



## An ex vivo biomechanical comparison of a novel vertebral compression fracture treatment system to kyphoplasty

Derek C. Wilson<sup>a</sup>, Ryan J. Connolly<sup>b</sup>, Qingan Zhu<sup>a</sup>, Jeff L. Emery<sup>b</sup>, Stephen P. Kingwell<sup>a</sup>, Scott Kitchel<sup>c</sup>, Peter A. Cripton<sup>a,d</sup>, David R. Wilson<sup>a,\*</sup>

<sup>a</sup> Department of Orthopaedics, University of British Columbia & Vancouver Coastal Health Research Institute, Canada

<sup>b</sup> Benvenue Medical, Inc., United States

<sup>c</sup> Orthopedic Spine Associates, United States

<sup>d</sup> Department of Mechanical Engineering, University of British Columbia, Canada

### ARTICLE INFO

#### Article history:

Received 17 January 2011

Accepted 7 November 2011

#### Keywords:

Vertebral compression fracture

Vertebroplasty

Kyphoplasty

Spine

Biomechanics

Fracture

### ABSTRACT

**Background:** Vertebral compression fracture repair aims to relieve pain and improve function by restoring vertebral structure and biomechanics, but is still associated with risks arising from polymethylmethacrylate cement extravasation. The Kiva® Vertebral Compression Fracture Treatment System, a stacked coil implant made of polyetheretherketone and delivered over a guide-wire, is a novel device designed to provide height restoration and mechanical stabilization, while improving cement containment and minimizing disruption of cancellous bone. The objective of this study was to determine whether the Kiva system is as effective as balloon kyphoplasty at restoring mechanical properties in osteoporotic vertebral compression fractures.

**Methods:** Wedge fractures were created in the middle vertebra of fourteen osteoporotic three-vertebra spine segments and then repaired with either the Kiva or kyphoplasty procedure. Height, stiffness and displacement under compression of the spine segments were measured for four conditions: intact, fractured, augmented, and post-cyclic eccentric loading (50,000 cycles, 200–500 N, 30 mm anterior lever arm).

**Findings:** No significant differences were seen between the two procedures for height restoration, stiffness at high or low loads, or displacement under compression. However, the Kiva System required an average of 66% less cement than kyphoplasty to achieve these outcomes (mean 2.6 (SD 0.4) mL v. mean 7.5 (SD 0.8) mL 0;  $P < 0.01$ ). Extravasations and excessive posterior cement flow were also significantly lower with Kiva (0/7 v. 4/7;  $P < .05$ ).

**Interpretation:** Kiva exhibits similar biomechanical performance to balloon kyphoplasty, but may reduce the risk of extravasation through the containment mechanism of the implant design and by reducing cement volume.

© 2011 Elsevier Ltd. All rights reserved.

### 1. Introduction

Up to 700,000 osteoporotic vertebral compression fractures (VCFs) occur in the United States each year and affect 20% of people above the age of 70, with the rate in women almost twice that of men (Cooper et al., 1992). These fractures are associated with a pathological “stooped” posture, increased mortality (Browner et al., 1996; Cauley et al., 2000; Center et al., 1999; Ismail et al., 1998; Johnell et al., 2004) and increased risk of further fracture (Lindsay et al., 2001; Ross et al., 1991). Furthermore, VCFs often lead to chronic pain, physical impairment, and a negative effect on activities of daily living (Hall et al., 1999; Lips et al., 1999; Melton et al., 1989; Nevitt et al., 1998). Osteoporotic VCFs are more commonly found at the thoracolumbar

junction than at other levels due to the natural kyphotic angle and load distribution in that region (De Smet et al., 1988). Magerl/AO-Spine Type A compression fractures occur in approximately 66% of all cases, and the typical Type A1 wedge fractures are most often associated with osteoporotic VCFs (Magerl et al., 1994). Compression fractures with posterior wall involvement (Type A3) are considered the most severe within this population and are generally contraindicated for minimally invasive surgical intervention, although some physicians are treating such fractures with emerging technologies (Kruger et al., 2010).

Minimally invasive approaches based on injecting cement into the vertebral body have been used to stabilize the vertebral column and alleviate acute and/or chronic pain in patients who do not respond to non-operative management of their symptoms. Vertebroplasty and balloon kyphoplasty (BKP) are the most widely used non-conservative treatment methods for VCFs and have provided pain relief in many patients (Klazen et al., 2010; McKiernan et al., 2004; Taylor et al., 2006), although full restoration of pre-fracture height is rarely

\* Corresponding author at: Department of Orthopaedics University of British Columbia and Vancouver Coastal Health Research Institute Room 3114, 910 West 10th Ave. Vancouver, BC V5Z 4E3, Canada.

E-mail address: [dawilson@interchange.ubc.ca](mailto:dawilson@interchange.ubc.ca) (D.R. Wilson).

achieved clinically (Taylor et al., 2006). Both of these procedures increase spine segment stiffness from the fractured state (Wilson et al., 2000), and pain reduction may be due to reduced micromotion between bone fragments (Mohit and Orr, 2007) that is reflected as increased stiffness from the fractured state. However, the increased stiffness of the augmented vertebral body may increase the risk for adjacent level fracture (Ahn et al., 2008; Baroud et al., 2003; Berlemann et al., 2002; Frankel et al., 2007). Neither procedure is indicated for fractures with posterior wall involvement.

These minimally invasive approaches have been associated with complications, mainly involving cement extravasation outside the margins of the vertebral body. While level I clinical evidence has shown kyphoplasty to reduce cement leakage over vertebroplasty in osteoporotic cases (72% of treated levels with vertebroplasty v. 27% with kyphoplasty) (Taylor et al., 2006), the resulting 2% symptomatic complication rate (Hulme et al., 2006; Taylor et al., 2006) still allows room for improvement. Cement can enter the venous system via defects in the body or injection techniques (Do, 2002), and pulmonary cement embolism has been reported in up to 0.1% of kyphoplasty-treated vertebrae (Hulme et al., 2006; Taylor et al., 2006; Wardlaw et al., 2009). Cement has also been found to leak into the epidural space, disk space, and paraspinal tissues through defects or fracture surfaces in the vertebral body (Jensen et al., 1997). Cement leakage into the disk space has been suggested as a precursor for adjacent level fractures, although this effect is contentious (Lin et al., 2004; Syed et al., 2005).

Reducing the reliance on cement as the primary stabilizer in vertebral compression fractures may reduce or eliminate concerns about cement leakage. The Kiva® VCF Treatment System (Benvenue Medical, Santa Clara, CA, USA) is designed to address extravasation risk by placing into the vertebral body a coiled implant made from the biocompatible polymer polyetheretherketone (PEEK), which is commonly used in load-bearing applications in the spine. The device is designed to help restore vertebral height through a helical wedge-distraction effect from the inserted implant (Fig. 1), which provides a primary support structure to mechanically stabilize the vertebra in axial compression. Once deployed, the implant directs the flow of polymethylmethacrylate (PMMA) bone cement through ports along its inner circumference to contain the cement within the boundary of the implant while still allowing cranial and caudal cement flow towards the vertebral endplates (Fig. 2). A small volume of PMMA is utilized to anchor the device into the surrounding intact cancellous bone to produce a structure that resists loads in all directions.

For the Kiva device to be considered a clinically suitable alternative to treating osteoporotic vertebral compression fractures, it should exhibit biomechanical performance comparable to a well-established procedure. Therefore, the objective of the current study was to compare the effect of treatment with the Kiva device on the biomechanics of 3-vertebra spine segments with a compression fracture in the central vertebra to that of balloon kyphoplasty (Medtronic, Inc, Sunnyvale, CA, USA). The latter

procedure was chosen for comparison because it was designed to restore vertebral body height and reduce cement extravasation. Our specific research questions were:

- 1) Does fracture augmentation using the Kiva system restore compressive stiffness as effectively as kyphoplasty?
- 2) Does fracture augmentation using the Kiva system restore vertebral height as effectively as kyphoplasty?
- 3) Does the Kiva system maintain vertebral height and stiffness in the acute post-operative period?

## 2. Methods

### 2.1. Specimens

Fourteen osteoporotic 3-vertebra spine segments were used in this study (six T9–T11, seven T12–L2, and one L1–L3) from nine fresh-frozen human cadavers (5F/4M, avg. 74 yrs, range 58–87), with topographical localization of the T10, L1 and L2 vertebrae for fracture augmentation. To confirm that the specimens tested were osteoporotic, donor spines were selected with anteroposterior (AP) bone mineral density (BMD) measurements (DXA, Hologic QDR 4500W, Waltham, MA, USA) less than 0.8 g/cm<sup>2</sup> (Ryan et al., 1992). An additional eight specimens were radiographically excluded from the study for significant defects, disease, or deformity (i.e. existing VCFs, osteophytes, or severe disk degeneration), or adjacent-level fracture (after fracture creation in the middle vertebrae). Specimens were then randomized into two treatment groups (BKP or Kiva) after stratifying for BMD, donor, and sex. Each specimen was dissected of musculature while preserving the ligaments, disk and vertebrae. The top and bottom vertebra of each specimen was potted in dental stone (Tru-Stone, Modern Materials, South Bend IN, USA) with the potted surfaces parallel to the endplates of the middle vertebra. For vertebral height measurements, two antero-lateral and two anterior 0.8 mm diameter tantalum beads were attached to the superior and inferior vertebral bodies near the endplates of the middle vertebra and secured with epoxy (Fig. 3).

### 2.2. Creation of fracture

After completion of the intact biomechanical testing described in 2.4, below, additional dental stone was added to the specimens such that the intervertebral disks and middle vertebral endplates were completely covered. This additional material effectively reinforced the adjacent vertebrae during fracture creation, protecting them from damage or fracture, and was removed prior to subsequent biomechanical testing. Pilot tests confirmed that this yielded a consistent wedge fracture of the middle vertebra.

Wedge-compression fractures classified as AO1.2.1 were created in the middle vertebrae of the spine segments using a custom apparatus

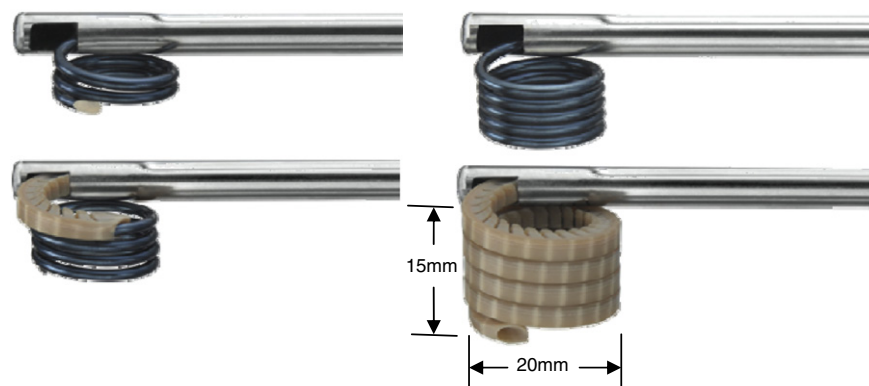
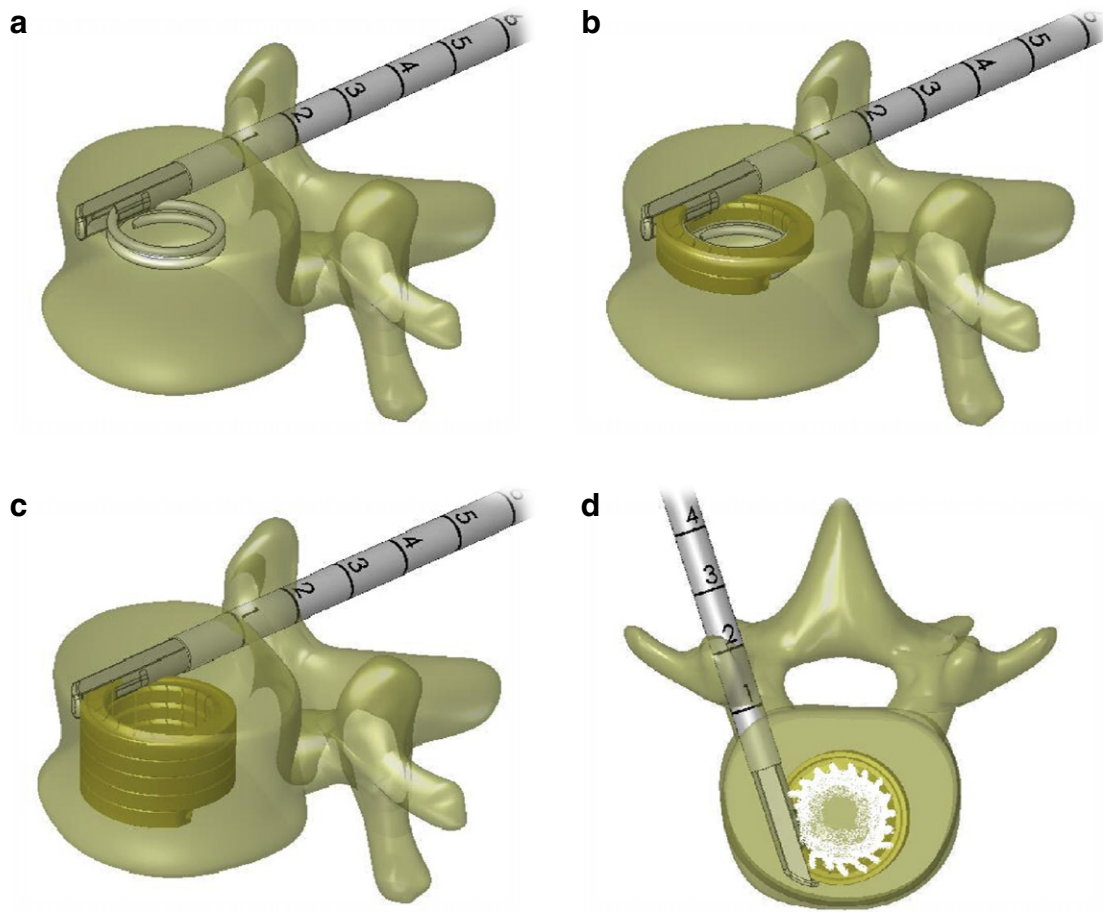


Fig. 1. The Kiva implant, advanced over the nitinol guide-wire coil.



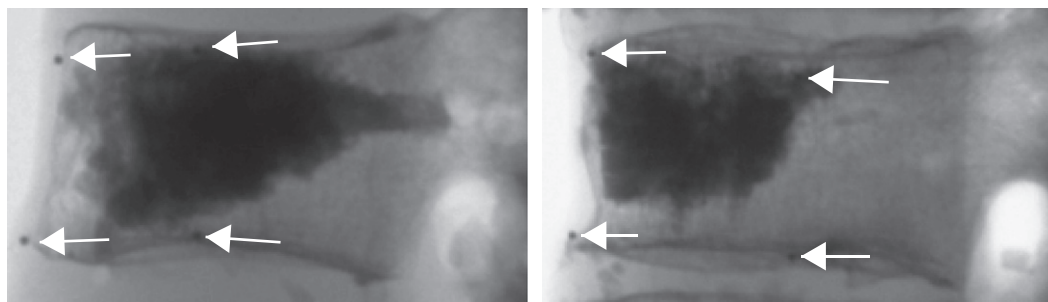
**Fig. 2.** Procedural overview of the Kiva System: initial access and deployment of the nitinol guide-wire coil (a); initial deployment of the PEEK implant over the guide-wire (b); final desired amount of PEEK implant is deployed and guide-wire removed (c); injection of PMMA cement, contained within the confines of the PEEK implant (d).

(Fig. 4), which was loaded using a servohydraulic materials testing system (Instron 8874, Instron, Canton MA, USA). The apparatus was attached to the actuator and test machine base using rotational joints that allowed flexion of the vertebrae during the application of the eccentric compression. The specimen was positioned in the apparatus so that the posterior wall was protected from compression fractures. Preliminary testing showed that this was achieved when the line of action of the compressive force was 15 cm anterior to the approximate center of the vertebral body, as measured manually with digital calipers. Load was applied at 1 mm/s and continued until the middle vertebra was compressed to 50% of its initial height, as measured manually with digital calipers during compression. Specimens with adjacent level fractures or fracture involvement of the posterior wall were excluded by examining

fluoroscopic video of all stiffness tests to ensure no movement of the adjacent endplates took place under loading, as well as by examining all load-deflection curves to detect abnormalities that suggested an adjacent level fracture.

### 2.3. Treatment of fracture

Fractures were treated using either the Kiva system or balloon kyphoplasty, and were performed using the same PMMA bone cement (Spineplex PMMA; Stryker Inc., Kalamazoo, MI, USA) with injected volumes recorded during each procedure. Augmentations were consistent with clinical practices, and each manufacturer's instructions for use



**Fig. 3.** Lateral fluoroscopic views of BKP (left) and Kiva (right) showing cement distribution and relative volume. Tantalum reference markers (indicated with arrows) were placed at the anterior-lateral and anterior regions of the upper and lower endplates.

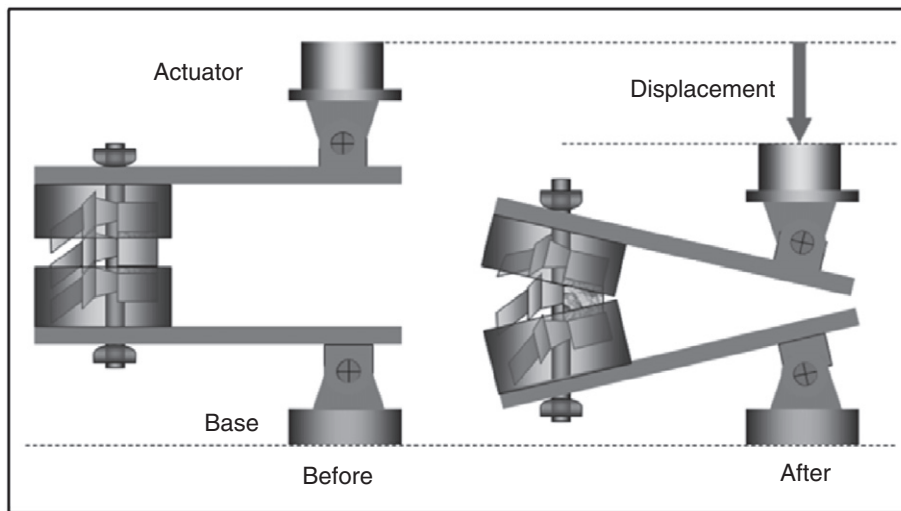


Fig. 4. The apparatus used to create anterior wedge fractures in the central vertebra of the specimens.

and technique guides were followed by trained clinicians (Drs. Kingwell, Kitchel).

Throughout each augmentation procedure, the specimens were placed in an apparatus that applied a 100 N compressive load to simulate supine trunk loads on the thoracolumbar spine (Wilke et al., 1999). This load was applied for the duration of each procedure and for 15 min after cement injection to allow for polymerization prior to specimen manipulation. Each of the two procedures was performed under fluoroscopic guidance by a single clinician trained in the procedure. Access to the vertebral body was performed in a similar manner for both procedures: initial access into the vertebral body was made transpedicularly with a Jamshidi needle, which was then exchanged for a larger dilating stylet to provide cannulated access for the systems.

The Kiva system uses a unipedicular approach. A nitinol guide-wire is first advanced through a cannula into the vertebral body where it forms into its pre-shaped 15 mm diameter coil (Fig. 2a). Coil placement is at midline and within the anterior third and two-thirds of the vertebral body, as confirmed with AP and lateral fluoroscopy. The PEEK implant is then advanced over the wire, creating a 20 mm diameter coiled construct (Fig. 2b and c) and deployed until the desired amount of height restoration is attained or significant filling of the vertebral body is accomplished. After the guide-wire is removed, bone cement is injected in a semi-liquid state into the PEEK implant until the column of cancellous bone contained by the implant is filled with cement (Fig. 2d). Unlike kyphoplasty, this device does not require the creation of a void in the cancellous bone and preserves more of the native vertebral structure.

For kyphoplasty, the standard bipedicular approach was used. Two sizes of balloon tamp (10/3, 15/4) were available to accommodate vertebral body size. Balloon tamps were inflated to full recommended volume until contact with the vertebral endplates or cortical shell, or if inflation pressure reached the recommended maximum of 2.75 Mpa, as read from the balloon insufflator gage. This is consistent with published procedural guidelines for the procedure (Becker and Ogon, 2008). Cement injection volume for each kyphoplasty procedure was matched to the inflated balloon tamp volume unless clinically relevant patient risks manifested (cement extravasation or excessive posterior cement flow) as judged by the clinician. A maximum of 4 mL of PMMA was injected per side into the void created by the balloon.

#### 2.4. Biomechanical testing

Measurements of the middle vertebral height, the 3-segment compressive stiffness over two load ranges (as defined by the slope

of the linear regression of the load-deflection curve), and the compressive displacement of the entire specimen were acquired for four conditions: intact; fractured (after wedge fracture of the middle vertebra); augmented (after fracture reduction with the Kiva system or kyphoplasty); and post-cyclic loading.

Prior to fracture creation, the compressive balance point (Tencer and Ahmed, 1981; Wilder et al., 1989) was determined for each specimen by applying 200 N to the specimen in the materials testing system using a custom apparatus that was free to move in flexion–extension and AP translation. The specimen was translated in the AP direction until the location for compressive load application was found where the unconstrained apparatus did not rotate or translate in the AP direction. This was used as the load application point for all other measurements. AP translation of the apparatus was then constrained for all subsequent measurements.

Wedge-fracture deformities of the A1.2 type do not affect posterior vertebral height. As such, anterior and anterior–lateral vertebral height (similar to quantities that would be measured clinically) were measured under a 100 N compressive load in the materials testing system. A single lateral fluoroscopic image of the specimen (and a 28 mm diameter spherical calibration target) was collected under this load and the distance between the two anterior tantalum beads was measured (by a single observer) from the digital image (Fig. 3). We performed a validation study of the height measurement in which we embedded markers comparable to those used in the study into wood bases. We imaged the markers and the calibration target using the fluoroscope with the markers at six different, known separations ranging from 15.35 to 24.35 mm. The initial separation was measured with vernier calipers and subsequent separations were achieved by moving the base with the embedded marker using a precision linear stage (Model M4022M, Parker Daedal, Irwin, PA, USA, which moved the marker with an accuracy of 0.002 mm). This was repeated five times for each of the six separations. The accuracy was defined as the mean absolute difference between the known separation of the markers and the measured separation using the method described in this article for the 30 measurements. The precision was defined as the mean standard deviation of the five measurements for each of the six positions. The accuracy was 0.19 mm and the precision was 0.12 mm.

Compressive stiffness was measured. To precondition the specimens, a 15 cycle triangular compressive load cycle was applied at 0.1 Hz from 0 N to a maximum load of 600 N. Force and displacement were recorded at a rate of 20 Hz. Stiffness was calculated from the last cycle of the series in all conditions. Compressive stiffness was calculated over two ranges of load: a low range of 100–200 N to represent lying supine and a high range of 450–550 N to represent standing, walking, or light activity



(Wilke et al., 1999) by determining the slope of the linear regression line in these regimes. The overall compressive displacement of the specimen was defined as the maximum displacement of the specimen during the last cycle of the high-range stiffness testing.

### 2.5. Eccentric cyclic loading

Prior to the final set of biomechanical measurements, each of the specimens was subjected to 50,000 cycles of flexion–compression loading. A 3 Hz ramp wave loading cycle ranging from 200 to 500 N was applied at a point located 30 mm anterior to the balance point to model the forces associated with post-operative daily activity (Khanna et al., 2008). The specimens were sprayed with saline solution every hour during the testing.

### 2.6. Statistical methods

For each of the four biomechanical outcome measures, the two procedures were compared using analysis of covariance (ANCOVA). The outcome measurement was change from intact state (baseline) with the procedure (Kiva or kyphoplasty) included as a factor and the baseline measurement (e.g., stiffness) included as a covariate. Point and interval estimates for the difference between the two procedures were determined. Diagnostic checks based on visual inspection of model residuals revealed no violations of the assumptions underlying the ANCOVA model. The amount of cement used was compared between the two procedures using Student's two-sample *t*-test, and cement extravasation was compared using a Pearson Chi-squared test.

## 3. Results

There were no significant differences in the outcome measures or BMD between the two groups at baseline (Table 1 and Figs. 5,6 and 7). For both groups, the fracture condition significantly increased the maximum compressive displacement from the intact state ( $P < 0.001$ ), reduced vertebral body height ( $P < 0.001$ ) and reduced both the high range stiffness ( $P < 0.001$ ) and low range stiffness ( $P < 0.001$ ). There were no significant differences in the outcome measures between the two groups after fracture.

The Kiva procedure used less cement than kyphoplasty, mean 2.6 (SD 0.4) mL v. mean 7.5 (SD 0.8) mL (difference = 4.9 mL, 95% confidence interval (CI): 4.1 mL to 5.7 mL,  $P < 0.001$ ) (Table 1). The mean volume of PEEK implant deployed in the Kiva procedures was 2.0 (SD 0.3) mL, or 3.4 (SD 0.5) implant loops. No cement extravasation was observed using the Kiva procedure. Cement injection was stopped, per clinician discretion and in accordance with standard clinical practice (Becker and Ogon, 2008), in a significantly higher number of specimens undergoing kyphoplasty (BKP: 4 specimens; Kiva: 0 specimens,  $P < .05$ ) due to visible cement extravasation through the endplates or cortical shell in 3 specimens or to cement flow towards the posterior wall in the other, as observed using fluoroscopy. These outcomes are similar to those seen in clinical reports of cement augmentation procedures such as kyphoplasty and vertebroplasty (Klazen et al., 2010; Taylor et al., 2006).

There were no statistically significant differences between the two augmentation procedures on anterior vertebral body height (Kiva: mean 50% (SD 22%) restored anterior height, BKP: mean 66% (SD 13%)), low and high range stiffness, and maximum compressive displacement immediately after treatment, as compared to the intact state (Table 1 and Figs. 5,6 and 7), although the small sample size contributed to large confidence intervals. In all cases there was a steady but diminishing height reduction of the augmented vertebrae through the course of the 50,000 cycles of loading. There were no statistically significant differences between the effects of the two augmentation procedures on the same measures after 50,000 cycles of loading.

**Table 1**  
Biomechanical quantities for each state for each of the two procedures.

	Kiva (n = 7) <sup>a</sup>	BKP (n = 7)	Kiva–BKP difference (95% CI)	P-value
Mean (SD) BMD (g/ cm <sup>2</sup> )	0.63 (0.09)	0.66 (0.11)		
Mean (SD) injected cement volume (cc)	2.6 (0.4)	7.5 (0.8)	4.9 (4.1 to 5.7)	<0.001
	Unadjusted means (SD)		Adjusted difference <sup>b</sup>	
Low range stiffness (N–mm)				
Intact	821 (238)	1043 (589)		
Fractured	225 (76)	217 (136)		
Augmented	428 (142) <sup>a</sup>	507 (198)	22.9 (–136 to 182)	0.78
Post-cycled	404 (127)	574 (268)	115 (–85 to 315)	0.26
High range stiffness (N–mm)				
Intact	1559 (327)	1835 (804)		
Fractured	688 (83)	632 (137)		
Augmented	936 (180) <sup>a</sup>	981 (326)	–31.8 (–258 to 194)	0.78
Post-cycled	982 (163)	1158 (400)	90 (–177 to 357)	0.51
Maximum displacement (mm)				
Intact	0.64 (0.16)	0.59 (0.23)		
Fractured	1.64 (0.32)	1.86 (0.55)		
Augmented	1.06 (0.24) <sup>a</sup>	1.04 (0.40)	0.04 (–0.26 to 0.34)	0.80
Post-cycled	1.06 (0.24)	0.93 (0.38)	–0.09 (–0.39 to 0.21)	0.55
Height (mm)				
Intact	19.9 (2.9)	21.3 (4.3)		
Fractured	17.4 (2.3)	18.5 (4.5)		
Augmented	18.1 (2.4)	20.4 (4.3)	0.5 (–0.2 to 1.2)	0.15
Post-cycled	18.1 (3.0)	20.0 (4.4)	0.5 (–0.1 to 1.2)	0.11

<sup>a</sup> n = 6 for Kiva augmented.

<sup>b</sup> Adjusted difference from analysis of covariance.

## 4. Discussion

The goal of this study was to determine whether the Kiva VCF Treatment System is as effective as balloon kyphoplasty for restoring and maintaining the initial vertebral height and compressive stiffness when treating osteoporotic vertebral compression fractures. No significant differences were seen between the two procedures for height restoration, stiffness at high or low loads, or displacement under compression. However, the Kiva System required an average of 66% less cement than kyphoplasty to achieve these outcomes. Increases in vertebral body height and stiffness relative to the fractured state after augmentation are considered to be clinically important (Mohit and Orr, 2007), and the similarities in this study between kyphoplasty and the Kiva procedure suggest that both procedures have a similar effect on these associated clinical functions. Effects after cyclic loading are important because they may reflect long-term results post-operatively. These results suggest that the benefits of height restoration and increased stiffness relative to the fractured state are retained after cyclic loading for both the Kiva system and balloon kyphoplasty.

The method for inducing compression fractures in the middle vertebrae of 3 vertebra segments is consistent with previous work (Kettler et al., 2006; Khanna et al., 2008; Kim et al., 2006) and produced a moderate to severe version of the most common type of compression fracture (A1.2) with regard to anterior height loss (Klazen et al., 2010). Findings for vertebral body height restoration and changes in stiffness differ somewhat between studies that have used different loading protocols. The average initial anterior height restoration after kyphoplasty observed in the current study (1.9 (SD 0.7) mm) was lower than that reported by Kim et al. (3.2 (SD 1.7) mm) (Kim et al., 2006), but we found less than 1/10th the vertebral height loss after cyclic loading of Kim et al. (0.3 (SD 0.2) mm vs. 4.2 mm). The difference in immediate post-fracture height restoration is most likely attributed to our use of a compressive preload during augmentation, which likely resulted in height loss after balloon deflation that has been reported both clinically and in ex vivo studies with kyphoplasty (Rotter et al.,

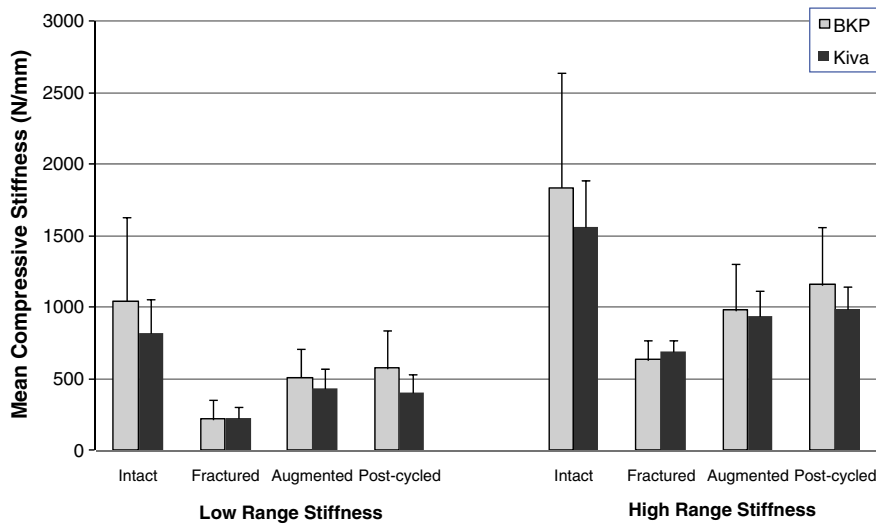


Fig. 5. Measurements of mean low and high range stiffness across experimental conditions and for each procedure subgroup (BKP or Kiva). Error bars show standard deviation.

2010; Voggenreiter, 2005). These differences may also be due to apparently higher cyclic load levels in the Kim et al. study than in the current study, and their utilization of single vertebrae rather than three-vertebra spine-segments. Our finding that high-range stiffness decreased from 1835 N/mm in intact specimens to 981 N/mm after kyphoplasty (a 47% reduction) is generally consistent with a similar study that found a decrease in stiffness from about 1200 N/mm in intact specimens to about 800 N/mm after kyphoplasty (a 33% reduction) using PMMA cement (Perry et al., 2005). Also, while the axial load component applied during cyclic testing in this study represents a lower range of expected physiological spinal loads for a healthy individual (Wilke et al., 1999), the resulting peak bending moment of 15 Nm is consistent with previous biomechanical test protocols (Wilke et al., 2006), wherein those authors concluded that the moments were greater than what patients suffering from osteoporotic VCFs would experience in typical daily activities prior to fracture healing. Thus, this test parameter may be considered a worst-case scenario, associated with higher loads than those seen during activities such as bending over or carrying loads in the immediate post-treatment and recovery phase.

The significantly lower injected cement volume with the Kiva procedure (on the order of 1/3 the cement used in kyphoplasty)

may be clinically advantageous because it may reduce the risk of cement extravasation and associated potential complications. This is reflected in the lack of extravasation in specimens undergoing the Kiva procedure, compared with minor extravasations or posterior cement flow in 4 of 7 of specimens undergoing kyphoplasty. It should be noted that the cement leakages experienced in the kyphoplasty subgroup were judged to be clinically significant by the treating physician, although the ability to visibly detect leakages through the endplates and cortical walls, rather than reliance on fluoroscopy, could have contributed to the higher extravasation rate seen in the study (43% vs. 27% in Taylor et al., 2006). Because less cement was used in the Kiva subgroup, the PEEK implant likely plays a central role in transmitting compressive load through the vertebra, and may explain why the augmented stiffnesses between procedures were similar despite significant differences in cement volumes. The Kiva procedure also leaves more cancellous bone intact throughout the vertebra than kyphoplasty, which may also contribute to load transfer through the vertebra.

The strengths of this study include a) using three-vertebra spine segments, which better simulates physiologic biomechanics on the treated vertebra than a single vertebra alone because the inclusion of the intervertebral disks allows more physiological transmission of

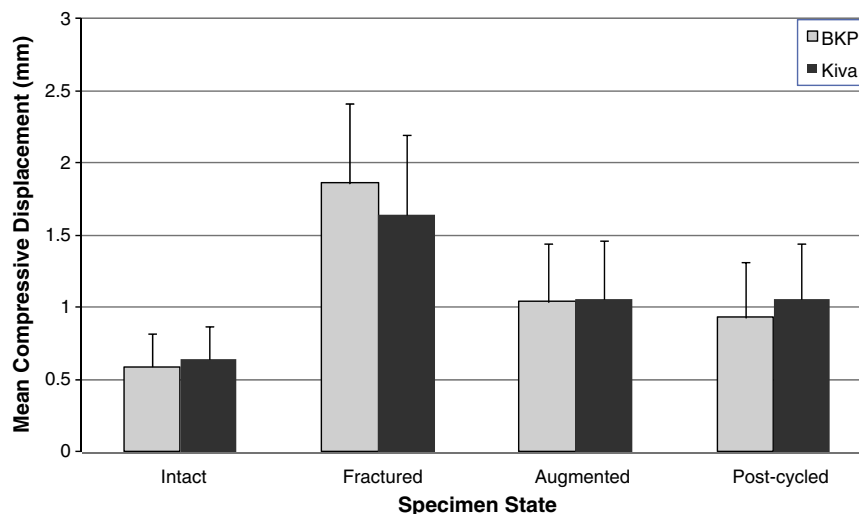
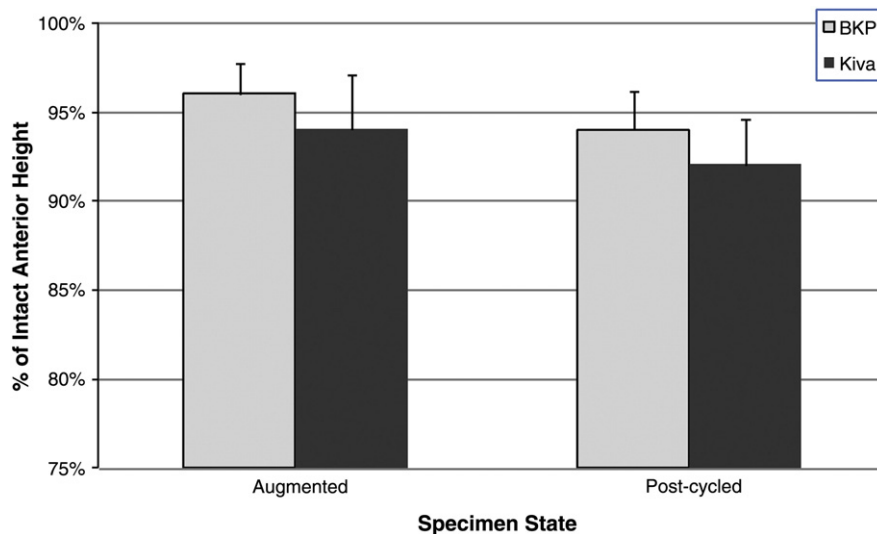


Fig. 6. Measurements of mean maximum compressive displacement (under 600 N of pure axial compression) across experimental conditions and for each procedure subgroup. Error bars show standard deviation.



**Fig. 7.** Mean anterior vertebral height across experimental conditions, normalized to the intact state of each procedure subgroup. Prior to augmentation, specimens were compressed to 50% of the intact anterior height of the middle vertebra. Error bars show standard deviation.

load to the fractured vertebra than biomechanical testing fixtures; b) creation of a consistent fracture model and exclusion of adjacent-level fractures; c) use of a preload during augmentation to simulate in vivo loads; d) careful use of clinical augmentation protocols by trained spine surgeons; e) careful identification of the balance point to ensure measurements are made under unconstrained pure compression and f) assessment of the effect of augmentation both before and after cyclic loading.

One key limitation of this ex vivo study is that it simulates conditions immediately post-treatment, and the effects of healing and gradual restoration of activity cannot be simulated. We feel the results are nonetheless important because they may reflect both the immediate post-operative state and an approximation of the state after some period of in vivo loads after augmentation. A second limitation is that the confidence intervals are quite wide, although it is not clear how narrow they should be because there are no clear guidelines for clinically significant differences in the quantities measured. A third limitation is that we did not assess the specimens under lateral bending or axial rotation. While the current work followed a similar protocol to previous studies having tested only compressive stiffness (Perry et al., 2005; Rotter et al., 2010; Upasani et al., 2010), full characterization of spine segment biomechanics should include applying lateral bending and axial rotation, and measuring the relative movement between each vertebra for such measures as intersegmental range of motion.

One aspect of vertebral augmentation not explored in this study was the potential increase in the clinical occurrence of adjacent level fractures (Frankel et al., 2007; Moon et al., 2007; Pflugmacher et al., 2006), and whether the repair techniques investigated have any different effect on this phenomenon. Stress-shielding from vertebroplasty and BKP has been suggested as a potential link to adjacent fractures (Gillies et al., 2010), and inter- and intrabody biomechanics may be altered through these procedures. The comprehensive long-term effects of such procedures should be evaluated.

In conclusion, the biomechanics of vertebral fracture repair (specifically, anterior height restoration, maximum compressive displacement, and stiffness) using the Kiva system were not different from kyphoplasty in a 3-segment model of acute and sub-chronic VCF repair, but required about 66% less cement. The reduced cement requirement for Kiva may reduce the risk of cement extravasation associated with augmentation procedures for vertebral compression fractures.

### Author's roles

Derek C. Wilson BScE designed the study, performed the experiments, analyzed the data, and drafted and edited the manuscript. Ryan J. Connolly, MS designed the study, performed the experiments, analyzed the data, and drafted and edited the manuscript. Qingan Zhu PhD designed the study, performed the experiments, analyzed the data, and drafted and edited the manuscript. Jeff L. Emery PhD analyzed and interpreted the data and edited the manuscript. Stephen Kingwell MD performed the experiments and edited the manuscript. In particular his clinical expertise was essential for performing the Kiva procedures and providing a clinical perspective on the results. Scott Kitchel MD performed the experiments and edited the manuscript. In particular his clinical expertise was essential for performing the balloon kyphoplasty procedures and providing a clinical perspective on the results. Peter A. Crompton PhD designed and oversaw the study and edited the manuscript. David R. Wilson DPhil designed and oversaw the study and wrote the manuscript.

### Conflict of interest statement

Ryan Connolly and Jeff Emery are employees of Benvenue Medical Inc, the makers of the Kiva system which is tested in this article. David Wilson and Peter Crompton are investigators on a grant funded by Benvenue Medical to perform this work. Scott Kitchel is a shareholder in Benvenue Medical Inc. and a member of that company's Scientific Advisory Board.

### Acknowledgments

This work was supported by funding from Benvenue Medical, Inc. We are grateful to Dr. Penny Brasher for the statistical analysis and to Marianne Black for performing the validation study of the height measurement method.

### References

- Ahn, Y., Lee, J.H., Lee, H.Y., Lee, S.H., Keem, S.H., 2008. Predictive factors for subsequent vertebral fracture after percutaneous vertebroplasty. *J. Neurosurg. Spine* 9, 129–136.
- Baroud, G., Nemes, J., Heini, P., Steffen, T., 2003. Load shift of the intervertebral disc after a vertebroplasty: a finite-element study. *Eur. Spine J.* 12, 421–426.
- Becker, S., Ogon, M., 2008. *Balloon kyphoplasty*. Springer Wien, New York.

- Berlemann, U., Ferguson, S.J., Nolte, L.P., Heini, P.F., 2002. Adjacent vertebral failure after vertebroplasty. A biomechanical investigation. *J. Bone Joint Surg. Br.* 84, 748–752.
- Browner, W.S., Pressman, A.R., Nevitt, M.C., Cummings, S.R., 1996. Mortality following fractures in older women. The study of osteoporotic fractures. *Arch. Intern. Med.* 156, 1521–1525.
- Cauley, J.A., Thompson, D.E., Ensrud, K.C., Scott, J.C., Black, D., 2000. Risk of mortality following clinical fractures. *Osteoporos. Int.* 11, 556–561.
- Center, J.R., Nguyen, T.V., Schneider, D., Sambrook, P.N., Eisman, J.A., 1999. Mortality after all major types of osteoporotic fracture in men and women: an observational study. *Lancet* 353, 878–882.
- Cooper, C., Atkinson, E.J., O'fallon, W.M., Melton III, L.J., 1992. Incidence of clinically diagnosed vertebral fractures: a population-based study in Rochester, Minnesota, 1985–1989. *J. Bone Miner. Res.* 7, 221–227.
- De Smet, A.A., Robinson, R.G., Johnson, B.E., Lukert, B.P., 1988. Spinal compression fractures in osteoporotic women: patterns and relationship to hyperkyphosis. *Radiology* 166, 497–500.
- Do, H.M., 2002. Intraosseous venography during percutaneous vertebroplasty: is it needed? *AJNR Am. J. Neuroradiol.* 23, 508–509.
- Frankel, B.M., Monroe, T., Wang, C., 2007. Percutaneous vertebral augmentation: an elevation in adjacent-level fracture risk in kyphoplasty as compared with vertebroplasty. *Spine J.* 7, 575–582.
- Gillies, M., Becker, S., Hogg, M., Dabirrahmani, D., Appleyard, R., 2010. The impact of cement stiffness and filling volume after cementoplasty on the risk of adjacent vertebral fractures. *J. Bone Joint Surg. Br.* 92-B, 209.
- Hall, S.E., Criddle, R.A., Comito, T.L., Prince, R.L., 1999. A case-control study of quality of life and functional impairment in women with long-standing vertebral osteoporotic fracture. *Osteoporos. Int.* 9, 508–515.
- Hulme, P.A., Krebs, J., Ferguson, S.J., Berlemann, U., 2006. Vertebroplasty and kyphoplasty: a systematic review of 69 clinical studies. *Spine (Phila Pa 1976)* 31, 1983–2001.
- Ismail, A.A., O'Neill, T.W., Cooper, C., Finn, J.D., Bhalla, A.K., Cannata, J.B., et al., 1998. Mortality associated with vertebral deformity in men and women: results from the European Prospective Osteoporosis Study (EPOS). *Osteoporos. Int.* 8, 291–297.
- Jensen, M.E., Evans, A.J., Mathis, J.M., Kallmes, D.F., Cloft, H.J., Dion, J.E., 1997. Percutaneous polymethylmethacrylate vertebroplasty in the treatment of osteoporotic vertebral body compression fractures: technical aspects. *AJNR Am. J. Neuroradiol.* 18, 1897–1904.
- Johnell, O., Kanis, J.A., Oden, A., Sernbo, I., Redlund-Johnell, I., Pettersson, C., et al., 2004. Mortality after osteoporotic fractures. *Osteoporos. Int.* 15, 38–42.
- Kettler, A., Schmoelz, W., Shezifi, Y., Ohana, N., Ben-Arye, A., Claes, L., et al., 2006. Biomechanical performance of the new BeadEx implant in the treatment of osteoporotic vertebral body compression fractures: restoration and maintenance of height and stability. *Clin. Biomech.* 21, 676–682.
- Khanna, A.J., Lee, S., Villarraga, M., Gimbel, J., Steffey, D., Schwardt, J., 2008. Biomechanical evaluation of kyphoplasty with calcium phosphate cement in a 2-functional spinal unit vertebral compression fracture model. *Spine J.* 8, 770–777.
- Kim, M.J., Lindsey, D.P., Hannibal, M., Alamin, T.F., 2006. Vertebroplasty versus kyphoplasty: biomechanical behavior under repetitive loading conditions. *Spine* 31, 2079–2084.
- Klazen, C.A., Lohle, P.N., De Vries, J., Jansen, F.H., Tielbeek, A.V., Blonk, M.C., et al., 2010. Vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures (Vertos II): an open-label randomised trial. *Lancet* 376, 1085–1092.
- Kruger, A., Zettl, R., Ziring, E., Mann, D., Schnabel, M., Ruchholtz, S., 2010. Kyphoplasty for the treatment of incomplete osteoporotic burst fractures. *Eur. Spine J.* 19, 893–900.
- Lin, E.P., Ekholm, S., Hiwatashi, A., Westesson, P.L., 2004. Vertebroplasty: cement leakage into the disc increases the risk of new fracture of adjacent vertebral body. *AJNR Am. J. Neuroradiol.* 25, 175–180.
- Lindsay, R., Silverman, S.L., Cooper, C., Hanley, D.A., Barton, I., Broy, S.B., et al., 2001. Risk of new vertebral fracture in the year following a fracture. *JAMA* 285, 320–323.
- Lips, P., Cooper, C., Agnusdei, D., Caulin, F., Egger, P., Johnell, O., et al., 1999. Quality of life in patients with vertebral fractures: validation of the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO). Working Party for Quality of Life of the European Foundation for Osteoporosis. *Osteoporos. Int.* 10, 150–160.
- Magerl, F., Aebi, M., Gertzbein, S.D., Harms, J., Nazarian, S., 1994. A comprehensive classification of thoracic and lumbar injuries. *Eur. Spine J.* 3, 184–201.
- Mckiernan, F., Faciszewski, T., Jensen, R., 2004. Quality of life following vertebroplasty. *J. Bone Joint Surg. Am.* 86-A, 2600–2606.
- Melton III, L.J., Kan, S.H., Frye, M.A., Wahner, H.W., O'fallon, W.M., Riggs, B.L., 1989. Epidemiology of vertebral fractures in women. *Am. J. Epidemiol.* 129, 1000–1011.
- Mohit, A.A., Orr, R.D., 2007. Percutaneous vertebral augmentation in osteoporotic fractures. *Curr. Opin. Orthop.* 18, 221–225.
- Moon, E.S., Kim, H.S., Park, J.O., Moon, S.H., Lee, H.M., Shin, D.E., et al., 2007. The incidence of new vertebral compression fractures in women after kyphoplasty and factors involved. *Yonsei Med. J.* 48, 645–652.
- Nevitt, M.C., Ettinger, B., Black, D.M., Stone, K., Jamal, S.A., Ensrud, K., et al., 1998. The association of radiographically detected vertebral fractures with back pain and function: a prospective study. *Ann. Intern. Med.* 128, 793–800.
- Perry, A., Mahar, A., Massie, J., Arrieta, N., Garfin, S., Kim, C., 2005. Biomechanical evaluation of kyphoplasty with calcium sulfate cement in a cadaveric osteoporotic vertebral compression fracture model. *Spine J.* 5, 489–493.
- Pflugmacher, R., Schroeder, R.J., Klostermann, C.K., 2006. Incidence of adjacent vertebral fractures in patients treated with balloon kyphoplasty: two years' prospective follow-up. *Acta Radiol.* 47, 830–840.
- Ross, P.D., Davis, J.W., Epstein, R.S., Wasnich, R.D., 1991. Pre-existing fractures and bone mass predict vertebral fracture incidence in women. *Ann. Intern. Med.* 114, 919–923.
- Rotter, R., Martin, H., Fuerderer, S., Gabl, M., Roeder, C., Heini, P., et al., 2010. Vertebral body stenting: a new method for vertebral augmentation versus kyphoplasty. *Eur. Spine J.* 19, 916–923.
- Ryan, P.J., Blake, G.M., Fogelman, I., 1992. Fracture thresholds in osteoporosis: implications for hormone replacement treatment. *Ann. Rheum. Dis.* 51, 1063–1065.
- Syed, M.I., Patel, N.A., Jan, S., Harron, M.S., Morar, K., Shaikh, A., 2005. Intradiskal extravasation with low-volume cement filling in percutaneous vertebroplasty. *AJNR Am. J. Neuroradiol.* 26, 2397–2401.
- Taylor, R.S., Taylor, R.J., Fritzell, P., 2006. Balloon kyphoplasty and vertebroplasty for vertebral compression fractures: a comparative systematic review of efficacy and safety. *Spine (Phila Pa 1976)* 31, 2747–2755.
- Tencer, A.F., Ahmed, A.M., 1981. The role of secondary variables in the measurement of the mechanical properties of the lumbar intervertebral joint. *J. Biomech. Eng.* 103, 129–137.
- Upasani, V.V., Robertson, C., Lee, D., Tomlinson, T., Mahar, A.T., 2010. Biomechanical comparison of kyphoplasty versus a titanium mesh implant with cement for stabilization of vertebral compression fractures. *Spine (Phila Pa 1976)* 35, 1783–1788.
- Voggenreiter, G., 2005. Balloon kyphoplasty is effective in deformity correction of osteoporotic vertebral compression fractures. *Spine (Phila Pa 1976)* 30, 2806–2812.
- Wardlaw, D., Cummings, S.R., Van Meirhaeghe, J., Bastian, L., Tillman, J.B., Ranstam, J., et al., 2009. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. *Lancet* 373, 1016–1024.
- Wilder, D.G., Pope, M.H., Seroussi, R.E., Dimnet, J., Krag, M.H., 1989. The balance point of the intervertebral motion segment: an experimental study. *Bull. Hosp. Joint Dis. Orthop. Inst.* 49, 155–169.
- Wilke, H.J., Neef, P., Caimi, M., Hoogland, T., Claes, L.E., 1999. New in vivo measurements of pressures in the intervertebral disc in daily life. *Spine (Phila Pa 1976)* 24, 755–762.
- Wilke, H.J., Mehnert, U., Claes, L.E., Bierschneider, M.M., Jaksche, H., Boszczyk, B.M., 2006. Biomechanical evaluation of vertebroplasty and kyphoplasty with polymethyl methacrylate or calcium phosphate cement under cyclic loading. *Spine (Phila Pa 1976)* 31, 2934–2941.
- Wilson, D.R., Myers, E.R., Mathis, J.M., Scribner, R.M., Conta, J.A., Reiley, M.A., et al., 2000. Effect of augmentation on the mechanics of vertebral wedge fractures. *Spine* 25, 158–165.