



Alternatives to Balloon Kyphoplasty for Surgical Treatment of Vertebral Compression Fractures: A State-of-the-Art Review

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Author's contribution

The sole author designed, analyzed and interpreted and prepared the manuscript.

Article Information

DOI: 10.9734/JAMMR/2018/42418

Editor(s):

(1) Dr. Muhammad Torequul Islam, Nuclear of Pharmaceutical Technology (NTF), Federal University of Piaui, Brazil.

Reviewers:

(1) Luigi Meccariello, Vito Fazzi Hospital, Italy.

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(3) Tamer A. Gheita, Cairo University, Egypt.

Complete Peer review History: <http://www.sciedomain.org/review-history/25345>

Review Article

Received 20th April 2018

Accepted 26th June 2018

Published 30th June 2018

ABSTRACT

Background: For patients in whom the pain due to osteoporosis-induced vertebral compression fracture(s) is severe, persistent, and refractory to a conservative treatment (such as, analgesics, back bracing, or physical therapy), it is common to resort to surgical intervention, in the form of a vertebral augmentation method, most commonly, balloon kyphoplasty (BKP). Although there are some reports of the efficacy of this procedure (for example, provision of pain relief), there is lack of consensus on this matter as well as recognition of various shortcomings of BKP. Four principal shortcomings are damage to the trabecular bone when the bone tamp is inflated, loss of the restored height in the period between deflation of the bone tamp and injection of the cement dough, extravasation of the cement dough, and fracture of adjacent vertebral body/bodies.

Purpose: Presentation of a critical review of clinical performance of alternative surgical methods to BKP that are aimed at addressing the aforementioned and other shortcomings of BKP.

Design and Methods: A literature search for articles on BKP and alternative surgical methods was conducted using relevant keywords and public databases, such as PubMed, MEDLINE, and Google Scholar.

Results: These comprised succinct descriptions of salient features of various alternative surgical methods, such as radiofrequency kyphoplasty, vertebral body stenting, and lordoplasty; a critical

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examination of the results of clinical studies involving these methods (in particular, vis a vis BKP); and presentations of suggestions for future study.

Conclusion: Various deficiencies of the clinical literature mean that definitive statements cannot be made on each of the alternative surgical methods discussed as a viable alternative to BKP.

Keywords: Vertebral compression fracture; balloon kyphoplasty; alternative vertebral augmentation methods; radiofrequency kyphoplasty; vertebral body stenting; Shield kyphoplasty; cavitational kyphoplasty; lordoplasty.

1. INTRODUCTION

Symptomatic vertebral compression fractures (VCFs) and the principal concomitant morbidities, such as severe back pain, kyphotic deformity, and reduced lung function, are a common presentation. Thus, much is known about myriad aspects of VCFs. For example, in the preponderance of cases, its etiology is severe osteoporosis [1]; the spine levels most often affected are thoracic, thoracolumbar, and lumbar [2]; the incidence of osteoporosis-induced VCFs (OVCF) is high (for example, in the USA, annually, there are 700,000 new cases [3], resulting in 150,000 hospitalizations [4]; it has a higher prevalence among some population subsets compared to others (for example, in Italy, for persons > 50 years old, the age-adjusted incidence among women is 87% higher than among men [5]; the cost of treating/managing these fractures is very high, with the total new-case cost being ~\$17,200 in 2014 in the US [5] and ~\$11,000 in 2013 in one trauma center in Austria [2]. For most OVCF(s), the first step in treatment/management of the resulting acute and chronic pain is application of a conservative therapy, such as ingestion of analgesic

medication(s) (most commonly, a bisphosphonate, such as alendronate), back bracing, physical therapy, and chiropractic care (either alone or in combination with another conservative measure [6]). However, when the pain is refractory to relief by a conservative modality and/or there is progression in the collapse of the fractured vertebral body (VB), current clinical practice is to use a surgical technique (generically, referred to as a vertebral augmentation method), most commonly, balloon kyphoplasty (BKP) [6-10]; for example, in one patient group (Medicare patients in the USA), 63,000 BKPs were performed in 2013 [11].

BKP involves unipedicular or bipedicular insertion of a balloon-like device (inflatable bone tamp) percutaneously, under two-dimensional radiographic guidance using C-arm fluoroscopy, into the center of the fractured VB, inflating the tamp (thus, creating a cavity within the fractured VB), deflating and withdrawing the tamp, and, then, injecting a doughy mixture of a cement (usually, a poly (methyl methacrylate) (PMMA) bone cement, a calcium phosphate cement, or a glass ceramic-reinforced polymer), under pressure, into the cavity (Fig. 1) [6,8,12-16].

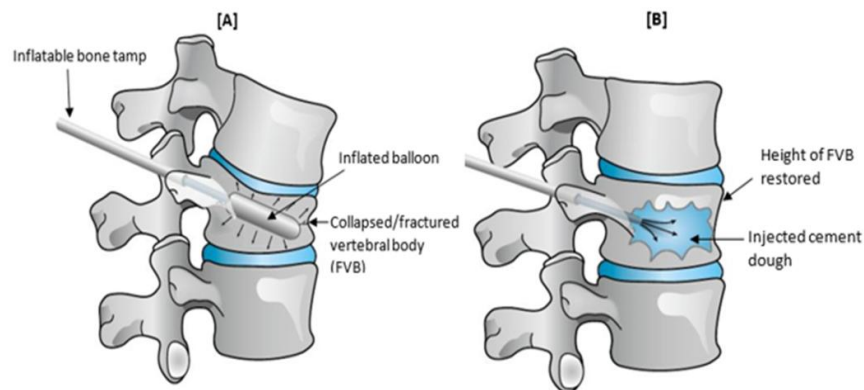


Fig. 1. A schematic illustration of the steps in balloon kyphoplasty: an inflatable bone tamp (IBT) is inserted into the middle of the fractured vertebral body (A); then, the IBT is inflated, creating a void, and, then, the IBT is deflated and withdrawn; after that, a dough of a bone cement is injected into the void (B).

The theoretical benefits of BKP are restoration of the lost height of the fractured VB, correction of kyphosis, and augmentation/stabilization of the weakened bone (achieved when the cement dough cures in the restored VB) [6,9]. A review of the very large volume of the extant literature on BKP reveals that there is agreement about a few aspects, namely, the mechanical effects of the procedure, its most common risk, cost, and the level of radiation exposure to both patient and attending surgical team members. With regard to the first-mentioned aspect, the use of the tamp to create the cavity is problematic in that it causes significant displacement of and damage to the trabecular bone and there is likelihood of some loss of height of the restored VB post-operatively [17,18]. The most common risk is cement extravasation (incidence ~1.9-25% of cases) [6,19-23], most often into paravertebral soft tissues [24]. Such leakage may be consequential because of its potential to lead to devastating clinical adverse events, such as embolism of the pulmonary artery, neurological deficit, and cardiac perforation [25-27]. In the USA, BKP is associated with significantly higher hospitalization cost compared to non-surgical care (by about 85%) [28]. Since BKP is performed with the aid of fluoroscopy, the patient and surgical team members are exposed to a substantial dosage of ionizing radiation during the procedure (for example, for single-level cases, mean patient exposure time and effective dose in the lateral and anterior-posterior planes combined are between 3.8 min and 10.0 min and between 4.3 mSv and 10.6 mSv, respectively, depending on the fluoroscopy modality used [29-31]).

The literature review also revealed lack of consensus or minimal information on an array of other aspects of BKP, such as appropriateness criteria (expectation that benefits will outweigh harms), incidence of surgery-related complications (notably, new adjacent- and remote-level fractures) [25,32-34], statistical nature of the difference in measures of clinical outcomes (notably, Visual Analogue Scale (VAS) score and Oswestry Disability Index in the long term (follow-up of ≥ 1 year) between patients treated with BKP compared to those who received conservative/non-surgical treatment [14, 32,35-37]), and the mechanism(s) responsible for pain relief (some postulates are chemical necrosis by the PMMA bone cement and mechanical stability after curing of the cement due to cessation of cleft motion in the augmented VB [25,38]).

The literature review revealed that there are four principal shortcomings of BKP. First, creation of the void in the fractured VB is accompanied by sizeable displacement of and damage to the trabecular bone. Second, there is loss of the restored height of the fractured VB in the period between the restoration and the injection of the cement dough. Third, a pervasive risk is cement extravasation. Fourth, there have been a number of reports of fracture of VB(s) adjacent to the augmented one(s). In the last several years, much research attention has been given to surgical methods that could compete as alternatives to BKP in that they would achieve restoration of height of a fractured VB and stabilization of the fracture without any of the stated principal shortcomings of BKP. These emerging methods (hereafter, designated "alternative surgical methods") may be grouped into two types. In one type, a bone cement dough is injected into a cavity created in the fractured VB, with examples being radiofrequency kyphoplasty (RFK) (sometimes called, radiofrequency-targeted vertebral augmentation) [39-42], vertebral body stenting (sometimes called stentoplasty) (VBS) [17,43-45], the KIVA Vertebral Compression Fracture (VCF) Treatment System [46-48], and Shield kyphoplasty [49-51]. In the other type, VB height restoration and stabilization are achieved without the aid of bone cement, with an example being Optimesh[®] [52].

Two drivers provide the motivation for the present review. First, with one exception [53], there are no published reviews of any kind dedicated to alternative surgical methods; rather, these methods are covered, in a very limited manner, within reviews of vertebroplasty and/or BKP [6,8,54] or within reviews of emerging techniques in spine surgery [55]. However, the exception review, that is, that by El-Fiki et al. [53], includes only a very small volume of data on the clinical performance of the alternative surgical methods identified. In contrast, the present review is devoted exclusively to alternative surgical methods. Second, although there have been a number of *ex vivo* biomechanical studies of various alternative surgical methods [41,47,56-60], the present contribution is limited to a critical review of the body of literature on clinical and radiological performance of these methods.

Four points are to be noted with regard to the scope of the present review. First, it does not include reviews of studies of alternative surgical methods that have not been the subject of

clinical evaluations *per se* or in comparison to BKP. One such method is cavuplasty [61,62]. Second, it does not include reviews of studies on modification of techniques used to perform BKP. Two examples of such work are use of two cement applications to limit formation of defects or clefts [63] and use of the eggshell technique to bring the procedure to a successful completion when cement extravasation is observed during the procedure [64,65]. Third, reviews of studies involving injection of a dough of a new or improved material into the void created during BKP are not included since these studies do not present new methods, but, rather, are variants of BKP. Examples of such materials are a PMMA bone cement in which the powder is modified by inclusion of strontium and hydroxyapatite particles (hence, the cement is bioactive) [66] and an elastomer (polysiloxane) (its stiffness is close to that of trabecular bone and, hence, may reduce the incidence of adjacent fractures [34,67]. Fourth, reviews of studies involving emerging methods that aim to relieve pain arising from OCVF(s) without addressing the associated loss of VB height and kyphosis increase, such as facet blocking [68], are not included. With these four points in mind, the remainder of the present review is organized into four sections. In the next section, Alternative Surgical Methods, the salient features and steps in clinical employment are presented. In the third section, Clinical Performance, the foci are individual alternative surgical methods, comparison between an alternative surgical method and a conservative method, and comparison between an alternative surgical method and BKP. In the fourth section, Areas for Future Study, suggestions for future study are described. The final section, Summary, contains summaries of the key points made in the review.

2. ALTERNATIVE SURGICAL METHODS

By way of typology, these methods may be divided into two types: a method in which augmentation/stabilization is provided by the injected dough of a bone cement (“bone cement-stabilized methods”) and a method in which bone cement is not used (“bone cement-free methods”).

2.1 Bone Cement-Stabilized Methods

For RFK (StabiliT[®] Vertebral Augmentation System; DFINE, Inc., San Jose, CA, USA), a working cannula is placed along the fractured VB and then an initial cavity is created in the VB by

inserting a straight-coring osteotome. After that, a navigational osteotome is inserted into the working cannula. After appropriately orienting the navigational osteotome and several passes of it, several small targeted channels and a small cavity are created in the center of the VB. A PMMA bone cement dough is fed into an activation element that is heated by application of radiofrequency just prior to the dough entering the delivery cannula, thus converting it into an ultra-high-viscosity cement dough. That dough is then injected through the channels into the cavity. At various times during the delivery of the dough, intravertebral filling is monitored using fluoroscopy for determining if the fractured VB is adequately filled and/or for signs of cement extravasation. This protocol is meant to ensure controlled infiltration of the cement dough into the surrounding fractured bone [40,69]. The procedure ends when it is deemed that the cement dough is evenly distributed within the fractured VB and its height is fully restored [39, 41,42,70]. RFK has three theoretical advantages. First, use of a navigational osteotome allows creation of cavities with specific sizes, which improves the treatment of the fracture. Second, use of a radio-controlled system in which radiofrequency is used to heat the cement just before injection increases the viscosity of the cement and, hence, its working time, and, third, this methodology reduces the radiation exposure of the patient and the surgical staff.

For the VBS System (VBS; Synthes GmbH, Oberdorf, Switzerland), balloon-expandable metal stent(s) are mounted on balloon catheter(s) and, then, the subsequent steps are the same as those followed with BKP. This means that the stent(s) are advanced to the center of the fractured VB and, then, it/they are expanded, under fluoroscopic control, thus creating a cavity in the center of the fractured VB. Then, the catheter(s) are withdrawn, after which syringes are used to inject a cement dough into the cavity when the viscosity of the dough (as measured with a viscometer attached to the cement delivery system) is deemed appropriate. VBS can be performed using a unipedicular or a bipedicular approach. The essential feature of VBS is that after the catheter(s) are withdrawn, the stent(s) remain within the cavity created in the fractured VB [43, 50,54,71-74].

The KIVA VCF Treatment System (Benvenue Medical, Santa Barbara, CA, USA) has two principal components, namely, a Ni-Ti coil and an

implant fabricated from a particulate composite material (matrix: poly (ether ether ketone) (PEEK); particulate: 15% BaSO₄ particles). In the procedure, the coil is guided through a cannula into the middle of the fractured VB, where it forms into its pre-shaped configuration. The actual position of the coil is confirmed under fluoroscopy. The coil thus serves as a guidewire for the path the implant will follow as it is advanced incrementally over the coil. The resulting coiled construct (combination of coil and the implant) is deployed until the desired amount of height restoration is achieved. After that, the coil is removed, leaving the implant in the middle of the fractured VB and, then, a bone cement dough is injected slowly into the lumen of the implant, which allows the dough to flow into the middle of the fractured VB. This continues until the restored fractured VB is filled with the dough [46-48,75]. A theoretical advantage of KIVA is that a void is not created in the fractured VB, thus ensuring that the trabecular bone of the VB is not damaged.

The Shield Kyphoplasty System (Sorieta, Inc., Natick, MA, USA) allows the fractured VB to be accessed through a unipedicular approach, after which a cavity is manually created in it. Then, an implantable self-expanding stent that is fabricated from a mixture of Nitinol, textiles, and polymers and which has perforations along its anterior surfaces only (cement director) is used to deliver the dough of a high-viscosity PMMA bone cement into the cavity. The functions of the cement director are, first, to contain the cement dough injected into the cavity until it is completely filled and, second, to extrude the excess dough through the perforations, thus directing cement flow away from the dorsal parts of the augmented VB [49-51].

For the Jack vertebral dilator (SuZhou Xinrong Best Medical Instruments Co. Ltd., Jiangsu, China), two hollow needles are inserted into the posterior edge of a fractured VB by traversing both pedicles. Guide wires are then inserted through the shafts of the needles and then withdrawn. After that, first, a round-shaped working tube is threaded along the wire towards the posterior end of the VB, and, then, an oval-shaped working tube is similarly introduced. The Jack vertebral dilator is then inserted into the middle of the VB and slowly expanded, creating a cavity and restoring the height of the body in the process. Finally, a PMMA bone cement dough is injected into the cavity and the working tubes are removed [44,45].

Using a transpedicular approach under fluoroscopic guidance, the SpineJack G2 device (Vexim, Balma, France) is inserted into the fractured VB. Then, the device is expanded by using a special tool that pulls its two ends each other and this is followed by release of a central Ti component. A rack-and-pinion arrangement along the retraction axis that the device follows is used to stop its expansion when the desired VB height restoration is achieved. This is followed by injection of a high-viscosity PMMA bone cement dough. Theoretical attractions of this device include 1) prevention of height correction before injection of the cement dough and 2) prevention of loss of correction after fracture reduction [76-77]. Another jack system that uses a similar approach is the Vertect Jack Device [78].

Using a coaxial manual drill, a cavity is created in the middle of the fractured VB, after which the VerteLift system (SpineAlign Medical, Inc., San Jose, CA, USA) (which, essentially, is a compressed Nitinol cage) is inserted into that cavity. Then, the cage is opened and filled with a PMMA bone cement dough. After augmentation of the fractured VB is complete, the cage is left within the VB [79].

For the SKy Bone Expander System (Disc-O-Tech Medical Technologies Ltd., Herzeliya, Israel), using a unilateral, intra-pedicular approach and fluoroscopic guidance, a cannula is inserted into the fractured VB, after which the Expander is inserted into the middle of the VB in its original (unexpanded) configuration. Then, the Expander is slowly expanded to its pre-determined height and length of 14 mm and 17 mm, respectively, thereby creating a void in the fractured VB. The Expander is then contracted and removed and, after that, a cement dough is injected into the void [80,81].

In vesselplasty (Vessel-XTM Bone Filling Container System; A-Spine Holding Group Corp., Taipei, Taiwan), a porous (mean pore size: 100 μm) polyethylene terephthalate balloon container (one or two layers) is inserted into the middle of the fractured VB and, then, a cement dough is injected into the balloon, thereby expanding it to its maximum (20-25 mm diameter). After release of the resulting pressure generated inside the container, the cement dough penetrates the pores of the container, flows out of it, and interdigitates with the trabecular bone of the fractured VB. The surgical approach could be transpedicular (uni- or bipedicular) or parapedicular and the procedure is carried out

under fluoroscopy control. In vesselplasty, therefore, the balloon serves two purposes: expanding the fractured VB and containing the cement dough within it [22,66,82-85].

In the Parallax[®] Contour[®] Vertebral Augmentation System (ArthroCare Corp., Austin, TX, USA), a small access needle is used to insert the device into the fractured VB, after which a curved mobile stylet is manually advanced and rotated, displacing trabecular bone in the VB, and, thus, creating a cavity. The cavity is then filled with an acrylic bone cement dough [23].

The BeadEx Implant (Expandis Ltd., Hof Hacarmel, Israel) comprises Ti rolls (diameter and length = 3 mm and 4 mm, respectively). In use, the rolls are pressed into the middle of the fractured VB using special designed hollow pedicle screws, thus creating a void in the VB. After that, a bone cement dough is injected through the pedicle screws into the void. A thin metallic strip that is wrapped around the rolls ensures that, during the procedure, the rolls remain compact. Since the screws remain in place after insertion of the rolls, additional cement dough could be injected, if deemed necessary [58].

Cavitation kyphoplasty is performed under biplanar fluoroscopy using either a unilateral transpedicular approach or an extrapedicular approach. After positioning a cannula in the fractured VB, a needle is inserted in the cannula. Upon removal of the needle, an instrument (Cavity Creation System, DePuy Synthes, PA, USA), which has a curette-like tip, is inserted, through the needle, to the middle of the fractured VB. Then, the instrument is rotated and translated, thereby creating a cavity in the VB. After that, the instrument is withdrawn and a side-opening cannula is inserted. Cement dough is injected through this cannula, under low pressure. After the dough cures, the cement-injection cannula is removed followed by the rest of the instrumentation. Cavitation kyphoplasty is not regarded as a “general-purpose” alternative to BKP for treating all cases of fractured VBs; rather, it is indicated for patients with isolated endplate fractures with minimal loss of VB height [86].

In lordoplasty, using intraoperative fluoroscopy, the VBs above and below the fractured one (adjacent VBs) are bipedicularly instrumented with the type of cannulas used in vertebroplasty. Then, cement dough is injected into these

adjacent VBs, the aim being to augment them bilaterally. After that, the fractured VB is reduced indirectly by applying a lordotic moment via the cannulas to the adjacent VBs, using their facets as a fulcrum [87-91].

2.2 Bone Cement-Free Methods

One such system is made up of expandable mesh cages fabricated from commercially-pure Ti and Ti-6Al-4V alloy (Osseofix[®]; Alphatec Spine, Inc., Carlsbad, CA, USA), which are available in different sizes for use in different spine levels. For example, for a cage to be used at L1-L2, the initial diameter, initial length, maximum diameter when fully expanded, and length when fully expanded are 5.5, 26.4, 13.0, and 30 mm, respectively [92-94].

Another system utilizes a polyethylene mesh sac (Optimesh[®]; Spineology, Inc., Stillwater, OK, USA). In use, the procedure is conducted under fluoroscopy with a guide pin being used to locate the desired target position in the fractured VB. A dilator is inserted over the guide pin and inserted into the fractured VB, a cannula is placed over the dilator and secured, the guide pin and dilator are removed, and a drill is used to create a cavity in the VB. After that, an appropriately-sized sac is inserted through the cannula into the middle of the VB, the mesh is filled with the morcelized bone chips, and, finally, the neck of the mesh sac is crimped and detached [52,95].

In a third system (StaXx FX System; Spine Wave, Inc., Shelton, CT, USA), a gun is used to insert 1-mm-thick PEEK wafers sequentially into the middle of the fractured VB [26,96].

3. CLINICAL PERFORMANCE

In the literature search, 28 reports on the clinical performance of BKP and various alternative surgical methods, comprising results of radiological and functional parameters in a number of patient sets, were found. Each of these reports was reviewed, allowing the clinical studies that were the subject of these reports to be divided into three types. In the first (Type I studies; 13 studies), the subject of the study was an alternative surgical method *per se*, with the purpose of the study being comparison of various indices of performance of patients prior to and following treatment with the method. In the second group (Type II study; one study), the study reported comparison of various performance parameters between patients treated with an alternative surgical method and

those treated using a conservative modality. In the third group (Type III studies; 14 studies), the studies reported comparison of various performance parameters between patients treated with BKP and those treated using an alternative surgical method. Four aspects of results obtained in these studies (as summarized in Table 1) are noted.

First, there is a paucity of Type II studies (only 1), which means that there is lack of evidence of the efficacy of alternative surgical methods as a group. Second, in only 40% of the studies was the follow-up ≥ 12 mo. This means that any statement about the true clinical performance of an alternative surgical method should be guarded. Third, among the studies, different units were used to report results for some parameters. Three examples are VB height (expressed in mm in some reports [72, 80, 87], as % change in others [88, 98], and as a ratio in one report [100]); vertebral kyphotic angle (expressed in degrees in some reports [80, 87, 100] and as %change in others [43, 45, 101]; and VAS score (expressed as a number (ranging from 1 to 10) in some reports [44, 80, 97] and in mm in others [40, 101, 103]). Fourth, in each of the Type III studies, results regarding all of the four principal shortcomings of BKP either are lacking or only a minimal volume is reported.

Subject to the observations presented above, it appears that, compared to BKP, RFK demonstrates a marginally lower PMMA bone cement leakage incidence and a noticeably greater amount of pain relief (lower VAS score). However, it is stressed that the present clinical evidence is insufficient to form the basis for recommending RFK (or, indeed, any of the alternative surgical methods considered) as an alternative to BKP.

4. AREAS FOR FUTURE STUDY

Four such areas are identified. First, the summary presented in Table 1 shows wide variability in the scope and quality of the clinical studies that have been conducted, in terms of, for example, the number of alternative surgical methods compared to BKP (this ranges from many in which RFK was the subject to very few in which, for example, Optimesh[®] was the subject); type of study (prospective, retrospective, and RCT), number of patients in each study group (n; 30-550); and the follow-up length (f; 3-24 months). Thus, clinical studies of many more alternative surgical methods compared to BKP are needed. Each of these

future clinical studies should, at the minimum, have the following characteristics: RCT, $n \geq 100$; and $f \geq 12$ mo.

Second, in each future clinical study, the results should, at the minimum, include information that addresses each of the principal shortcomings of BKP. That is, information on 1) the state of the trabecular bone in the fractured VB (morphology and strain distribution) prior to and immediately after use of an alternative surgical method. This would require development of tools that could be deployed in real time; for example, variants of digital volume correlation [105] and multiscale correlative tomography [106]; 2) the extent of loss of restored height before injection of the cement dough; 3) cement leakage (for example, total incidence and affected sites), when a bone cement-stabilized alternative surgical method is used; and 4) fracture(s) of adjacent VB(s) (for example, total incidence, incidence per specific spinal level, and morphologies of fracture(s)).

The third area of future work should entail developing a consensus document (akin to an ASTM Standard or an ISO Standard for determination of material properties) on the units to be used for each quantifiable clinical and radiological parameter. This will facilitate comparison of results among various studies.

With two exceptions [43, 89], comparative cost of an alternative surgical method versus BKP is not given in literature reports. However, each of these exception reports has shortcomings. In the report by Werner et al. [43], only the costs of materials (balloons, cement, stents, and instruments) were considered in computing that, in 2010, in Switzerland, the total of these costs for vertebral body stenting was ~29% lower than that for BKP, for one treated VB. Kim et al. [89] found that, in 2010, in Korea, the cost of lordoplasty was ~58% lower than that for BKP, without stating, for example, the number of levels treated, the type of costs considered (direct, indirect, or total), or presenting a breakdown of the costs. Thus, as the fourth area for future work, in each future clinical study, a detailed economic analysis of specified alternative surgical method versus BKP (for a given patient population) should be conducted. At the minimum, comparative direct and indirect costs should be one of the deliverables. This information will be invaluable to relevant entities (for example, health insurance companies in the US and the National Health Service in the UK), which, almost invariably, pay all or a sizeable proportion of the cost of a given procedure.

Table 1. Comparison of outcomes in literature studies of alternative surgical methods^a and balloon kyphoplasty

Source (Ref. #)	Study groups ^a	Type ^b ; number ^c	Follow- up (mo)	Cement leakage (%)	Mid-height of VB (mm)	Vertebral kyphosis angle (°)	VAS score (1-10)	ODI ^d score (%)	Adjacent body fracture (%)
Type I studies									
Orler et al. [87]	Pre-op LP	P; 36	2		14.1 ± 6.4	24.1 ± 7.7	7.3		
Foo et al. [80]	Pre-op Sky (post-op) Sky	-; 40	12		7.7-14.4 15.5-21.3 15.4-20.8	8.9 ± 5.8 12.6+23.6 7.1-17.4 7.1-17.5	2.4 5.0-9.8 0.0-4.0		
Iundusi et al. [85]	Pre-op Vessel	-; 327	12	6.1			8.3 2.1		3.4
Klezl et al. [73]	Preop VBS	P; 20	12			9.7 5.2	8.9 2.5	14-58	
Olivarez et al. [46]	Pre-op KIVA	-; 57	12				79.3 ± 17.2 23.2 ± 23.3	68.1 ± 16.9 23.3 ± 15.5	
Diel et al. [72]	Pre-op VBS	CR; 100	6		17.6 24.6	13.1 8.9			
Ender et al. [94]	Pre-op Osseofix	P; 24	12			11.7 10.4	7.7 1.4	70.6 30.1	
Moser et al. [39]	Pre-op RFK	P; 23	3				7.9 2.7	74.0 40.0	
Rollinghoff et al. [40]	Pre-op RFK (postop) RFK RFK RFK	P; 30	3 2	6.6	20.9 ± 2.7 24.1 ± 3.0 23.9 ± 3.1		6.9 ± 0.8 cm 3.4 ± 0.6 cm 3.0 ± 0.6 cm		2.2
Li et al. [44]	Pre-op Jack dilator	R; 16	10-27		23 ± 4 26 ± 4	15.6 ± 9.8 12.7 ± 10.4	6.7 ± 2.1 2.0 ± 2.8		

Table 1 (Continued/1). Comparison of outcomes in literature studies of alternative surgical methods^a and balloon kyphoplasty

Source (Ref. #)	Study groups ^a	Type ^b ; number ^c	Follow-up (mo)	Cement leakage (%)	Mid-height of VB (mm)	Vertebral kyphosis angle (°)	VAS score (1-10)	ODI ^d score (%)	Adjacent body fracture (%)
Noriega et al. [77]	Pre-op SpineJack	P; 108	12	39.8		14.5 ± 8.1	7.8	80	
Renaud [76]	Pre-op SpineJack G1 and G2 (post-op)	CS; 83				8.5-10.1	0.4	4.4	
	SpineJack G1 and G2 (post-op)		12					7.9	
	SpineJack G1 and G2							1.8	
Hoppe et al. [91]	Pre-op LDP	R; 69	33	10.4		22.0		1.1	2.4
	LDP					8.7			11.0; 24.6
<u>Type II study</u>									
Bornemann et al. [97]	CON(Pre-op)	P; 67	1.5		24.0	12.0	7.5	70	
	CON				22.0	15.0	6.8	65	
	RFK (Pre-op)		1.5		21.0	15.0	6.5	65	
	RFK				22.0	14.0	1.0	20	
<u>Type III studies</u>									
Kim et al. [89]	BKP (pre-op)	P/R; 36	3	26.9	68.7 ± 1.4% ^e	18.1 ± 2.6			29.2
	BKP				73.4 ± 1.3% ^e	15.0 ± 1.8			
	LPD (pre-op)		3	50.0	64.7 ± 3.6% ^e	25.0 ± 3.3			
	LDP				82.5 ± 4.5% ^e	18.9 ± 3.0			
Shen et al. [45]	BKP (pre-op)	P; 110	-			7.8 ± 1.2 ^f			
	BKP								
	Jack (pre-op)		-						
	Jack dilator					9.5 ± 2.6 ^f			

Table 1 (Continued/2). Comparison of outcomes in literature studies of alternative surgical methods^a and balloon kyphoplasty

Source (Ref. #)	Study groups ^a	Type ^b ; number ^c	Follow- up (mo)	Cement leakage (%)	Mid-height of VB (mm)	Vertebral kyphosis angle (°)	VAS score (1-10)	ODI ^d score (%)	Adjacent body fracture (%)
Endres and Badura [49]	BKP (pre-op)	P; 76	6				90.0 ± 7.1	77.0 ± 4.2	
	BKP Shield (pre-op)						36.5 ± 6.4	43.1 ± 19.5	
Licht and Kramer [98]	BKP (pre-op)	-; 203	6				88.2 ± 15.1	75.7 ± 9.1	
	BKP RFK (pre-op)						40.2 ± 7.4	56.1 ± 7.6	
Pflugmacher et al. [69]	BKP (pre-op)	P; 228	12	18.7	6.85/4.6 ^g		5.4/3.4 ^f		
	BKP RFK (pre-op)						12.8	5.9 ^g	4.8 ± 1.5 ^f
Georgy [99]	BKP (pre-op)	P; 106	6	27.8	3.1 ^g	3.8	84.0		
	BKP RFK (pre-op)						6.1	3.1 ^g	4.4
Korovessis et al. [100]	BKP (pre-op)	RCT; 185	12	12.0	0.70 ± 0.23 ^h	14.9 ± 8.0	7.8 ± 1.2	62.0 ± 14.0	
	BKP KIVA (pre-op)						5.0	7.8 ± 1.2	62.0 ± 14.0
Werner et al. [43]	BKP (pre-op)	P; 100	12	4 ± 0.03	0.89 ± 0.14 ^h	11.5 ± 7.0	2.5 ± 3.0	26.3 ± 15.7	13.0
	BKP VBS (pre-op)						0.74 ± 0.25 ^h	13.7 ± 7.0	8.2 ± 1.4
	BKP VBS				0.88 ± 0.18 ^h	7.8 ± 6.0	2.7 ± 3.0	31.7 ± 19.0	12.2
						4.5 ± 3.6 ^f			
						4.7 ± 4.2 ^f			

Table 1 (Continued/3). Comparison of outcomes in literature studies of alternative surgical methods^a and balloon kyphoplasty

Source (Ref. #)	Study groups ^a	Type ^b ; number ^c	Follow- up (mo)	Cement leakage (%)	Mid-height of VB (mm)	Vertebral kyphosis angle (°)	VAS score (1-10)	ODI ^d score (%)	Adjacent body fracture (%)
Tutton et al. [48]	BKP (pre-op)	R; 300	12				71.8 ^f	42.1 ^f	
	KIVA (pre-op)								
Petersen et al. [101]	KIVA	P; 80	12				8.4 ± 1.0 cm	38.1 ^f	
	BKP (pre-op)		12						
	BKP		12						
	RFK (pre-op)		12						
Riesen et al. [102]	RFK	P; 162	-	60.8		2.8 ^f	3.5 ± 2.0 cm		
	BKP (pre-op)								
	BKP								
Bornemann et al. [103]	RFK (pre-op)	R; 303	-	63.9			8.5 ± 1.2 cm	80.9 ± 7.4	
	BKP		24						
	BKP		24						
	RFK (pre-op)		24						
Bornemann et al. [78]	RFK	-; 90	24	9.4	24.5 ± 2.8	10.6 ± 2.2	1.2 ± 1.7 cm	12.6 ± 7.5	
	BKP (pre-op)		6						
	BKP		6						
	Vertect(pre-op)		6						
	Vertect		6			3.1 ^g			

Table 1 (Continued/4). Comparison of outcomes in literature studies of alternative surgical methods^a and balloon kyphoplasty

Source (Ref. #)	Study groups ^a	Type ^b ; number ^c	Follow- up (mo)	Cement leakage (%)	Mid-height of VB (mm)	Vertebral kyphosis angle (°)	VAS score (1-10)	ODI ^d score (%)	Adjacent body fracture (%)
Palm et al. [104]	BKP (pre-op)	-;142	-			11.5 ± 6.0			
	BKP					6.2 ± 4.6			
	RFK (pre-op)					9.9 ± 6.2			
	RFK					6.3 ± 4.4			

^aLDP: lordoplasty; Sky: Sky Bone Expander System[®]; Vessel: vesselplasty; VBS: vertebral body stenting; KIVA: KIVA VCF Treatment System[®]; Osseo: Osseofix[®]; RFK: radiofrequency kyphoplasty; CON: conservative treatment modality; Jack: Jack vertebral dilator; SpineJack: SpineJack G2 device[®]; Vertect: Vertect Jack Device.

^bType of study: P: prospective, non-randomized; CR: chart review; R: retrospective, nonrandomized; CS: case series; RCT: randomized controlled trial.

^cNumber of treated fractured vertebral bodies.

^dOswestry Disability Index.

^eComparison group on which %change of results was computed was not clearly stated in the report.

^fDecrease, relative to the result for the relevant preoperative group.

^gIncrease, relative to the value for the relevant preoperative group.

^hMidline vertebral body height ratio.

5. CONCLUSION

The following is a summary of the key points made in this review:

- Balloon kyphoplasty (BKP) is a widely-used method to treat patients who are experiencing severe and persistent pain, arising from osteoporosis-induced vertebral compression fracture(s), that is not relieved using a conservative method.
- Although the efficacy of BKP has been reported in some clinical series (for example, pain relief and correction of kyphotic angle), there is much debate on this issue. In the meantime, there is agreement about many shortcomings of BKP, two of which are damage to the trabecular bone in the fractured vertebral body when the bone tamp is inflated and cement extravasation into various anatomical sites.
- There are many reports in the clinical literature on a number of alternative surgical methods to BKP, such as RFK and VBS; however, any kind of review of this body of literature is lacking. The present contribution fills this gap and the topics covered include succinct descriptions of the steps involved in each of these alternative surgical methods, a critical examination of the clinical performance of a given alternative surgical method compared to that of BKP, and suggestions for future research work. Limited clinical results indicate that PMMA bone cement leakage rate for RFK is lower than that for BKP and among suggestions for future work is performance of randomized clinical trials with follow-up of at least 12 mo.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Author has declared that no competing interests exist.

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