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Disadvantages of Balloon Kyphoplasty with PMMA – a Clinical and Biomechanical Statement

S. Becker[1], D. Dabirrahmani[2,3,4], M. Hogg[2,4], R. Appleyard[2,3], G. Baroud[5], M. Gillies[2,3,4]

Abstract: Balloon kyphoplasty (BKP) and vertebroplasty (VP) are clinically effective procedures. However, BKP has been occasionally associated with failure, although the cause has not been established thus far. We believe that, especially in patients with severe osteoporosis and osteonecrosis, BKP fails due to the so-called stress shielding effect and the stiffness of cement. In these patients, other bone-preserving kyphoplastic procedures and vertebroplasty, as well as recently introduced cements adjusted to the severity of osteoporosis, might be beneficial. Furthermore, it is essential to achieve complete straightening intraoperatively when performing BKP, because any persistent residual kyphosis will aggravate the burden on the adjacent vertebral bodies following the creation of a cavity filled with cement. Therefore, it would be meaningful to consider alternative bone-preserving kyphoplastic measures instead of BKP. In cases of older fractures, one should consider the use of VP and the recently introduced cements.. **J Miner Stoffwechs 2011; 18 (Supplement 1): 9–12.**

Introduction

About 20 years after the introduction of vertebroplasty (VP) and 10 years after the introduction of balloon kyphoplasty (BKP), it is now time to update the pros and cons of these methods on the basis of several years of clinical experience and recent biomechanical outcomes.

The present article will not address the still ongoing and now rekindled discussion as to whether VP or BKP exert any clinical effect at all, but will present considerations based on clinical observation that have not been given significant attention thus far.

In view of the controversial discussion concerning the basic benefit of VP and BKP, it is now especially important to focus on the principle of *primum non nocere* with regard to both techniques.

While VP involves filling intact bone with PMMA for the purpose of genuine augmentation, balloon kyphoplasty was developed to reduce the facture and kyphosis. The theoretical advantages of such reconstruction of kyphosis have been established in medical studies [1], but a comprehensive clinical and surgical study addressing the relevance of fracture reduction through BP is yet to be performed. As scientific evidence of the advantages of reduction procedures has not been presented yet, other differences between VP and BKP may be discussed.

Basically it should be mentioned that reduction procedures (BKP, vertebral stenting and many others) sacrifice intact bone to a greater or lesser extent in order to achieve kyphotic / vertebral height correction of the vertebral body. VP enhances the bone structure of the vertebral body by injecting cement into the spongious bone. Here one is confronted with the question of a negative effect of bone-destructive reduction by the creation of a cavity.

Clinically, every user of BKP has experienced failures. These may be divided into early complications with cement dislocation and bone loss (Figure 1), and late complications with loss of kyphosis and further bone absorption around the cement (Figure 2). Fortunately these occurrences are rather rare, but of sufficient importance to be noted and analyzed.

These clinical processes led us to perform a finite-element simulation and investigate the effect of the creation of a cavity and bone cement filling (PMMA) on bone in the presence of osteoporosis and vertebral body fractures. We hoped this would permit identification of those patients who would be most likely to experience the above mentioned processes.

Methods

Based on CT investigations of cadavers, a three-dimensional finite-element model of the lumbar spine (L2 to L4) with two Junghanns motion segments, including all ligaments and the intervertebral disks was created. The intervertebral disk with the nucleus pulposus and the annulus fibrosis was simulated by using a composite material consisting of collagen fibers in a solid matrix with eight layers of different fiber angles of 30 degrees. Seven ligaments of the spine (anterior and posterior longitudinal ligament, the ligamentum flavum, the ligamentum transversum and interspinosum, and the ligamentum supraspinosum and capsular ligaments) were included in the calculations.

Simulation of the vertebral body included visualization of an intact as well as a fractured vertebral body by way of an A1.3 fracture (Figure 3).

Three different bone densities were simulated: normal bone (BMD +1), osteopenic bone (BMD –1.5) and osteoporotic

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bone (BMD –2.5). The operation was simulated by way of a BKP technique with a cement volume of 15 % and 30 % relative to the volume of the vertebral body (equals 2–3 and 4–6 ml of total cement [2, 3]). The compression of bone around the cement caused by the balloons could be calculated as a 1-mm interface. Three different stiffnesses of cement (E-module) were simulated: 0.5, 2 GP (correspond to the elastic modulus of commercially available PMMA) and 8 GP (corresponds to the newer non-absorbable silicate cements).

Furthermore, complete straightening was compared with a residual postoperative kyphosis of 10° [4]. We thus performed FEM analysis based on the parameters of cement volume and stiffness as well as kyphosis at three different bone densities.

Results

Comparative analysis of the quantity of cement used in BKP (15 % or 30 % of the volume of the vertebral body) exerted no major impact on primary fracture stability and no significantly greater stress in the adjacent vertebral bodies. The stiffness of cement at 0.5 GP and 2 GP also showed no difference in stress behavior in the treated or adjacent vertebrae. The first significant differences were noted between cements of 2 GP and 8 GP stiffness in terms of greater "stress shielding" in the treated vertebral body and local maximal stresses in the treated and adjacent segments (Figure 4). A separate investigation of the stress-shielding effect of 2-GP cements in osteopenia and osteoporosis revealed a significant increase in the ventral and dorsal region around the cement, i.e. in the

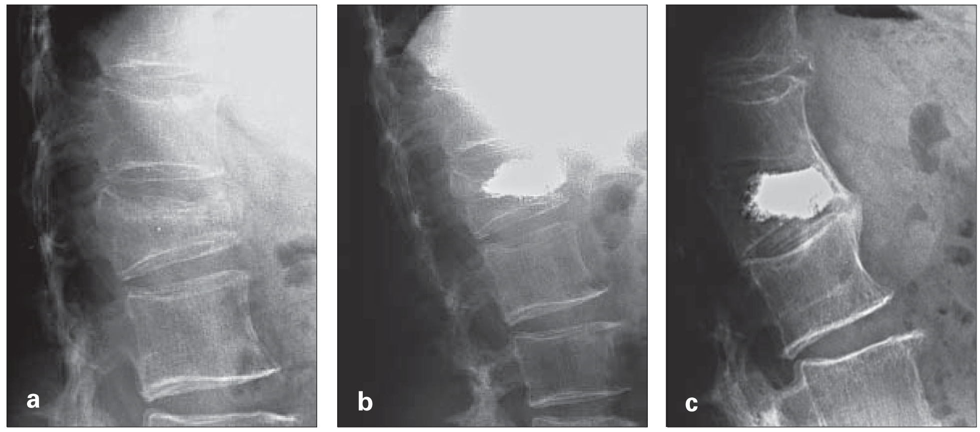

Figure 1: (a) 63-year-old woman, fracture of the first lumbar vertebra, BMD –2.5. **(b)** Postoperatively after BKP. **(c)** Six years postoperatively: resorption of the vertebral body and increase of kyphosis

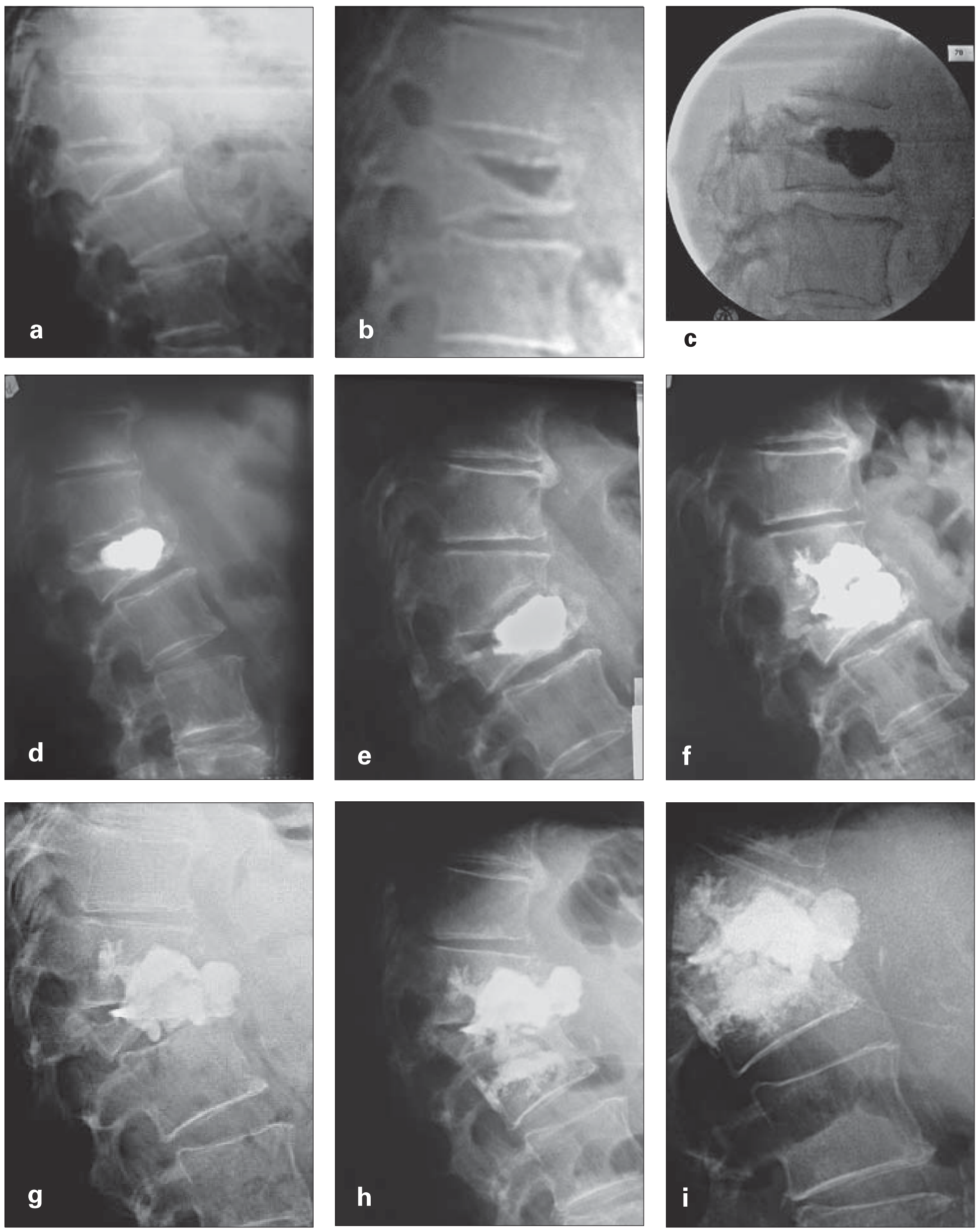

Figure 2: (a) 74-year-old man, fracture of the twelfth thoracic vertebra with osteonecrosis. **(b)** Closed reduction on the operating table. **(c)** Postoperatively after BKP. **(c)** Collapse of vertebra after six weeks. **(d)** Further resorption and collapse after ten weeks. **(e)** Second operation with BKP at the eleventh thoracic vertebra. **(f)** Further collapse and resorption six weeks after the second BKP. **(g)** Third operation with VP at the first lumbar vertebra, cement leakage dorsally, no neurology. **(i)** Further collapse and resorption six weeks after the third operation.

region of the fracture, with maximal stress shielding in the presence of osteoporosis (Figure 5). The impact of residual postoperative kyphosis on the adjacent vertebral bodies is demonstrated best when using the very stiff 8-GP cement. Here one finds the maximum increase in stress in the treated and adjacent segments (Figure 6).

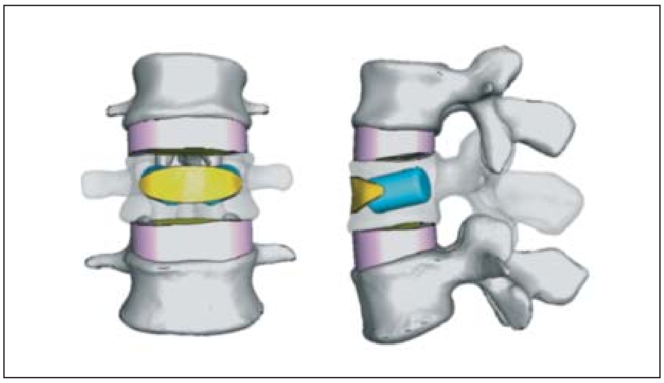

Figure 3: FEM simulation of the fracture and BKP in the mobile segment of L2–L4.

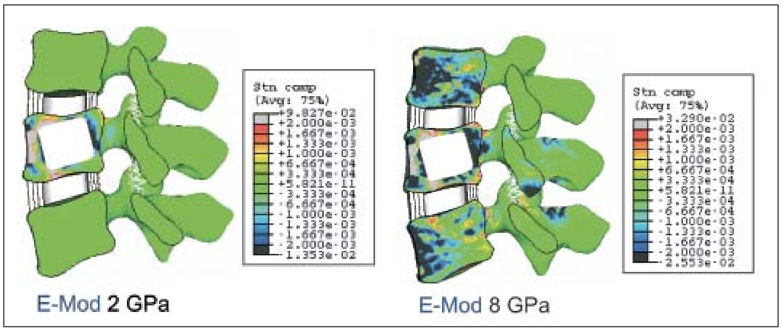

Figure 4: Impact of cement stiffness on the subsequent fracture rate and on local stress. Markedly higher stress in the adjacent vertebrae and greater local stress shielding when using 8 GP. Model BMD –2.5, volume of cement 30 %, compressive stress.

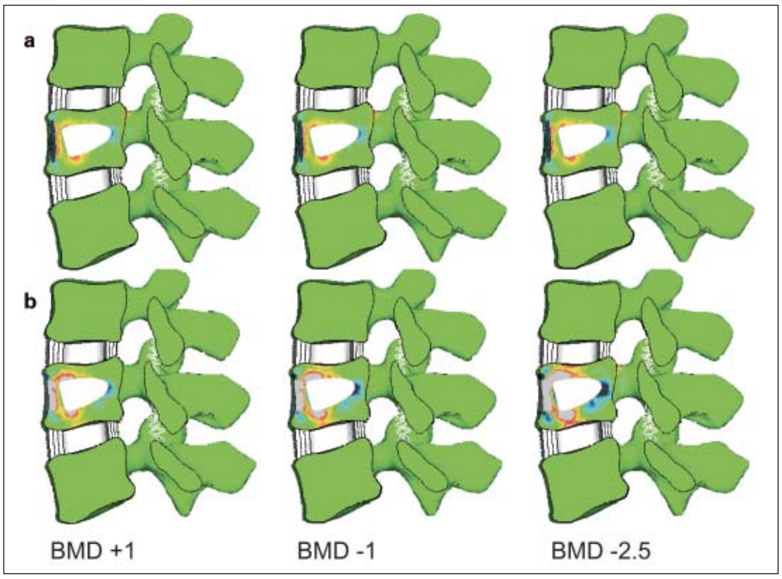

Figure 5: Effect of various bone densities on stress shielding. Increased stress shielding ventrally and dorsally around the BKP cement; enhancement of the effect particularly in the dorsal aspect around the cement and reduction of BMD. Model 2-GP cement, volume of cement 15 %, **(a)** Compressive stress, **(b)** Compressive strain.

■ Discussion

Balloon kyphoplasty yielded good outcomes in clinical studies [5]. Complications have been reported in rare instances. However, we still lack long-term results. Regrettably, failures are encountered here as well as with any other technique. In the current experimental protocol we tried to clarify the causes of these failures.

The industry has reacted to the increased popularity of BKP and the concomitant increase in VP, and has introduced innovations in both techniques. The innovations concern the instrumental procedure (viscosity measurement, new kyphoplasty procedures) as well as cements (ultra-high viscosity PMMA, resorbable cements, mixed types).

In terms of technique, current cementing procedures for osteoporosis may be divided into bone-conserving interventions (vertebroplasty and new kyphoplasty procedures such as StabiliT®, DFine and KIVA™, Benvenue) and bone-destructive procedures which involve compression of bone by the use of catheters and other aids, and the creation of a cavity (BKP, vertebral stenting etc.). Given the absence of surgical evidence of the benefit of fracture reduction to the present day, the question arises as to whether the benefits of correcting kyphosis – which at least have not been proven surgically by suitable BKP studies – justify damage to bone consequent to the creation of a hollow space. In this regard we need additional studies to achieve suitable scientific evidence for the use of this technique.

It would appear that straightening of a fracture can be achieved by the use of recently introduced bone-preserving kyphoplasty procedures. However, in the future a compromise could possibly be achieved between the correction of kyphosis and greatest possible preservation of bone.

A historical argument regarding the creation of a cavity was the rate of cement leakage associated thus far with this approach [6]. However, with the new vertebroplasty techniques using ultra-high viscosity cement, this approach is comparable with BKP even without the creation of a cavity [7].

In terms of biomechanics, the majority of the investigations performed thus far have shown that complete filling of a vertebral body with bone cement increases the rate of subsequent fractures [3, 8, 9]. However, this process could not be confirmed clinically in the FREE study (comparison of BKP with conservative therapy, showing a re-fracture rate of 41.8 % for BKP and 37.8 % for conservative treatment; p = 0.53).

Our analysis revealed that higher stresses are dependent on the stiffness of cement and the severity of osteoporosis. Common PMMA cements can be used without major risks in patients with osteopenia. However, cements of greater stiffness are a cause of concern. The quantity of cement as such is of secondary importance compared to its stiffness.

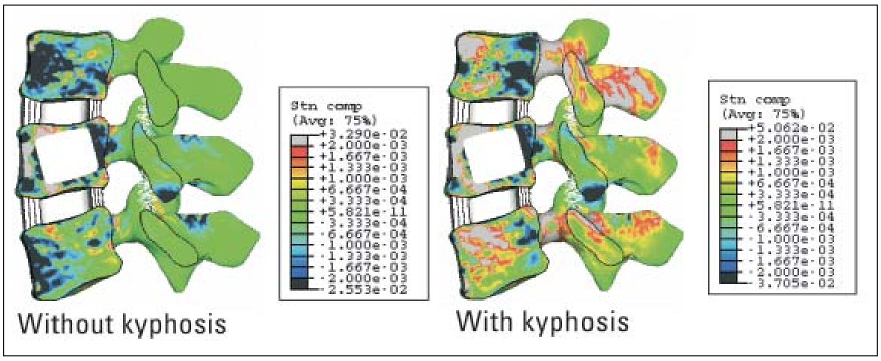

Figure 6: Effect of residual kyphosis on the local and adjacent vertebra. Significant increase in maximum stresses at a ventral shift of the axis by only 1 cm. Model 8-GP cement, volume of cement 30 %, compressive stress.

On the other hand our experiment showed that, regarding the subsequent fracture rate, the currently available PMMA cements are the best possible solution for PMMA because of their elastic moment. Very stiff cements with a high elastic coefficient cause correspondingly higher subsequent fracture rates. The trend in the industry favors mixed cements (PMMA and ß-TCP) and absorbable ones of low stiffness. These cements are a compromise between primary stability and subsequent fracture rates, but their value in clinical routine is yet to be proven.

Stress shielding is a well known effect of total prosthetics of knee or hip: physiological loads are taken over by a substitute material, in the case of BKP by cement, and the surrounding bone is relieved of load. According to Wolff's law this off-loading causes osteolysis and resorption. Sustained off-loading of a fracture does not cause fracture healing in this setting, but resorption of the areas off-loaded by stress shielding. Analogously, bone in the spine should also behave in similar fashion. This, in our opinion, is the explanation for the clinical cases described above. According to our analysis, stress shielding is especially effective in cases of severe osteoporosis. In addition to osteoporosis, any pre-existing osteonecrosis is also a risk factor for bone absorption, as in the case described above (Figure 1).

Thus, we believe that a kyphoplastic procedure that destroys bone to create a cavity should be used with caution in patients with severe osteoporosis or osteonecrosis. Such caution is also advised when using vertebroplasty in patients with osteonecrosis, because the cement penetrates the spongious bone as a mass with no significant interdigitation, analogous to BKP. In cases of other osteoporotic fractures, VP and novel kyphoplastic procedures without destruction of bone might be advantageous because they possibly achieve better distribution of stress and exert a lesser stress-shielding effect. However, studies on this issue have not been conducted thus far.

Another factor that exerts a decisive effect on the subsequent fracture rate is postoperative kyphosis (Figure 6). Only in the presence of a completely straightened vertebral body do the cement as such and the procedure play a decisive role. If a residual kyphosis is present (in cases of an older fracture or when the surgeon has failed to achieve complete fracture reduction intraoperatively), the negative impact of the cement is potentiated. This should be taken into account when using BKP or other procedures of this type. Whether similar mechanisms occur when VP is performed on osteoporotic bone has not yet been investigated.

It may be summarized that currently no statements can be made as to the time point beyond which a spine is too osteoporotic for a cementing procedure. However, the use of these procedures, especially BKP and similar techniques should be viewed critically when the orthopedic surgeon is confronted with increasing degrees of osteoporosis.

Clinical relevance

1. BKP is associated with early and late complications involving bone absorption and loss of straightening.
2. BKP-related complications appear to be caused by stress shielding and the stiffness of cements.
3. The creation of a cavity filled with cement causes greater stress shielding in patients with severe osteoporosis.
4. The negative biomechanical effects of BKP are not increased in cases of incompletely reduced fractures.
5. Especially in cases of severe osteoporosis and osteonecrosis, the use of BKP and similar procedures should be used with great caution.

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