Treatment of painful osteoporotic compression and burst fractures using kyphoplasty: a prospective observational design

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Object. The aim of this study was to test the hypothesis that kyphoplasty is an effective treatment in painful osteoporotic vertebral fractures, even with involvement of the posterior cortical wall.

Methods. Between December 2001 and May 2004, 74 consecutive patients were treated with kyphoplasty for 118 painful osteoporotic compression (38%) or burst (62%) fractures. Additional decompression of the spinal canal was performed in six patients, internal fixation in three. Data were collected in a prospective observational design until May 2005. The preoperative workup included neuroimaging (plain x-ray films, densitometry, short tau inversion recovery magnetic resonance imaging, and computed tomography scanning) and clinical parameters (general and neurological examinations, visual analog scale [VAS], Karnofsky Performance Scale [KPS], and 36-Item Short Form Health Survey [SF–36]). At predefined time intervals (at discharge and 6 weeks and 3, 6, 12, and 24 months post-therapy) the patients were evaluated (x-ray films, neurological status, VAS, KPS, and SF-36).

Kyphoplasty led to a significant reduction in kyphotic deformity (mean ± standard error of the mean, sagittal index: preoperative 10 ± 1°, postoperative 5 ± 1°), and an improvement in pain (VAS: preoperative 70 ± 3, postoperative 23 ± 2°, activity (KPS score: preoperative 51 ± 3, postoperative 71 ± 2), and mental and physical health (SF-36, mental status: preoperative 43, postoperative 58; SF-36, physical status: preoperative 24, postoperative 35). No secondary narrowing of the spinal canal by the retropulsed posterior wall was observed after the procedure. Clinical improvement was durable (mean follow up 15 ± 1.1 months), although the VAS score secondarily increased slightly. All patients, who suffered from a compression-induced motor deficit, recovered completely during the follow-up interval. The main procedural complications consisted of one symptomatic extratrabecular cement leakage (permanent monoparesis) requiring open revision, two nerve root contusions (transient radiculopathy), and one wound infection.

Conclusions. Kyphoplasty is effective in the treatment of painful osteoporotic vertebral compression and burst fractures, at least under medium-term conditions. The potential complication of procedure-related secondary narrowing of the spinal canal by the retropulsed posterior wall in burst fractures appears to be more of a theoretical than an actual risk.

KEY WORDS • vertebral burst fracture • osteoporosis • bone cement • kyphoplasty • polymethylmethacrylate

With the increasing life expectancy in the Western and Asian world, osteoporosis and its sequelae have become increasingly important. Due to a loss of mineral content, reduced bone strength, and trabecular connectivity, individuals suffering from osteoporosis have a massively increased risk of bone fracture. Approximately 50% of all osteoporotic fractures affect the spine, accumulating to more than 400,000 VB fractures annually in the European Union and approximately 700,000 in the US. Of these, more than one third are painful and do not respond to nonsurgical, symptomatic care. Fracture-induced kyphotic deformity causes altered biomechanics, resulting in excessive stresses to adjacent vertebrae, which exhibit an at least fivefold increase in the risk of subsequent collapse. Osteoporotic vertebral fractures often induce chronic pain, sleep disorders, eating disorders, early satiety, clinical depression, anxiety, and diminished quality of life. Moreover, patients with vertebral compression fractures have a significantly reduced life expectancy, primarily related to pulmonary causes.

During bed rest—an important measure in the classic treatment for painful osteoporotic fractures—the bone density decreases even faster. Metal implants, which are important in the treatment of nonosteoporotic fractures, exhibit an increased probability of secondary material failure in the rarified cancellous bone. From this therapeutic dilemma have emerged minimally invasive stabilizing techniques: vertebroplasty and kyphoplasty. The strength of
both techniques is that they render the fractured vertebra immediately stable to mechanical loading, resulting in immediate and durable postoperative pain relief and improved physical mobility.\textsuperscript{1,3,13,15,25} A certain shortcoming of both techniques, however, is the problem of an adjacent-level fracture. As yet, it is not definitely known whether vertebroplasty and kyphoplasty further increase the fracture risk through the placement of a hard material (for example, PMMA) in close position to the soft, osteoporotic bone of neighboring vertebrae.\textsuperscript{39} An improved ability to reduce traumatic kyphosis and a decreased risk of cement leakage from fractured vertebrae (that is, extravasation) are considered further advantages of kyphoplasty. Accordingly, the risk of a PMMA-induced pulmonary embolus or a neurological deficit seems reduced after kyphoplasty compared with that after vertebroplasty.\textsuperscript{1,10,11,20,24,35,41,43}

The objective in the current study was to test the hypothesis that kyphoplasty is safe and effective for the treatment of painful osteoporotic vertebral fractures in a patient with a significant number of burst fractures typically seen in a major neurosurgical department, that is, fractures involving the posterior cortical wall.

Clinical Material and Methods

Patient Characteristics

Between December 2001 and May 2004, 74 consecutive patients (mean age 72 years, range 34–95 years) underwent 81 kyphoplasty procedures for 118 painful osteoporotic thoracolumbar fractures. Data were collected in a prospective observational design until May 2005, and analysis began thereafter. Informed consent was obtained in all cases. All patients suffered from significant pain at the fracture site (mean duration of pain 4.6 ± 1.3 months), which was refractory to conservative treatment with analgesic therapy, bed rest, and, in some cases, bracing. All patients had profound osteoporosis as revealed on densitometric studies (mean T score −3.6 ± 0.2). In 62\% of the cases, the fracture included the posterior cortical wall (burst fracture), resulting in a mean traumatic narrowing of the spinal canal of 14 ± 0.5\%. Seven percent of the patients suffered a neurological deficit due to compression of neural tissue (Table 1).

The preoperative neuroimaging workup included plain x-ray films, CT densitometry, short tau inversion recovery magnetic resonance imaging, and CT scanning through the levels demonstrating acute fractures in the short tau inversion recovery sequences. Patients responded to the SF-36 questionnaire and the VAS and underwent general and neurological examinations. The KPS score was determined as well. Immediately postoperatively, a CT scan was obtained, and the patient’s neurological status was reevaluated. At discharge, a plain x-ray film was obtained, the VAS and KPS scores were recorded, and antosteoporotic medication (vitamin D, calcium, and bisphosphonates) was prescribed. At predetermined intervals (6 weeks and 3, 6, 12, and 24 months postdischarge), the patients were evaluated in the outpatient clinic (plain x-ray film studies, neurological status, VAS score, KPS score, and SF-36 score). If the patient did not appear at his or her outpatient appointment, a telephone interview was conducted to acquire the SF-36, VAS, and KPS scores.

<table>
<thead>
<tr>
<th>Characteristic Value (%)</th>
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<tbody>
<tr>
<td>no. of patients 74</td>
</tr>
<tr>
<td>sex (male/female) 22:52</td>
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<tr>
<td>mean age ± SEM (yrs) 72 ± 1</td>
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<tr>
<td>±65 60</td>
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<tr>
<td>±70 51</td>
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<tr>
<td>±80 14</td>
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<tr>
<td>mean duration of symptoms ± SEM (mos) 4.6 ± 1.3</td>
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<tr>
<td>mean T score ± SEM −3.6 ± 0.2</td>
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<tr>
<td>Frankel grade A 0</td>
</tr>
<tr>
<td>B 0</td>
</tr>
<tr>
<td>C 2 (3)</td>
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<tr>
<td>D 3 (4)</td>
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<tr>
<td>E 69 (93)</td>
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<tr>
<td>no. of kyphoplasty procedures 81</td>
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<tr>
<td>no. of levels/patient 1 53</td>
</tr>
<tr>
<td>2 18</td>
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<tr>
<td>3 10</td>
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<tr>
<td>no. of fractured VBs 118</td>
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<tr>
<td>w/o retropulsed pst wall 45 (38)</td>
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<tr>
<td>w/ retropulsed pst wall 73 (62)</td>
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<tr>
<td>mean % traumatic narrowing of spinal canal (in fractures w/ retropulsed pst wall) ± SEM 14 ± 0.5</td>
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<tr>
<td>mean follow up ± SEM (mos) 15 ± 1.1</td>
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* pst = posterior.

Kyphoplasty Procedure

All procedures were performed in the operating room with the patient in a state of general anesthesia. Each patient was positioned prone on a gel-filled mattress that supported the upper thorax and pelvis to bring the lower thoracic and lumbar spine into a slight hyperlordosis. A single dose of prophylactic antibiotics (usually 2 g cefazolin) was administered 30 minutes before skin incision. Using biplanar fluoroscopy, the VB was cannulated percutaneously with an 11-gauge needle. A transpedicular approach in the lumbar spine and an extrapedicular approach in the thoracic spine were used, aiming toward the lower anterior quadrant of the VB. The needle was exchanged over a K-wire for an obturator and a working cannula. The tip of the working cannula was positioned approximately 5 mm ventral to the posterior wall of the VB. The obturator was removed, and a channel was created through the VB by using a tamp. The balloon was then inserted into the channel and inflated with contrast medium under fluoroscopic and balloon pressure control. Inflation was stopped when one of the cortical walls of the VB, or a maximal pressure of 350 psi, was reached. Polymethylmethacrylate was injected via filling cannulas when it reached a toothpaste-like consistency. Thus, the hole in the VB created by the balloon was filled from ventral to dorsal directions with the aid of lateral fluoroscopic control. The goal was to pack the fractured vertebra as tightly as possible with PMMA. Injection was continued until the hole in the vertebra was filled and the surrounding cancellous bone was infiltrated with PMMA, or until cement leakage was noted. In cases of a retropulsed posterior wall, special attention was paid to the fact that the balloon was positioned as close to the anterior vertebral
Kyphoplasty for osteoporotic fractures

cortex as possible, and the retropulsed fragment was carefully observed during balloon inflation and PMMA insertion.

Additional decompression (interlaminar fenestration or hemilaminectomy) was indicated during surgical planning in two cases because of disc herniation or a ligamentum flavum cyst, causing sciatica, and in four cases because of a retropulsed posterior wall causing lateral recess stenosis and radicular pain and/or deficit. Internal fixation was indicated in three cases during surgical planning because of supposed profound instability of the fracture (complete burst fractures). The fixation was performed in an open fashion in two cases with additional decompression and in a percutaneous fashion in one case, because opening of the spinal canal was not indicated.

Measurement of Kyphotic Deformity

Lateral radiographs obtained while the patient remained standing were used to measure the kyphotic deformity of the fractured segment. In some patients, preoperative standing films could not be obtained because of the pain involved. In such cases measurements were taken from the available supine films. Sagittal alignment across the fractured level was calculated using the SI technique; that is, the angle between the caudal endplates of the fractured vertebra and the adjacent vertebra above is measured. This value is then corrected using the normal angle between the endplates at the different levels of the vertebral column, that is, 5˚ at T5–11, 0˚ at T12–L1, and 10˚ at L2–5, through subtraction. For example, a measured angle of 13˚ in a fracture at L-2 results in an SI of 23˚ \( (13˚ \pm [\text{range}] = 23˚). \) Accordingly, the SI allows a certain level-independent description of the VB silhouette. A positive angle expresses kyphosis; a negative angle, lordosis. Measurements were performed by one of the authors who was not involved in the respective operation and blinded to the clinical situation of the patient.

Statistical Analysis

To test the influence of the surgical treatment on the study parameters, the data acquired before the operation, at discharge, and at the last follow-up visit were analyzed using the one-way analysis of variance on ranks followed by a pairwise comparison with the Tukey test. Data are presented as the means \( \pm \) SEM. The Pearson linear correlation coefficient was calculated to analyze the effect of kyphosis reduction (\( \Delta \)SI) on the VAS and KPS scores (\( \Delta \)VAS score and \( \Delta \)KPS score) and the effect of the injected PMMA volume on \( \Delta \)SI, \( \Delta \)VAS score, and \( \Delta \)KPS score. A probability value less than 0.05 was required to reject the null hypothesis and to indicate a statistically significant difference.

Results

One hundred eighteen fractures between T-7 and L-5 were treated. Seventy percent (83 fractures) were located in the thoracolumbar transition zone from T-11 to L-2 (Fig. 1). The mean duration of surgery (53 one-level, 18 two-level, and 10 three-level procedures) was 62 \( \pm \) 5 minutes (range 20–180 minutes). Thus, the operating time was 53 \( \pm \) 3 minutes (20–125 minutes) when only kyphoplasty was performed and 140 \( \pm \) 15 minutes (range 90–180 minutes) when additional decompression or fixation was conducted as well. The balloons were inflated to a mean of 3 \( \pm \) 0.2 ml (range 1–9 ml) on each side, reaching a mean pressure of 137 \( \pm \) 8 psi (range 37–350 psi). A mean of 4 \( \pm \) 0.2 ml PMMA (range 1–12 ml) was introduced into the fractured vertebra on each side. Five patients initially presented with a motor deficit (three with Frankel Grade D and two with Frankel Grade C)\(^3\) three due to a traumatic narrowing of the spinal canal, one due to a herniated disc, and one due to a history of severe spondylodiscitis and myelitis. Apart from the patient with myelitis, who was treated with kyphoplasty alone, all patients recovered completely from the motor deficit after kyphoplasty and decompression.

The 30-day complications are listed in Table 2. In 33 cases, the postprocedural CT scan revealed an asymptomatic extravertebral cement leakage: 17 burst and 16 compression fractures. The leakage reached the paraspinous space in 23 of the 118 PMMA-augmented vertebrae, the disc space in four levels, and the spinal canal in 12 levels. Thus, the leakage into the spinal canal in all cases but one occurred within the vertebral venous system and not through cortical deficiencies. Polymethylmethacrylate in the spinal canal led to a permanent monoparesis of the right leg in a patient with a compression fracture of T-12 (that is, without a retropulsed posterior wall), although the PMMA was instantly evacuated via a hemilaminectomy. Twice, the kyphoplasty balloon ruptured during inflation to moderate pressures (180 and 200 psi) without consequences. Two patients suffered a transient radicular paresis due to nerve root contusion during the approach. One patient died on postoperative Day 1 because of a myocardial infarct. Another patient died 3 weeks postoperatively following secondarily acquired pneumonia and septicemia. After a complex operation, which included the explantation of a dislocated internal fixator, bilateral decompression of the spinal canal, and a kyphoplasty in T-12, one patient suffered a wound infection that had to be surgically revised. One potential complication that never occurred was a secondary narrowing of the spinal canal by pressure-induced migration of the retropulsed posterior wall in burst fractures.

FIG. 1. Bar graph showing the distribution of 118 VB fractures along the thoracolumbar spine. Th = thoracic.
Prior to the 1-year follow-up evaluation, seven patients died—two within the 30-day postoperative period (as mentioned previously) and five as a result of unrelated disease. Among the remaining 67 patients, 52 (78%) have been evaluated over a mean follow-up period of 15 months (range 8–32 months). Kyphoplasty led to a significant reduction in traumatic kyphosis, from a preoperative SI of 10° to 5° at discharge (Fig. 2); therefore, the individual reduction in kyphosis ranged from 0 to 21°. Likewise, the clinical status of the patients, as expressed by the VAS and KPS scores, improved significantly until discharge (Fig. 3). This clinical improvement persisted during the follow-up period, but part of the benefit was secondarily lost (Fig. 3 left, p < 0.05, VAS score at the last follow up compared with the postoperative score). The results of the SF-36 questionnaire are shown in a dichotomized fashion: a mental and a physical health component (Fig. 4). Both components reflect statistically significant improvement in subjectively determined health between the preoperative and postoperative period until the final follow-up evaluation.

A statistically significant linear correlation was not found between the reduction in kyphosis (ΔSI) and the improvement in the VAS and KPS scores (ΔVAS score and ΔKPS score) or between the injected PMMA volume and the ΔSI, ΔVAS score, or ΔKPS score (data not shown).

Within the follow-up period, six patients experienced new osteoporotic fractures. The fractures were located at levels adjacent to the PMMA-augmented vertebra in four patients (one patient even had a third fracture episode), whereas they were located at remote levels in two patients. All new fractures were actively treated with kyphoplasty. All parameters of the new fractures were included in the current study data for the same patient; the follow-up time was measured from the first treatment forward.

**Discussion**

In this study we summarize our experience with kyphoplasty for the treatment of painful thoracolumbar fractures in primary and secondary osteoporosis. The data confirm the ability of this method to reduce traumatic kyphosis and instantly improve fracture-induced pain (VAS) and activity levels/independence (KPS). Furthermore, our findings reveal that the effects of kyphoplasty on pain, activity levels, and mental and physical health (SF-36) are durable under medium-term conditions. These effects were achieved in a patient group with a high percentage of burst fractures (> 60%) by using the optional combination of kyphoplasty with decompressive or further stabilizing operative steps, with a low rate of severe procedure-induced complications.

![Fig. 2. Left: Bar graph demonstrating the SI of the fractured vertebral segment. Kyphoplasty led to a significant reduction in traumatic kyphosis from an SI of 10° preoperatively to 5° on discharge. Right: Radiographs showing an example of pre- and postoperative, respectively, SI measurement in a patient with an osteoporotic fracture of L-2.](image-url)
Cement Leakage

The incidence of 33 asymptomatic extravertebral cement leakages in 118 cement-augmented VBs (that is, 28% per treated vertebra) in the current study is higher than in most other kyphoplasty reports. After kyphoplasty of vertebral compression fractures, most authors describe cement leakage in 2.7 to 10.2%. Note, however, that there have been leakage rates of up to 33%.

Most of these findings are based on postoperative radiographs, which do not adequately visualize intradiscal and posterior cement leaks, as pointed out by Gaitanis et al., who used radiographic and CT studies. In contrast, in the current study we evaluated cement leakage on routine postoperative CT scans. As shown in Table 2, the risk of asymptomatic cement leakage is not increased in burst fractures.

During this study, we endeavored to pack the fractured vertebrae as tightly as possible with PMMA to prevent secondary instability. However, no dose-dependent effect of the injected PMMA on the restoration of VB strength/stiffness and on the reduction in pain was detected. In contrast, a dependency between cement leakage and cement viscosity and volume has been identified. Both of these parameters might be reasons for the high rate of extravertebral cement leakage in the present study. Accordingly, any future treatment strategy should incorporate the use of less PMMA per vertebra with higher viscosity to better avoid cement leakage.

Effect on Pain and Activity

Authors of several studies have already proven that PMMA-augmenting techniques can improve fracture-induced pain rapidly and durably. This result is confirmed by our observation, although the VAS score increased slightly, but significantly, between discharge and the last follow up. Note, however, that this finding might have occurred as a result of an initial tendency to overinterpret pain reduction immediately after the operation. Perhaps the gradual weaning of painkillers until the last follow up contributed to this result. At the same time the KPS score remained stable and exhibited even further improvement.

Correction of Kyphotic Deformity

Besides the reduced probability of PMMA leakage, the correction of kyphotic deformity is supposed to be the main advantage of kyphoplasty compared with vertebroplasty. A restoration of spinal statics increasing the treatment effects, improving kyphosis-induced pulmonary restrictions, and decreasing subsequent adjacent-level fractures has been expected of this technique. Indeed, in accordance with our experience, several other groups have reached approximately 40 to 60% correction in kyphotic deformity. Others have achieved markedly less correction or such positive results in only a small percentage of patients. Note, however, that the results of Grafe et al. as well as our own data lack a correlation between kyphosis reduction and the clinical outcome parameters (VAS, KPS, and European Vertebral Osteoporosis Study mobility scores). Accordingly, vertebroplasty and kyphoplasty allow similar results with respect to pain relief and improvement in mobility. The expectation of kyphoplasty’s positive effect on pulmonary restrictions has not been proven thus far either, at least to the best of our knowledge.

The incidence of a refracture in the 1st year after an osteoporotic fracture without intervention (natural history) is 19%, as determined from a large patient sample (2725 women). However, only 23% of these fractures are symptomatic. Accordingly, the incidence of symptomatic refractures in the 1st year after osteoporotic fractures without intervention is approximately 4.5%. After kyphoplasty,
refracture rates range from 3 to 29% (8% of symptomatic refractures in the current series); after vertebroplasty, between 12 and 52%, depending on the aggressiveness of the radiological follow up. These results are most likely due to the fact that, although the strength of the treated segment itself is increased after PMMA injection, the strength of the whole multisegment vertebra decreases, with failure occurring in the nonaugmented vertebrae. Whether these data unequivocally translate into an increased incidence of refracture after vertebroplasty and kyphoplasty and whether kyphoplasty is superior to vertebroplasty in this respect remain unknown. Clear answers to such questions are pending. Taken together, it is not clear whether the reduction in kyphotic deformity by kyphoplasty translates into a clinical benefit for the patient.

Treatment of Burst Fractures

The fear that burst fractures are more prone to procedure-related spinal canal narrowing either by epidural PMMA leakage along the fracture clefts (resulting in space-occupying intraspinal PMMA) or by balloon-induced retropulsion of the posterior cortical wall has yet to be systematically validated. Nevertheless, according to the literature, fractures involving the posterior cortical wall are still considered at least relative contraindications for vertebroplasty and kyphoplasty. Reports about other experiences in treating osteoporotic burst fractures are scarce. The first group to publish data on their enlarged spectrum of kyphoplasty in treating burst fractures was Boszczyk et al. Through a series of four cases, these authors described a standard approach (that is, extrapedicular for thoracic and transpedicular for lumbar fractures), an open interlaminar, and an anterolateral optionally endoscopic approach with-out procedure-related complications. Hsiang reported on a 79-year-old woman with traumatic spinal canal narrowing at T-12 and bilateral leg weakness and in whom an open kyphoplasty was performed after decompression laminectomy. Recently, Singh et al. published data on the first series of osteoporotic burst fractures and symptomatic spinal stenosis; vertebroplasty or kyphoplasty, respectively, was used in an open approach after decompression—again, without serious adverse effects. The present study, in which kyphoplasty was always applied percutaneously, represents the largest reported series of kyphoplasty treatments for burst fractures (73 vertebrae). Polymethylmethacrylate augmentation was combined with decompression of the spinal canal in only six patients with radicular symptoms, and with a transpedicular fixation in three patients (complete burst fractures). Five patients recovered completely from the compression-induced motor deficits. A secondary narrowing of the spinal canal by pressure-induced migration of the retropulsed posterior wall or a space-occupying epidural PMMA leakage along the fracture clefts was never observed. Therefore, we consider PMMA augmentation by percutaneous kyphoplasty a valid and safe option in the treatment of painful osteoporotic burst fractures. In cases of secondary symptomatic loss of correction in these fractures, cement-augmented transpedicular fixation and decompression remain a retreatment option.

Conclusions

Kyphoplasty is effective for the treatment of painful osteoporotic vertebral compression and burst fractures, because it leads to a profound improvement in pain, activity levels, and mental and physical health. The potential complication of procedure-related secondary narrowing of the spinal canal by the retropulsed posterior wall in burst fractures appears to be a theoretical risk rather than an actual one.

References

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