

Basic Science

# In vitro biomechanics of an expandable vertebral body replacement with self-adjusting end plates

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## Abstract

**BACKGROUND CONTEXT:** Unstable burst fractures of the thoracolumbar spine may be treated surgically. Vertebral body replacements (VBRs) give anterior column support and, when used with supplemental fixation, impart rigidity to the injured segments. Although some VBRs are expandable, device congruity to the vertebral end plates is imprecise and may lead to stress risers and device subsidence.

**PURPOSE:** The objective of this study was to compare the rigidity of a VBR that self-adjusts to the adjacent vertebral end plates versus structural bone allograft and with an unsupported anterior column in a traumatic burst fracture reconstruction model.

**STUDY DESIGN:** Biomechanical flexibility testing with rod strain measurement.

**PATIENT SAMPLE:** Twelve T11–L3 human spine segments.

**OUTCOME MEASURES:** Range of motion, neutral zone, and posterior fixation rod stress (moments).

**METHODS:** Flexibility testing was performed to  $\pm 6$  Nm in flexion-extension, lateral bending, and axial rotation on 12 intact human T11–L3 specimens. Burst fractures were created in L1, and flexibility testing was repeated in three additional states: subtotal corpectomy with posterior instrumentation (PI) only from T12 to L2, reconstruction with a femoral strut allograft and PI, and reconstruction with a VBR (with self-adjusting end plates) and PI. The PI consisted of pedicle screws and strain gage instrumented rods that were calibrated to measure rod stress via flexion-extension bending moments.

**RESULTS:** There was no statistical difference in range of motion or neutral zone between the strut graft and VBR constructs, which both had less motion than the PI-only construct in flexion/extension and torsion and were both less than the intact values in flexion/extension and lateral bending ( $p < .05$ ). Posterior rod moments were significantly greater for the PI-only construct in flexion/extension relative to the strut graft and VBR states ( $p = .03$ ).

**CONCLUSIONS:** This study, which simulated the immediate postoperative state, suggests that a VBR with self-adjusting end plate components has rigidity similar to the standard strut graft when combined with PI. Posterior rod stress was not significantly increased with this type of VBR compared with the strut graft reconstruction. The benefits of burst fracture stabilization using a self-adjusting VBR ultimately will not be known until long-term clinical studies are performed. © 2010 Elsevier Inc. All rights reserved.

**Keywords:** Corpectomy; Spinal fracture; Vertebral body replacement; Vertebral end plate; Biomechanics

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## Introduction

Traumatic thoracolumbar burst fractures typically involve the vertebral body with a fracture fragment in the anterior spinal canal and varying degrees of kyphosis.

Surgical treatment often applies to patients with an unstable type of burst fracture or a neurologic deficit, and usually the procedure includes an indirect or direct decompression with stabilization. In most cases of surgical

stabilization, an arthrodesis procedure is used in combination with internal instrumentation.

For patients treated surgically, there are a number of options. One such option is an anterior spinal fusion (ASF), which typically uses a structural interbody bone graft spanning across the fractured segment and instrumentation with fixation to the vertebrae directly above and below the injured segment. This approach also allows for direct decompression of the spinal canal by removal of bony fragments in the spinal canal via a concurrent corpectomy [1–4]. However, anterior fixation (which usually consists of screws with purchase into cancellous vertebral body bone) may not be sufficient in patients with osteopenia or in patients who are unable or unwilling to follow a restricted postoperative activity regimen [5]. For patients with poor bone quality or unstable burst fractures, those who have additional disruption to the posterior elements/ligaments, a combined ASF/posterior spinal fusion (PSF) provides the greatest rigidity and the greatest ability to correct kyphosis [6–8]. Anterior spinal fusion/PSF also allows direct decompression, but this combined approach is associated with increased surgical time and bleeding [9,10]. Both ASF only and ASF/PSF may use structural bone allografts or vertebral body replacements (VBRs) combined with morselized bone autograft in lieu of structural bone autografts. Vertebral body replacements have distinct advantages, such as avoiding the potential for infectious disease transmission that may be seen with the use of allograft. They also avoid the morbidity associated with autogenous bone graft harvesting [11]. Vertebral body replacements also are easily available and come in a variety of sizes, allowing the surgeon to tailor the interbody device to the patient's needs. Additionally, expandable type VBRs and specialized instrumentation used in conjunction with VBRs may save surgical time and allow for more efficient operation.

Generally, surgical treatment with ASF or ASF/PSF results in dramatic improvement for patients compared with their injury state [3,10–16]. However, not all patients get back to their baseline function and some have residual pain [8,12–15,17–19]. For a fraction of these patients, the residual pain may be because of VBR subsidence and secondary kyphosis or pseudarthrosis. Currently available VBRs may be available in various fixed angulation; however, end plate congruity and alignment is not precise, and thus stress risers may still be present, which clinically may lead to subsidence [14,20–23]. This has led to numerous biomechanical investigations attempting to identify mechanisms to decrease implant/bone interface stress and the risk of subsidence [24–28].

Despite the overall success of surgical intervention, treatment with VBRs can still be optimized. Another option that attempts to reduce subsidence is a partially elastic anterior stabilization device, which is the subject of this biomechanical study. The experimental VBR evaluated in this study is flexible under low loads and rigid under high loads,

and it can be expanded for restoration of vertebral height and kyphosis correction. Specifically, it consists of two elastic (springlike) members attached to a central expandable fixation member (which becomes locked in the elongated position). It is designed to allow a minimal amount of axial compression (1 to 1.5 mm) and unlimited bending motion (within a 30° arc for each member) so that it can self-adjust to changes in vertebral end plate angulation that occur during device elongation and, therefore, reduce stress risers at the implant/bone interface. Porous metallic surfaces allow for fixation by bony ingrowth to the end plates.

The purpose of this study was to assess the *in vitro* rigidity of fusion constructs employing this experimental VBR with self-adjusting end plates supplemented with posterior instrumentation (PI) by simulating early postoperative loading and observing the resulting rotations. A secondary objective was to determine bending moment changes to supplemental PI in reconstruction of a subtotal corpectomy model with this “dynamic self-adjusting” VBR compared with the standard femoral cortical shaft allograft.

## Materials and methods

Twelve thoracolumbar human spines (mean ± standard deviation donor aged 53 ± 14 years) were obtained and stored at –20°C until use. The specimens were free of bony disease. Their bone density was measured (DEXA; GE Lunar Prodigy, Fairfield, CT, USA) as well as baseline anterior-posterior and lateral plain radiographs and computed tomography scans were performed. The dual energy X-ray absorptiometry (DXA) measurements found a mean bone density of 1.17 ± 0.23 g/cm<sup>2</sup> and corresponding *t* scores of –0.2 ± 1.9. In comparison, normal bone *t* scores of the World Health Organization classification are between +1.0 and –1.0 and osteopenia is between –1.0 and –2.5. Specimens were isolated to T11–L3 segments, and the ends were potted in epoxy (Fast Cast 891; Goldenwest Manufacturing Inc., Cedar Ridge, CA, USA) and reinforced with coarse threaded screws into the vertebrae of T11 and L3. Soft tissues were removed except for the discs and ligaments.

Specimens were first tested in the intact state by applying pure moments of 6 Nm along with a 100 N axial preload in flexion/extension, lateral bending, and axial torsion. These load magnitudes have been previously used [7,29–34]. Furthermore, they have clinical support based on a previous *in vivo* study of a telemetrized VBR [35]. Axial loads were applied using the actuator of a load frame (Enduratec; Bose, Eden Prairie, MN, USA). Moments were applied in an unconstrained fashion at 0.5 Nm/sec using a load frame–mounted spinal loading fixture that has been described in detail in a previous publication [36]. All tests were repeated three times with a 10-second dwell time between loading cycles; only the third cycle was used for data analysis.

Reflective markers placed at the T12 and L2 vertebral bodies were tracked with an infrared video measurement system (Vicon; Oxford Metrics, Oxford, UK), and their motions were reduced to rigid body rotations using Euler angle formulations. Local coordinate systems were constructed for the T12 and L2 vertebra from each segment with the x-axis pointing left lateral, the y-axis pointing superiorly, and the z-axis pointing anteriorly. Motion of the T12 vertebral body was described with respect to the L2 vertebral body for each test in terms of rotations about the axes of the respective applied moment. Euler angles were calculated in the y, z, x order. Experimental calibration found the system to accurately track displacements to 0.1 mm and rotations to 0.1°.

An unstable traumatic burst fracture model was chosen over a stable burst fracture model to simulate the worse case and because there is minimal controversy over the indications for surgical treatment of unstable fractures. Fractures were experimentally (vs. surgically) created to best simulate damage to the bony structures, including end plates and surrounding soft tissues. After obtaining radiographs of intact specimens, unstable L1 burst fractures were created using a method similar to that previously reported [7,37]. L1 was chosen as this is the most common site of injury [12,38–41]. Briefly, this entailed scoring the L1 vertebra using a sagittal saw in five locations around the perimeter of the vertebral body and then impacting the superior vertebrae (T11) with a 7-kg weight dropped 1.5 m through a vented drop tower. The impact was delivered to a wedge on the superior surface of the potting material above T11 to yield a combined flexion moment and axial load. Postinjury plain radiographs and computed tomography scans of the unloaded specimens were obtained to confirm burst fracture creation in L1 and assess the integrity of the adjacent vertebrae (Fig. 1). Two specimens were discarded because of adjacent-level fracture. The computed tomography images revealed a mean ( $\pm$ standard deviation) vertebral height loss of  $23.3\% \pm 13.3\%$  and a mean spinal canal compromise (decreased anterior-posterior diameter) of  $36.6\% \pm 14.7\%$ . The burst fractures were then made unstable by surgical disruption of the supra- and interspinous ligaments, facet capsules, and ligamentum flavum.

All injured specimens then had a subtotal corpectomy procedure performed from a lateral approach by an experienced spine surgeon followed by three types of surgical reconstructions (Fig. 2). One construct included reconstruction of the vertebral body using a human femoral strut graft (heights of 38, 42, and 49 mm; 42 mm most commonly used) and PI. A second construct included reconstruction of the vertebral body with a dynamic self-adjusting VBR (Dynamic Spine, San Diego, CA, USA; not approved by the US Food and Drug Administration). The VBR is modular and composed of two compressible/flexible components made of multiple springs between upper and lower metallic plates attached to an expandable central fixation component. The devices' compressible mechanical

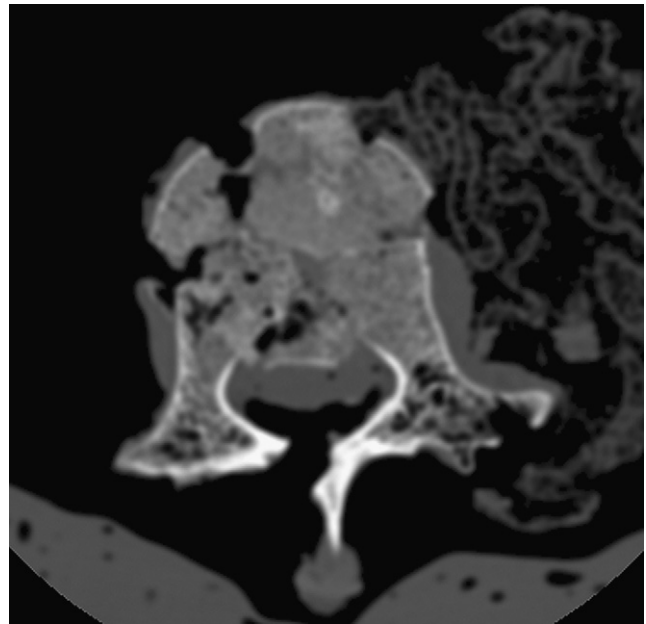


Fig. 1. Computed tomography scan confirming experimental creation of a traumatic burst fracture of the L1 vertebral body.

properties of 160 kN/m axial stiffness have been previously reported [42]. The device may be implanted by placing the individual components in the fracture site and then assembling them in situ, as performed in this study, or by implanting the preassembled device with the fixation component in its shortened state. With either technique, the fixation device is then expanded with a 100-N tensioner, allowing the spring components to flex, secondarily allowing the device plates to self-adjust to the bony end plate angulations, and then the fixation component is locked in an elongated state. Posterior instrumentation was also used in conjunction with the VBR. Both interbody structures had the same diameter at the end plate interface: the VBR had a diameter of 25 mm, and the strut graft was machined to approximately 25 mm. The position of the VBR and strut allograft on the vertebral end plates was the same for both because the subtotal corpectomy, instead of total corpectomy, limited the space to the 25-mm diameter required for both types interbody supports. The interbody height for the strut graft measured on radiographs was  $49.5 \pm 4.6$  mm (mean  $\pm$  standard deviation) and for the VBR was  $50.1 \pm 3.6$  mm. The interbody lordosis for the strut graft was  $8.8^\circ \pm 4.3^\circ$  and for the VBR was  $10.3^\circ \pm 2.9^\circ$ . On a pairwise basis, the mean differences of interbody height and lordosis were  $0.6 \pm 3.9$  mm and  $1.4^\circ \pm 4.2^\circ$ , respectively, over all specimens.

The third reconstruction had only minimal vertebral body support, consisting of only partially fractured posterior and contralateral vertebral body wall bone, combined with PI (PI only). Although it is clinically rare to perform a partial corpectomy and not reconstruct the intervertebral defect, this testing state has been used previously to

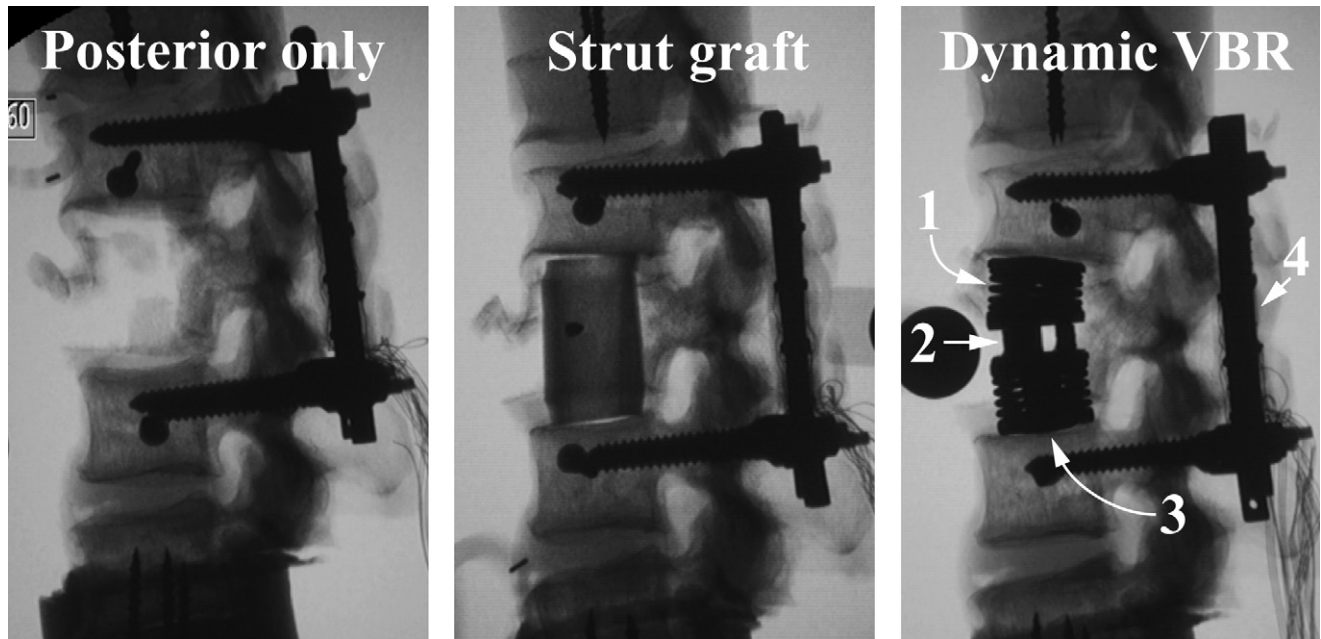


Fig. 2. (Left) Lateral radiograph of L1 subtotal corpectomy with posterior only transpedicular T12–L2 instrumentation but no anterior support. (Middle) L1 corpectomy reconstructed with femoral shaft allograft and posterior transpedicular instrumentation. (Right) L1 corpectomy reconstructed with a dynamic VBR and posterior transpedicular instrumentation (1=flexible component, 2=expandable component, 3=metallic plate below springs with bone ingrowth surface, 4=posterior rods show the lead wires from strain gages used to measure rod strain under various load states).

simulate a comminuted vertebral body fracture or as a comparison to more rigid constructs [6,7,43,44].

Posterior supplemental fixation was performed using a pedicle screw and rod system (ISOLA, 6.35-mm-diameter rod and 6.5-mm-diameter screws; Johnson & Johnson DePuy Spine, Raynham, MA, USA) spanning the T12–L2 levels. The length of the rods was dictated by the height of the strut graft that gave a snug fit and then the rod-to-screw connections were tightened with the specimen under a 100-N axial preload. The length of the rods between the pedicle screws was maintained for all load states. All specimens were kept moist during testing with saline spray.

Posterior fixation rods were instrumented with strain gages to enable the measurement of bending moments in the sagittal (ie, flexion-extension) plane, similar to a previous report [45]. To facilitate placement of the strain gages, two 5-cm-long flat surfaces were milled to a depth of 0.5 mm on opposite sides of each rod. On each rod, strain gages (031CE; Vishay Micro-Measurements, Shelton, CT, USA) were cemented (M-bond 610; Vishay Micro-Measurements) on the flattened surfaces and the lead wires were configured for stress relief. A silicone polymer (Dow Corning 3145 RTV; Dow Corning Corp., Midland, MI, USA) was applied to protect the gages from the saline environment. Two bilateral strain gages placed on opposite sides of the rods were used in a half-bridge configuration to monitor bending moments. The posterior rod-measured bending moments were calibrated to within 3% of known applied moments. Calibration was repeated after testing to confirm gage integrity. For each specimen, the posterior

rods were positioned such that the flat milled surfaces were parallel to the coronal plane, thereby, allowing measurement of bending moments that occurred in the sagittal plane (positive values indicated a flexion moment and negative values indicated an extension moment). The uniformity of rod rotation was optimized by using a 10-cm-long K-wire that was inserted into a small hole drilled near the end of each rod in a medial to lateral direction. Each rod was then rotated until the wire pointed in a true lateral direction and secured in place using the lock nuts in the pedicle screw heads. This minimized error because of possible rod rotation between specimens.

All specimens had repeat flexibility testing performed after which each specimen had the alternate reconstruction performed and then had its flexibility tested again (second and third load states). The testing sequence was randomized among the specimens for the VBR and strut graft states; however, the corpectomy with PI-only state (no anterior support) was always tested last because of concern for potential bone-screw interface failure precluding any additional testing. This repeated measures testing procedure was performed in lieu of cyclic loading to achieve more accurate construct-to-construct comparison.

#### Statistical analysis

Graph bars represent median values, and error bars represent the interquartile range. For the rod moments, the values represent the sum of the right and left rod moments (12 pairs). Data were presented for flexion range of motion

(ROM), extension ROM, bilateral bending ROM and bilateral axial torsion ROM, and for the neutral zone (NZ) in each test plane as suggested by Wilke et al. [46]. Descriptive statistics were calculated using the median and interquartile range because of the nonnormal distributions of some measures and to better illustrate the variability of the data. The ROM, NZ, and calibrated rod moments were compared using repeated measures analysis of variance for the various constructs using statistical software (SigmaStat, San Jose, CA, USA). For tests exhibiting a nonnormal distribution, as determined by the statistical software, a repeated-measures analysis of variance on ranks was performed. Where significant global differences were noted, a Tukey test was performed on pairwise comparisons.

## Results

The rigidity of the strut graft and VBR reconstructions were similar and generally greater than that of the other load states as detailed below. Conversely, the subtotal corpectomy with posterior-only pedicle screws construct resulted in an increased ROM and NZ versus the other reconstructed states. Rod moments were greater with the posterior only compared with VBR and strut graft reconstructions; these interbody reconstructed states did not differ. Qualitatively, the VBR was better able to conform to the end plates of adjacent vertebrae compared with a strut graft, and one of the more divergent end plate cases of this study is shown in Fig. 3.

Specifically, the ROM values significantly decreased compared with the intact state for both the strut graft and

VBR groups in flexion (both  $p < .05$ ), extension (both  $p < .05$ ), and lateral bending (both  $p < .001$ ) but were significantly greater in axial torsion (VBR  $p < .001$  and strut graft  $p \leq .02$ , Fig. 4). The NZ results were similar and significantly decreased compared with the intact state for both the strut graft and VBR groups in flexion-extension (both  $p < .05$ ) and lateral bending (both  $p < .001$ ) but were significantly greater in axial torsion (VBR  $p < .001$ , strut graft  $p < .004$ , Fig. 5). Compared with the intact state, the PI-only construct exhibited a significantly smaller ROM in lateral bending ( $p < .001$ ) and a significantly greater ROM and NZ in axial torsion (both at  $p \leq .001$ ); all other flexibility parameter differences between these two states were not statistically significant.

Differences among groups did not reach statistical significance for the VBR versus strut graft groups in any direction. The PI-only state had a trend for greater flexion compared with both VBR and strut graft, a significantly increased ROM in extension compared with the VBR ( $p < .05$ ), and a significantly increased ROM in torsion compared with the strut graft ( $p < .05$ ). The NZ was greater for the PI-only state versus the strut graft and VBR groups in combined flexion-extension ( $p < .05$ ).

The sum of combined left and right rod moments was significantly greater in flexion and extension for the PI-only state compared with the strut graft and VBR states ( $p = .03$ , Fig. 6). The median moment experienced in the individual rods in flexion was 0.7 Nm for the VBR, 0.6 Nm for the strut graft, and 2.8 Nm for the PI-only state. In extension, the median individual rod moment was 0.5 Nm for the VBR, 0.5 Nm for the strut graft and 1.8 Nm for the PI-only state. The maximum moment in an individual rod

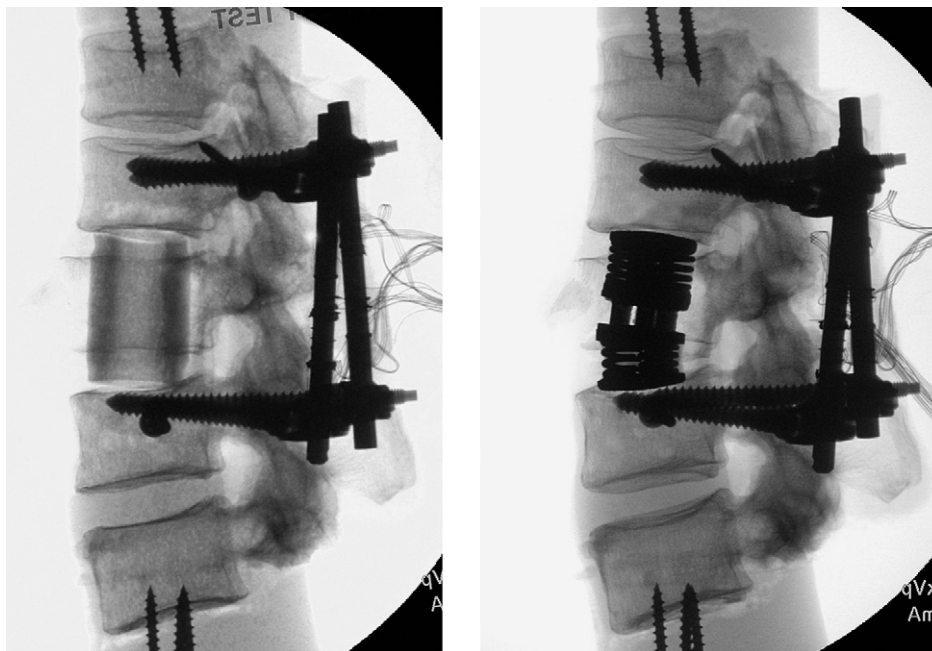


Fig. 3. Example of vertebral body replacement conforming to diverging adjacent vertebral body end plates compared with interbody strut allograft.

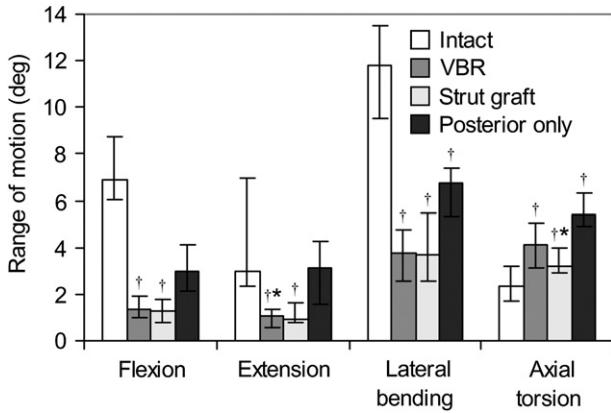


Fig. 4. Range of motion (median and interquartile) for intact corpectomy with posterior instrumentation (PI) only, and corpectomy reconstructed with femoral strut allograft or dynamic vertebral body replacement combined with PI. The † indicates significant difference from the intact state. Within the reconstructed states, \* indicates significant difference from the posterior-only state.

was 17.3 Nm and was found in one of the PI-only specimens. Rod moments did not differ significantly in the strut graft versus VBR states.

For the range of DXA scores of our specimens, there was no correlation between DXA and rod moments or ROM for any of the flexibility test conditions (linear regression,  $R^2 \leq 0.2$ ).

**Discussion**

Anterior partially elastic stabilization is a new concept in spinal trauma surgery. The present study is the first to report one type of such device and specifically investigates the biomechanical rigidity of a VBR that inherently adjusts to the vertebral end plates. The flexibility results of the present study found that with supplemental PI the VBR

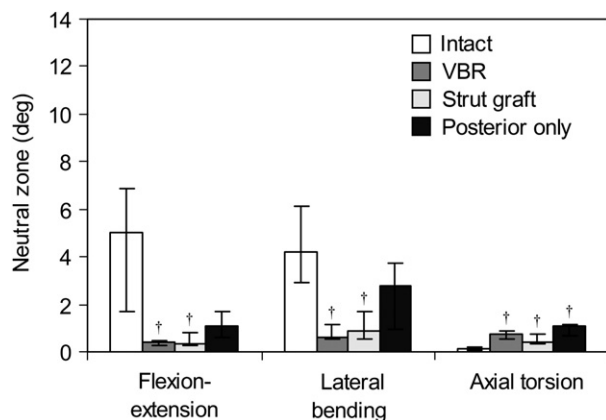


Fig. 5. Neutral zone (median and interquartile) for intact corpectomy with posterior instrumentation (PI) only, and corpectomy reconstructed with femoral strut allograft or dynamic vertebral body replacement combined with PI. The † indicates significant difference from the intact state.

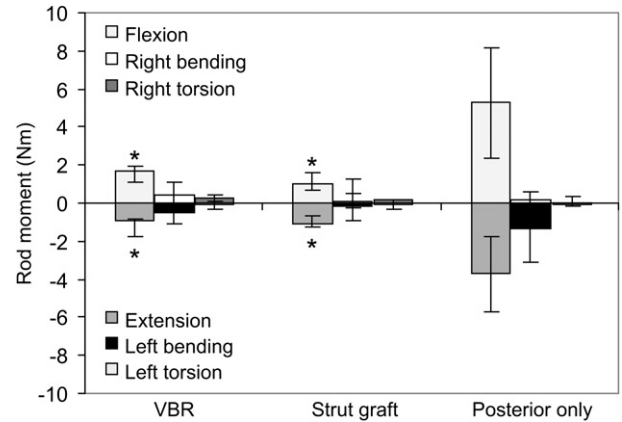


Fig. 6. Rod moment (median and interquartile) results for various load states. Data show the sum of right and left rod moments. Within the reconstructed states, \* indicates significant difference from the posterior-only state.

and strut graft reconstructed states had similar decreased ROM and NZ in flexion/extension and lateral bending compared with the intact state. Both of these anterior column reconstructions had greater rigidity than the PI-only reconstruction. Our results are comparable with prior human cadaveric testing of intact, corpectomy, and reconstructed states [7,33,43,47,48]. These prior studies had interbody reconstructions with currently available VBRs and structural bone grafts. The prior studies also found generally that the solid VBRs were similar in rigidity to the structural bone. A prior independent study comparing expandable with nonexpandable VBR constructs found no differences in rigidity between the two types [33]. The VBR of the present study is similar to prior studies of expandable VBRs, which also found a general increase in rigidity over the intact state [33,47]. Specifically, expandable VBRs, including that of the present study, found a decreased ROM in flexion/extension and in lateral bending. Axial rotation was increased in the present study relative to the intact state, and this is consistent with one prior report of an expandable VBR [47]. However, another study of an expandable VBR, with intact posterior elements, found a decreased ROM in axial torsion [33].

A unique aspect of the present study was investigating the rod moments (determined by calibrated strain measurements) during flexibility testing of the T12–L2 posterior supplemental fixation. As expected, the greatest moments were in the PI-only construct. The greater moments are thought to be because of the difference in location of the instantaneous axis of rotation relative to the applied axial load, axial preload magnitude, and lack of load sharing between the rod and interbody device. The maximum sagittal bending moments in the posterior rods for the VBR and strut graft reconstructions were in the upper range of posterior rod moments of a prior in vivo study [49]. Moments in the supplemental PI rods were not increased in the VBR compared with the standard bone strut reconstructions.

Given that there is a small amount of axial compressibility of the VBR, one may speculate that at higher applied loads that a difference would be detected in the rod moments between the two interbody reconstruction states. Conversely, the partially elastic VBR becomes solid at high loads and then would be expected to behave similar to a noncompressible strut graft. The stresses on the rods for both interbody reconstructions were below bending fatigue-level limits [50]. One may thus speculate that there is no increased risk of rod fatigue failure for the anterior dynamic VBR construct during the bony healing (and end plate ingrowth) period. Small rod moments noted in lateral bending and axial rotation are thought to be because of coupled motion and small flexion moments presumably because of the axial preload applied anterior relative to the rod position.

The present study has several limitations that must be considered. These *in vitro* tests were only representative of the immediate postoperative condition and could not account for healing of the strut graft fusion construct that would result in an increase in stiffness. Thus over time, the ROM and NZ should decrease relative to the findings of the present study. Experimental animal studies have suggested that healing is improved with structural bone graft compared with vertebral body cages [51]. Recent clinical studies using VBRs suggest that solid fusion only occurs in approximately 85% of patients and may be lower because fusion assessment is often difficult [14,15]. The VBR investigated in the present study is designed for bone ingrowth from the vertebral end plates that may also result in an increase of construct stiffness over time. If bone graft is placed alongside the device, the construct could presumably heal to the same rigidity as a solid bony fusion formed by traditional structural bone graft. Additional preclinical animal testing is required to confirm this healing, particularly because a small amount of axial displacement may occur with the particular experimental device of this study. Additional limitations also include that multiple constructs were tested on each specimen, and cyclic testing was, therefore, not performed in an effort to maintain specimen integrity. Cyclic loading may better represent the *in vivo* case and may be a better predictor for the risk of subsidence. There was not a significant correlation between specimen flexibility and DXA score. Differences because of bone density may have been observed if the testing had been conducted to higher moments or if cyclic loading had been applied [21]. Additionally, in this *in vitro* study, the intact state was always tested first and thus cannot account for order-related effects [52]. *In vivo*, the VBR tested in the present study, similar to other VBRs composed of metallic alloy, could make imaging in fusion assessment and revision surgery more difficult compared with structural bone graft.

Clinically, VBRs have become more popular relative to structural grafts because of their greater availability and size options. The adjustability afforded by expandable VBRs is appealing, particularly in late posttraumatic

deformity cases. The dynamic self-adjusting VBR used in the present study is expandable and also has mechanical elasticity that allows for optimizing apposition to the patient's end plates of the adjacent vertebrae. That is, the elasticity of the device allows self-adjustment of its plates to match whatever vertebral end plate angle changes occur during distraction. This modification to the standard VBR is intended to enhance device-to-bony end plate congruity to reduce peak bony stresses, which in turn may have the potential to decrease subsidence risk that has been found for present commercially available devices [14,20–23]. Although the present study only investigated construct rigidity with the VBR, quantifying end plate congruity and localized stress is the subject of a companion study using pressure sensitive film.

## Conclusion

The present *in vitro* study is the first step in the evaluation of a new concept for the operative treatment of burst fractures. When used with supplemental rigid instrumentation, a VBR that self-adjusts and is intended to optimize end plate congruity was shown to have similar rigidity to a structural bone graft in the reconstruction of an unstable burst fracture when simulating the early postoperative period. Additionally, the present flexibility study, representing the immediate postsurgical fixation state, found that despite the partially elastic properties of the device, there was no increased stress on the supplemental instrumentation.

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