



# Comparison of PMMA Bone Cement Dosage Used in Vertebroplasty and Balloon Kyphoplasty: A Meta-analysis of Data from Randomized Controlled Trials

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## Authors' contributions

This work was carried out in collaboration between all the authors. Author GL designed the study, carried out the article selection procedure, extracted the relevant data from the selected articles, checked the output from the software package and wrote the first and final drafts of the manuscript. Authors FF and RM ran the software package. All the authors read and approved the final manuscript.

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## ABSTRACT

**Background and Aim:** Vertebroplasty (VP) and balloon kyphoplasty (BKP) are widely used to treat patients in whom the pain, arising from vertebral body fracture(s), is refractory to conservative treatment(s). Currently, poly(methyl methacrylate) (PMMA) bone cement is the cement of choice in VP and BKP. The relationship between the volume of the PMMA bone cement used ("PMMA bone cement dosage") and cement extravasation, a common complication in both procedures, has not been established. The purpose of the present study was to conduct a meta-analysis in order to determine the statistical nature of the difference in cement dosage used in these two procedures.

**Methods:** Computerized and manual searches of the literature on VP and BKP were conducted to identify relevant articles in the open literature. These articles were scrutinized against a set of exclusion and inclusion criteria, such as type of study (for example, randomized controlled trial (RCT) and case series), for acceptance for use in the meta-analysis.

**Results:** The final dataset were taken from 6 articles. A larger cement dosage was used in VP than in BKP but the difference is not significant; for example, with a random-effects model,

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odds ratio = 2.883; 95%CI = 0.419, 19.845; Z = 1.076; p = 0.282.

**Conclusion:** The difference in cement dosage used in VP and that used in BKP is not significant.

**Keywords:** *Vertebroplasty; balloon kyphoplasty; PMMA bone cement dosage; meta-analysis.*

## 1. INTRODUCTION

Various aspects of osteoporosis-induced vertebral compression fractures (VCFs) are now well-known. For example, 1) they are a common complication of severe osteoporosis [1]; 2) the incidence is high (for example, in the United States and western Europe, ~ 1.7 million new cases are diagnosed per annum [2] and, worldwide, the incidence is rising over time (by an estimated 6% per annum), reflecting the rise in the incidence of osteoporosis with the “graying” of the population [3]; 3) they have an adverse effect on a patient’s quality of life [4]; and 4) associated costs are high (for example, in European Union countries, direct costs are estimated to be ~\$440 million per year [4]). The appropriate treatment modality for the pain arising from VCF(s) depends on the pain profile. Thus, when the pain is mild, management is achieved using a conservative method/medical therapy, such as non-steroidal anti-inflammatory pain medication, spinal extensor-strengthening exercises, and back bracing [1,5]. In contrast, when the pain is severe, persistent, and has proved refractory to treatment by conservative method(s), a surgical method is used [4]. Surgical methods may be grouped into two categories. In the first are well-established procedures, these being vertebroplasty (VP) and balloon kyphoplasty (BKP) [6]. In the vast majority of VP and BKP cases, a poly(methyl methacrylate) (PMMA) bone cement is used [6]. In the second category are methods that either are variants of VP or BKP or use a different principle, examples being decompressed percutaneous vertebroplasty [7], radiofrequency kyphoplasty [8], insertion of expandable titanium mesh cages [9], stentoplasty [10], a Nitinol coil with an external handle guiding mechanism (Kiva System) [11] and a cranio-caudal expandable implant (SpineJack®) [12].

Being well established, there is a very large body of literature on VP and BKP and, from these results, there is agreement that each is safe but there is lack of consensus on practically all other aspects, such as timing of intervention (for example, fracture diagnosis time < 3 weeks versus > 2 months), the optimal volume of PMMA bone cement injected into the fractured vertebral body (hereafter referred to as “PMMA

bone cement dosage”), extent of kyphotic reduction, incidence of cement extravasation into peri-vertebral tissues and other tissues and organs, incidence of new symptomatic fractures of non-augmented vertebral bodies (especially, adjacent ones), extent of pain relief (relative to that provided by a conservative method), and improvement in functional outcomes and quality of life [4,13-17].

For each of the aforementioned controversies, attempts at resolution have taken the form of meta-analysis of the results of clinical studies [18-26]. However, to the best of the present workers’ knowledge, the issue of the difference in the “cement dosage” used in VP and that used in BKP has been addressed in only two meta-analyses [23,24], both of which have a common shortcoming in that data were taken from a mixture of study types (for example, randomized controlled trials (RCTs), prospective comparative trials (PCTs), and retrospective cohort studies (RCSs)). The level of evidence provided by results from a PCT or an RCS is much lower than that provided by an RCT, which is considered the “gold standard” in evidence-based medicine [27]. Thus, the true difference between cement dosage used in VP and that used in BKP can only be obtained from meta-analysis of data taken from RCTs only.

The purpose of the present work was to perform a meta-analysis of PMMA bone cement dosage data given in reports on RCTs in which VP and BKP were compared.

## 2. MATERIALS AND METHODS

### 2.1 Literature Search

In the first instance, we conducted a computerized search of international databases, such as Current Contents, EMBASE, Google Scholar, MEDLINE, and PubMed. The purpose was to identify relevant articles, which were defined as those with key words, such as “vertebroplasty”, “percutaneous vertebroplasty”, “kyphoplasty”, “balloon kyphoplasty”, “percutaneous kyphoplasty”, “cement volume”, “cement dosage”, “vertebral compression fractures”, “osteoporotic vertebral compression fractures”, “osteoporosis-induced vertebral compression fractures”, “cervical compression

fractures”, “lumbar compression fractures”, and “thoracic compression fractures,” and which were published in English or with an English translation (where the original language was not English). After that, we conducted a manual search of the table of contents of relevant peer-review journals, such as European Spine Journal, European Journal of Orthopaedic Surgery and Traumatology, Osteoporosis International, Spine, The Spine Journal, Journal of Spinal Disorders & Techniques (now called Clinical Spine Surgery), and International Orthopaedics, for articles in which the title contained one or more of the aforementioned keywords.

## 2.2 Study Selection

We read each of the articles obtained from our searches to determine its suitability for inclusion in the meta-analysis. The inclusion criteria were 1) the article was published in a peer-review journal, 2) it was a RCT comparing two groups of patients, in each of whom osteoporosis was the diagnosed cause of the VCF(s), 3) the study compared VP and BKP as the only treatment for the presenting pain, and 4) information was given on the PMMA bone cement dosage used in the VP and BKP cases. Exclusion criteria were 1) did not satisfy any one of the inclusion criteria and 2) the article was a duplication of an earlier article by the same group of researchers. Any unresolved disagreement among the present authors regarding inclusion or exclusion of an article was resolved by consulting a researcher who was not involved in our meta-analysis.

## 2.3 Data Extraction

For each of the selected articles, the information/data collected were: author(s), year of publication, number of patients in the VP group, number of patients in the BKP group, PMMA bone cement dosage (mean and standard deviation) in the VP group, and PMMA bone cement dosage (mean and standard deviation) in the BKP group. In two articles [28,29], only the range of PMMA bone cement dosage in each of the two groups was stated; as such, we used that information, together with the number of patients in a group, to compute the mean and standard deviation of the cement dosage for the group [30].

## 2.4 Statistical Analysis

This was conducted using a commercially-available meta-analysis software package

(Comprehensive Meta-Analysis (CMA), version 3.03.070; Biostat, Inc., Englewood, NJ, USA) to obtain Forest plots of 1) the standard difference in mean (SDM) between the VP and BKP groups and 2) the odds ratio (OR) between the VP and BKP groups. For each of these analyses, pooling of the data was based on both the fixed-effects model and the random-effects model [31] and the statistical significance of the difference in the pooled data was obtained using a variety of measures, such as Cochran’s Q-statistic, Z value, p value, and  $I^2$  [31]. Test for publication bias was performed by obtaining the funnel plot [31].

## 3. RESULTS

### 3.1 Included Articles

A schematic summary of the steps used in the articles selection process is shown in Fig. 1, from which it is seen that 6 articles were finally selected. The relevant information on each of these articles is given in Table 1.

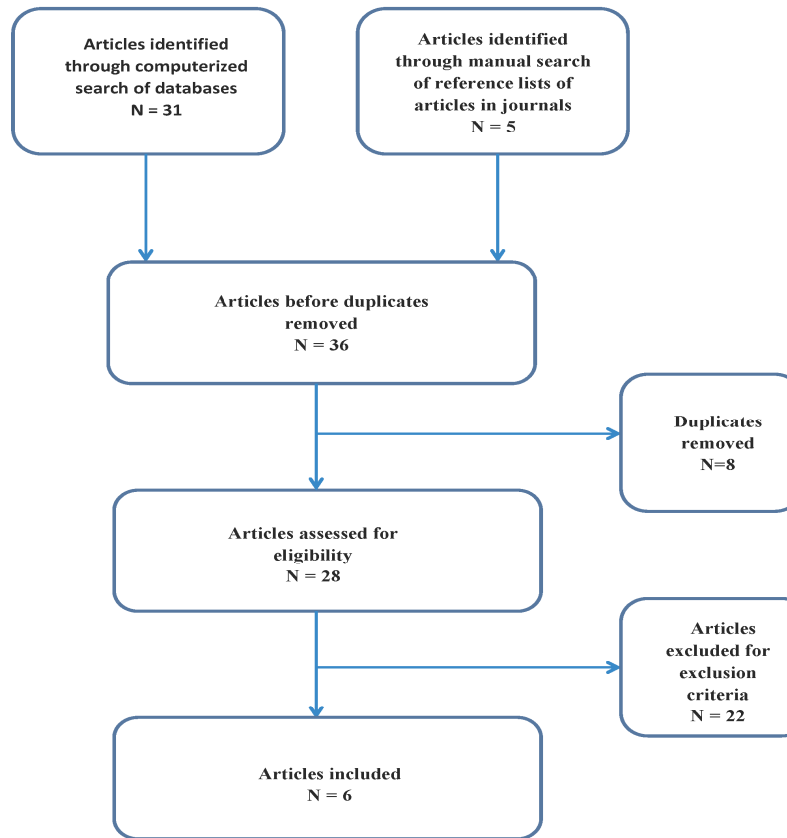
### 3.2 Outcomes Analysis

There was heterogeneity in the dataset ( $I^2 = 95.72\%$ ;  $p = 0.000$ ) (Figs. 2 and 3), suggesting that the random-effects model may be used to pool the data. However, we also used a fixed-effects model to pool the data. With the fixed-effects model, the overall SDM was 0.275 and 95%CI = -0.002, 0.431;  $Z = 1.941$ ;  $p = 0.052$ ; and with the random-effects model, the overall SMD was 0.58 and 95%CI = -0.46, 1.647;  $Z = 1.076$ ;  $p = 0.282$  (Fig. 2).

With the fixed-effects model, the overall OR was 1.476 and 95%CI = 0.996, 2.186;  $Z = 1.941$ ;  $p = 0.052$ ; and with the random-effects model, the overall OR was 2.883 and 95%CI = 0.419, 19.845;  $Z = 1.076$ ;  $p = 0.282$  (Figs. 3 and 4). Taken together, these results (Figs. 2-4) show that the difference between the PMMA bone cement dosage used in VP and that used in BKP is not significant.

### 3.3 Publication Bias

The funnel plot is very slightly asymmetrical, with one fewer study on the left-hand side compared to the right-hand side (Fig. 5). It thus appears that the evidence for publication bias, among the studies from which the data were extracted, is weak.



**Fig. 1. Flow chart of articles selection procedure**

#### 4. DISCUSSION

Although there are a number of meta-analyses of various aspects of VP and BKP in the literature [18-26], to the best of our knowledge, only two have focused on PMMA bone cement dosage [23,24] and, in neither of these were the data used limited to those reported in RCTs only. This was done in the present work.

In meta-analyses, it is usually suggested that a random-effects model should be used to pool the data when heterogeneity is large ( $I^2 > 75\%$ ) [30]. However, in cases where the dataset is small, such as the present one, consensus on this issue is lacking [31]. It is for this reason that, in the present work, the data were pooled using the fixed-effects model as well as the random-effects model.

Our analysis showed that although a larger PMMA bone cement dosage was used in VP than in BKP, the difference was not significant. It is to be noted that discussion of the implications of this finding, such as the role played by difference in cement dosage in the difference

between these two procedures in incidence of various clinical complications, such as cement extravasation (CE) and fracture of adjacent unaugmented vertebral bodies (FAVBs) [32-35] is outside the ambit of the present work. Nonetheless, it is appropriate to highlight two germane points. First, CE is the most common complication in each of these procedures and, arguably, the most serious, especially if leakage is symptomatic [4]. Second, it appears that whereas the clinical significance of PMMA cement dosage in VP is controversial (for example, no agreement on the influence of cement dosage on patient outcomes [36]), it appears that this is not case for BKP; thus, 1) some workers suggested that in unilateral BKP, the risk of CE and of FAVB are each directly related to cement dosage, prompting the recommendation that the PMMA bone cement volume fraction (defined as the ratio of cement dosage to the volume of the augmented vertebral body) used be no more than  $\sim 0.25$  [37]; and 2) there is evidence of a strong linear relationship between cement dosage and both pain relief [38] and sagittal alignment [39].

Model	Study name	Statistics for each study							Std diff in means and 95% CI				
		Std diff in means	Standard error	Variance	Lower limit	Upper limit	Z-Value	p-Value	-3.00	-1.50	0.00	1.50	3.00
	Endres & Bedura, 2012	2.000	0.369	0.136	1.276	2.724	5.416	0.000					
	Kumar et al., 2010	0.877	0.291	0.085	0.307	1.448	3.013	0.003					
	Liu et al., 2010	-1.023	0.213	0.045	-1.440	-0.606	-4.811	0.000					
	Movrin et al., 2010	0.199	0.243	0.059	-0.277	0.675	0.819	0.413					
	Omid-Kashani et al., 2013	2.297	0.322	0.104	1.666	2.929	7.133	0.000					
	Scholier et al., 2009	-0.736	0.267	0.071	-1.259	-0.213	-2.759	0.006					
Fixed		0.215	0.111	0.012	-0.002	0.431	1.941	0.052					
Random		0.584	0.543	0.294	-0.480	1.647	1.076	0.282					

Study name	Weight (Fixed)	Weight (Random)	Residual (Fixed)	Residual (Random)
	Relative weight	Relative weight	Std Residual	Std Residual
Endres & Bedura, 2012	8.96	16.18	5.07	1.15
Kumar et al., 2010	14.41	16.65	2.46	0.24
Liu et al., 2010	27.01	17.03	-6.81	-1.34
Movrin et al., 2010	20.69	16.89	-0.07	-0.32
Omid-Kashani et al., 2013	11.78	16.47	6.89	1.40
Scholier et al., 2009	17.16	16.78	-3.92	-1.09

Model	Effect size and 95% confidence interval						Test of null (2-Tail)		Heterogeneity			Tau-squared				
	Number Studies	Point estimate	Standard error	Variance	Lower limit	Upper limit	Z-value	P-value	Q-value	df (Q)	P-value	I-squared	Tau Squared	Standard Error	Variance	Tau
Fixed	6	0.215	0.111	0.012	-0.002	0.431	1.941	0.052	116.958	5	0.000	95.725	1.684	1.163	1.352	1.298
Random effects	6	0.584	0.543	0.294	-0.480	1.647	1.076	0.282								

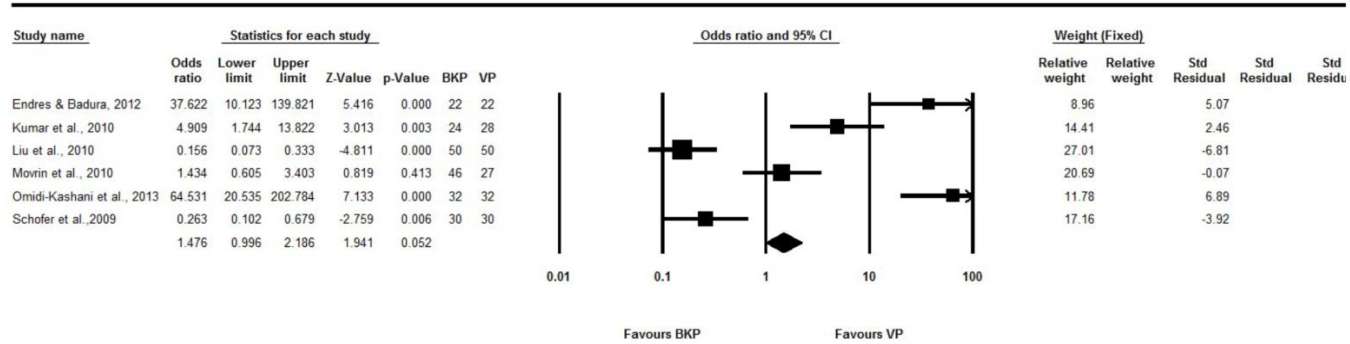
Fig. 2. Forest plot showing standard difference in means of cement dosage used in the vertebroplasty (VP) and balloon kyphoplasty (BKP) groups

Model	Study name	Statistics for each study					Sample size		Odds ratio and 95% CI					
		Odds ratio	Lower limit	Upper limit	Z-Value	p-Value	BKP	VP	0.01	0.10	1.00	10.00	100.00	
	Endres & Bedura, 2012	37.622	10.123	139.621	5.416	0.000	22	22						
	Kumar et al., 2010	4.909	1.744	13.822	3.013	0.003	24	28						
	Liu et al., 2010	0.156	0.073	0.333	-4.811	0.000	50	50						
	Movrin et al., 2010	1.434	0.605	3.403	0.819	0.413	46	27						
	Omid-Kashani et al., 2013	64.531	20.535	202.784	7.133	0.000	32	32						
	Schofer et al., 2009	0.263	0.102	0.679	-2.759	0.006	30	30						
Fixed		1.476	0.996	2.186	1.941	0.052								
Random		2.883	0.419	19.849	1.076	0.282								

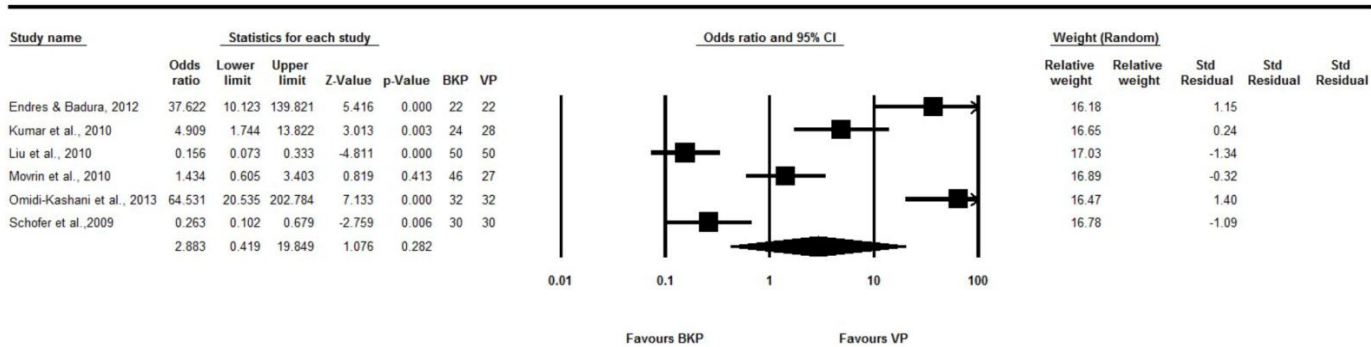
Study name	Weight (Fixed)	Weight (Random)	Residual (Fixed)		Residual (Random)	
	Relative weight	Relative weight	Std Residual		Std Residual	
Endres & Bedura, 2012	8.96	16.18	5.07		1.15	
Kumar et al., 2010	14.41	16.65	2.46		0.24	
Liu et al., 2010	27.01	17.03	-6.81		-1.34	
Movrin et al., 2010	20.69	16.89	-0.07		-0.32	
Omid-Kashani et al., 2013	11.78	16.47	6.89		1.40	
Schofer et al., 2009	17.16	16.78	-3.92		-1.09	

Model	Effect size and 95% interval				Test of null (2-Tail)			Heterogeneity			Tau-squared			
Model	Number Studies	Point estimate	Lower limit	Upper limit	Z-value	P-value	Q-value	df (0)	P-value	I-squared	Tau Squared	Standard Error	Variance	Tau
Fixed	6	1.476	0.996	2.186	1.941	0.052	116.958	5	0.000	95.725	5.540	3.826	14.637	2.354
Random effects	6	2.883	0.419	19.849	1.076	0.282								

Fig. 3. Forest plot showing odds ratio for difference of cement dosage used in the vertebroplasty (VP) and balloon kyphoplasty (BKP) groups

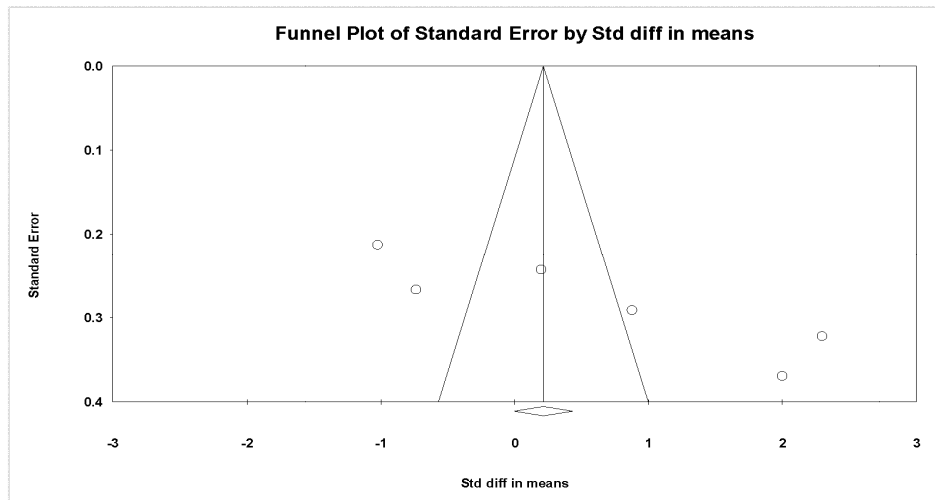


(A)



(B)

Fig. 4. High-resolution Forest plots showing odds ratio for cement dosage used in the vertebroplasty (VP) and balloon kyphoplasty (BKP) groups: Fixed-effects model results (A); random-effects model results (B)



**Fig. 5. Funnel plot for included articles on cement dosage used in the vertebroplasty (VP) and balloon kyphoplasty (BKP) groups**

**Table 1. Summary of the data on cement dosage used (in mL) in the randomized controlled trials on vertebroplasty (VP) versus balloon kyphoplasty (BKP), as reported in the six accepted articles**

Authors	VP			BKP		
	n <sup>a</sup>	Mean	SD <sup>b</sup>	n <sup>a</sup>	Mean	SD <sup>b</sup>
Enders and Badura [28]	22	(3.00–5.00) <sup>c</sup>		22	(2.00–4.00) <sup>c</sup>	
Kumar et al. [29]	24	(1.00–7.00) <sup>c</sup>		28	(0.75–5.00) <sup>c</sup>	
Liu et al. [32]	50	4.91	0.65	50	5.56	0.62
Movrin et al. [33]	46	5.80	1.70	27	5.50	1.10
Omidi-Kashani et al. [34]	32	5.10	0.90	32	3.50	0.40
Schofer et al. [35]	30	3.90	1.50	30	4.90	1.20

<sup>a</sup>Number of patients in study group

<sup>b</sup>SD: standard deviation

<sup>c</sup>Mean and SD not given; rather, the range of the results was given

There are no findings from the literature on meta-analysis of PMMA cement dosage data to which the present findings may be compared. This is because in each of the previous meta-analyses [23,24], data were taken from studies that included both RCTs and those with a lower level of evidence, such as PCTs and RCSs; in contrast, in the present work, only data from RCTs that met all of the other selection criteria were used. Indeed, this is the attraction of the present study.

We recognize two limitations of the study. First, the dataset analyzed was small (6 studies), this being a consequence of the fact that we only included data from RCTs. In fact, in each of the only relevant literature studies [23,24], the number of RCTs included in this analysis was also small (3 and 4). Second, within this dataset, there were some differences in the studies in terms of general factors, such as the surgical

approach used (for example, unilateral versus bilateral) and levels of vertebral bodies augmented, as well as in terms of PMMA bone cement-related issues, such as cement brand (and, hence, the cement viscosity-versus time profile) and cement delivery equipment used.

**5. CONCLUSION**

The difference in PMMA bone cement dosage used in vertebroplasty and that used in balloon kyphoplasty is not significant.

**CONSENT**

It is not applicable.

**ETHICAL APPROVAL**

It is not applicable.



## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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