Cement augmentation of pedicle screw fixation in spine surgery among patients with osteoporosis: a systematic review

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Abstract
Poly methylmethacrylate-augmented screw fixation is regarded to be an effective technique however many complications can occur after augmented screw fixation due to a leakage of cement. The aim of this systematic review was to evaluate the evidence supporting the use of cement expansion of pedicle screw obsession in spine surgery among osteoporotic patients, its efficacy and the associated complications. An electronic search in MEDLINE was conducted using a search strategy of related keywords and the reference lists of the resultant articles were screened for relevant articles. Studies included in the review met the predetermined inclusion criteria of studies which were clinical trials published in English. The evidence supported an application of cement augmented screw fixation since it increased the strength of the placed screws in the osteoporotic bone. It decreased the degree of spondylolisthesis, improved the quality of life, contributed to the protection against re-collapse and reduce back pain and spinal dysfunction in osteoporotic patients.

Keywords
Vertebrae; Surgery; Injuries; Spine; Outcomes; Spondylolisthesis
Introduction
In recent decades, osteoporosis vertebral compression fractures (OVCFs) has become progressively more common and a worldwide public health problem [1,2]. In addition to vertebral compression fractures, degenerative spinal diseases with osteoporosis may present as spinal canal stenosis and intervertebral disc protrusion [3]. Pedicle screw instrumentation is commonly used to achieve rigid internal fixation for the surgical treatment of degenerative spinal diseases in osteoporotic patients [4].

Because of the low bone mineral density, augmenting the screw fixation strength in osteoporotic patients can be a challenge for spinal surgeons [5-7]. Many complications can occur when applying pedicle screws such as pullout, migration and screw loosening [7,8]. In order to increase the strength of fixation, several techniques have been established like using bone cement-augmented pedicle screw [9-11], improving the design of the screw-rod, and increasing the diameter [12,13] or length of the screw [14,15]. Nowadays, polymethylmethacrylate (PMMA)-augmented screw fixation due to PMMA leakages such as paraplegia, pulmonary embolism, ventricular fibrillation, and death. In order to prevent these complications, bone cement injectable cannulated pedicle screw (CICPS) has been developed [18,19]. The aim of this systematic review was to evaluate the evidence supporting the use of cement expansion of pedicle screw ob- session in spine surgery among osteoporotic patients, its ef- ficacy and the associated complications.

Material and Method
An electronic search in MEDLINE was conducted using search strategy (osteoporosis AND (“spine surgery” OR “pedicle screw fixation”) AND (cement) AND (healing OR complications OR fracture OR stability)). There were no exclusion criteria regarding years of publication, however, included studies were mainly clinical trials published in English.Population characteristics include osteoporotic patients who underwent spine surgery with cement augmentation used in pedicle screw fixation. The search was conducted in May 2018, and no limits were applied regarding the age of the patients or the type of spine injury because the studied surgical procedures are relatively recent and any available study would add significantly to the review. Included studies were aimed to evaluate the effectiveness and associated complications of PMMA cement augmentation used in pedicle screw fixation in spine surgery in patients with osteoporosis. Any study these inclusion criteria were eligible to be selected during the primary screening stage when the re- searcher read the titles and abstracts of the articles and based on this reading they excluded articles which were irrelevant (have different aim) or duplicated. No previous systematic review was found in the search; only a literature review conducted in 2005 i exploring the initial clinical experience of the inter- vention [20]. In addition, the reference list of this review was screened and any relevant studies were evaluated for inclusion in the review. Then the full texts of the eligible studies were retrieved and further studies with inconsistent outcomes were excluded. Studies with inconsistent outcomes were those with outcomes other than efficacy or complications of surgery. The data about important characteristics and outcomes of included studies were extracted using data extraction sheet and summary of the findings was demonstrated in the Table 1. These characteristics included study design, sample size, the mean age of patients, the severity of osteoporosis, the technique of intervention. Moreover, data about the method of assessment, duration of follow up, outcomes and complications of surgery were extracted. The findings of the included studies were discussed in a qualitative approach and the effectiveness of the intervention was highlighted.

Results
The search resulted in 32 studies, of which 28 were as a result of electronic search and 4 were retrieved after the screening of the reference lists. During primary screening, 22 studies were excluded because they had irrelevant aims, in addition to one study because it was a literature review. Thus, the full texts were retrieved for nine studies, and then two studies were ex- cluded due to inconsistent outcomes. Finally, seven studies were included in this review as they met the inclusion criteria (Table/Figure1). Total of 313 patients with osteoporosis were recruited in the included studies. Both sexes were included, although females were predominant in most of the included studies since they constituted 70% of the studied patients.

Age of the included patients ranges from 46 up to 91 years old. Only one study mentioned its inclusion criteria regarding the severity of osteoporosis in vertebrae, as they included only grade I and grade II spondylolisthesis [21]. Two of the included studies mentioned that osteoporosis was diagnosed according to the osteoporosis diagnostic criteria of the World Health Organ- ization’s (T-score ≤ -2.5) as demonstrated in Table and in Figure 2 [21,22].

Regarding type and technique of cement augmentation, four included studies assessed fixation of the pedicle screw using bone cement [21-24]. Two of included studies used kyphoplasty by PMMA cement via bilateral portals and vertebroplasty. After that, PMMA was inoculated into the vertebral body using bilat- eral portals [25,26]. Only one study used high and low viscosity bone cement introduced by injection syringe and special hy- draulic propulsion pump [27]. Only three included studies docu- mented the number of vertebrae recruited in fixation. Song et
### Table 1. Study characteristics and summary of the findings reported by the included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample size</th>
<th>Study design</th>
<th>Age of patients (Mean or range)</th>
<th>Severity of osteoporosis in vertebra</th>
<th>Type and technique of cement augmentation</th>
<th>Vertebrae involved in fixation</th>
<th>Assessment of treatment efficacy</th>
<th>Follow up period</th>
<th>The outcome of cement augmented screw fixation</th>
<th>The complications of cement augmented screw fixation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shen et al. [26]</td>
<td>71</td>
<td>A retrospective clinical trial</td>
<td>52-91 years (Mean age 71.5 years)</td>
<td>Not reported</td>
<td>Percutaneous PMMA kyphoplasty</td>
<td>171 vertebrae</td>
<td>Change in anterior and middle vertebral body height, Cobb angle, VAS and Oswestry functional score</td>
<td>Follow up 7-18 months (average 14 months)</td>
<td>Rapid and significant improvement in back pain following PKP</td>
<td>Lung-related complications, recurrence vertebral fractures</td>
</tr>
<tr>
<td>Vemula et al. [21]</td>
<td>25 participants</td>
<td>A prospective study</td>
<td>Mean age 78.10 years</td>
<td>Not reported</td>
<td>Kyphoplasty using PMMA*** cement via bilateral pedicle screws, using bone fillers, adaptors, and screw extenders</td>
<td>51 vertebrae</td>
<td>Not reported</td>
<td>Follow up 12 to 24 months</td>
<td>Protection against re-collapse</td>
<td>(PMMA) leakage, postoperative neurologic deficit and pulmonary embolism</td>
</tr>
<tr>
<td>Zeng et al. [27]</td>
<td>51</td>
<td>A retrospective clinical trial</td>
<td>Mean age 73.4 years</td>
<td>Not reported</td>
<td>Application of PMMA cemented pedicle screws</td>
<td>111 cement applications in group A and 38 in group B</td>
<td>Not reported</td>
<td>Follow up period: Group A: 51 to 80 months (mean period 51.8 months) Group B: 26 to 61 months (mean period 41.2 months)</td>
<td>Increase the pullout strength of screws placed in the osteoporotic bone. Reduction of the grade of listhesis. Significant improvement in the quality of life.</td>
<td>No new neurological deficits or wound-related complications</td>
</tr>
<tr>
<td>Erdem et al. [24]</td>
<td>51</td>
<td>A retrospective clinical trial</td>
<td>Mean age 68.1 years in group A and 67.2 years in group B</td>
<td>Not reported</td>
<td>High and low viscosity bone PMMA cement injected by injection syringe and special hydraulic propulsion pump</td>
<td>Not reported</td>
<td>(VAS), (ODI), injured vertebral height restoration (Cobb Angle) and bone cement leakage rate, subsequent fracture rate of vertebrae body with or without surgical treatment were measured</td>
<td>Follow up 0.8 to 3.0 years</td>
<td>Bone cement leakage rate reduced obviously in high viscosity bone cement with good clinical effect and prognosis in vertebroplasty for treatment of osteoporotic thoraco-lumbar compression fractures</td>
<td>Cement leakage, pulmonary embolism, dyspnea, tachypnea, and neurological deficit</td>
</tr>
<tr>
<td>Zong et al. [21]</td>
<td>49</td>
<td>A prospective, clinical trial</td>
<td>Mean age 59 to 88 years (Mean age 66.4±9.8 years)</td>
<td>Not reported</td>
<td>PMMA augmentation of bone cement-injectable cannulated pedicle screws.</td>
<td>Not reported</td>
<td>(VAS), (ODI), low back pain of 15.7±5.6 months</td>
<td>Follow up 6 to 35 months (mean of 15.7±5.6 months)</td>
<td>Significant reduction in back pain and improve spinal dysfunction in osteoporotic patients</td>
<td>Intraoperative cement leakage, no neurological complications were observed</td>
</tr>
<tr>
<td>Dai et al. [22]</td>
<td>48</td>
<td>A prospective, clinical trial</td>
<td>Mean age 46 to 82 years (T-score ≤ -2.5)</td>
<td>Not reported</td>
<td>PMMA augmentation of bone cement-injectable cannulated pedicle screws.</td>
<td>Not reported</td>
<td>Mean follow-up of 18 months</td>
<td>Mean follow-up of 18 months</td>
<td>Mean follow-up of 18 months</td>
<td>Mean follow-up of 18 months</td>
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| **PMMA: Polymethylmethacrylate**
**ODI: Oswestry Disability Index**
**VAS: Visual Analog Scale**

*VAS: Visual Analog Scale
**ODI: Oswestry Disability Index
***PMMA: Polymethylmethacrylate
Spine surgery among patients with osteoporosis

Fixation with pedicle screw using bone cement is found to be an effective technique in surgical treatment of osteoporotic patients. It resulted in marked improvement in the quality of life, as most patients end up with a marked decrease in back pain and improvement of the spinal dysfunction [21,22,26]. In addition, it was noted that after cement augmentation there may be a significant reduction of the already existing listhesis [21]. One of the important outcomes of the application of the pedicle screw fixation is their effect in re-collapse protection [25]. Furthermore, such adverse effects of the cement pedicle screw in spine surgery as increase the rate of cement-related complications were reported [24], however, the benefits outweigh the harms. The patients with osteoporosis usually have good outcomes with improved life quality and low relapse rate. The absence of significant neurological complaints in most cases may be considered as an evidence of the effectiveness of this procedure and its importance in the treatment of patients with osteoporosis.

Intra-operative complications such as PMMA leakage and pulmonary cement embolism [24,25] are preventable and treatable, and they could be considered as iatrogenic complications rather than being side effects of the treatment. One of the serious reported complications is pulmonary embolism [25] since it is a common postoperative complication especially in elderly patients and it also can be preventable. Other reported complications such as thrombophlebitis, pulmonary complications, and ventricular fibrillation are common postoperative problems [23,26]. The reported dyspnea, tachypnea and tachycardia [24] can be regarded as anesthesia-related complications rather than procedure-associated complications.

Limitations of this review included the lack of quality assessment of the included studies, which can provide a basis for grading the evidence obtained in this review. If the primary data of the included studies can be obtained, then the test of heterogeneity and meta-analysis techniques can be applied. Thus, fixation with cement augmented screw has many advantages, particularly, among patients with osteoporosis and associated complications were similar to those related to major surgeries due to anesthesia, immobility, and bleeding.

Conclusions

We concluded that application of pedicle screw with bone cement augmentation is very effective in the spinal surgery of osteoporotic patients. Surgeons should choose the most appropriate modality and proper timing of spinal surgery based on patient fitness. If the benefits outweigh harm or if the patient cannot tolerate the pain the screw fixation with bone cement augmentation is the best treatment option.

Scientific Responsibility Statement

The authors declare that they are responsible for the article’s scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study were in accordance with...
the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

Conflict of interest
None of the authors received any type of financial support that could be considered potential conflict of interest regarding the manuscript or its submission.

References

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