



Is vertebral body stenting in combination with CaP cement superior to kyphoplasty?

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Abstract

Purpose In the evolution of the minimally invasive treatment of vertebral compression fractures, vertebral body stenting (VBS) was developed to reduce intraoperative and secondary loss of vertebral height. Particularly in combination with the usage of biodegradable cement, the influence of VBS on the rate of intraoperative complications and long-term outcome is unclear. The purpose of this study was to investigate the differences between balloon kyphoplasty (BKP) and VBS regarding their long-term clinical and radiological outcome in combination with calcium phosphate (CaP) application instead of polymethyl methacrylate (PMMA).

Methods This retrospective study included 49 patients with fresh mono-segmental thoracolumbar fractures without neurological signs treated with VBS or BKP and CaP cement (Calcibone). The outcome was evaluated with the visual analogue pain scale (VAS), the Oswestry disability score (ODI), and radiologically assessed.

Results In the course of the radiological follow-up, the VBS group showed statistically significant less vertebral height loss than the BKP group. However, with respect to VAS and ODI scores there were no statistically significant differences between the VBS and BKP group in the clinical follow-up. The rate of cement leakage was comparable in both groups.

Conclusions Both techniques facilitated good clinical results in combination with absorbable cement augmentation. In particular, the VBS enabled us to benefit from the advantages of the resorbable isothermic CaP cement with an improved radiological outcome in the long term compared to BKP. However, there was a mentionable loss of reduction in the follow-up in both groups compared to previously published data with PMMA cement.

Graphical abstract These slides can be retrieved under Electronic Supplementary Material.

The graphical abstract consists of three slides from a presentation. The first slide, titled 'Key points', lists three main findings: 1) VBS was developed to reduce height loss compared to BKP; 2) VBS with CaP shows better height restoration than BKP with CaP; 3) The study aims to clarify differences in long-term clinical and radiological outcomes. The second slide, titled 'Mean ODI Kyphotic Angles', contains four line graphs showing the change in local kyphotic and Cobb angles over time for both groups. The third slide, titled 'Take Home Messages', summarizes the study's conclusions: 1) CaP with BKP/VBS ensures good results with low complications; 2) VBS with CaP shows better height restoration than BKP with CaP; 3) The loss of reduction in the follow-up was more distinct with CaP compared to PMMA cement. Each slide includes the 'Spine Journal' logo and the authors' names.

Keywords Vertebral fracture · Kyphoplasty · Vertebral body stenting · Absorbable cement · Calcium phosphate

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Introduction

Vertebroplasty (VP) is considered as an established minimally invasive surgical procedure and has frequently been used to treat osteoporotic vertebral fractures in the last

three decades. The technique involves the injection of polymethylmethacrylate (PMMA) cement with high pressures to achieve the restoration of vertebral body height. This may lead to extravasation of PMMA in the surrounding soft tissues [1]. Especially, the leakage in the spinal canal can lead to severe complications. Spinal cord lesions of variable extent up to paraplegia have been described [2]. The evolution of this method is the balloon kyphoplasty (BKP). The injection of PMMA is performed under low pressures into a cavity preformed by an inflatable balloon. There is evidence that BKP reduces the rate of extravasation compared to VP [1, 3, 4]. The main advantage of PMMA is the high primary stability. However, the main disadvantages are the heat generated during the hardening process [5], the cytotoxicity [6], and the absent resorption capacity. A fibrous capsule forms around the synthetic material without any remodeling process [7]. Furthermore, the biomechanical properties of PMMA with its high stiffness may facilitate the risk of adjacent fractures, even leading to efforts to reduce compression strength of PMMA by addition of isotonic saline [8].

The trend to treat vertebral fractures minimally invasive with VP or BKP also in young patients led to the first application of absorbable bone substitutes. In the meantime, especially calcium–phosphate (CaP) cements have been used as an alternative to PMMA. The clinical results in comparison with PMMA vary depending on the CaP product applied. *In vitro* and *in vivo* studies clarify that the most important factor for the utilization in BKP is the initial compressive strength of the cement, ideally equal to healthy cancellous bone with 30 megapascal (MPa) [7, 9–12]. The compressive strength of PMMA cements varies between 50 and 90 MPa, in comparison with 20–60 MPa for absorbable cements [7]. Calcium–phosphate cements with a high compressive strength up to 60 MPa, for example, Calcibone (Biomet Merck, Darmstadt, Germany), have succeeded in *in vitro* and *in vivo* studies [7, 11–13].

Since deflation of the balloon in BKP can lead to secondary loss of the initial reduction with a decrease in vertebral height, the idea of vertebral body stenting (VBS) was established [14]. In theory, the advantage of this method is a better reconstruction of the fractured vertebra without loss of reduction. [2, 14–17] The quantifiable benefit of VBS compared to BKP in the postinterventional kyphotic correction described by some authors *in vitro* [16, 18] has not been demonstrated *in vivo* [19]. Furthermore, it remains unclear whether the long-term kyphotic correction and clinical outcome of VBS are superior to BKP.

The aim of the study was to clarify the differences in the long-term clinical and radiological outcome after BKP or VBS with CaP augmentation.

Materials and methods

This retrospective study was conducted at a single trauma center of maximum care (Level I) in Austria. The study was approved by the institutional review board (Ref. No. 02/2014), and written informed consent was received from all enrolled patients.

Patients

Patients with fresh mono-segmental vertebral fractures of the thoracic, thoracolumbar, or lumbar spine referred to the trauma center between 2008 and 2012 were included in the study. Only patients with back pain refractory to conservative treatment—including analgesics according to the World Health Organizations (WHO) guidelines for pain control and physiotherapy—were eligible.

Magnetic resonance imaging (MRI) was performed for every patient after admission to the hospital to exclude multi-segmental fractures and detect whether a fresh fracture was visible in the short tau inverted recovery (STIR) sequence, as described previously [20]. A fresh fracture was defined as a sharp pain onset not longer than 6 weeks ago with a positive STIR sequence in the MRI scan. The fractures were regarded as osteoporotic fractures that occurred as a result of minimal trauma in most of the cases. However, bone mineral density (BMD) scans were not obtained at our institution; therefore, the included patients were referred to the osteologist after discharge from hospital.

Furthermore, fractures were classified according to the AO classification on preoperative X-rays and computed tomography (CT) scans, as published before [21]. Only patients with fracture types A1 and A3.1 were included. Fracture types necessitating additional posterior instrumentation were excluded (Table 1).

Surgical technique

All interventions were performed under general anesthesia. The procedures were performed through a percutaneous transpedicular approach under radiographic control as described previously [18, 22]. After a canal was established in the vertebral body, either a balloon kyphoplasty (KyphX; Kyphon, Medtronic, Minneapolis, Minnesota) or a vertebral body stenting (Synthes, Oberdorf, Switzerland) system was used to restore the vertebral body height. Either two balloons (BKP group) or two stents (VBS group) were positioned, and inflation was performed slowly under fluoroscopic and manometric control. We aimed for maximal filling without transgressing the endplates or exceeding the maximum pressure (according to the manufacturer) under maintaining the

Table 1 Patient baseline characteristics

	VBS		BKS		Total	
	<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
<i>N</i>	36	73	13	27	49	100
Sex						
Male	9	25	5	38	14	29
Female	27	75	8	62	35	71
Age						
Mean ± SD	68.5 ± 11.5		69.2 ± 9.7		68.7 ± 11.0	

height of the vertebra achieved through the preoperative positioning of the patient. The balloons were removed, and the two produced cavities were filled with bone-filler canulas and stylets with CaP cement (Calcibon; Biomet Merck, Darmstadt, Germany). The same CaP cement (Calcibone) was used in both treatment groups for all treated vertebrae (Fig. 1).

At our institution, all augmentation procedures are performed with CaP cement. We are not using PMMA for the augmentation of vertebral fractures.

Clinical and radiological evaluation

Clinical assessment was performed using visual analogue pain scale (VAS) and Oswestry disability score (ODI) [23] with a minimum follow-up of 2 years (mean follow-up 45 ± 13.5 months). VAS was used to indicate the degree of back pain (10 = maximum pain—0 = no pain). Subsequently, ODI was evaluated to measure the degree of disability and the quality of life in our patient collective. The postoperative mobility of the thoracic spine was determined by Ott's test and of the lumbar spine by Schober's test [24].

Radiographs of the affected segment of the spine were performed pre- and postoperatively, as well as during short-term (6–18 weeks after the surgical procedure) and long-term follow-up. The initial and postinterventional radiographs were conducted with the patient in inclined position.

However, the X-rays during the short- and long-term follow-up were achieved in upright standing position. Two independent examiners, with the use of a picture archiving and communication system (PACS) implemented goniometer, evaluated the local kyphotic angle and the Cobb angle for each patient at all time points. The local kyphotic angle was measured from the superior to the inferior endplate of the fractured vertebral body. The Cobb's angle was measured from the superior endplate of the vertebral body one level above the injured vertebral body to the inferior endplate of the vertebral body one level below [25].

As described in the literature, the rate of cement leakage is underestimated by standard X-ray [1] that is the reason why a second postoperative CT scan was performed with the patient still under general anesthesia to determine the distribution of the cement and eventually cement leakage.

Statistical analysis

Statistical analyses were done using the free software environment R [26] version 3.3.1 on a PC running Linux Ubuntu version 16.04.2 LTS. Linear mixed effects models were fitted using the R package lme4 [27]. Where appropriate, results are given as mean and standard deviation (SD). To estimate the effect of surgery technique on outcome over time, linear mixed effects models were employed with subject as random

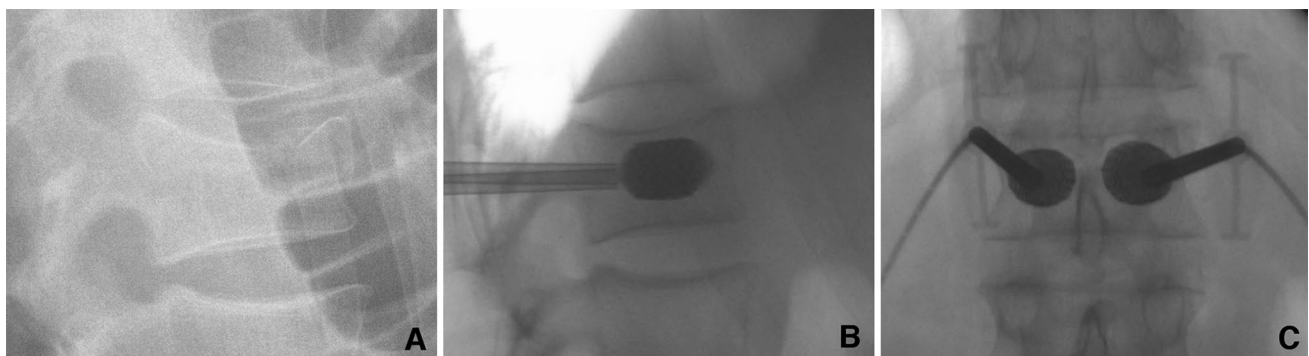


Fig. 1 Radiographic example of a 73-year-old male patient treated with vertebral body stenting. **a** AO type A1.2 fracture of L1, intraoperative X-rays; **b** sagittal- and **c** ap-view

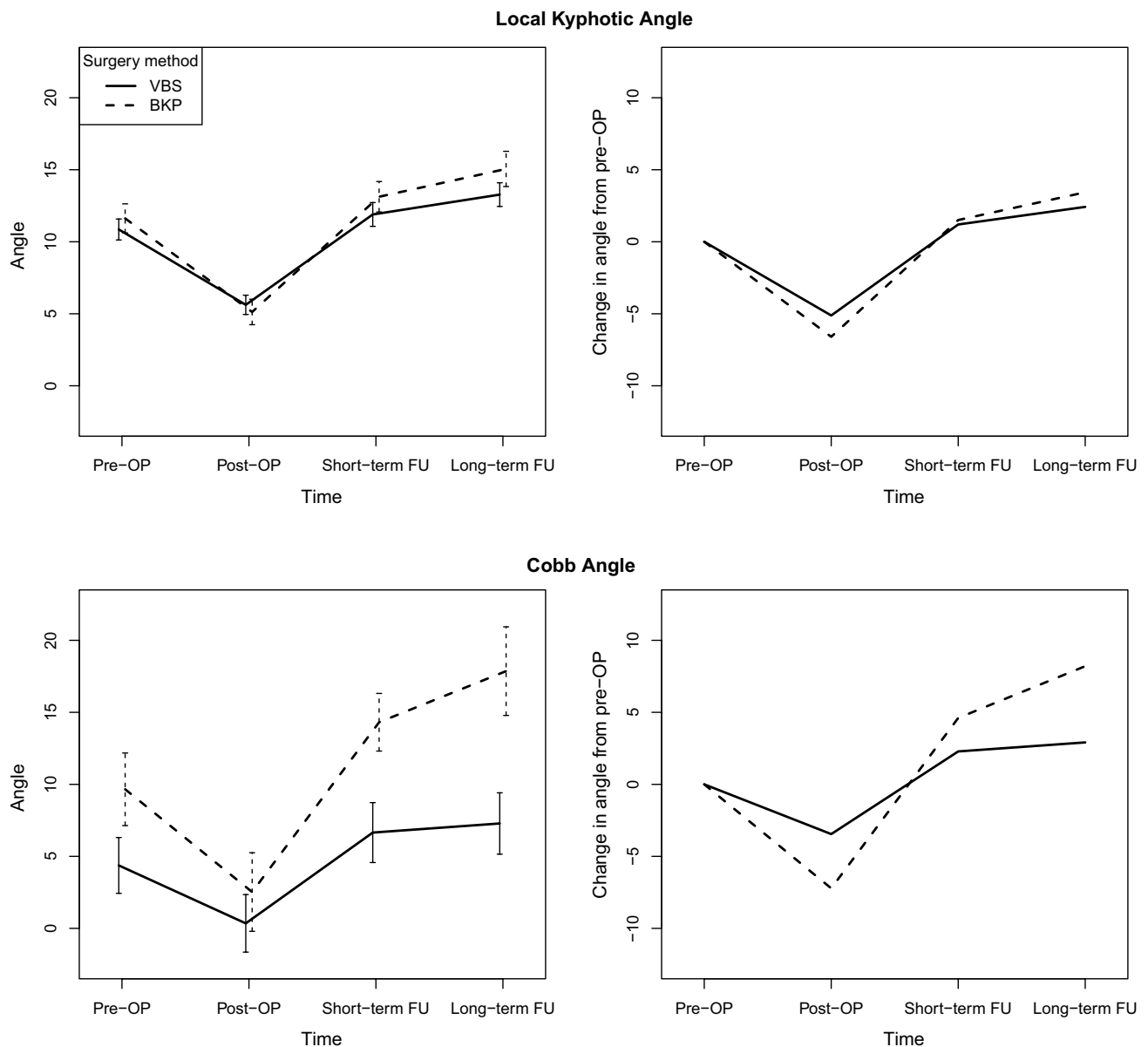


Fig. 2 Mean (SD) kyphotic angles—in the figures on the left side the local kyphotic angles and Cobb angles are shown at all time points; in the figures on the right side the change in angle from the first X-ray preoperatively (concerning the local kyphotic angles and Cobb angles) is shown

factor and surgery method and visit as well as their interaction effects as fixed factors (Fig. 2).

Results

Patients

Forty-nine patients with mono-segmental vertebral fractures of the thoracic, thoracolumbar, or lumbar spine were treated 10.2 ± 6.3 days (mean \pm SD) after being admitted to the trauma center. The gender distribution showed a majority of

female patients in both groups. The analysis of fracture type according to the AO classification showed particularly 34 type-A1 fractures (69%) compared to 15 type-A3.1 fractures (31%). There were no significant differences between the two treatment groups concerning baseline characteristics.

Clinical outcome

The VAS scores at the follow-up examination were 2.0 ± 2.3 in the VBS group and 2.2 ± 2.5 in the BKP. There were no significant differences between the VBS and the BKP

group concerning the pain score at the long-term follow-up ($P=0.7729$).

Furthermore, the ODI scores were 16.6 ± 17.6 in the VBS group and 16.7 ± 19.7 in the BKP group. There were no significant differences concerning the disability score at the long-term follow-up ($P=0.9897$).

The Ott's test showed normal mobility in the thoracic spine in eight patients (22%) in the VBS group and in one patient (8%) in the BKP group. However, Schober's test showed normal mobility in the lumbar spine in thirty patients (83%) in the VBS group and in twelve patients (92%) in the BKP group. Hence, there were also no significant differences in the mobility scores (Ott $P=0.412$ /Schober $P=0.658$) at the long-term follow-up.

Radiological outcome

The local kyphotic angle could be reduced from 10.9 ± 6.0 to 5.7 ± 5.8 in the VBS group and from 11.6 ± 4.8 to 5 ± 4.3 in the BKP group. The Cobb angle could be reduced from 4.4 ± 16.4 to 0.9 ± 16.9 in the VBS group and from 9.7 ± 12.8 to 2.4 ± 13.7 in the BKP group. Hence, there were no significant differences of the local kyphotic angles ($P=0.883$) and Cobb angles ($P=0.421$) before surgery.

The mean local kyphotic correction angles were -5.1 ± 3.6 in the VBS group and -6.6 ± 3.2 in the BKP group. The mean Cobb correction angles were -3.5 ± 5.6 in the VBS group and -7.2 ± 3.8 in the BKP group. Thus, even if there were no significant differences of the local kyphotic correction angles between the two treatment groups ($P=0.182$), we observed a slight difference in the Cobb correction angles in the BKP group versus the VBS group ($P=0.012$).

However, the local kyphotic angles and Cobb angles increased during the follow-up with inferior values in the balloon kyphoplasty group. The loss of reduction mostly happened in the early postoperative phase until the short-term radiographic follow-up. The local kyphotic angles increased to 13.3 ± 6.8 in the VBS group and 15.1 ± 6.2 in the BKP group at the final follow-up. The Cobb angles increased to 7.3 ± 17.7 in the VBS group and 17.9 ± 15.7 in the BKP group at the final follow-up. The loss of reduction (concerning the local kyphotic angle) was 7.5 ± 4.8 in the VBS group and 10.0 ± 5.3 in the BKP group. The loss of reduction (concerning the Cobb angle) was 6.5 ± 8.0 in the VBS group and 15.4 ± 11.0 in the BKP group. The loss of reduction (concerning the Cobb angle) was slightly better in the VBS group versus the BKP group ($P=0.012$); there was no significant difference in the loss of reduction (concerning the local kyphotic angle) between the two treatment groups ($P=0.182$).

In the linear mixed effects models, the correction of the Cobb angle was significantly better over the course of the

follow-up in the VBS group compared to the BKP group ($P<0.001$). There was no significant difference between the two treatment groups in the local kyphotic correction over the course of the observational period ($P=0.290$).

Interventions

The mean duration of the operation was significantly longer in the VBS (35 ± 20 min) group compared to the BKP group (22 ± 8 min) ($P=0.003$).

No neurologic or cardiovascular complications were documented in any patient enrolled in this study. Furthermore, none of the patients required revision surgery following the primary intervention. The only adverse events observed were clinically asymptomatic cement leakages (determined in postoperative CT-scans) in 37% of the treated vertebrae. The leakage rates were 44% in the VBS group and 23% in the BKP group, with no significant differences between the two intervention groups ($P=0.205$).

Discussion

In vitro studies have shown improved height restoration of the VBS system compared to kyphoplasty. The vertebral body stent prevented the loss of reduction during balloon deflation, observed in the BKP procedure [16–18]. However, this effect could not be shown in vivo. The only clinical study directly comparing VBS and BKP in combination with PMMA cement demonstrated no beneficial effects of VBS with regard to the amount of kyphosis correction, radiation exposure time, or cement leakage [19]. A systematic review of the effectiveness of stentoplasty concluded that VBS is comparable to BKP concerning the radiological outcome and the complication rate [28]. Accordingly, in our study the amount of local kyphotic correction achieved intraoperatively in the VBS group and in the BKP group was also not significantly different, consistent with previously published data on BKP and VBS [2, 19].

The literature on the application of CaP in BKP is controversial. Although some authors published that it is as safe and effective as PMMA in the clinical setting [7, 11, 13], other authors described a higher risk of cement failure followed by loss of reduction dependent on the CaP product applied [10, 29–31]. Nevertheless, there is evidence that CaP cement is gradually resorbed without compromising stability as demonstrated in a recent study with a 3-year follow-up [32].

Our study shows—to our knowledge for the first time—the clinical application of the VBS in combination with CaP cement. We were able to demonstrate comparable results in the pre- and postoperative radiographic measurements with the usage of CaP instead of PMMA in both intervention

groups. However, we found a significant loss of reduction in both treatment groups over the course of the follow-up compared to previous publications where PMMA was applied instead of CaP [33]. In both treatment groups, the loss of reduction was measured to a lesser extent in comparison with the outcome after conservative treatment in the literature [34, 35]. In that respect, no definite conclusion is possible, because neither the comparison of CaP to PMMA, nor the comparison between minimally invasive surgical treatment and conservative treatment, was the primary focus of this study.

Interestingly, the VBS facilitated significantly better correction of the Cobb angle in comparison with BKP in the long-term follow-up. The superior radiological results achieved in the VBS group are not reflected in the clinical results. However, the patients in both treatment groups only suffered from mild pain and minimal disability at the long-term follow-up. There were no significant differences in the visual analog scale for pain or the Oswestry disability score between the VBS and the BKP groups.

Conclusion

Although the usage of CaP in our study facilitated good clinical results with a low complication rate, the application in osteoporotic vertebral fractures should be reconsidered with regard to the loss of reduction in the long-term follow-up. If CaP cement is applied, to avoid the risk of thermal necrosis and absent resorption capacity of PMMA [10, 13], the vertebral body stent can increase stability compared to implantation via kyphoplasty.

Compliance with ethical standards


Conflict of interest All authors declare that they have no conflict of interest.

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