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Kyphoplasty for treatment of osteoporotic vertebral fractures

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Fax: +41-31-6323600, e-mail: paul.heini@insel.ch **Abstract** Cement reinforcement for the treatment of osteoporotic vertebral fractures is efficient mean with high success in pain release and prevention of further sintering of the reinforced vertebrae: however, the technique does not allow to address the kyphotic deformity. Kyphoplasty was designed to address the kyphotic deformity and help to realign the spine. It involves the percutaneous placement of an inflatable bone tamp into a vertebral body. Restoration of VB height and kyphosis correction is achieved by inflation of the bone tamp with liquid. After deflation, a cavity is created that eases the cement application. The potential of kyphosis reduction is given in fresh fractures with a range of 0-90% for

height restoration and absolute correction of the kyphotic angle of 8.5°. The cavity formation, on one hand, and the different cementing technique leads to lower risk for cement extravasation. An alternative method for kyphosis correction represents the so-called lordoplasty where the adjacent vertebrae are reinforced first and with the cannulas in place acting as a lever the reduction of the collapsed vertebra can be performed. The results with respect to kyphosis correction are superior in comparison with a kyphoplasty procedure.

Keywords Spine · Osteoporosis · Kyphoplasty · Vertebroplasty · Lordoplasty

Introduction

Osteoporosis is the epidemic of this century in the western and Asian countries. Vertebral compression fractures (VBF) are a common and often debilitating expression of this disease. Progressive loss of posture as a result of these fractures is one of the major problems related with an enormous impact on the quality of life [9, 17, 21, 30, 31, 32, 33].

Vertebroplasty has gained popularity during the past years for the treatment of osteoporotic compression fractures. Several reports document its usefulness in addressing pain and prevention of further collapse and preservation of posture. Rapid regression of pain has been found in 80–90% of treated patients with a long-lasting effect at a similar rate [1, 13, 18, 19, 20, 28]. Despite the high success seen with vertebroplasty, it does not address the as-

sociated spinal malalignment as it "freezes" the deformity. Furthermore, if a low viscous cement injection technique is used, the incidence of cement leakage is higher when compared with kyphoplasty [26, 29, 34, 39]. As mentioned above, progressive loss of posture results in a compromise of the pulmonary function and sometimes gastrointestinal function as well [23, 32].

Kyphoplasty was designed to address the kyphotic deformity and help to realign the spine [16, 40]. It involves the percutaneous placement of an inflatable bone tamp into a vertebral body. Restoration of vertebroplasty height and kyphosis correction is achieved by inflation of the bone tamp with liquid. After deflation, a cavity is created that eases the cement application.

Height restoration and decrease of cement leakage are the main points that differentiate this technique from vertebroplasty [29].

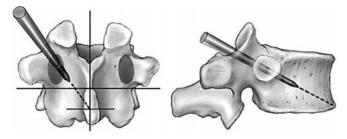


Fig. 1 The pedicles serving as landmark. A K-wire is inserted under biplanar fluoroscopic control. Ideally, the final position of the balloons should be centered between the end plates within the anterior two-thirds of the vertebral body (see Acknowledgements)

Surgical technique

A bilateral (in rare cases monolateral) approach (trans- or parapedicular) is chosen to insert a working cannula into the posterior part of the vertebral body (VB; Fig. 1). 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. The balloons are available in lengths of 15 and 20 mm (maximal volume 4 and 6 ml, respectively). The balloons should ideally be centered between the end plates in the anterior two-thirds of the vertebral body. Their placement is checked by two radioopaque markers. Once inserted, the balloons are then inflated using visual volume and pressure controls to reduce the compressed vertebra and create a cavity. The behavior of the vertebral body is monitored under lateral fluoroscopic control. Inflation is stopped when pressure is raised above 250 psi (the compliance of the fractured VB, i.e. the gradient of the pressure increase provides important infor-

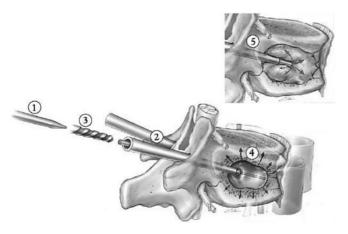


Fig. 2 Five steps of kyphoplasty: *1* placement of a guide wire; *2* insertion of a working cannulas; *3* reaming of working channels; *4* inflation of the balloons, and *5* injection of polymethylmetacrylate (see Acknowledgements)

mation about the potential of height restoration), when the balloon contacts the cortical surface of the VB, or if it expands beyond the border of the vertebral body and if the VB height is restored, then the balloons are sequentially deflated and removed and the cavity is filled with polymethylmetacrylate (PMMA) under continuous fluoroscopic control. Cement is applied with a bone filler device – a plunger system with a nozzle and a stylet. Its small diameter allows to build up an enormous force and pressure which enables to inject the cement at a high viscosity (Fig. 2).

The technique is more demanding in comparison with a simple VB procedure as proper placement of the balloons is mandatory and several steps need to be taken until cement can be applied; therefore this procedure is performed under general anesthesia in the majority of the cases.

Literature review

A Medline search revealed 40 hits for kyphoplasty; among them, we found 10 clinical papers and 6 biomechanical investigations and a series of reviews.

Biomechanical investigations

In vitro studies demonstrate the potential of height reduction and restoration of the mechanical properties. Belkoff et al. published two studies where they showed the potential of height restoration in vitro and the mechanical effectiveness with PMMA and CaP cement [3, 4]. Furthermore, he investigated the potential of height restoration under load conditions. It was possible to reduce the VB height significantly in comparison with the postcompression situation [2]. Verlaan et al. [36] investigated the potential for end-plate restoration of traumatic fractures in combination with internal fixation in a cadaver model and the subsequent defect reconstruction with CaP cement. The balloon was able to decrease the end-plate impression. Wilson et al. compared vertebroplasty and kyphoplasty for a wedge fracture cadaver model and found similar reduction of the compliance in comparison with the native state [38]. Tomita et al. did assess the effect of kyphoplasty and vertebroplasty with PMMA and CaP cement in embalmed vertebrae and did not find a difference in between these groups but significant differences in comparison with the native state for vertebro- and kyphoplasty [35].

Clinical studies

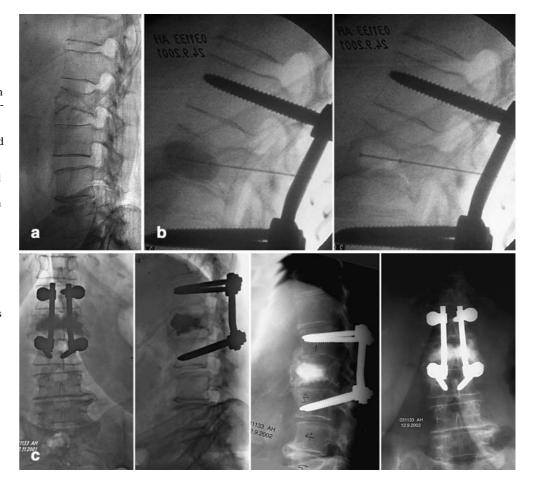
The first experience with the use of kyphoplasty was published by Wong et al. [40] in the Journal of Women's Imaging in 2000. This journal is not indexed in the index

medicus. They report on the experience of 85 patients. Over 90% of patients report good or excellent pain relief. The height restoration was 62%. Lieberman et al. presents a prospective clinical investigation on the phase-I investigation of the treatment of 30 patients with 70 kyphoplasty procedures performed. Local cement leakage was observed in 8.6%. The restoration of the VB height was 47% in 70% of cases, and in the remainder 30% no measurable correction was achieved. The SF36 assessment did show a highly significant improvement for pain and physical functioning [24]. Garfin et al. [16] gives an overview on the treatment of the first 340 patients treated. Six hundred three fractures were reduced and reinforced. Of patients, 90% did show a functional and symptomatic improvement. Height restoration was possible with an increase from 83 to 99% of the normal. Complications due to leakage were observed in 2 patients, one epidural and one cement embolization [16].

Dudeney et al. [12] reports on the treatment of VB fractures in metatstatic lesions. In 18 patients they performed 55 kyphoplasty procedures. Of height loss, 34% was restored, and leakage was observed in 4% of vertebrae. Outcome was assessed by the SF36. Significant improvement in SF36 scores occurred for bodily pain (23.2–

55.4, p=0.0008), physical function (21.3–50.6, p=0.0010), vitality (31.3–47.5, p=0.010), and social functioning (40.6– 64.8, p=0.014) [12]. Theodorou et al. [34] reports on the treatment of 15 patients with 24 kyphoplasty procedures. Height restoration was best in the mid-vertebral body with 65%. Kyphosis correction was 9.5° in average or by 62%. Pain was improved in all patients at a follow-up of 6-8 months [34]. Coumans et al. [11] presents a prospecitve study with kyphoplasty with a minimal follow-up of 1 year. Of 78 patients with 188 kyphoplasty procedures, 62% were available for a follow-up evaluation. They report five cases of asymptomatic extravasation SF36; Oswestry score and pain (VAS) did improve immediately postoperatively with lasting effect at FU. The kyphosis correction is not mentioned [11]. Fourney et al. [14] report on the treatment of tumorous lesions with vertebroplasty and kyhoplasty in 56 paitents undergoing 65 vertebroplasties and 32 kyphoplasties. Leakage was observed in 9% of vertebroplasties and 0% in kyphoplasties. Restoration VB height was 42%. Pain relief was seen in 84% of patients in both groups [14]. Ledlie and Renfro [22] assessed the restoration of VB height and clinical outcome of 26 patients with 41 osteoporotic fractures treated with a FU of 1 year. Height restoration was between 65 and 90% and pain decrease

Fig. 3a, b A 68-year-old woman. a Pincer-type fracture of L2 after minor trauma. In order to restore the end-plate impression, a combined procedure with internal fixation and bisegmental fusion and balloon kyphoplasty was planned. b Intraoperative sequence with internal fixation in place and inflation of the balloons. The end plates have been pushed in a better position with the balloons. After deflation, the void in the vertebral body is well visible; however, the reduction of the end plate is lost, to a certain degree. c Standing X-ray after the procedure and follow-up control after 1 year. There is some local cement leakage on the left side which is clinically not symptomatic. After 1 year, the alignment of the spine is preserved. There is spontaneous ossification at anterior longitudinal ligament. The patient is doing well



was from 8.6 to 1.4 points measured with the VAS at 12-month follow-up [22]. Weisskopf et al. [37] shows the experience on the treatment of 22 paptients with 37 VB treated. They compared them with a conservatively treated group of 20 patients. Kyphosis reduction was achieved in only 4 cases with 8.5° in average, and leakage was seen in

5 of 37 VB [37]. Boszczyk et al. reports on the use of the bone tamp in different techniques among others in combination with open procedures for the treatment of burst fractures, either as an isolated measure or in combination with internal fixation [8].

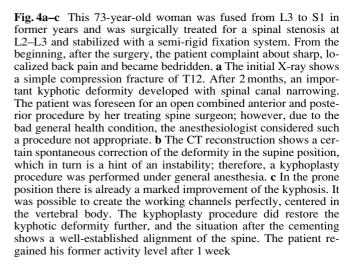
Focus on kyphosis correction

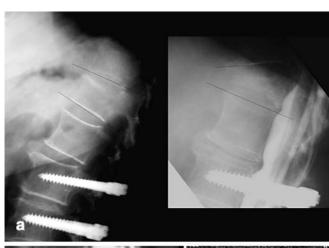
Most clinical papers report restoration of VB height between 0 and 90%. They give the relative amount of height gain and use as reference height the adjacent VB. For instance, when the preoperative height of the VB was 60% of the normal, and 90% after kyphoplasty, the relative height reduction was 75% and the absolute value was 30%. The correction of the kyphotic angle is reported only in the minority of papers. The reported absolute values are 8.5° on average $(0-18^{\circ})$.

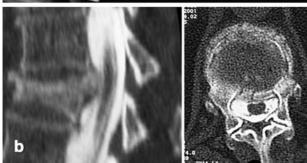
Focus on leakage

The incidence of leakage is reported for kyhoplasty ranging from 0 to 13.5% [14, 37] and for vertebroplasty from 2 to 67% [10, 27, 41] of which clinical sequelae are extremely rare. The values for kyphoplasty are definitively lower. This is related, to a certain extent, to the cavity creation and, in addition, to the different cementing technique.

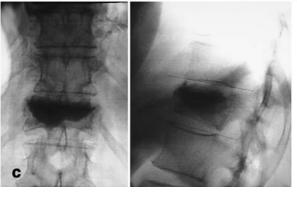
The problem of cement leakage was assessed in a more sophisticated manner by Phillips et al. [29]. They compared the behavior of contrast die injection before and after cavity formation in the vertebral body. Phillips et al. describe a significantly decreased rate of vascular and transcortical extravasation after cavity formation [29]. Experimental data show that the most important aspect with respect to extravasation risk represents the cement viscosity [7] and, therefore, an important aspect with respect to these different

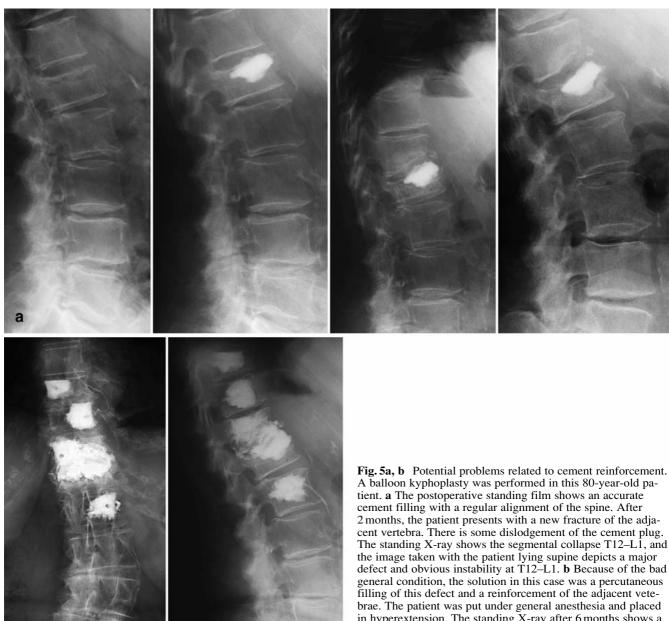












leakage incidences is based on the different cementing techniques between vertebroplasty and kyphoplasty.

Own experience

b

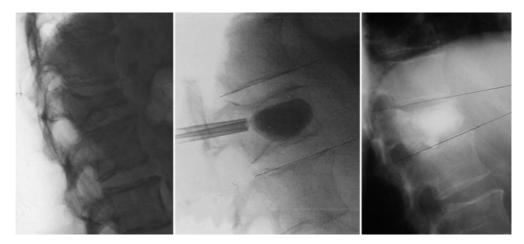
We started using kyphoplasty in 2000 with much anticipation. During a 3-year period 74 kyphoplasty procedures have been performed in 68 patients. A first follow-up study of 24 of our patients with a minimal FU of 1 year with 27 fractures treated revealed an average correction of the kyphotic deformity of 8° or 47%, with no correction in fractures older

A balloon kyphoplasty was performed in this 80-year-old patient. a The postoperative standing film shows an accurate cement filling with a regular alignment of the spine. After 2 months, the patient presents with a new fracture of the adjacent vertebra. There is some dislodgement of the cement plug. The standing X-ray shows the segmental collapse T12-L1, and the image taken with the patient lying supine depicts a major defect and obvious instability at T12-L1. b Because of the bad general condition, the solution in this case was a percutaneous filling of this defect and a reinforcement of the adjacent vetebrae. The patient was put under general anesthesia and placed in hyperextension. The standing X-ray after 6 months shows a well-preserved alignment. The patient is doing well. She does complain about lower back pain that is not related to the changes at thoraco-lumbar junction

than 3 months. Furthermore, the intraoperative height reduction after balloon inflation showed to be 25% better than the resulting reduction after cementing due to the partial collapse after balloon deflation. Local cement leakage without clinical symptoms was seen in 9 of 27 VB. The pain decrease was significant in all but 1 patient.

Based on the initial experience we did reserve the indication for the technique for fresh fractures with remaining kyphotic deformity of more than 15° after positioning of the patient in prone position with the spine in hyperextension. Furthermore, the balloon is used in certain cases of traumatic fractures in combination with internal fixation in

Fig. 6 Loss of reduction after balloon deflation and cementing indicates an inherent problem related to the technique of kyphoplasty. The vertebral body height was restored to 85% normal with the balloons inflated. After cementing, the resulting correction seen on the standing X-ray is only half of the intraoperative situation



order to reduce the impressed end plates (Fig. 3). Finally, we did find an indication for this technique in cases of spinal stenosis that becomes symptomatic due to an osteoporotic fracture and consecutive instability (Fig. 4). In these cases the balloon can be used to restore the segmental height, which in turn can provide stability and relieve the critical pressure of the emerging nerve roots or in spinal canal itself.

Alternatives for restoration of lordosis

Vertebroplasty in its proper sense is not able to restore a kyphotic deformity; however, in fresh fractures and in cases of "dynamic mobility" [25], positioning of the patient can reduce the deformity to a certain extent and this reduction can be preserved by cementing the VB (Fig. 4).

Based on the experience of loss of reduction during balloon deflation in kyphoplasty, on one hand (Fig. 6), and the problem of adjacent VB fracture, on the other hand (Fig. 5) [5, 6], the following procedure was introduced: the VB above and below the fractured one are reinforced bilaterally. When the cement is cured the cannulas are used as a lever and a lordotic moment is applied and by the facet joints, acting as a hypomochlion, the collapsed VB is reduced. The cannulas maintain this force until the fractured VB is cemented and the cement dries (Fig. 7). This provides improved means for fracture reduction and can even be combined with balloon-kyphoplasty in selected cases and help to overcome the shortcoming of reduction loss after deflation with kyphoplasty alone. Preliminary results of the treatment of 30 patients with this technique with respect to kyphosis correction showed an average correction of 14° or 68%. The technique is very inexpensive: the costs are 20 times lower in comparison with a standard kyphoplasty procedure.

Stenting of a VB in order to correct a deformed VB has been performed in vitro, and thus far there is no clinical experience available [15].

Conclusion

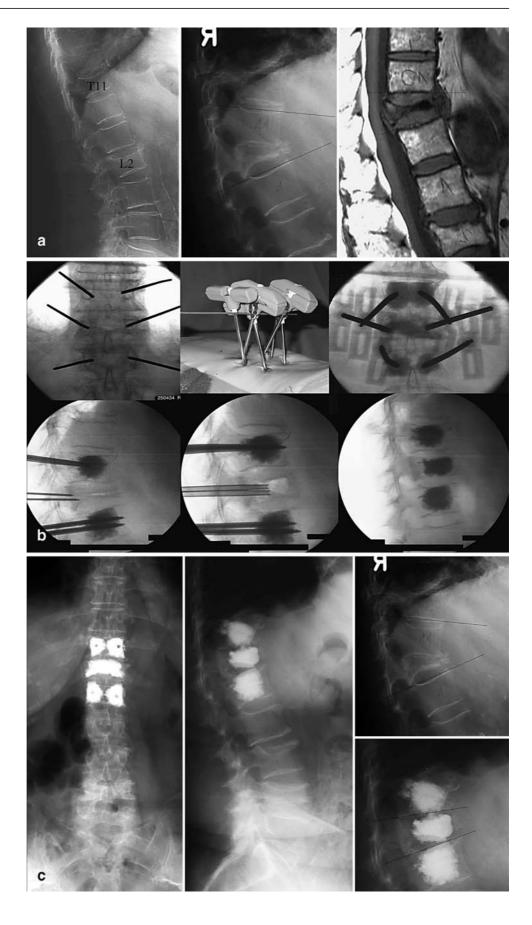
Kyphoplasty represents a brilliant idea for correction of compressed VB. The potential of the technique offers the possibility to apply localized pressure in the bone and push fragments in a well-controlled manner. This offers a wide possibility of applications except the treatment of osteoporotic vertebral fractures.

In the treatment of osteoporotic VB fractures, the initial euphoria, however, has been calmed as the achieved kyphosis correction appears moderate and the problem of adjacent segment fracture is not solved. In selected cases impressive restoration of a deformed VB can be achieved. The creation of a cavity is a secondary effect of this technique and provides a container for the injected cement and thereby seems to reduce the risk for extravasation [29]. In clinical series where leakage of VP is compared with kyphoplasty it is not mentioned that the crucial parameter for the risk of leakage is the cement viscosity [7]. In most techniques of VP low viscous cement is injected, whereas in kyphoplasty a more viscous cement is applied with a very powerful plunger system.

The odd thing is that the device is very expensive – an issue that needs to be considered in times of cost problems in nearly every health care system; therefore, the use of these techniques appears restricted to very selected cases, for instance, in order to avoid an open surgical procedure (treatment of traumatic VB fractures with CaP injection, problems of symptomatic spinal stenosis due to the kyphotic deformity of a vertebral body, severe kyphosis after an osteoporotic fracture) or avoid an additional anterior approach (reduction of end-plate impression) in traumatic superior burst fractures. The use of this technique for simple osteoporotic compression fractures with minor deformities appears with respect to the extremely positive experience with vertebroplasty not justified. The decreased risk for leakage can be overcome by adapting the cementing techniques accordingly.

The treatment of metastatic lesions appears less predictive technically and clinically and seems to be related with

Fig. 7a-c Natural history of osteoporotic fractures in a 73year-old woman. a Both fractures (T11 and L2) were qualified as old as the patient had only minor complaints. Over a period of 4 months, the patient complained about increasing pain. The standing X-ray shows the severe kyphotic deformity at T11. The MRI scan shows a nearly complete collapse of T11, but furthermore, some degree of spontaneous correction of the kyphosis. **b** Alternative method of kyphosis correction: lordoplasty means cementing of the adjacent vertebrae in a classical manner. When the cement is dried, the cannulas are used as a lever in order to apply a lordotic moment. The facet joints are acting as a hypomochlion. The collapsed vertebral body has gained height (radiolucent area), and the kyphotic deformity is corrected to a major extent. Cementing of the fractured vertebrae: when the cement is cured, the tension is released and the cannulas are removed. c Standing X-ray, 6 months postoperatively. The patient is free of pain in unrestricted activity



a high incidence of leakage. In this group of patients the use of a balloon and the creation of a cavity might be advantageous.

Acknowledgments Reproduction of Figure 1 and 2 with kind permission of the Journal of Neurosurgery, and the authors, Golakasan et al. 2003.

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