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Pullout characteristics of percutaneous pedicle screws with different cement augmentation methods in elderly spines: An in vitro biomechanical study

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ABSTRACT

Background: Vertebroplasty prefilling or fenestrated pedicle screw augmentation can be used to enhance pullout resistance in elderly patients. It is not clear which method offers the most reliable fixation strength if axial pullout and a bending moment is applied. The purpose of this study is to validate a new in vitro model aimed to reproduce a cut out mechanism of lumbar pedicle screws, to compare fixation strength in elderly spines with different cement augmentation techniques and to analyze factors that might influence the failure pattern.
Materials and methods: Six human specimens (82–100 years) were instrumented percutaneously at L2, L3 and L4 by non-augmented screws, vertebroplasty augmentation and fenestrated screws. Cement distribution (2 ml PMMA) was analyzed on CT. Vertebral endplates and the rod were oriented at 45° to the horizontal plane. The vertebral body was held by resin in a cylinder, linked to an unconstrained pivot, on which traction (10 N/s) was applied until rupture. Load-displacement curves were compared to simultaneous video recordings.
Results: Median pullout forces were 488.5 N (195–500) for non-augmented screws, 643.5 N (270–1050) for vertebroplasty augmentation and 943.5 N (750–1084) for fenestrated screws. Cement augmentation through fenestrated screws led to significantly higher rupture forces compared to non-augmented screws (*P* = 0.0039). The pullout force after vertebroplasty was variable and linked to cement distribution. A cement bolus around the distal screw tip led to pullout forces similar to non-augmented screws. A proximal cement bolus, as it was observed in fenestrated screws, led to higher pullout resistance. This cement distribution led to vertebral body fractures prior to screw pullout.
Conclusion: The experimental setup tended to reproduce a pullout mechanism observed on radiographs, combining axial pullout and a bending moment. Cement augmentation with fenestrated screws increased pullout resistance significantly, whereas the fixation strength with the vertebroplasty prefilling method was linked to the cement distribution.

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1. Introduction

Minimally invasive surgery (MIS) has increased over the last decade and percutaneous instrumentation techniques have enlarged surgical treatment options for certain indications [1]. Unstable osteoporotic thoracolumbar fractures, osteonecrosis of the vertebral body and vertebral metastases can be managed by

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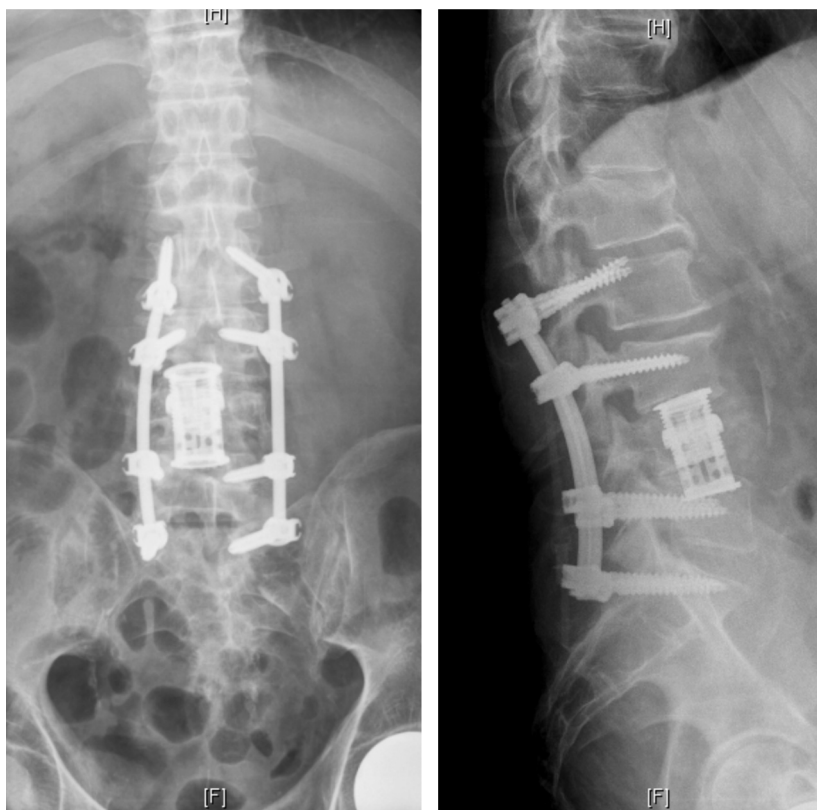*E-mail address:* yann.philippe.charles@chru-strasbourg.fr (Y.P. Charles).

Fig. 1. Failure pattern of screw pullout observed on radiographs in an elderly patient.

percutaneous instrumentation, eventually combined with mini open decompression. The minimal access reduces intraoperative blood loss and risk for infection, which seems valuable in elderly patients with higher co-morbidities. However, the decreased bone mineral density represents a risk factor for mechanical failure. This can be addressed by multiplying the number of anchor points using bi-cortical percutaneous pedicle screws, which may expose to some risk of anterior vascular injury. Expandable screws represent an alternative that can optimize pullout resistance [2,3]. Cement augmentation is the most popular method for increasing screw fixation strength in the elderly spine. Two techniques are mainly used: vertebroplasty with secondary screw insertion, or cannulated and distally perforated screws, which allow cement injection through the screw [4–7]. This principle has been used with MIS, and its clinical application is safe when following the cement flow carefully under fluoroscopic control [1,8].

The pullout resistance of augmented pedicle screws is usually tested in vitro by applying a posterior axial force to the screw [2,4,9,10]. However, this failure model does not exactly reflect observations that can be made on radiographs (Fig. 1). In vivo, a combination of axial compression in the cranio-caudal direction, antero-posterior shear, and flexion-extension moments are probably simultaneously transmitted through the spine. It may be the more clinically relevant loading that the instrumentation must withstand. This can result in progressive toggle migration in the elderly spine and finally lead to screw pullout [11,12]. It would therefore be interesting to set up an experiment, which allows several stress components rather than axial pullout of the screw. In vitro models have theoretical limitations because different stress components interact irregularly on the patient during daily physical activity. Other in vivo conditions such as muscle forces and sagittal balance cannot be reproduced.

The purpose of this study was to validate the functioning of a new in vitro model, to compare the fixation strength of percutaneous lumbar pedicle screws in the elderly spine using different augmentation methods, and to analyze subsequent factors that might influence the failure pattern.

2. Materials and methods

A preliminary test, including 4 vertebrae (L3 and L4) from a 93-year-old male and a 42-year-old male, was performed to validate the functioning of the experimental setup. The behavior of screw pullout these specimens with different bone quality was compared first.

Six fresh-frozen human cadaveric trunks were then screened for osteoporotic fractures at levels other than L2, L3 and L4 using fluoroscopy. The average age of the donors was 89.8 years and ranged from 82 to 100 years. There were 4 males and 2 females. The specimens were thawed to 6 °C 3 days before starting instrumentation. Percutaneous pedicle screw placement was performed under fluoroscopy bilaterally from L2 to L4. A 4.5 mm tap was used at the pedicle only. Cannulated pedicle screws of 6.5 mm diameter and 45 mm length (Mantis Augmentable, Stryker Spine S.A., Cestas, France) were inserted over a guide wire. In each specimen, one level was instrumented without additional augmentation. At the second level, a vertebroplasty was performed through Jamshidi needles with 2 ml high viscosity polymethylmetacrylate (PMMA) cement (VertaPlex HV, Stryker Instruments, Kalamazoo, MI, USA) on each side, and screws were then inserted. At the third level, a 2 ml PMMA cement augmentation was performed through each cannulated screw, while the distal fenestration was made of 3 rows of 3 holes oriented at 120° each (Fig. 2). Each configuration was respectively distributed on two L2, L3 and L4 levels in all specimens to limit the influence of anatomical level related effects.
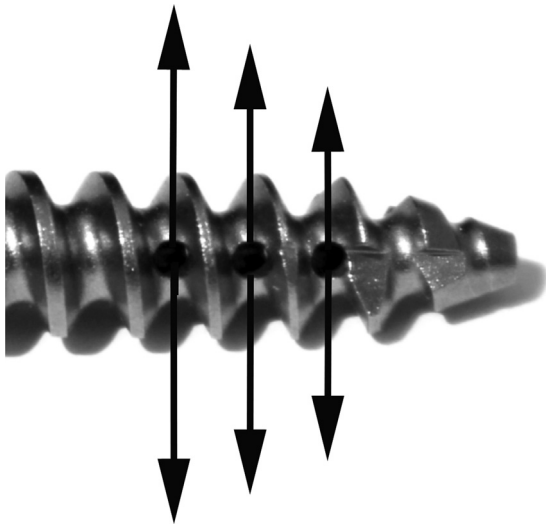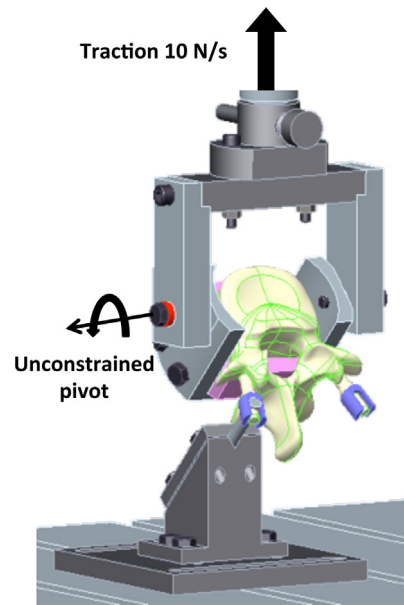
Fig. 2. Distal part of the fenestrated screw showing amount of cement flow schematically.

Fig. 3. Experimental setup applying traction to an unconstrained pivot at the level of the vertebral body.

Comparisons between the 3 configurations were performed intra-individually.

The specimens were then dissected: muscles, ligaments, joint capsules and discs were removed, leaving the bony structures intact. Each instrumented vertebra was individualized and sealed in double plastic bags. A computed tomography (CT) and a three-dimensional reconstruction of each vertebra were performed (Somatotom Definition AS 128, Siemens, Erlangen, Germany) to analyze screw positioning and cement distribution. The experiment was then performed at room temperature.

The cranial half of the vertebral body was embedded in a plastic container using an acrylic resin (VersoCit-2, Struers, Ballerup, Denmark). The molded resin block was then fixed in a metal container that was designed for this purpose. This container was linked via an unconstrained pivot to a servo-hydraulic traction machine with a load cell of 2.5 kN (Zwick Roell Z2.0, Zwick GmbH, Ulm, Germany). Only one screw per vertebra was tested. The right pedicle screw was fixed to a 6 mm diameter titanium rod in a 90° orientation by a blocker screw, which was tightened at 12 Nm using a counter torque to avoid screw loosening by manipulation. The rod was then fixed in a metal block, which was screwed to the table. In the sagittal plane, this construct oriented the rod and the vertebral endplates at 45° in relation to the horizontal plane. This setup allowed applying a combination of axial pullout and bending moment to the screw, aiming for a failure mechanism observed on radiographs (Fig. 1). The rod length between the screw head and the block was 20 mm (Fig. 3). After the specimens were mounted, pullout force was applied by traction to the pivot at a constant crosshead rate of 10 N/s until complete rupture of the screw-bone fixation. This point was recorded as the maximum pullout force before the load decreased abruptly. The experiment was filmed using a camera with a 2 Mpx resolution (Canon MVX3i, Canon Inc., Tokyo, Japan). This allowed detecting beginning screw loosening and toggling before rupture and subsequent comparison with the load-displacement curve.

Statistical evaluation was performed with R Software Version 2011 (R Foundation for Statistical Computing, Vienna, Austria). The rupture forces of the 3 configurations were compared by paired samples using a Kruskall-Wallis test with a Bonferroni correction. The significance level was set at 0.017.

3. Results

3.1. Preliminary test

A preliminary test was performed on L3 and L4 respectively in a younger and in an older specimen. The load-displacement curves demonstrate that the maximum pullout force was around 400 N in an elderly and around 1000 N in a younger spine (Fig. 4). The curve aspect was relatively reproducible. The linear part of the curve corresponded to continuous loading, which was followed by a curve portion with a decreased slope. This part of the loading phase was usually associated with audible cracks and it corresponded to progressive screw migration with a cutout mechanism on the films. In elderly bone, the rupture point was reached after a very short period of screw migration with abrupt subsequent pullout as demonstrated by preliminary test specimen 1.

3.2. Forces at rupture

Table 1 demonstrates rupture forces for non-augmented screws, screws with vertebroplasty and fenestrated screws. Cement augmentation through fenestrated screws led to significantly higher rupture forces compared to non-augmented screws ($P = 0.0039$). Although the median rupture force was higher in vertebroplasty augmentation versus non-augmented screws, this difference was not significant ($P = 0.1495$). The same applied when comparing fenestrated screws versus vertebroplasty augmentation ($P = 0.0547$). The inter-specimen variations between rupture forces with the vertebroplasty augmentation technique are evidenced in Fig. 5. The load-displacement curves of specimen 4 are close to the average curve distribution for the 3 configurations, which are represented in Fig. 6.

Table 1
Rupture forces (Newton) for non-augmented screws, vertebroplasty screw augmentation and cement augmentation through fenestrated screws.

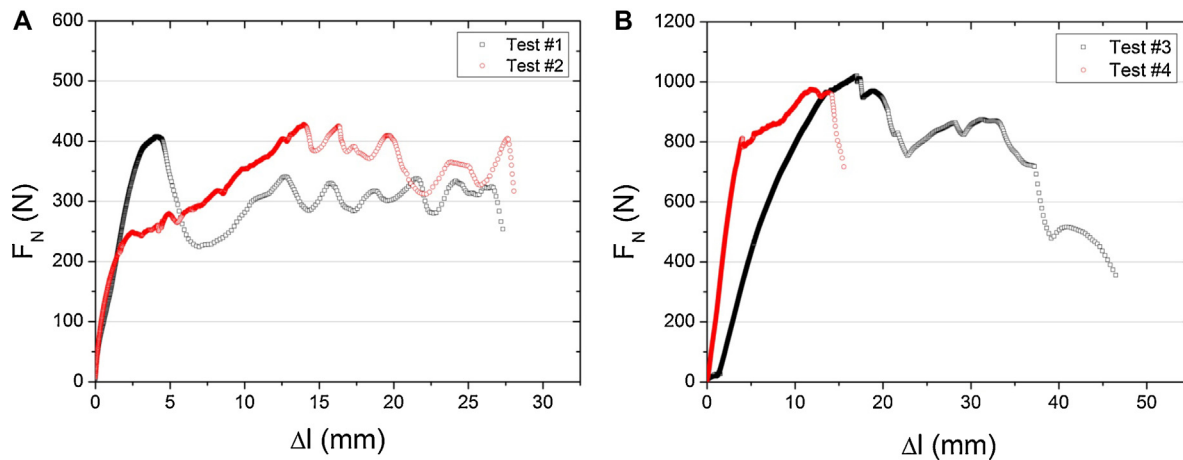|	Median	Average ± S.D.	Minimum	Maximum
Without cement ($n = 6$)	488.5	452.8 ± 138.7	195	580
Vertebroplasty ($n = 6$)	643.5	658.3 ± 274.3	270	1050
Fenestrated screw ($n = 6$)	943.5	941.7 ± 114.9	750	1084

Fig. 4. Load-displacement curves of preliminary test on 2 vertebrae of a 93-year-old male (A) and 2 vertebrae of a 42-year-old male (B).

3.3. Influence of cement distribution

When analyzing CT images, it appeared that the cement distribution was homogeneous around fenestrated screws, whereas the location of the cement bolus around the screw was more variable when performing a vertebroplasty and inserting the screw afterwards (Fig. 7). A proximal cement distribution located in the middle of the vertebral body, closer to the pedicle, was regularly achieved in fenestrated screws. A similar cement distribution was observed with vertebroplasty in 3 specimens (1, 5, 6), whereas the cement bolus was mainly located around the distal tip of the screw in the 3 other specimens (2, 3, 4).

3.4. Rupture patterns

Two rupture patterns were observed and closely linked to the cement distribution. A pullout of the screw was observed in all vertebrae without cement augmentation and in vertebroplasty augmented screws, where the cement bolus was located around the distal part of the screw (specimens 2, 3, 4). A fracture of the vertebral body without detachment of the screw from the pedicle was observed in all fenestrated screws. The same applied to vertebroplasty augmentation with a proximal cement distribution (specimens 1, 5, 6).

4. Discussion

Pullout resistance is usually tested as axial pullout force until complete dislocation of the pedicle screw. Reference values for conventional screws without augmentation in normal bone range from 812 to 1546 N [2,13–15]. The results of our preliminary test on the younger specimen fit within this range. Variations may be due to different experimental settings and different vertebral dimensions. The instrumentation technique itself, using different screw insertion torques and screw insertion angles, play a role for pullout resistance [13,16,17]. Screw design parameters, such as screw diameter, length, conical or cylindrical shape and the thread, may also influence the pullout resistance [18,19]. In elderly specimens, these technical variables seem to have less influence compared to normal bone, especially if a cement augmentation method is used [5].

Pullout resistance has also been largely analyzed in elderly specimens. In vitro average axial pullout forces of non-augmented pedicle screws range from 159 to 663 N [2–4,15,16,20,21]. Although the rupture mechanism was different in our experimental setup, including a bending moment, the pullout forces were comparable to the findings of studies performing axial pullout. The pullout resistance may be influenced by the degree of bone mineral density, the screw diameter and length.
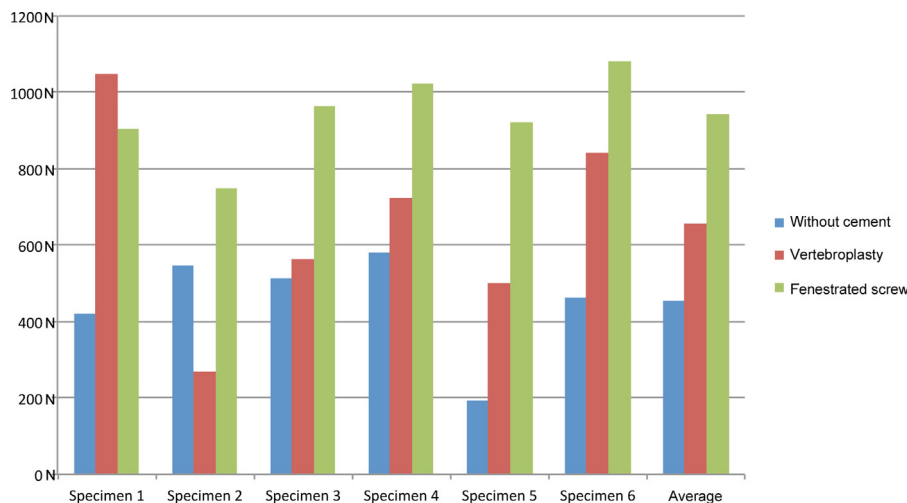

Fig. 5. Rupture forces (Newton) for non-augmented screws, vertebroplasty augmentation and fenestrated screw augmentation in each specimen and averages.
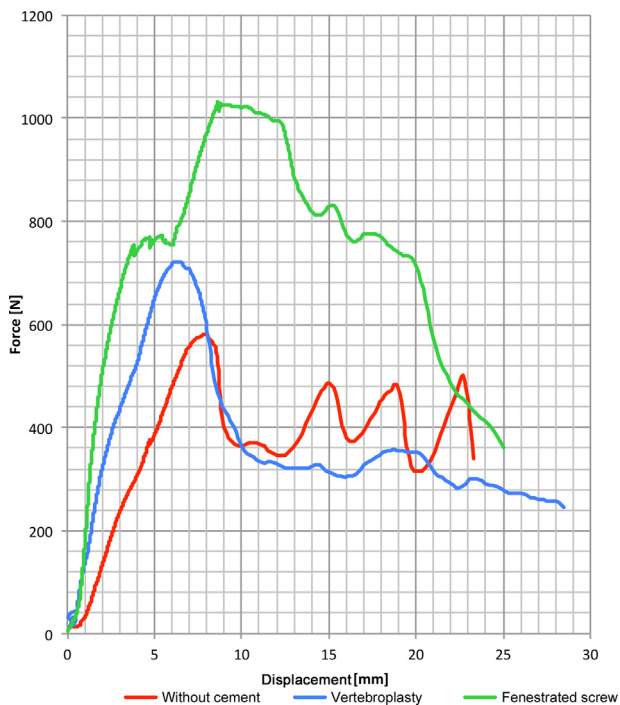
Fig. 6. Exemplary load-displacement curves for each configuration in specimen 4.

Cement augmentation is usually performed through cannulated and fenestrated screws using PMMA. This method is standardized and allows increasing the axial pullout resistance, which ranges between 501 and 1320 N [2–4,15,20,21]. The values measured in the present study fit within this range, which still keeps relatively large. Apart from differing experimental conditions, technical factors that influence pullout resistance may be due to the design of the screw and its fenestration, cement viscosity and volume [10,20,22].

The cement augmentation method combining vertebroplasty and secondary screw insertion also leads to higher axial pullout forces compared to non-augmented screws, with average values reported between 516 and 920 N [2–4,23]. Forces measured in our study fitted within the lower range of these values. Important variations were noticed between the specimens, which were mainly related to the cement distribution. The major difference with fenestrated screws is the irregularity of cement distribution around the screw when using a prefilling technique. A clinical CT evaluation reports the possible cement distribution around the screw in the vertebral body and within the pedicle when using this technique [24]. A pullout test performed on synthetic osteoporotic bone indicated that complete cement prefilling around the pedicle screw

would lead to a higher pullout resistance than cement injection through a fenestrated screw. This may be valid for experimental conditions. In clinical practice, however, complete retrograde filling of the pedicle and the posterior part of the vertebral body is not suitable because of the risk of cement leakage. The cement bolus should therefore be injected around the middle of the cranial half of the vertebral body. This has been performed in our percutaneous instrumentation technique. Nevertheless, CT imaging evidenced that the location of the cement bolus was not as precise as expected. This technical aspect had an influence on pullout resistance. An anterior position of the cement in the vertebral body, around the distal tip of the screw, did not increase pullout forces and this configuration was comparable to non-augmented screws. A proximal cement distribution in the posterior two thirds of the vertebral body led to higher pullout resistance comparable to fenestrated screws. Furthermore, an experiment on synthetic bone showed that the pullout resistance increased in fenestrated screws if the holes were located more proximal [10].

The injected cement type and its volume could also play a role for pullout resistance. A finite element analysis showed that volumes between 2 and 3 ml increased pullout resistance significantly compared to non-augmented screws, and volumes between 3 and 4 ml could theoretically further increase pullout strength [25]. In vitro, the realization of a balloon kyphoplasty, which concentrates a higher cement volume around the screw, did not increase pullout resistance in comparison to a fenestrated screw augmentation [4]. Clinically, it seems that volumes between 1 and 3 ml allow an adequate screw-bone fixation in elderly specimens [5]. The exact cement volume injected intra-operatively is triggered by fluoroscopy, showing its distribution around the screw. A clear mechanical advantage of increased pullout strength of high viscosity cements was not found in vitro [25].

The present study showed that rupture patterns were linked to anchoring of the screw in the vertebral body. A pullout was observed in non-augmented screws and in screws surrounded by a distal cement bolus. In screws augmented by a proximal bolus, the vertebral body fractured before pullout would occur. This failure mode may be linked to the combination of axial traction and a bending moment, comparable to fractures observed in proximal junctional kyphosis. Nevertheless, similar observations were made with axial pullout [5,16,21]. The amount of osteoporosis might further play a role and it would be interesting to correlate bone mineral density and rupture pattern.

Choma et al. [11] developed a foam model, which allowed a combination of axial pullout and flexion bending moment, having unconstrained screw motion within the foam. They hypothesized that pedicle screw loosening was further due to compressive loads resulting in viscoelastic creep of demineralized cancellous bone. Multiple loading cycles in vivo would result in progressive
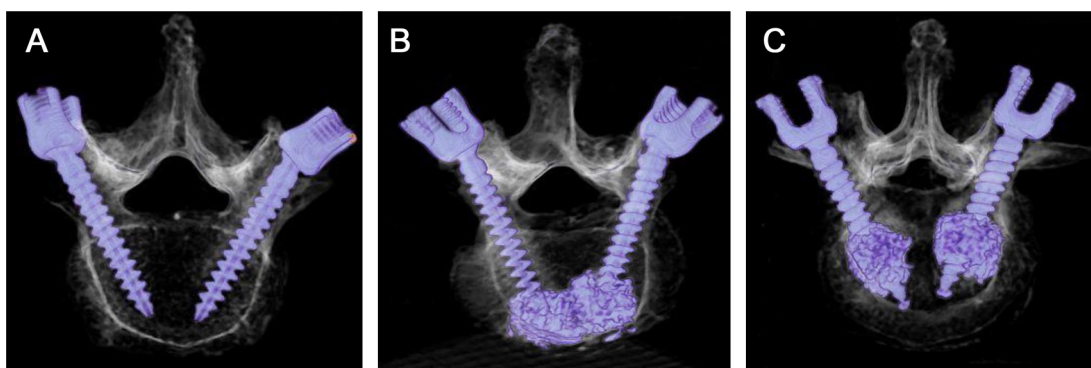

Fig. 7. CT reconstruction of non-augmented screw (A), vertebroplasty with distal cement bolus (B) and augmentation through fenestrated screw with proximal cement bolus (C).

micro-fractures and toggle migration until a certain threshold force is exceeded, leading to screw pullout [12]. The exact screw loosening process remains a complex interaction of different loading patterns in vivo and sagittal balance or muscle forces would also need to be considered. Although this is difficult to reproduce, our experimental setup tends to mimic failures observed on radiographs in elderly patients. Nevertheless, rupture loads were similar to axial pullout reported by in vitro experiments [2–4,15,16,20,21].

5. Conclusion

The new experimental setup tends to reproduce a screw pullout mechanism observed on radiographs by combining axial pullout with a bending moment. Cement augmentation with fenestrated screws increases pullout resistance significantly compared to non-augmented percutaneous pedicle screws. The pullout strength with the vertebroplasty prefilling method is linked to the cement distribution around the screw. A proximal cement bolus leads to higher pullout resistance and fracture of the vertebral body prior to screw pullout.

Disclosure of interest

The first author is consultant for Stryker.

Acknowledgments

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