

Vertebroplasty and Kyphoplasty for the treatment of thoracic fractures in osteoporotic subjects: a Finite Element comparative Analysis

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Abstract

Background. One of the most frequent clinical consequences of osteoporosis is vertebral compression fractures, which occur mainly in the thoraco-lumbar junction and cause the collapse of the vertebral body. For their treatment two mini-invasive surgical procedures, vertebroplasty and balloon kyphoplasty, are used. In terms of efficacy, cost and safety, in particular about the risk of new adjacent fractures, it is still unknown which technique is preferred.

Methods. Finite element models of the thoracic human spine were developed to evaluate the biomechanical outcomes of vertebroplasty and kyphoplasty, with a computational comparative analysis. An intact model and two fractured conditions were generated in order to study a wedge compression fracture and the possible treatments. With the aim to determine the stress distribution in the adjacent structures to the treated vertebral body, stresses on the endplates and intradiscal pressures were extrapolated.

Findings. In case of mild fracture we noticed an average von Mises stress reduction of about 20%. For a severe fracture, when there is a partial height restoration, an average stress reduction of 15% was calculated, while with a full recovery of the anterior wall of the fractured vertebrae a further stress reduction of about 35% was obtained.

Interpretation. The effect of cement injection in the fractured vertebra is negligible compared to the effect of the geometry. In our opinion, in order to reduce the stresses and consequently the risk of fracture, the best choice is to perform a kyphoplasty trying to restore the physiological situation.

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Keywords

vertebroplasty, kyphoplasty, finite element, vertebral compression fractures

Introduction

One of the most frequent clinical consequences of osteoporosis is vertebral compression fractures (VCF) which occur mainly in the thoraco-lumbar junction [Coumans et al. 2003, Gaitanis et al. 2005, Ledlie and Renfro 2005, Lee et al. 2007, Suzuki et al. 2009, Voggenreiter 2005].

5 In the last few decades two minimally invasive techniques consisting of the percutaneous injection of bone cement in the fractured vertebral body have been developed: vertebroplasty and kyphoplasty. While the former is used only to stabilize the fracture, the latter allows to restore the height of the vertebral body, using the mechanical action of a balloon or other expandable devices inserted with a catheter before injecting the cement. Both of these techniques have good outcomes
10 in the short-term: after the treatments there is a decreasing of pain quantified with the VAS score and a low rate of complications [Coumans et al. 2003, Gaitanis et al. 2005, Ledlie and Renfro 2006, Lee et al. 2007, Voggenreiter 2005]. Moreover, kyphoplasty improves the wedge angle between 2° and 8° and the vertebral body height between 2 mm and 8 mm [Gaitanis et al. 2005, Lee et al. 2007]. However kyphoplasty is more recent than vertebroplasty, long-term clinical follow up are
15 not available yet and so it is difficult to determine which technique is more effective.

After these treatments recurrence of a new vertebral fracture is often reported, with a percentage that varies from 6 to 33%. The location of these fractures is mainly (70-90 percentage) adjacent to the previous operated vertebral body [Fribourg et al. 2004]. Adjacent vertebral fractures are probably due to the increased stiffness of the vertebral body, load transferring in adjacent vertebra,
20 shifted body weight and the ongoing progression of osteoporosis as demonstrated in clinical studies, through experimental tests and computational models [Rohlmann et al. 2006B, Sun and Liebschner 2004].

Computational models have been used to study different aspects of vertebroplasty and kyphoplasty: microstructural models have been used to study the efficacy of vertebroplasty according to damage,

cement quantity and the effect of disc degeneration [Kosmopoulos et al. 2009], while Sun et al. studied the effect of position and volume of the injected cement in a single vertebra [Sun and Liebschner 2004]. The biomechanical effects of vertebroplasty in treated and adjacent vertebrae, the influence of different type of augmentation and the role of cement on the load transfer have been
5 investigated with models of a single functional spinal unit (FSU) [Wilcox 2006].

Also multi-segment models have been implemented: Dabirrahmani et al. developed a two-functional unit (L2-L4), osteoporotic, fracture model with a weakened anterior wall to compare and evaluate the importance of three parameters: height restoration, stiffness and volume of the injected cement following kyphoplasty [Dabirrahmani et al. 2011]. Rohlmann et al. used a three-
10 dimensional, non-linear finite element model of the osteoligamentous lumbar spine (L1-L5) to estimate the forces of the muscles during standing for an intact lumbar spine, as well as after vertebroplasty and kyphoplasty and to determine intradiscal pressure and maximum von Mises stress in the vertebral endplates before and after cement augmentation [Rohlmann et al. 2006A-B].
In another work the same model was used to determine in a probabilistic manner the effects of bone
15 fracture shape, amount and distribution of bone cement as well as elastic modulus of bone cement, cancellous bone and fracture region on the von Mises stresses in the bone and cement after vertebroplasty [Rohlmann et al. 2010].

Since the highest incidence of wedge fracture is observed in T9-L4 segment [Coumans et al. 2003; Ledlie and Renfro 2005; Suzuki et al. 2009], the present work is part of a project that aims at the
20 creation of a finite element model of the whole thoraco-lumbar junction.

To the authors' knowledge, in literature, there are no models that investigate the thoraco-lumbar tract, particularly as far as the influence of bone injection and the effectiveness of the kyphoplasty: the objective of this study is therefore the evaluation of the biomechanical outcomes of vertebroplasty and kyphoplasty through the use of a computational comparative analysis, in terms
25 of the stresses arisen within the adjacent anatomical structures.

Material and methods

Finite element model of the intact spine (I)

A three-dimensional, non-linear finite element model of the thoracic spine (T9-T11) was created from CT scans of a healthy human male without any spinal pathology (age 40). The CT scans, 5 having 512x512 pixels/slice and a slice thickness of 0.625 mm were obtained using a BrightSpeed scanner (General Electric Medical System).

The intact (I) model comprised two functional spinal units (FSUs) complete with the intervertebral discs and ligaments.

The 3D geometry of the vertebral bodies (VBs) were extracted by thresholding the grey values 10 scale. Since CT scans were obtained in a lying supine position, the position of each vertebra was readjusted on the sagittal plane, considering the mean curvature of a normal subject. Then the anterior part of each VB was divided from the posterior processes (PP). The anterior part was divided into cortical and trabecular bone and was meshed using 8-node linear hexahedral elements (C3D8), while the posterior part was meshed using 4-node linear tetrahedral elements (C3D4). All 15 materials were assumed to be linear elastic isotropic, with the exception of the trabecular bone which was modeled as transverse isotropic, as reported in Table 1.

Since vertebral compression fractures affect in most cases osteoporotic patients, the mechanical properties of the cortical and trabecular bone were assumed to be about a 36% and 88% with respect the normal values, respectively, according to [Chae et al. 2010].

20 The intervertebral discs (IVD) were thus obtained extruding the adjacent endplates (EPs) using Rhinoceros 4.0 Evaluation CAD (McNeel and Associates, Indianapolis, IN, USA). The height of each disc was in accordance with anatomical data available in literature [Busscher et al. 2010]. The IVDs were divided into the nucleus pulposus (NP) and annulus fibrosus (AF). The lateral surface of

the NP was created rescaling the external surface of the AF, so that the volumetric ratio between the AF and the NP was equal to 7:3 according to Kapandji [Kapandji 1974]. Finally the center of the NP was identified moving its external surface 3.7 mm from the IVD center [Eberlein et al. 2004]. Both the NP and AF were meshed in ICEM CFD 12.1 (© ANSYS Inc) using 8-nodes linear
5 hexahedral elements (C3D8). To take into account the presence of collagen fibers, four composite rebar layers were embedded in an isotropic solid matrix as described in previous studies [Dabirrahmani et al. 2011]. For each layer two bundles of tension-only linear elastic fibers, having an orientation angle of $\pm 30^\circ$ with respect to the horizontal plane [Dabirrahmani et al. 2011], an area per bar of 0.1 mm^2 [Galbusera et al. 2011] and a spacing of 0.1 mm, were assumed. In order to
10 define fibers orientation a local coordinate system was used, identifying the horizontal and tangential directions for each shell elements composing the rebar layer.

On the upper and lower surfaces of each IVDs, a cartilaginous EP about 0.7 mm thick was considered [Vena et al. 2005, Galbusera et al. 2011].

Seven groups of ligaments were modeled: anterior longitudinal (ALL), posterior longitudinal
15 (PLL), intertransverse (ITL), flavum (LF), capsular (CL), interspinosus (ISL) and supraspinosus (SSL). They were modeled using tension-only non-linear spring elements (SPRINGA). The initial stiffness values [Alizadeh et al. 2010] were rescaled considering the difference in the initial length and then readjusted within the validation step in order to match available literature data in terms of range of motion (ROM) of the thoracic spine. The number of spring elements, as well as the used
20 stiffnesses are reported in Table 1.

The final number of element of the model was about 435800 element.

Validation of the intact spine

Each FSU (T9-T10 and T10-T11) was validated in flexo-extension, lateral bending and axial rotation, applying a pure moment of 10 Nm to a reference point coupled kinematically to the higher endplate of the superior vertebra. The inferior endplate and the articular facets of the lower vertebra were constrained in all their degrees of freedom.

- 5 The moment vs. angle of rotation curves were obtained in all conditions, calculating the overall ROM and the stiffness of the FSUs. The results were then compared to literature data [Gregersen and Lucas 1967, Markolf 1972, Panjabi et al. 1976, White and Panjabi 1990].

Effect of geometry: Fractured models

Since in most cases a vertebral compression fracture causes the collapse of the vertebral body, giving the typical wedged shape [Coumans et al. 2003, Gaitanis et al. 2005, Ledlie and Renfro 2005, Lee et al. 2007, Suzuki et al. 2009, Voggenreiter 2005,], such a clinical condition was modeled. In particular, two fractured models were constructed: F25 model was obtained reducing of 25% the anterior VB height of T10 intact geometry while F50 model accounted for a 50% reduction of anterior VB height. In order to obtain the fractured model, a cutting plan was defined and used to create two portions of the VB and a remeshing of the obtained fractured VP was then performed using ICEM CFD. The position of T9 was readjusted and rotated to compensate for the missing part and the superior IVD was redrawn and meshed, as already described. The fractured shape corresponds to an angle of 13° and 26° respectively in F25 and F50 models: in Figure 1, the three models are reported:

- 20 - intact model (I);
- model with a 25% wedge shape fracture of T10 (F25);
- model with a 50% wedge shape fracture of T10 (F50).

Effect of material: vertebroplasty (VP) and kyphoplasty models (KP)

To study the effect of different surgical treatments on the state of stress (i.e. risk of fracture) on adjacent vertebrae, both vertebroplasty and kyphoplasty were simulated.

To simulate vertebroplasty technique, a core of composite material was inserted into T10 vertebral body. Its mechanical properties were chosen in accordance with Chae and colleagues [Chae et al. 2010]. Kyphoplasty was simulated considering that balloon expansion causes a compaction of the trabecular bone having a thickness of about 2.5 mm and mechanical properties according to Sun et al. [Sun and Liebschner 2004]. In both cases, the quantity of PMMA injected is about 20% of the total VB volume [Sun and Liebschner 2004, Rohlmann et al. 2010], corresponding to about 5 ml of bone cement, as commonly used in clinical practice [Gaitanis et al. 2005].

10 Finally the following conditions have been considered for each model (Figure 2):

- intact osteoporotic bone (OP);
- vertebroplasty performed on T10 (VP);
- kyphoplasty performed on T10 (KP).

15 Boundary and loading conditions

Each of the 9 models was loaded according to the scheme proposed by Rohlmann [Rohlmann et al. 2006B] and reported in Figure 3. A follower load (FL) of 200N that takes into account the local muscles forces, was applied just behind the center of the vertebral body: its position was optimized for each functional spinal unit in order to minimize any rotation about the anatomic planes (percentual rotation with respect to the total ROM < 5%). An upper body weight (F_{BW}) of 100N was then applied anteriorly. The F_{BW} loads were reduced with respect to Rohlmann and colleagues [Rohlmann et al. 2006A, 2006B, 2009A, 2009B], to take into account that the loads acting on the thoracic segments are lower than those beared by the lumbar segments [Iyer et al. 2010].

The lever arm of each force was recalculated, considering the natural curvature of the thoracic spine segment and its higher position on the sagittal plane [Rohlmann et al. 2006B]. Thus the projection of lever arm of F_{BW} in the vertical and horizontal direction were 84.1 mm and 67.2 mm, respectively. The lever arm of F_{ES} was set equal to 35 mm.

5 The condition of standing was obtained applying the follower load and then the upper body weight, which induces a flexion on the spine. This rotation was then compensated applying an extension, which represents the contraction of the dorsal muscles, in particular of the erector spinae (having an action line parallel to the curvature of T9-T11 segment). Since F_{ES} increases with the fracture degree of T10, its contribution to the axial compression of the thoracic segment was taken into
10 account and summed to the initial value of FL. Finally the I, F25 and F50 models were loaded with a total FL force of 351 N, 374 N and 395 N respectively.

In all simulations the inferior endplate of T11, as well as its lower facets joint have been constrained in all their degrees of freedom.

Considered cases and data analysis

15 In conclusion the analyzed situations are:

- Evaluation of the influence of the application of forces and moments on the reference model (I-OP);
- Evaluation of the effect of surgical technique (VP and KP) with respect to the OP case, for each set of models (I, 25, 50);
- 20 - Evaluation of the effect of fractured geometry (25, 50) with respect to the Intact model, for each treatment condition (OP, VP, KP);
- Comparison between the outcomes of the treatment of vertebroplasty and kyphoplasty performed on patients with mild or severe T10 fractures.

In order to determine stress distribution in the adjacent structures to the treated VB, maximum values of von Mises stress, maximum and minimum principal stresses were extrapolated for the EPs, cortical bone and trabecular bone. Maximum intradiscal pressure (IDP) values within each IVD have also been extracted.

5 **Results**

Validation

A preliminary validation phase was performed, to ensure that each functional unit of the reconstructed model reproduces the correct in vivo and in vitro kinematics. The total ROM and moment-angle curves obtained with the computational model are compared with literature data in
10 Table 2 and in Figure 4, respectively.

Effect of geometry and material

To evaluate the effect of the geometry, the results of the fractured models (F25, F50) were compared with those of the Intact one for each treatment conditions (OP, VP, KP) and reported in Table 3.

15 The state of stress increases in all considered levels: von Mises stress rose between 11% and 65% in the EPs, while IDPs grew up to 18%.

To evaluate the effect of bone-injection, the results of the fractured models (VP, KP) were compared with those of the osteoporotic one for each geometrical condition (I, F25, F50) and reported in Table 4. Augmentation with bone cement increased IDP values up to 3%, while von
20 Mises stress slightly decreased.

Clinical outcomes

The first clinical case analyzed is a mild fracture (25% reduction of the anterior VB height) treated with vertebroplasty or kyphoplasty, respectively without height improvement or with full restoration. In Figure 5, the absolute values of von Mises stresses in the EPs and IDP are shown.

Following vertebroplasty, there is an increase of IDP, 2% and 1% respectively above and below the fractured level; moreover the stress values on the EPs decrease of less than 2%. Kyphoplasty causes a reduction both of IDP (7.5%) and maximum von Mises stresses (between 12 and 31%).

The second clinical case taken into account is a severe fracture (50% reduction of the anterior VB height) treated with vertebroplasty or with kyphoplasty with a partial or complete restoration of the original height. In Figure 6, the absolute values of von Mises stresses in the EPs and IDP are shown. Vertebroplasty causes an increase of IDP, 2.5% and 1.4% respectively above and below T10, while the stress values on the EPs decrease by about 1.7%.

A partial recovery through kyphoplasty causes a 3% increase of IDP in the superior disc, a 4% decrease of IDP in the inferior one and maximum von Mises stress up to 28%. With a total restoration, reduction of IDP values are observed (7% above the fracture and 14.5% below), while the reduction of von Mises stress in EPs is greater than in the case of a partial recovery (between 35% and 65%).

In Figure 7 the average stress reduction on the EPs is shown, with respect to the anterior vertebral body height of the fractured vertebra.

Discussion

The aim of the present study is the evaluation of the biomechanical outcomes of vertebroplasty and kyphoplasty through the use of a computational comparative analysis in terms of stresses that arise within the adjacent anatomical structures. Nine different finite element models considering T9-T11 spinal segment were built up, modifying the original normal shape of T10 VB (effect of geometry) or simulating two surgical techniques (effect of material).

The predicted values of IDP are of the same order of magnitude as those obtained in previous published numerical works and they are in good agreement with values measured in vivo during standing [Rohlmann et al. 2006B, Wilcox 2006]. Since in these works lumbar FSUs are considered, any quantitative difference with respect to our values is probably due to differences both in

geometrical parameters and in mechanical properties. Moreover the increase of IDP following augmentation is consistent with the trend previously observed [Rohlmann et al. 2006B].

Most of the clinical studies available in literature do not clarify where the fracture phenomena could start and they distinguish only between fracture occurring above or below with respect to a treated
5 level. Fribourg et al. found that 90% of the subsequent fractures were at adjacent levels and in particular 60% above, 25% below, and 5% between the fractured vertebra [Fribourg et al. 2004]. In the study of Trout et al. 41.4% out of 186 fractures occurred in vertebrae adjacent to the vertebral body treated with vertebroplasty. 50.6% of the adjacent-level fractures were cephalic to the treated vertebra and their conclusion is that vertebral bodies adjacent to those treated with vertebroplasty
10 show a risk of fracture more than four times greater than the risk of fracture of non-adjacent ones [Trout et al. 2006A].

Only a few authors stated that the structures that are most likely to be the locus of initiation of a new fracture could be the EPs, pointing out the importance of reducing the local state of stress to reduce fracture risk. A clinical study by Trout and colleagues found that the majority of
15 spontaneous and incidental fractures (57% of 274 and 59% of 186 respectively) occurring in osteoporotic patients before vertebroplasty was located along the superior EP. Furthermore 41.4% of the 186 incident fractures occurred adjacent to treated vertebral levels and the proportion of inferior endplate fractures in adjacent vertebral bodies above a treated level was significantly greater than in any other group. The authors suggest that using endplate fractures as an indicator of
20 force distribution in the spine after vertebroplasty adds valuable information to the debate surrounding new-onset fractures [Trout et al. 2006B].

Our model pointed out a significant increase in von Mises stress in the inferior EP of T9 and the superior EP of T10, as the VB assumes a more prominent wedged shape. This fact seems to be confirmed by Wilcox, who noticed a relation between augmentation and greater EP deflection in the
25 superior vertebra [Wilcox 2006]. This effect of stress increase can be due in part to the presence of

cement, as found by Wilcox [Wilcox 2006], but in a negligible way compared to the effect of the geometry, as found by Rohlmann et al. [Rohlmann et al 2006B-2010]. In another computational study, Dabirrahmani et al. noticed that the EPs of the treated vertebra are the most prone to fracture, followed by those of the superior and inferior level respectively [Dabirrahmani et al. 2011].

- 5 Concerning the clinical cases of mild and severe vertebral fractures treated with vertebroplasty and kyphoplasty, our model underlines the importance of the height restoration after the treatment. Aquarius et al. found that the load resulting from a change in spinal alignment increases the fracture risk of adjacent vertebrae and restoring vertebral body height in order to eliminate the occurrence of off-axis loads in neighboring vertebrae seems to be clinically convenient [Aquarius et al. 2011].
- 10 Vertebroplasty produces only a consolidation of the vertebra with a slight decrease of stresses on the EPs (less than 2%). Patients report pain relief that probably is due to the consolidation of the fracture and to the presence of the cement that supports the load: as a consequence there is a reduction of the stresses in the periosteum, which is the structure with nerve endings that cause pain in the fractured situation. On the other hand, Trout et al. reported that implanting cement in a
- 15 vertebral body during vertebroplasty can result in altered forces within the spine and leads to an increased incidence of fractures of the adjacent endplate immediately cephalic to the treated vertebra [Trout et al. 2006B].

Differently from vertebroplasty, kyphoplasty guarantees a height improvement of the anterior part of the vertebral body and our results show that the reduction of the stresses on the EPs is

20 proportional to this restoration: in fact in the case of partial recovery we noticed a reduction of von Mises stresses up to 27% while the reduction doubles when a theoretical full recovery is reached.

Some limitations affect our model: the validation phase has been performed comparing the ROM of the single FSU, during typical movements (flexo-extension, lateral bending and axial rotation), only with a few literature data. Moreover, since literature data refer to a single patient and the measured

angular values are often affected by errors (even of a few degrees), the information provided in these works can be of limited accuracy.

Furthermore, the ROM of the thoracic region, in particular during axial rotation, is limited by the presence of the costo-vertebral joint and in our opinion the predictivity of the analyses could be improved including these structures in the model.

It must be taken into account that this is only a preliminary part of a project that aims at the reconstruction of the thoraco-lumbar spinal segment where vertebral fracture are most common (T9-L2): this improvement will permit to analyze also the stress distribution in the whole thoraco-lumbar junction and to simulate the effect of vertebroplasty or kyphoplasty in spinal levels different from the one considered in this work.

Conclusions

Summarizing, in case of mild fracture we noticed an average von Mises stress reduction on EPs of about 20%. In their study Rohlmann et al. found the same trend for a fractured vertebra with a reduction of the anterior part of the vertebral body of 35% treated with vertebroplasty or kyphoplasty leading to a correction of 90% of the original height [Rohlmann et al. 2006B]. In the case of severe fracture, when there is a partial height restoration, an average stress reduction of 15% is calculated, while with a full recovery of the anterior wall of the fractured vertebrae there is a further stress reduction of about 35%.

In our opinion, in order to reduce the stresses and consequently the risk of fracture, the best choice is to perform a kyphoplasty trying to restore the physiological situation, as confirmed by the numerical results of both clinical situations and previous literature data.

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