Eur J Trauma Emerg Surg (2013) 39:445–453
DOI 10.1007/s00068-013-0265-7

REVIEW ARTICLE

Percutaneous cement augmentation techniques for osteoporotic spinal fractures

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Received: 26 December 2012 / Accepted: 4 February 2013 / Published online: 20 February 2013

Abstract Minimally invasive vertebral augmentation-based techniques have been used for the treatment of spinal fractures (osteoporotic and malignant) for approximately 25 years. In this review, we try to give an overview of the current spectrum of percutaneous augmentation techniques, safety aspects and indications. Crucial factors for success are careful patient selection, proper technique and choice of the ideal cement augmentation option. Most compression fractures present a favourable natural course, with reduction of pain and regainment of mobility after a few days to several weeks, whereas other patients experience a progressive collapse and persisting pain. In this situation, percutaneous cement augmentation is an effective treatment option with regards to pain and disability reduction, improvement of quality of life and ambulatory and pulmonary function.

Keywords Osteoporosis · Spine · Fractures · Surgery · Cement augmentation · Vertebroplasty · Kyphoplasty

Introduction

Osteoporotic fractures of the spine affect 1.4 million people per year worldwide and are an economic burden for many health care systems [1]. Besides typical pain, they can lead to a significant reduction of physical function and increased morbidity and mortality [2–4]. In some cases, non-surgical conservative treatment has no or just minimal clinical effect, resulting in the progression of deformity, persisting pain and/or significant reduction of quality of life (QoL).

Minimally invasive vertebral augmentation-based techniques [e.g. vertebroplasty (VP) and kyphoplasty (KP)] have been used for the treatment of spinal fractures (osteoporotic and malignant) for approximately 25 years. Previously used in open tumour surgery to refill the bony defect in the vertebral body [5], the percutaneous application of polymethylmethacrylate bone cement (PMMA) was first described by Galibert et al. for the treatment of vertebral angiomas [6]. Since then, the technique was adapted to its present form.

In this review, we try to give an overview of the current spectrum of percutaneous augmentation techniques, safety aspects and indications.

Indications

Most compression fractures present a favourable natural course, with reduction of pain and regainment of mobility after a few days. After the initial diagnosis of a vertebral compression fracture (VCF) we, therefore, recommend to always first try a conservative treatment with sufficient analgesia and support in mobilisation. Seven to ten days after the onset of pain, we perform a clinical and radiological control by a spine specialist to assess whether the kyphotic deformity is progressive under load and if the pain shows a mechanical quality as a hint for persisting fracture mobility. Given a relevant progression of deformity, persisting pain and poor bone quality, a percutaneous intervention can be indicated, as there is a high chance that the final result will be a relevant kyphotic deformity. Many of these aged patients with concomitant sarcopaenia and otherwise rigid spines are limited in compensating this

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sagittal dysbalance. Other fractures show a persisting mobility or cause neurological symptoms by secondary bony stenosis of the spinal canal. Prior to any intervention, a computed tomography (CT) or magnetic resonance imaging (MRI) scan in the supine position should be performed in order to rule out malignancy or a more complex fracture. Furthermore, intraosseous clefts with vacuum sign can be observed on CT as an indication of persisting mobility and potential for active restoration of lordosis.

Which of the techniques described below is to be applied is dependent on the fracture type and location, bone quality and the patient's activity. Simple compression fractures Magerl type A1 can be treated with a stand-alone cementation technique. In the case of a relevant kyphotic deformity, especially if located at the thoracolumbar junction, and insufficient spontaneous reposition by positioning in prone lordosis, a balloon kyphoplasty (BKP) or lordoplasty (or combinations) can be performed. Vertebral body stents (VBS) are extremely powerful and an expansion beyond the vertebra or into the disc, respectively, secondary migration has been observed, which is why caution is needed in highly osteoporotic bone. Split fractures (Magerl types A2 and A3.2) are not suited for stand-alone VP, as the bone cements only can reliably neutralise axially applied forces but not shear forces that occur in this type of fracture. In elderly patients, superior burst fractures without a split component (A3.1) can be treated with stand-alone cementation as, in this group of patients, the adjacent intervertebral disc is often already dehydrated and no secondary segmental instability or discogenic pain is to be expected. BKP is helpful to achieve anatomic reposition of the endplate; whether this influences the survival of the disc and preserves segmental mobility is the subject of ongoing research, but, often, a spontaneous fusion to the next segment is observed (Fig. 1). All complete burst- (A3.3) and B- and C-type fractures require additional instrumentation.

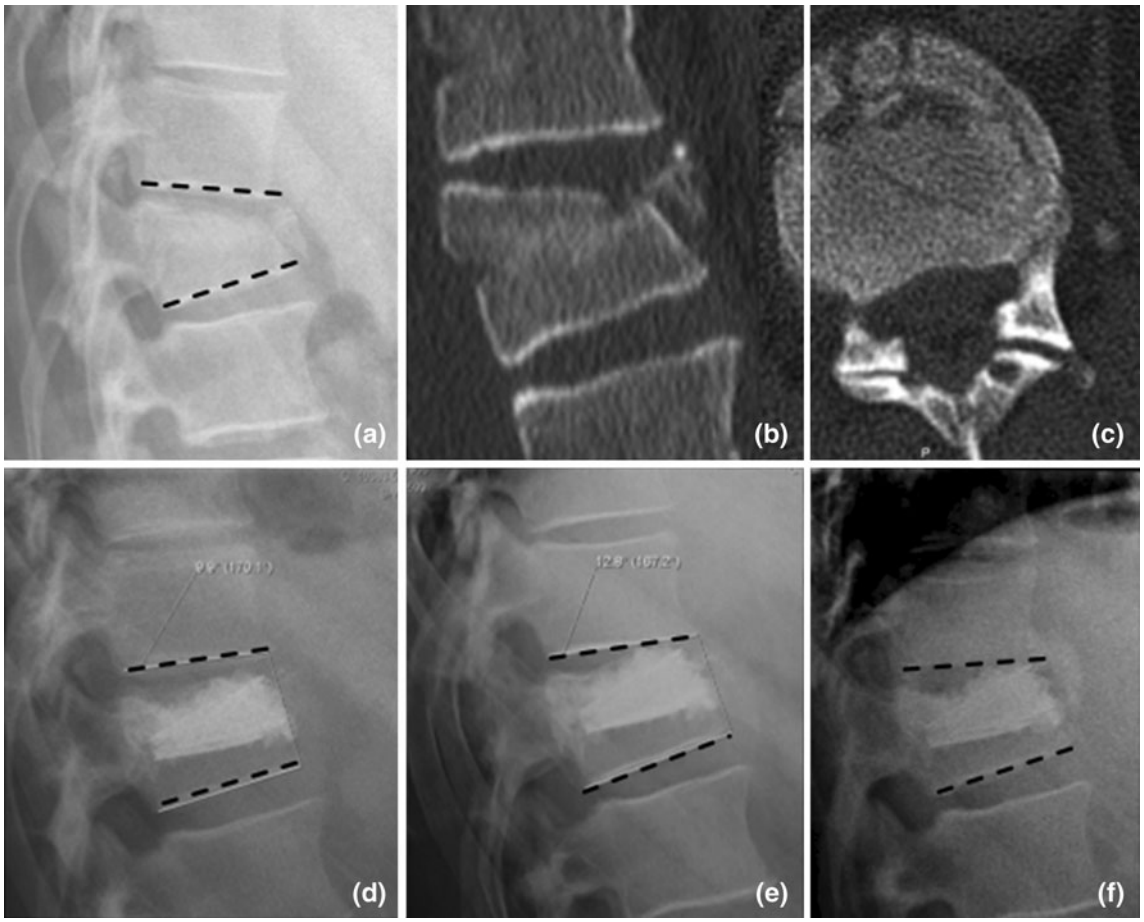

Fig. 1 Incomplete superior burst fracture of T12 (45-year-old male patient) treated with vertebral body stent and polymethylmethacrylate bone cement (PMMA). **a** Standing preoperative radiograph. **b**, **c** Preoperative computed tomography (CT) shows persistent kyphosis, destruction of the anterior part of the endplate, intact posterior wall and pedicles. **d** First postoperative standing radiograph with reduction of the segmental kyphotic deformity from 30° to 10°. **e** Loss of intervertebral disc height at 2 months follow up and increase of segmental kyphosis to 13°. **f** 'Spontaneous' fusion at 6 months follow up between T11 and T12, with segmental kyphosis of 15°

Techniques

Vertebroplasty

Percutaneous VP is a straightforward augmentation technique where the bone cement is directly injected via cannulas of 8–11G diameter. The technique is indicated for the treatment of simple compression fractures, haemangiomas and osteolytic neoplasms, where height restoration is not the primary goal but, rather, the prevention of further segmental or spinal malalignment, pain reduction, improvement of physical function and QoL. The intervention is performed under local or general anaesthesia in the prone patient position and the cannulas are placed via a transpedicular (lumbar) or extrapedicular (thoracal) approach into the anterior third of the vertebral body. Both mono- or bilateral approaches are possible; we use a bilateral approach for fractured vertebrae and a monolateral approach for prophylactic augmentation of intact vertebra that are at high risk for collapse. Correct placement of the cannulas is crucial and should be performed under biplanar fluoroscopic control or CT guidance; dependent on surgeon preference, the cannulas are introduced directly or over previously placed guide wires. High-viscous bone cement, usually PMMA, is injected into the vertebral body under fluoroscopy control [7], without the creation of a void, unlike in BKP. Depending on the type of cement and initial viscosity, the application is performed either with 1- or 2-cm^2 syringes or special high-pressure delivery systems. The recommended filling volume of 4–8 ml is dependent on the size of the vertebra and the grade of osteoporosis.

Re-establishment of lost vertebral body height is not possible with the procedure per se, but can possibly be achieved with additional positioning manoeuvres [8].

Balloon kyphoplasty

Kyphoplasty was introduced in 1998 to restore vertebral body height and help realign the spine, using an inflatable balloon to reduce the fracture before the injection of cement [9–11]. A bilateral (and in rare cases, monolateral) approach (trans- or parapedicular) is chosen to insert a working cannula into the posterior part of the vertebral body. Biplanar fluoroscopy is used to insert the tools and control the procedure (reaming, balloon inflation, cementing). With reaming tools, two working channels within the anterior aspect of the vertebral body are created and the appropriate balloons are inserted, ideally centred between the endplates in the anterior two-thirds of the vertebral body. Once inserted, the balloons are inflated using visual volume and pressure controls to reduce the compressed vertebra and create a cavity. Inflation is stopped when the pressure is raised above 250 psi, when the balloon contacts the cortical surface of the vertebral body or expands beyond the border of the vertebral body or if the vertebral body height is restored. The balloons are sequentially deflated and removed, and the remaining cavity is filled with bone cement under continuous fluoroscopic control (Fig. 2).

The pain relief and improvement of QoL experienced by patients after KP appear to be equal to VP, at least in the short term [12]. Restoration of approximately 70° of the initial vertebral body height is reported, reducing the local kyphosis significantly by up to 9.5° vertebral kyphosis angle (VKA) [13–15]. Today, a large variety of BKP systems are available from many different producers.

Stentoplasty and other intravertebral-implant-assisted techniques

Following deflation of the KP balloons, often, a loss of the achieved reduction has to be observed. To prevent this loss of vertebral body height and realignment after balloon deflation in BKP, the Vertebral Body Stenting System (VBS, Synthes GmbH, Oberdorf, Switzerland) was developed. It consists of a balloon-expandable metal stent mounted on a balloon catheter. After balloon deflation, the intrinsic mechanical stability of the expanded rigid stent construct keeps the created cavity open until PMMA-based cement is injected and has cured [16]. The stent consists of a cobalt–chromium alloy, which is also used in coronary and peripheral artery stenting.

Usually, two VBS are inserted bilaterally into the vertebral body. To symmetrically expand both stents, they are simultaneously inflated with contrast saline solution. The expanded stent comes pre-crimped on the balloon and is gradually expanded to its final diameter. After the balloon-assisted stent expansion is sufficient, the balloons are deflated and retrieved. Finally, PMMA cement is injected into the mesh structures to produce a stent-reinforced cement implant within the treated vertebral body (Fig. 3).

Similar systems are the Kiva VCF Treatment System (Benvenue Medical, Santa Clara, CA, USA), which uses a polyetheretherketone (PEEK) coil instead of an expandable cage. The StaXx Expandable Device (Spine Wave, Shelton, CT, USA), which uses an expandable PEEK spacer, SPIDER Somatoplasty System (Sintea Biotech, Miami Beach, FL, USA) and OsseoFix (Alphatec Spine, Carlsbad, CA, USA) are examples of stent-like expansion systems for the treatment of VCF without cement augmentation.

Lordoplasty

In 2006, Orler et al. [17] introduced the concept of lordoplasty, a cost-effective, minimally invasive cement

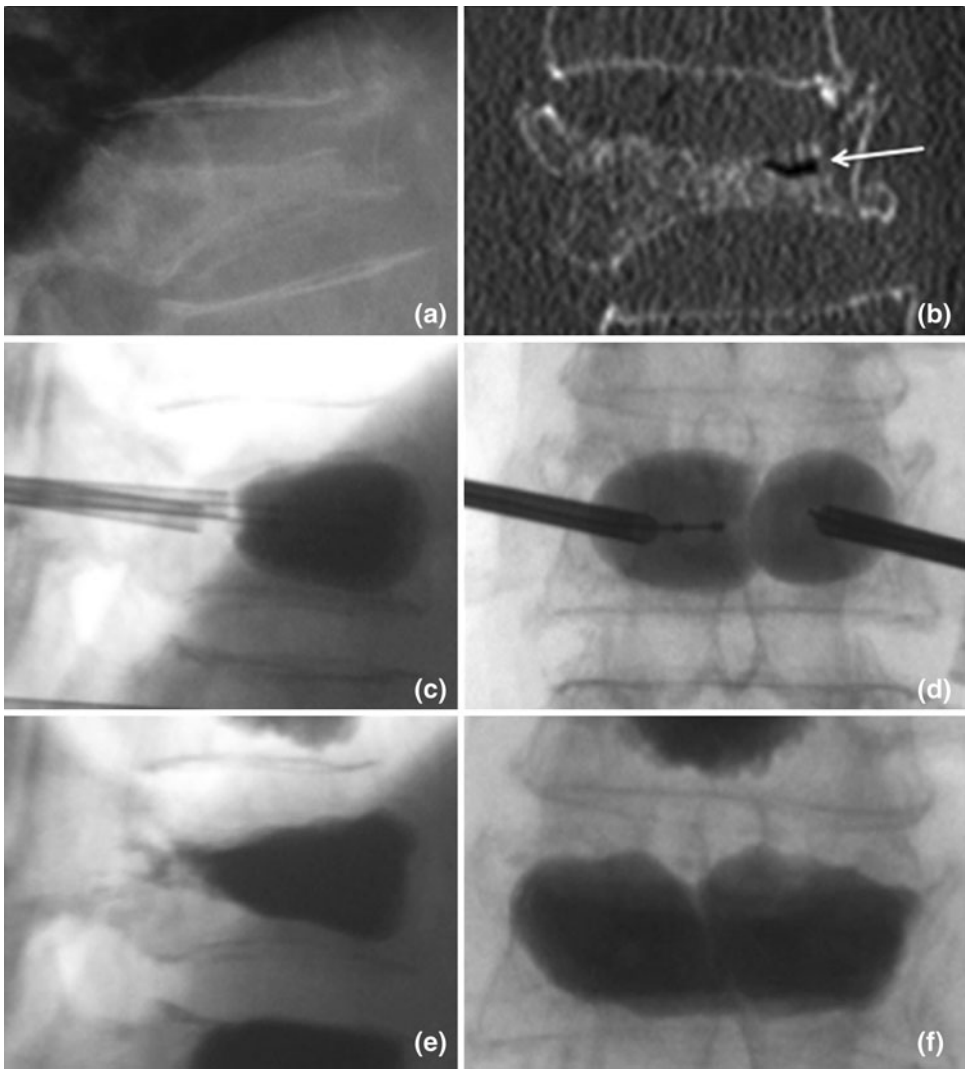

Fig. 2 Balloon kyphoplasty (BKP). An 83-year-old female patient with an old vertebral compression fracture (VCF) of T12 presenting as vertebra plana on standing preoperative radiographs (**a**). **b** Vacuum sign in the supine position at CT scanning indicates persisting mobility. **c**, **d** Intraoperative monitoring of kyphosis correction by the inflation of two transpedicularly introduced balloons (SynFlate, DePuy Synthes). After deflation of the balloons, usually, some loss of reduction is observed. **e**, **f** Filling of the resulting void with 9 cc of high viscous PMMA

augmentation technique that allows kyphosis correction of wedge-shaped VCF by the principles of ligamentotaxis, as it is used by an internal fixateur. The fractured and the adjacent vertebrae are bipedicular, instrumented with VP cannulas and the fracture is reduced indirectly by applying a lordotic moment via the cannulas and the facets as hypomochlion (Fig. 4). It is possible to combine this technique with a BKP or stentoplasty procedure to facilitate fracture reduction of impressed or comminuted endplates. The achieved mean correction of the VKA of 15° and 10° for the bisegmental angle is larger than that reported for VP, KP and VBS: VP follow up studies have shown reduction of the VKA of between 1.7° and 6.6° [12, 15, 18]. This effect is explained by the spontaneous fracture reduction when placing the patient in the prone position. The reported VKA correction by KP is between 4.8°–9.5° [12, 13, 19–22]) and 5.2°–7.3° by VBS, although these values are based on small heterogenic groups.

Compared to BKP, lordoplasty is 6–10 times less expensive. Moreover, the decision for reduction can be made intraoperatively.

Cement augmentation as an adjuvant tool with instrumentation

As adjuvant therapy, cement augmentation (vertebroplasty/kyphoplasty) is used in the treatment of anterior unstable type A and B fractures in addition to short-segment dorsal stabilisation (Fig. 5). New data show that augmentation seems to provide enough stability to support the anterior column. Compared to combined anterior/posterior approaches, which impose additional strain for the patient, resources augmentation is less invasive, with less morbidity and shorter hospitalisation [23–25]. Especially for aged patients where no implant removal is planned, this seems to be a valid alternative to anterior surgery.

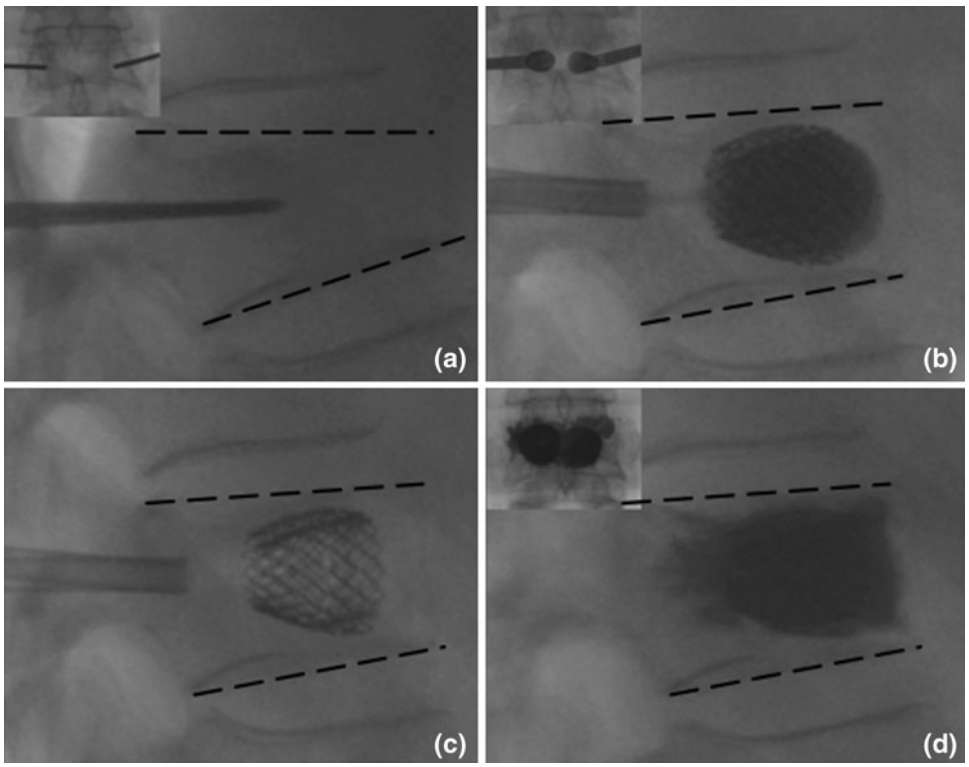

Fig. 3 Stentoplasty. A 68-year-old male patient with a T12 VCF after minor trauma. **a** Partial correction of the vertebral kyphosis angle (VKA) to 16° by prone positioning. **b** Correction to 3° VKA after slow and stepwise inflation of the stent/balloon system (VBS, DePuy Synthes). **c** The expanded stent prevents a secondary loss of reduction when deflating the balloon. **d** Filling of the void with 11 cc of high-viscous PMMA; final VKA of 4°

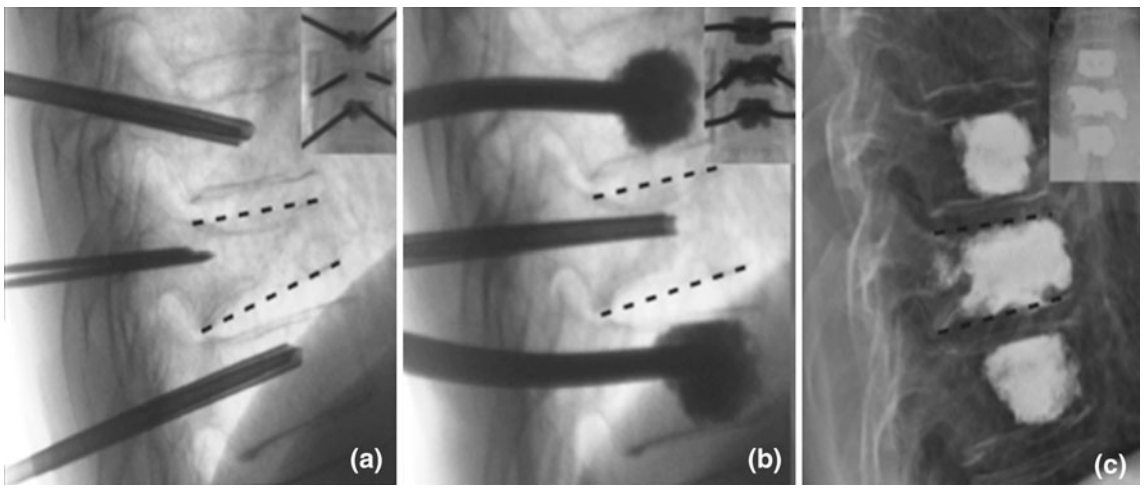

Fig. 4 Lordoplasty—kyphosis correction by ligamentotaxis. A 76-year-old female patient with a non-traumatic T10 compression type fracture. **a** In the prone position, a VKA of 13° persists (intraoperative fluoroscopy). **b** Application of a lordotic moment via the cannulas of the adjacent vertebra results in a VKA of 2°. In this case of known osteoporosis, the adjacent levels were cemented prior to the repositioning manoeuvre. **c** Standing X-ray 6 months after the intervention

Complications

The use of PMMA in the described augmentation techniques must be done with caution. There are a number of potential serious complications that may occur with the intraosseous injection of cement.

The risk of extraosseous cement leakage in various series ranged between 3 and 74 % [12, 26–29], with resultant neurological deficits such as radiculopathy and cord compression occurring in 0–3.7 % and 0–0.5 %, respectively [12, 26–28]. The risk of pulmonary embolism lies between 3.5 and 23 % [30–33].

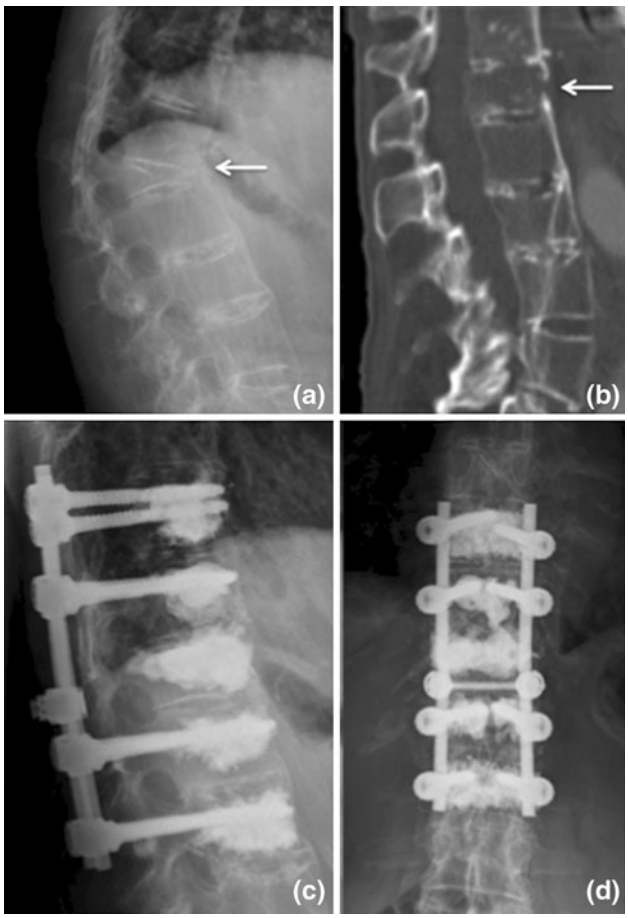

Fig. 5 A 72-year-old male patient with M. Bechterew and an unstable type B fracture of the ankylosed spine at T11/12. **a** Standing radiographs shows a relevant collapse of T12 that results in a large ventral defect after alignment in the supine position for the CT scan (**b**). The fracture was treated with cement-augmented stabilisation and filling of the anterior defect with PMMA (**c**, **d**)

The leakage rate in KP is reported to be significantly lower compared to in VP [12, 15], due to the cavity created by the balloon allowing low-pressure and higher-viscosity controlled cement filling. Once the cavity is filled, the leakage behaviour is similar to VP [10]. Besides the bone structure of the spine, the viscosity of the PMMA cement is the major risk factor for cement leakages [34]. By adapting the application technique, it is possible to influence the viscosity of the PMMA cement using the temperature gradient between body and room temperature, which accelerates the polymerisation process in the vertebral body. In a standard model, leakage can be significantly reduced by the sequential application of small cement amounts. Possible leakage paths are blocked before re-application of the low-viscous cement [35]. Moreover, the development of high-viscous PMMA cements have reduced the rate of cement leakages significantly, resulting in the disadvantage of the need for high-pressure injection devices that are more expensive and lack tactile feedback.

The injection of any material into cancellous bone inevitably displaces bone marrow into the circulation and creates some pulmonary fat embolism. To prevent pulmonary symptoms, the number of augmented vertebrae during prophylactic multi-segmental VP should be limited to six levels per session or 25–30 cc of PMMA [36]. In a sheep model, it could be shown that lavage of the bone marrow prior to VP prevents cardiovascular complications, reduces injection pressures and allows a better control of cement distribution, with less leakage [37, 38].

Discussion

More than 2,300 studies addressing cement augmentation in spinal surgery have been published and there is still ongoing debate as to whether VP or KP is more effective in pain management compared to non-operative treatment. This is remarkable, given that this treatment has been performed very frequently for over 20 years now and it is especially difficult to understand for surgeons who experience regularly the dramatic reduction of pain after the intervention. The majority of these studies conclude to be in favour for cement augmentation, but they have severe limitations in their study design, being mostly retrospective case series. The reason for this may be found in the heterogeneous and aged patient population and also the broad spectrum of specialists who perform the augmentation (orthopaedic/neurosurgical spine surgeons, general and trauma surgeons, radiologists).

Two randomised controlled trials (RCTs) published in the New England Journal of Medicine in 2009 [39, 40] could not significantly demonstrate the benefit of VP compared to a seemingly sham intervention, have lead to the ongoing debate and may be responsible for the recently experienced decrease of VP and KP since 2009 [41]. Although, compared to earlier publications, these studies were superior with regards to study design (double-blinded prospective randomised controlled trials), several limitations reduce the validity of the conclusions; especially, patient selection is one of the most criticised points, as many fractures were non-acute and the type of pain was not defined, ergo, it was possible that patients with other painful spinal conditions were included with no potential to benefit from the VP (but maybe from the sham intervention that consisted of an injection of local anaesthetics). Further it is remarkable that a majority of the eligible patients refused to participate in the trials and a high rate of crossover within the groups was observed, which may have led to a selection bias and resulted in a relatively small number of patients finally available for analysis. These studies also demonstrate that randomised controlled trials may not be the ideal study design when the effectiveness of

a surgical intervention should be investigated, especially if the criteria are not defined by surgeons. Similar to the dosage of a pharmacological agent, the amount of injected PMMA is very important, and the experience and technique of the surgeons are the relevant factors for a successful intervention. The used amount of cement in these New England Journal of Medicine studies are either not documented or have a filling volume of only 2.8 ml per vertebra below the recommendations or reported volumes from other studies and, interestingly, also violated their own study protocol [12, 42].

In the course of these New England Journal of Medicine publications, better designed studies have been performed and patient selection has become more restrictive to patients with persisting pain clearly related to the acute fracture. In such a subgroup, the Vertos II randomised controlled trial, for example, could demonstrate significant, immediate and lasting pain relief in the VP group as compared to conservative treatment. The FREE study compared KP against non-operative treatment with similar inclusion criteria as the Vertos II trial and reported a significantly superior pain relief at all time points over 2 years [43, 44]. Rousing et al. [45] found a significant pain reduction in the VP group compared to conservative treatment only in the initial phase and similar results after 1 year. Papanastassiou et al. found, for their systematic review, 27 prospective, multiple-arm studies with cohorts of more than 20 patients (level of evidence I or II) and concludes that VP and KP are superior with regard to pain relief and the occurrence of new vertebral fractures as compared to conservative treatment [15]. The reduced rate of subsequent fractures contradicts the common belief that the introduction of PMMA unfavourably alters spinal biomechanics and increases the risk for subsequent fractures [46]. Only intradiscal cement leakage, index fracture at the thoracolumbar junction and male gender have been identified as risk factors for subsequent fractures [18, 47, 48]. The epidemiological data suggest that the many observed subsequent fractures are more the result of the underlying disease and the biomechanical alterations where the kyphotic deformity transfers the centre of gravity ventrally and increases the load on the anterior column [49–51]. The long-term results of interventions that specifically aim for restoration of the sagittal profile, such as VBS or lordoplasty, may well reveal whether correction of the kyphotic deformity is protective for subsequent fractures.

The inconsistent results with regards to pain reduction after VP points out that pain may not be the ideal outcome parameter, as most of these aged patients have co-existing other sources of back pain that are difficult to differentiate. Several investigations, therefore, have focused on other parameters which should better reflect the benefit of the intervention: QoL can be assessed with a few simple questions and is reported to increase significantly after VP or KP. Again, as for pain and disability, the most benefit was observed in the first 3 months after the intervention [18, 29, 43, 52, 53]. Similarly, significantly less analgesics had to be consumed in the groups that received treatment, which is notable, as high-dosage analgesia-related complications are to be expected in this aged high-risk population [18, 52]. Dong et al. [54] could demonstrate a significantly better pulmonary function in patients receiving VP or KP. The improvement was negatively correlated with the kyphotic deformity and the best results were seen in the KP group, where greater fracture reduction was achieved. Earlier studies have already shown the relationship between kyphotic deformity and impaired lung function [55] and between the presence of VCF or kyphotic deformity and mortality due to pulmonary disease [2]. Mortality after VCF is known to be higher than in age-matched cohorts and increases with the number of sustained fractures [3, 4]. These factors may explain the impressive results of Edidin et al. [56], who found, in a large retrospective cohort of 858,987 aged patients with VCFs, a significantly improved survivorship at 4 years follow up for patients who received VP or KP (survival rate of 60.8 % compared to 50.0 % for patients in the non-operated cohort). Of course, the results of retrospective case cohorts should not be overinterpreted, as no causal relationship can be proven.

Conclusions

Since the first introduction of VP for vertebral haemangiomas in 1987 by Galibert et al. [6], cement augmentation has been established as an effective treatment option for osteoporotic or pathological VCFs with persisting pain under conservative treatment.

Crucial factors for success are careful patient selection, proper technique and choice of the ideal cement augmentation option. Most compression fractures present a favourable natural course with reduction of pain and regainment of mobility after a few days. After the initial diagnosis of a VCF, we, therefore, recommend to always first try a conservative treatment with sufficient analgesia and support in mobilisation. Seven to ten days after the onset of pain, we perform a clinical and radiological control by a spine specialist to assess whether the kyphotic deformity is progressive under load and if the pain shows a mechanical quality as a hint for persisting fracture mobility. If there is a progressive collapse of the vertebra and immobilisation due to mechanical pain, a percutaneous intervention can be indicated and a computed tomography (CT) or magnetic resonance imaging (MRI) scan is

performed to rule out malignancy or a more complex fracture. Fracture type, localisation, patient age and activity, and bone quality define which of the techniques described above is the most ideal. Radiological follow up with standing lateral radiographs are performed immediately after the first mobilisation and after 2 months to rule out subsequent fractures, which are known to occur mainly in the initial phase after the index fracture.

Percutaneous cement augmentation for VCFs with progressive collapse and persisting pain is an effective treatment option with regards to pain and disability reduction, improvement of QoL, and ambulatory and pulmonary function. The procedure has a low complication rate if the technical safety aspects described above are respected and if performed by experienced specialists. Which of the numerous modern cement systems is used may be of secondary importance, as long as the surgeon is aware of and used to the specific technical, biomechanical and rheological properties of the system.

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

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