

Vertebro-/Kyphoplasty History, Development, Results

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Abstract

Many investigations prove the significant analgetic effect of vertebral augmentation. The reasons for the decrease in pain are found in the stabilization of fracture fragments as well as the toxic-thermic effect of polymethylmethacrylate (PMMA), used in the majority of cases. The techniques, primarily in use since 1984, can be divided in vertebro- and kyphoplasty. Vertebroplasty is the direct injection of PMMA into the trabecular vertebral body, while kyphoplasty uses an inflatable bone tamp to create a cavity which is filled with highly viscous cement allowing a certain degree of vertebral height restoration. Both techniques are used percutaneously. Indications for augmentation are painful osteoporotic vertebral fractures, metastatic osteolyses, and painful or destabilizing vertebral hemangiomas. In this article, an overview of the techniques and the history of their development is provided. The materials used for augmentation, the possibilities, limits, and complications of the techniques are discussed.

Key Words

Vertebroplasty · Kyphoplasty · Osteoporosis · History

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Introduction

For the last, close to 15 years painful osteoporotic vertebral fractures have been treated with percutaneous vertebral augmentation. For countless patients this has provided significant reduction of pain and increased mobility immediately after augmentation, with a low risk of complications. Looking back at the experience with vertebral aug-

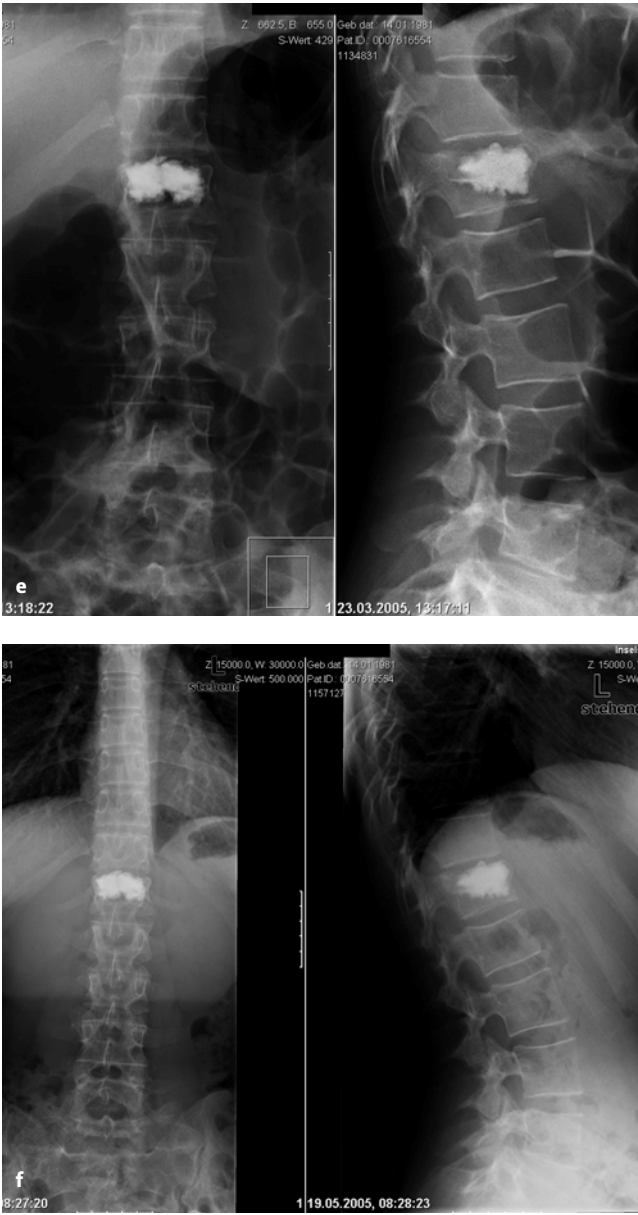
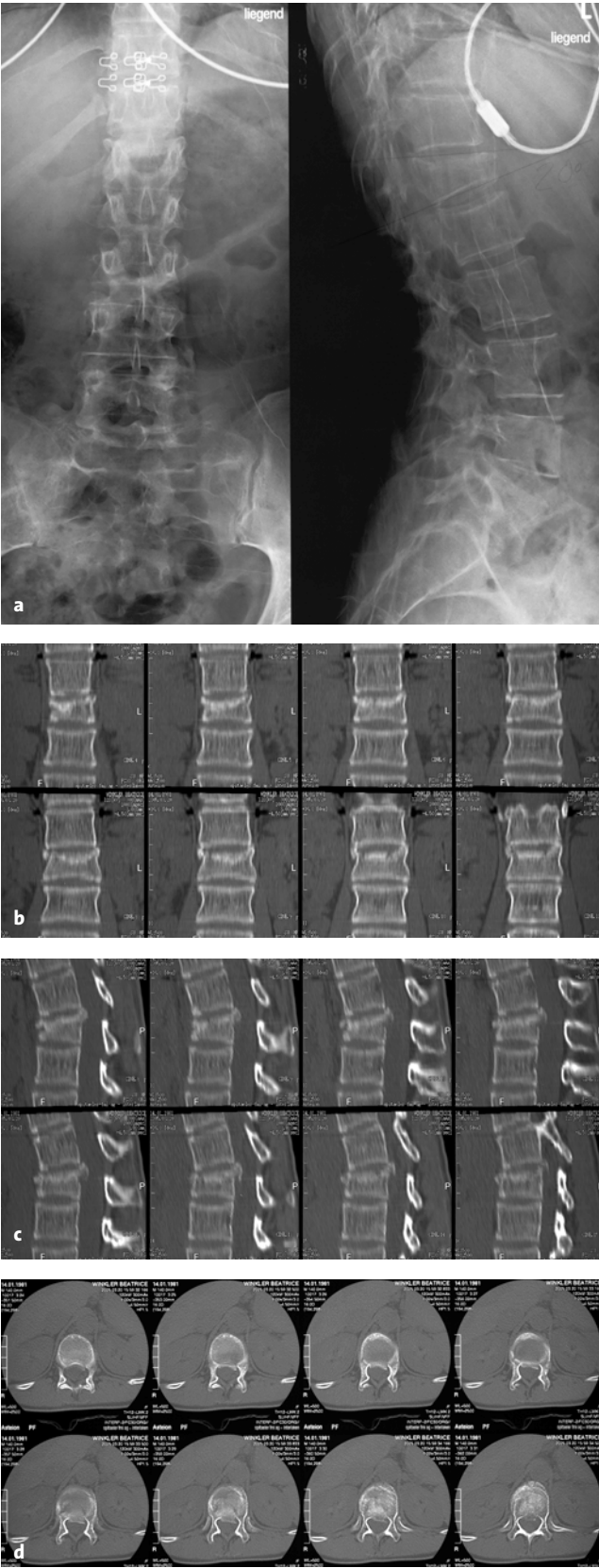
mentation in osteoporotic fractures and metastatic osteolysis in spine, the results are more than encouraging regarding reduction of pain, increased mobility and low morbidity of the procedure [1–4]. The exact mechanism of the analgetic effect of vertebral augmentation remains unclear. Some investigators attribute the reduction of pain to the toxic and/or thermal effect of the polymethylmethacrylate (PMMA) cement, in terms of destruction of nerve fibers [5–7]. A more mechanical view attributes the effect to the fixation of fragments and reduction of micromotion and associated irritation of periosteal nerve fibers.

The first implementation of “vertebroplasty” was in 1984 by Galibert et al. [8]. In this first case, a hemangioma of the second cervical vertebra was treated – primarily to achieve an embolization of the tumor through the exothermic and mechanical properties of PMMA cement. During the consecutive years, vertebroplasty was mainly used in surgical treatment of vertebral tumors. The encouraging analgetic effect led to the augmentation of osteoporotic vertebral fractures, the first report of which was in 1994 [9].

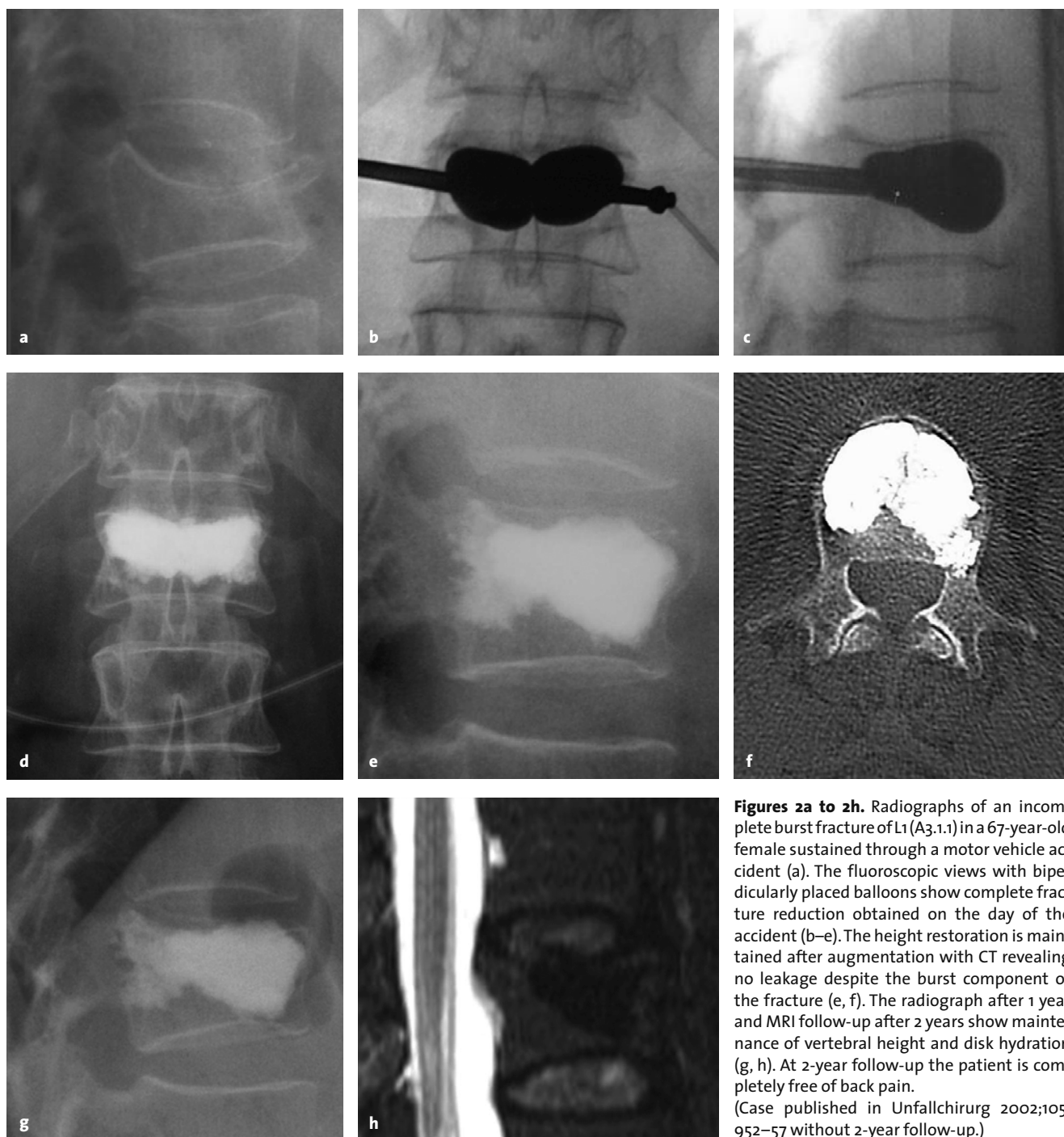
This minimally invasive technique added a surgical option to the traditionally conservative treatment of osteoporotic vertebral fractures, which includes analgetics, bed rest with graded mobilization, bracing, as well as medical treatment directed toward curbing the progression of osteoporosis. Through vertebroplasty, prolonged immobilization could often be avoided, which has been shown to aggravate loss of bone mineral density and raise the vertebral fracture risk [10]. The estimated, progressive [11] increase in mortality rate of 23% in patients > 65 years of age with vertebral fractures attributed to the adverse effects on pulmonary function (decreased vital capacity [12]), potential malnutrition through reduced abdominal volume and the impact of chronic pain, further provided powerful

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Figures 1a to 1f. 24-year-old female with an incomplete burst fracture (A3.1) without neurologic deficit sustained through a skiing accident (a–d). Correction of the kyphotic angle from 20° to 10° and a 95% restoration of height achieved through kyphoplasty (e). At 2-month follow-up (f) no loss of correction is seen with the patient experiencing only minor residual pain.



Figures 2a to 2h. Radiographs of an incomplete burst fracture of L1 (A3.1.1) in a 67-year-old female sustained through a motor vehicle accident (a). The fluoroscopic views with bipedicularly placed balloons show complete fracture reduction obtained on the day of the accident (b–e). The height restoration is maintained after augmentation with CT revealing no leakage despite the burst component of the fracture (e, f). The radiograph after 1 year and MRI follow-up after 2 years show maintenance of vertebral height and disk hydration (g, h). At 2-year follow-up the patient is completely free of back pain. (Case published in *Unfallchirurg* 2002;105: 952–57 without 2-year follow-up.)

arguments for the widespread use of vertebral augmentation techniques. This development has been paralleled by an extension of indications. Since objective evidence for recurring vertebral collapse or secondary osteolysis [13, 14] in augmented vertebrae has not been reported, vertebro- and kyphoplasty are increasingly

being performed in younger patients (Figures 1a to 1f and Figures 2a to 2h).

A number of authors advocate the use of vertebral augmentation in traumatic vertebral compression fractures. In certain cases, the surgical anterior reconstruction can be avoided in favor of augmentation [15].

To date (August 2005), 507 entries on “vertebroplasty” and 140 on “kyphoplasty” are found in the Pubmed database. Encouraged by the relatively simple technique, percutaneous vertebral augmentation has been adopted in numerous specialist departments. Nevertheless, this procedure requires good anatomic knowledge of the spine and, despite being “minimally invasive”, is a surgical intervention with rare but potentially serious complications.

Trends of the Technique, Mistakes, Profits Vertebroplasty

Over the years, the vertebroplasty procedure has principally not changed. The majority of patients are suitable for vertebroplasty in local anesthesia. Under general anesthesia an attempt can be made at closed fracture reduction through prone positioning with cushions under sternum and pelvis. Under fluoroscopic control the vertebral level to be treated is identified and the corresponding pedicles are marked. If local anesthesia is chosen, the cutis and subcutis are infiltrated with local anesthetic down to the surface of the bone. Through small incisions, vertebroplasty cannulas or, optionally, 2-mm K-wires are introduced via the transpedicular or transcostovertebral (extrapedicular) route into the vertebral body. Correct placement is confirmed during the passage of the pedicles and entry of the vertebral body through fluoroscopy in two planes. The use of K-wires allows these to be used as guide wires for large-bore vertebroplasty needles, which is the routine technique applied in our unit [2]. During the augmentation with PMMA cement, continuous fluoroscopic monitoring is performed, in order to immediately detect extravasations of cement. In case of extravasation, augmentation should be interrupted. Filling volumes usually range between 2–6 ml of PMMA. After the PMMA cement is cured, the needles are removed and the skin closed. Under regular circumstances patients are mobilized within the first hours.

The material cost of a single-level vertebroplasty is approximately 200 Euros.

Kyphoplasty

The kyphoplasty technique is a more recent development, first performed in 1998 [16]. In comparison to vertebroplasty, an inflatable balloon is used to restore vertebral body height and create a cavity into which PMMA is filled [17]. The possibility of injecting highly viscous cement and the impaction of trabecular bone around the cavity is thought to reduce cement extravasation

during augmentation. While a unipedicular approach is often sufficient in vertebroplasty, kyphoplasty is often performed bipedicularly.

The material cost of a single-level kyphoplasty is approximately 3,000 Euros.

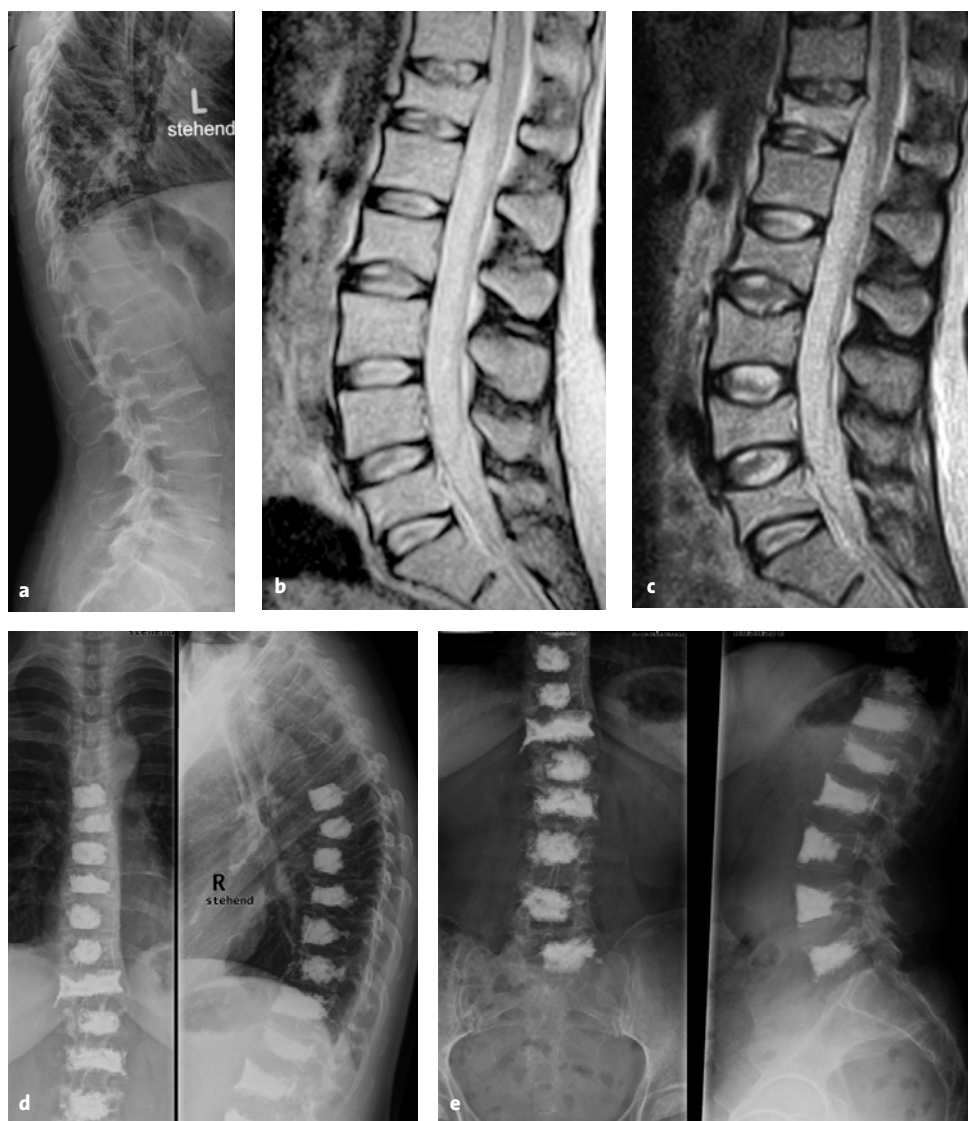
PMMA Cement Versus Resorbable Materials

Currently, the favored substance for filling the vertebrae in augmentation is PMMA cement. The advantages of modern PMMA formulations available for vertebroplasty lie in the ease of handling, optimal radiopacity through addition of contrast medium, the immediate stability after curing and the relatively low cost. The inherent disadvantages are nonresorbability and lack of osteocon- or -inductivity. There are multiple known cardiovascular side effects [18–21] and in vitro trials have proven its toxicity [22, 23].

Despite initially encouraging biomechanical studies on resorbable cements, e.g., calciumphosphate, hydroxyapatite [5, 24–26], it has not been widely applied in vivo [27]. Current indications focus mostly on traumatic vertebral fractures in younger patients [27]. Problems associated with current resorbable cements are the unknown properties under long-term cyclic loading in the traumatic fracture setting, relatively poor injectability that can lead to clogging of the cannulas, and difficulty in achieving an optimal vertebral filling. Radiopacity is inferior to contrast-laden PMMA. Developments will need to be aimed at providing resorbable, osteoinductive cements with optimized handling properties and enhanced elasticity closer to vertebral bone.

Adjacent-Level Fractures – Plurisegmental Injection

Secondary vertebral fractures after cement augmentation occur in 5–52% of patients [14, 28, 29] over a period of 1–5 years. The natural history of osteoporotic vertebral compression fractures suggests that 11.5% of patients with a single vertebral fracture and 24% of patients with more than two prevalent vertebral fractures [30] sustain a new fracture in the following year. The exact cause of adjacent fractures remains unclear. Effects such as the increase in loading of the spine after an initial treatment remain difficult to assess. There is, however, biomechanical evidence that the PMMA augmentation of an osteoporotic vertebra increases the risk of fractures at adjacent levels. Berlemann et al. [31], in a two-vertebrae functional-unit model with one vertebra augmented and the other not, revealed a trend ($p = 0.13$) toward lower failure loads in the non-



Figures 3a to 3e. 39-year-old female with factor V deficiency, requiring low-dose heparin therapy during pregnancy. After 8.5 months immobilizing back pain through minimal trauma occurred. The radiographs (a) revealed fractures in multiple lumbar vertebrae. In the MRI series 6 weeks apart (b, c) progressive vertebral collapse was seen despite optimized osteoporotic therapy. The measured loss of standing height was 6 cm in 6 months.

Due to the rapid progression of multisegmental vertebral collapse, multisegmental augmentation was performed in three operative sessions. In T12 bipedicular kyphoplasty, assisted with lordoplasty, distraction (d, e) was performed, the remaining vertebrae were treated with unilateral vertebroplasty. At 4-month follow-up the patient is ambulating freely with only residual sacroiliac pain remaining.

cemented vertebra with increased filling of cement of the other. Also, the volume of injected cement has been found to directly relate to the resulting stiffness and strength [32]. In order to investigate the efficacy of prophylactic vertebroplasty, Sun & Liebschner [33] implanted different volumes in a finite-element model. For successful reinforcement of osteoporotic vertebrae a volume comparable to that currently used in vertebroplasty (20% of the vertebral body) was determined. Avoiding adjacent fractures is a current research target, one of the aspects being the development of augmentation materials with a biomechanical performance closer to that of bone.

On the basis of osteoporosis as a systemic disease, multilevel vertebral collapse can occur. In these severe

cases, some investigators [1] have employed multilevel augmentation. Up to six vertebrae are filled in a single session, the goal being to treat not only the fracture itself, but the overall osteoporotic weakening of the thoracolumbar spine (Figures 3a to 3e).

Estimating the likelihood of further fractures remains difficult. Inevitably, these cases demand accurate clinical and especially individual evaluation. The number of vertebrae augmentable per session also remains unclear. Extensive augmentation is, however, known to increase the amount of floating bone marrow to the pulmonary capillary system in terms of fat embolism. Investigations on sheep [34] have proven clinically relevant fat embolism through the augmentation of four vertebrae. Although the same mechanism must occur in human vertebra, no

proven case of lethal fat embolism after augmentation has been described in the literature to our knowledge. Unfortunately, the amount of fatty degenerated bone marrow must be proportional to the grade of osteoporosis. In vivo studies concerning adverse effects on pulmonary function and identification of potential predictive factors are still lacking. As preexisting pulmonary hypertension most likely constitutes a risk factor, preoperative echocardiography may be valuable as a screening tool. Testing brain natriuretic peptide (BNP) concentration, which is elevated through distension of the right atrium, may be another factor indicative of an increased risk in the setting of pulmonary hypertension.

Realignment

Two factors must be considered regarding realignment and height restoring of fractured vertebrae. Most clinical papers report the restoration of vertebral height as the relative amount of height gained and use the adjacent vertebrae as reference. For instance, when the preoperative height of a vertebra was 60% of normal and 90% after a procedure, the relative height restoration is 75% and the absolute value 30%.

No report exists on how much fracture reduction is gained just by positioning the patient in hyperextension.

Majd et al. [35], in their cohort of 360 kyphoplasty procedures in 222 patients, achieved 30% height gain, measured anteriorly. The medial height restoration averaged 50%. The average correction of the kyphotic angle was 7°.

Boszczyk et al. [36], in severe osteoporotic fractures, found an average correction of the kyphotic angle of 5° with kyphoplasty and no correction through vertebroplasty.

Lieberman et al. [17] reported on 30 patients who underwent 70 kyphoplasty procedures with height restoration of 35% (0–100%) and a correction of the kyphotic angle of 6°.

Crandall et al. [37] found a higher grade of height correction (86%) in new fractures than in fractures older than 4 months (79%). The correction of the kyphotic angle in new fractures was 7°, in chronic fractures 5°.

With the exception of one investigation [61], no height restoration was found with vertebroplasty. Although high pressure (up to 20 bar) is developed in vertebroplasty [38], it does not seem possible to achieve a fracture reduction without the inflatable bone tamp used in kyphoplasty. As mentioned above, a correction

through positioning in hyperextension can achieve a certain correction on its own, with vertebroplasty this correction is simply fixed.

An alternative method was described by Heini & Orlor [39], whereby the vertebra above and the vertebra below the fracture are initially reinforced bilaterally. After the cement is cured, the cannulas are used as levers and a lordotic moment is applied with the facet joints acting as pivots. The cannulas maintain this distractive force until the fractured vertebra is cemented and the cement has cured. With the “lordoplasty” technique improved fracture reduction is achieved, which can also be combined with balloon kyphoplasty. In this initial report an average correction of the kyphotic angle of 14° was reached in 30 patients.

Leakage of Cement

Although clinical symptoms induced through cement leakage are rare, most of the severe complications are caused by cement leakage.

Krebs et al. [38] discovered a maximum injection pressure of 3,215 kPa in the syringe filled with cement. Effects on the resulting pressure in the syringe were related to the speed of cement injection and viscosity of the cement. The size of the chosen syringe (2 ml or 5 ml) had no influence. It remains unclear how well injection pressure correlates with intravertebral pressure. Baroud et al. [40] reported that intravertebral pressure was two orders of magnitude lower than injection pressure in vitro. Using this ratio, intravertebral pressure in the study of Krebs et al. [38] would be 150 mmHg. As Bohner et al. [41] showed, viscosity plays a central role in affecting the injection pressure and, therefore, cement leakage.

Investigations on cement leakage in vertebroplasty report a rate of 11–76% [2, 16, 42, 43]. In investigations on kyphoplasty, cement leakage data ranges from 4.8% to 39% [36, 39, 44, 45]. Cement leakage is reported at a higher rate if CT scans are used. Yeom et al. [46] examined postoperative CT scans and radiographs in 49 patients undergoing 76 vertebroplasty procedures. On the radiographs alone 49 (66%) of 74 cement leakages were identified. Remarkably, leakage in the spinal canal through the basivertebral vein (“b-type leakages”) was only identified in two of 28 cases (7%).

Schmidt et al. [47] found a consistency between radiographs and CT scans of only 48%. This implies that more than every second cement leakage remains undetected in the postoperative radiographs. Studies in

which patients underwent postoperative CT scans, reveal cement leakage rates between 97% [46] and 112% [47] (29 leakages in 26 vertebrae). To our knowledge, only one investigation has been published that directly compares vertebroplasty and kyphoplasty cement leakage in similar patient groups. Boszczyk et al. [36] investigated 24 patients in whom 34 vertebrae were augmented. In the vertebroplasty series 73% showed cement leakage in the postoperative CT scans opposed to 39% in the kyphoplasty series [36]. The data from the CT investigations by Yeom et al. [46], Schmidt et al. [47] and Boszczyk et al. [36] show that, like vertebroplasty, kyphoplasty also has higher rates of leakage than described in the literature until now.

In the majority of cases it is only a small amount of cement that leaks out from the vertebra. The relatively high rate of minor leakages does not correlate with an adverse outcome. If clinical symptoms occur [47], CT scan assessment is recommended. Accepting the high percentage of occult cement leakage, a preoperative venography remains without consequence. In cases of major spinal leakage, severe neurologic deficits have, however, been reported [48–50], underlining the necessity of meticulous technique and high-quality image intensifiers. The latter will also aid in detecting venous embolism, of which fatalities through pulmonary embolism and even paradox cerebral embolism have been reported [51–54].

Other rare complications occurring in percutaneous augmentation are intercostal neuralgia [55] and, rarely, radiculopathy [56]. Three reports have been made of spondylitis after vertebroplasty, treated conservatively [57], others requiring vertebrectomy [58].

Outcome

Many retrospective and prospective investigations have looked into the outcome of percutaneous vertebral augmentation [3, 4, 13, 35, 43, 59, 60]. Practically all studies document significant pain reduction, measured with the VAS (visual analog scale) in the majority of patients after the procedure. Winking et al. [60] prospectively followed 28 patients with osteolytic metastases and 38 patients with osteoporotic vertebral collapse treated with PMMA vertebroplasty. Immediately and 6 months after treatment 83% of tumor patients and 92% of osteoporotic patients had significant pain reduction.

Perez-Higueras et al. [13] treated 13 patients with a 5-year follow-up with vertebroplasty. The VAS fell from 9.07 ± 0.6 to 2.07 on the 3rd day, and averaged 2.15 at 5 years ($p < 0.001$).

Due to the obvious clinical benefit, randomized studies are rare. To our knowledge, only Kasperk et al. [4] undertook a prospective controlled study with 20 patients in the conservative control group. 24 h before the procedure these patients determined their inclusion either in the control group or the kyphoplasty group. 60 patients were treated with kyphoplasty. In opposition to the control group, pain was significantly reduced in the kyphoplasty group ($p = 0.007$ vs. not significant); their daily activity (EVOS Score) also rose significantly ($p = 0.001$ vs. not significant).

The long-term effects of vertebral augmentation nevertheless remain unclear. While follow-up studies over 5 years for 13 patients [13] and 4 years for over 40 patients exist [14] for vertebroplasty, long-term follow-up for kyphoplasty is still lacking. There is no evidence in existing studies of recurrence of symptoms at treated levels in the researched period of time, similarly no systematic signs of progressive osteolysis or mechanical failure have been found. Despite the supportive data available and clinical experience gained in thousands of patients, controlled randomized trials are in demand, to prove the efficacy and safety of the method beyond doubt and show a long-term benefit in comparison to conservative treatment.

Conclusion

Due to the rising number of elderly patients with spine disease, operative therapy of osteoporotic vertebral fractures and metastatic instability through augmentation techniques is gaining further importance. The significant positive results in the investigations to date will spread its use and extend the indications further. Besides the risk of rare but severe complications, the overall effect of the procedures for the patients, so far, must be regarded as very positive. It must nevertheless be accepted that our indications are based more on clinical experience than on high-class evidence. This especially holds true for the treatment of vertebral trauma, where the application of vertebro- or kyphoplasty is a departure from the generally accepted gold standard of open reduction and internal fixation. The data available on the outcome for these indications is still sparse, and there is a clear responsibility on the surgeons to provide prospective investigations when employing these techniques and novel materials.

Future investigations will need to be directed not only toward the biomechanical issues surrounding vertebral augmentation, but also the biological effects, one of the most pressing issues being the influence of aug-

mentation (and differences between materials) on the nutrition of the disks via the end plates. If further supportive evidence can be gathered, these techniques clearly have the potential of becoming a mainstay of spinal surgery.

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