significantly altered by the type of screw ($p > 0.998$, Mann-Whitney U test).

Discussion

This study proposed the combined use of experimental tests, µCT imaging, and µFE models to evaluate some of the several biomechanical factors that might affect pedicle screw anchorage with and without cement augmentation. Our hypotheses were that: 1) bone quality around the screws can affect fixation stiffness in pull-out and bending; and 2) that cement augmentation of pedicle screw increases fixation stiffness in both loading modes in relation to bone quality around the screws.

There are several limitations to our study. Firstly, a small number of specimens from only one level (L2) were used to compensate for the extensive nature of the analyses; this might result in a reduced range of bone density and morphology, and potentially impact the observed correlations. Secondly, the resolution of µFE calculations and BV/TV could not account for bone debris resulting from screw insertion or local damage induced by screw implantation which might alter fixation strength,[23] but these may have limited impact on correlations between predicted stiffness and experimental strength.[19] Thirdly, due to scanning and computational constraints, µFE analyses were done at an element size below the recommended size for bone structural analyses.[24] It is yet to be verified if improving resolutions would change the obtained correlations. Fourthly, due to the limitation of the µFE solver, the bone-implant interfaces in our study were bonded, which can result in unrealistic tension in zones where free interfaces would exist. Finally, constant and linear elastic bone properties in our µFE models do not reflect plasticity regional differences in tissue composition and could lead to over-predictions.

Despite these limitations, our µFE models correlated excellently with experimental strength measurements in pull-out and were better predictors of fixation strength than regional BV/TV around the screws. This was already shown for ROI models,[19] and with this study improved even further using full vertebral bodies. Although more computationally demanding, these larger models, because they include larger portions of bone around the pedicle screws, could be used to test the specific hypothesis of fixation stiffness in relation to surrounding bone quality and forward bending. They also allowed investigation of cementing scenarios around the pedicle screws. Simulated forward bending loads at the pedicle screw revealed similar trends as pull-out simulations of the role of bone quality on their fixation stiffness; namely that for most tested cases, increased local apparent bone density statistically significantly increased bending stiffness, providing improved fixation against bending loads in a similar trend as for axial pull-out. This suggests that our first hypothesis is valid, and highlights the role of bone quality on fixation of pedicle screws in both loading modes. No statistically significant effect of screw design was observed in our analyses.

The methods also showed how the stiffening effect of cement augmentation is dependent on local bone density, validating our second hypothesis. Statistically significant relationships were generally observed in both loading modes, and for the two tested cement augmentation scenarios. Such trends were previously suggested for bone anchoring devices in various loading modes.[17] The present study furthermore shows that cementing around each screw tip individually may already be sufficient to stiffen pull-out fixation by at least 16% depending on the screw type, as seen in regions of higher bone density, and provides a stiffening up to nearly 165% in weaker bone; these proportions were slightly increased to nearly 200% when cement bridged both screw tips. These findings are supportive of a recent study where poly(methyl methacrylate) augmentation has been proven to increase pedicle screw pullout forces by up to 348% in some situations.[25] They are also in agreement with cement augmentation of screws in other anatomical locations, where cementing was predicted to increase stiffness.[25] On the other hand, in bending loads, stiffening was more marginal despite statistically significant trends of increased stiffness with decreased bone density. Nevertheless, such results should be taken into account when using cement to augment fixation, such as the reported risks of leakage and difficulty of pedicle screw removal in cases of revisions or complications,[26] and could be used to optimize cement

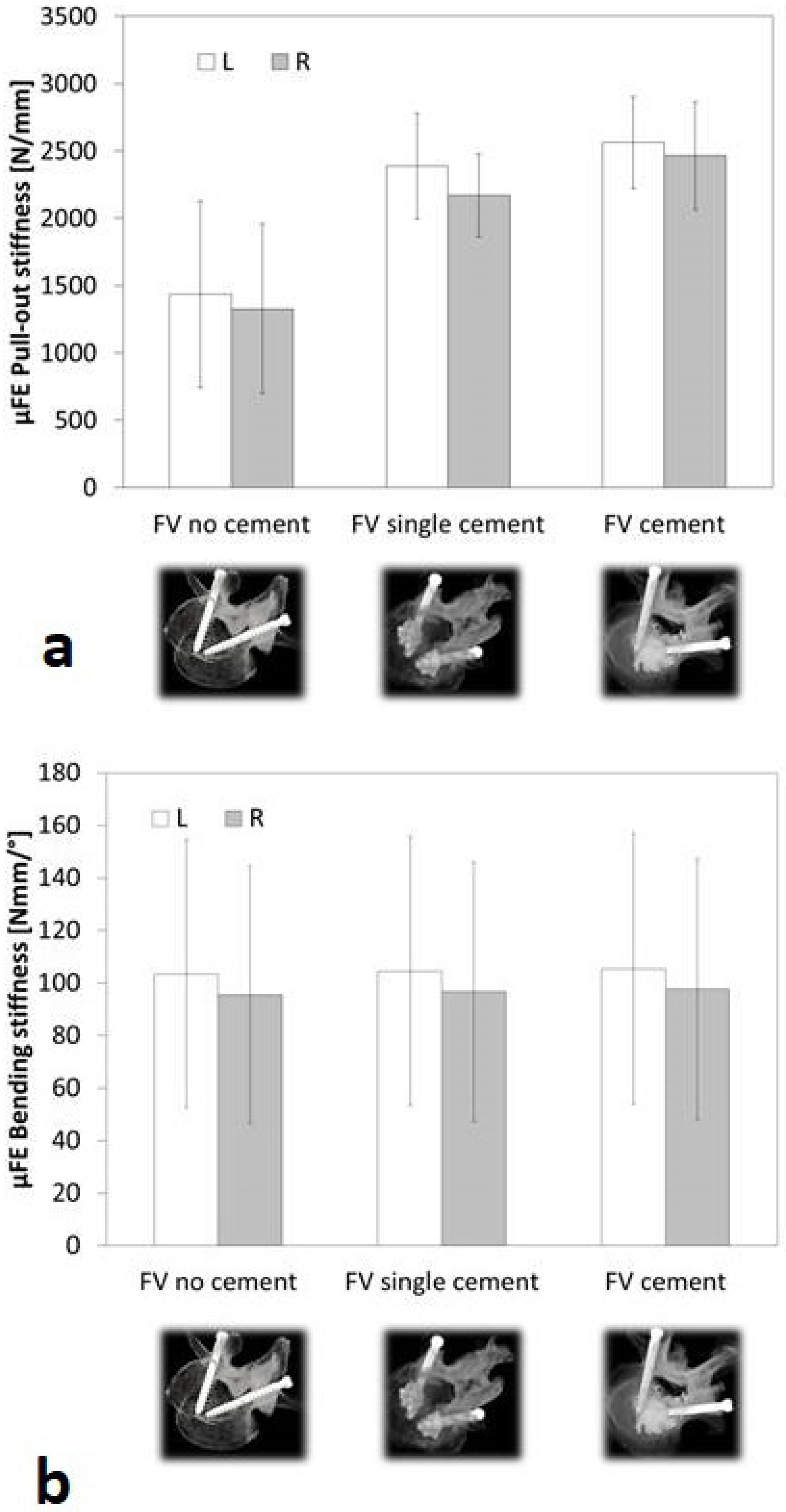

Fig. 6

The effect of different cement augmentation scenarios on the mean predicted stiffness in a) pull-out and b) bending from the full vertebral models. FV, full vertebra; L screw, Ennovate screw; R screw, S^4 screw; µFE, microfinite element.

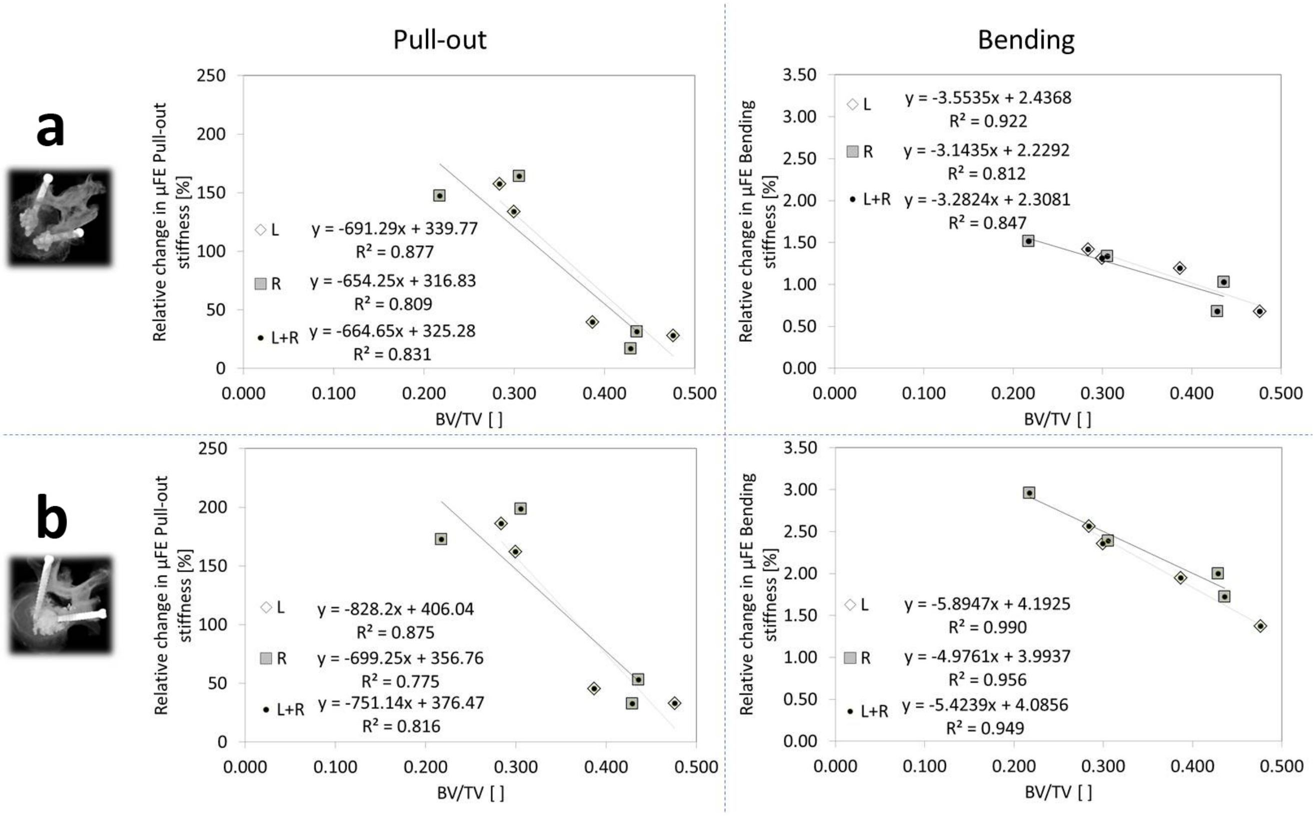

Fig. 7

Correlations between the relative stiffness change in pull-out and bending with bone volume fraction (BV/TV) around the screws for the two tested cementing scenarios (a: one screw tip; b: both screw tips). Trends show increased stiffness change with decreased BV/TV around the screws for both loading modes. μFE, microfinite element.

volumes and properties as well as targeting specific localization to avoid surgical and post-surgical complications.

In our study, we used μFE approaches similar to one which was previously validated for proximal humeral fixation systems.[27] A recent study using homogenized numerical approaches based on high-resolution quantitative CT scanners has also been applied to predict the effects of cement augmentation on screw fixation in the proximal humerus,[25] and could test the effect of different screw configurations on fixation stiffness. While computationally demanding, the extension of such μFE approaches to cement augmentation of screw fixation systems in long bones appears to be possible, but will evidently require proper validation with experimental results.

While such μFE approaches rely on resolutions not available for the spine, these findings can relate to clinically accessible methodologies, especially available resolutions for CT scanners in the clinical practice. A recent study has shown statistically significant relationships between CT-derived BMD and bone parameters obtained from μCT scanners.[28] To some extent, we can assume that the relationships between fixation stiffness and increased BV/TV around the screws would also be reflected by clinically accessible CT BMD. Hence, a priori knowledge of regional BMD through clinical scanners used during preoperative planning might help to better plan the clinical procedure and use of cement in low-quality bone, targeting specific areas for patients suffering from osteoporosis. We emphasize the structural role of bone density, typically measurable from CT images, in improving fixation of pedicle screws, and how cement can further stiffen this fixation when lower bone density can be measured in the planned trajectory around the screws. Such information could in the future be implemented in robotic surgery systems accounting for patient-specific factors.[29]

In conclusion, our combined experimental, μCT, and μFE analysis showed that fixation stiffness of pedicle screws may be predominantly influenced by regional bone quality. While no differences could be observed between the tested screw designs, our analyses suggested that stiffening due to cement augmentation might depend on the cementing scenario as well as surrounding bone quality. This methodology might be useful for future investigations on the effects of different cementing scenarios on the fixation of pedicle screws, involving a more exhaustive variation of volumes and cement properties as well as more specific targeting of cement localizations to strengthen fixation.

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