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Vertebroplasty Versus Kyphoplasty: A Comparison and Contrast*

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The phrase *vertebroplasty versus kyphoplasty* evokes images of competitive procedures and battling groups of entrenched physicians. Our involvement in the development and introduction of percutaneous vertebroplasty (PV) and kyphoplasty (KP) in the United States has given us a unique perspective on the safety and efficacy of both procedures. We believe that both procedures offer potential benefit with acceptable safety when used by skilled physicians. However, they are not the same; they have some distinct differences, including cost and possibly even complication rates. The real hurdles are to further assess and develop the appropriate indications, advantages, and shortcomings of each procedure. We must then select the appropriate method of therapy to maximally benefit our patients. Finally, all practitioners must venture beyond the dogma of their respective subspecialties and understand the full spectrum of tools and techniques that are available to treat vertebral compression fractures. This chapter reviews the published data regarding KP and PV and put these data in perspective with regard to the marketing comments so often encountered when dealing with sales personnel or physicians who use only one tool.

History

The history of the development of each procedure explains how a competitive environment has arisen among many of the physicians who use either PV or KP. Percutaneous vertebroplasty was introduced in France in 1984 by the interventional neuroradiologist Hervé Deramond and his colleagues (1). It was found useful for the treatment of pain associated with vertebral compression fractures (VCFs) resulting from benign and malignant tumors, as well as osteoporotic compression fractures (1,2). The technique began to be used by interventional neuroradiologists in the United States in 1993, with the first U.S. case series reported in 1997 (3). Percutaneous vertebroplasty has experienced a

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rapid rise in popularity in the radiologic community and with patients. There are approved reimbursement codes (CPTs) for PV with many third-party payers (including Medicare) who recognize and reimburse for the procedure.

Since the introduction of PV, many papers have documented the positive biomechanical effects of PV and the pain relief resulting from this treatment for VCFs (1–18). A review of this literature shows that all reports reveal favorable results of pain relief and restoration of activities of daily living following PV. (However, no prospective, randomized series comparing PV with alternative therapy has been accomplished.) Clinical complications are rare in the hands of experienced operators. Some reports do list a higher risk of complications for patients with malignant disease, which includes myeloma and osteolytic metastases (myeloma is thought to be less risky than osteolytic malignancy).

The idea of attempting to treat a VCF with an inflatable balloon tamp (and thereby restore the vertebral body height and minimize the associated kyphotic deformity) was conceived by an orthopedic surgeon, Dr. Mark Reiley, in the early 1990s. The initial biomechanical investigations of the Kyphx inflatable balloon tamp (Kyphon Corporation, Sunnyvale, CA) were performed as a combined effort by this orthopedic surgeon and an interventional neuroradiologist (J.M.M.) familiar with PV (19–21). The device was given 510k approval by the FDA as a "bone tamp." A randomized clinical trial that compared "kyphoplasty" with conservative medical management was attempted, but patient entry was slow, and this initiative was ultimately abandoned in favor of a clinical registry tabulating the results of patients treated with KP. Like PV, KP has not been tested in a comparison trial against conservative therapy. There are only a few peer-reviewed studies available with which to judge the safety and efficacy of KP (22,23). Case reports and opinion papers are also found (24–28).

In one study, pain relief with KP was found to be similar to that observed with PV, and the perioperative complication rate was 10% (although no complications related to the procedure were claimed by the authors) (22). The complications that occurred included a perioperative myocardial infarction and two patients who experienced rib fractures during the procedure. An 8.5% asymptomatic cement leak rate was observed. Height restoration was enthusiastically reported by the authors, but analysis of their data reveals that the average height gained per vertebra treated was 3 mm at the center of the vertebral endplate. This leaves open for debate the effectiveness of the KP procedure for predictably restoring significant vertebral height in vertebral compression fractures.

Another early series of 15 patients, who underwent 24 uncomplicated KP procedures for osteoporotic vertebral compression fractures that were present for an average duration of 14 weeks, reported immediate pain relief in all of the patients (23). The mean height restoration as measured on lateral radiographs was 1.5 mm in the posterior vertebral body, 4.7 mm in the midvertebral body, and 3.7 mm in the anterior vertebral body. In a larger series of 226 consecutive KP procedures,

similar results, with respect to height restoration, were reported (24). A 1% complication rate in this series included one case of epidural hematoma that required surgical decompression, one case of spinal cord injury, and one case with transient adult respiratory distress syndrome. A multicenter registry of 1,439 patients with 2,194 treated fractures with KP showed an efficacy of 90% with respect to pain relief and a major complication rate of 0.2% per fracture (25).

Only one report is available for KP as a treatment of pathologic VCFs. In a series of 18 patients with multiple myeloma who underwent 55 uncomplicated kyphoplasty procedures, significant pain relief was achieved in all patients (26). Height restoration was only reported in 39 treated levels and was listed as 34%.

The initial reports and editorials concerning KP were generated primarily in the orthopaedic literature and reflected an unqualified, positive opinion. Some of this literature seemed simply to echo marketing statements that were, as yet, unproved by clinical or laboratory investigation. The procedure, however, was not as well received in the radiologic community. This initial difference of opinion has not been substantially altered over time. Kyphoplasty has flourished in the surgical community as this physician group has been the direct beneficiaries of extensive marketing and educational support. They tend to see KP as a potential "high dollar" replacement for PV. There has been growing competition for patients between the two groups that favor one or the other of these two procedures. Unfortunately, the competitive environment between radiologists and surgeons has been compounded due to limited access by Kyphon to KP training courses for radiologists.

Substantial differences exist in the costs of PV and KP. The KP kit (without bone cement) is ~$3,400, while a PV kit (with bone cement) is less than $400. Although not a requirement of the procedure, KP is often performed in the operating room with general anesthesia. The patients are commonly kept overnight in the hospital for observation. Percutaneous vertebroplasty is usually performed with intravenous sedation only and a brief period of observation followed by discharge home after the procedure. All of these differences combine to make KP cost 10–20 times more than PV. This cost difference is acceptable only if there are proven, substantial positive benefits for the more expensive procedure. Kyphoplasty marketing claims that these benefits include improved safety due to fewer symptomatic cement leaks and substantial height restoration with kyphosis reduction that might improve pulmonary and gastrointestinal function. Actual published data are sparse that address these claims directly, but an attempt here is made to compare and contrast results based on published information.

Jargon Versus Reality

It seems that the majority of physicians would agree that both PV and KP have similar success rates for relieving the pain associated with VCFs. This would seem logical because KP relies on the same vertebral

stabilization principle used in PV, which is the introduction of bone cement into a structurally compromised vertebra. Kyphoplasty is even sometimes referred to as "balloon-assisted vertebroplasty" (29). Biomechanical data comparing the mechanical stabilization by PV and KP show similar results (19).

Beyond these basics, reality seems to be blurred by marketing jargon. Manufacturers and champions of any device always describe their individual advantages. This has been no less true of KP proponents who routinely point out the reduced likelihood for cement leaks with this procedure compared with PV (30). This is alleged to occur because the injection of cement in PV is purportedly under "high pressure," while KP fills a void created by the bone tamp and is therefore "low pressure." For years this marketing-driven claim went unchallenged, and it was often repeated by physicians even though no scientific data existed that actually measured or compared the injection pressures with these devices. Recently, independent groups of investigators demonstrated quantitatively that under usual operating conditions, intraosseus "high-pressure" was *not* observed with any (PV or KP) of these percutaneous vertebral fracture reduction procedures (31,32). In fact, the variables that seemed to influence intravertebral pressures were the rate of injection and the size of the cannula. Higher intravertebral pressures were recorded with higher injection rates and larger bore systems and when a metal trocar was used to drive cement through the cannula (31).

Lieberman et al. (22) reported a cement leak rate during KP of 8.6%. Fortunately, as with PV, the vast majority of cement leaks are asymptomatic. Reports of KP have noted very high cement leak incidences with PV but have usually failed to distinguish between symptomatic and asymptomatic leaks. When this is done, little difference seems to be present in the two procedures. Symptomatic cement leaks have occurred with both procedures (33) (Figures 9.1 and 9.2). Concern for patient safety prompted the FDA in April of 2003 (34) to issue a warning regarding the use of polymethylmethacrylate (PMMA) in both PV and KP.

Even in vitro the capability of KP to reliably produce height restoration in fractures and compressed vertebral bodies remains controversial (Figure 9.3). Biomechanical evaluations by Belkoff et al. (20) reported "significant" height restoration with KP than with PV. However, their investigation only looked at vertebrae that had a maximum height loss of 25%. Percutaneous vertebroplasty was noted to yield height recovery but less than KP in this study. The height gained by KP was on the order of 3 mm. Unfortunately, no in vitro investigations are available that determine if this effect can be achieved, without destroying the vertebra, when compression is more severe than 25%. Indeed, the data of Lieberman et al. (22), which shows an average height restoration of approximately 3 mm per vertebra treated, suggest that KP may have a limited effect at height restoration for many patients. Alternatively, this limited clinical result could be due to indiscriminate patient selection. Patients in the Lieberman et al. (22) series, whose average symptom duration was 5.9 months, were treated

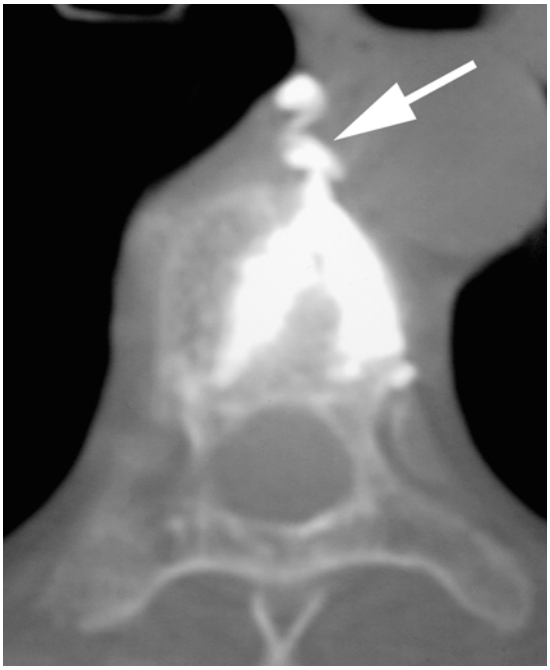


Figure 9.1. Computed tomography scan of a thoracic vertebra following kyphoplasty. There was a lateral blowout fracture of the vertebra caused by balloon inflation and a large cement leak (white arrow) into the mediastinum. The patient had severe pain requiring hospitalization and protracted analgesic therapy for weeks following therapy. (From Mathis [33], with permission.)

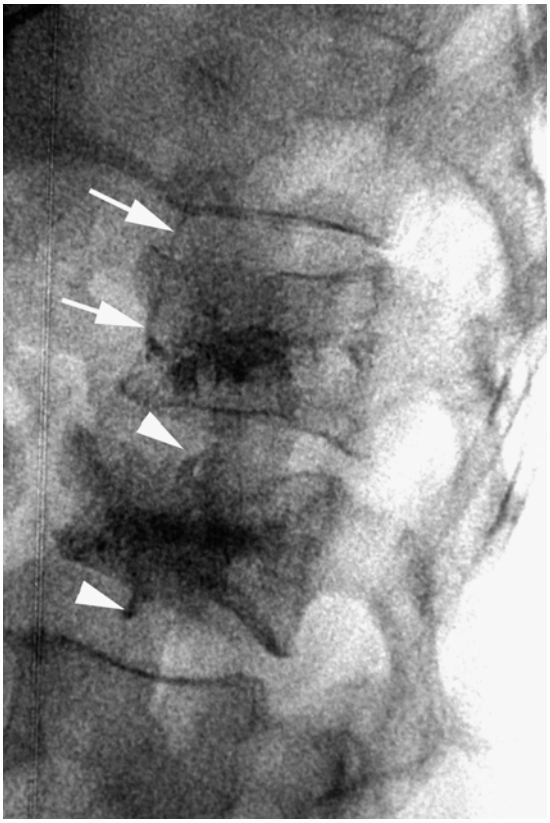
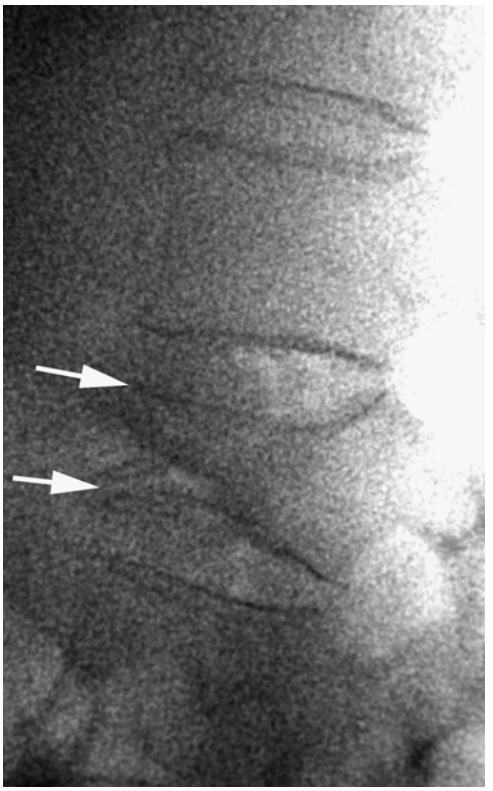


Figure 9.2. Radiograph following PV and KP showing small, asymptomatic cement leaks at both levels. The PV level (above) had a small cement leak into an adjacent vein (white arrows). The KP level (below) had small cement leaks into both adjacent disc levels (white arrowheads).



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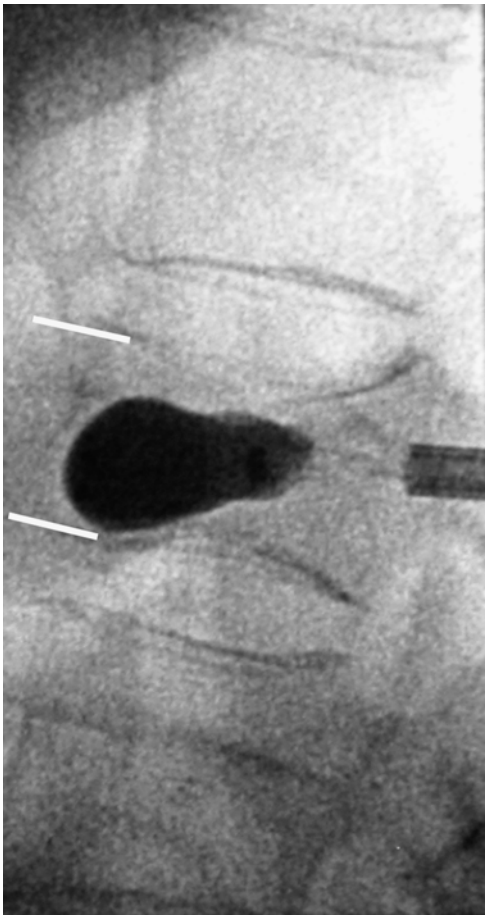

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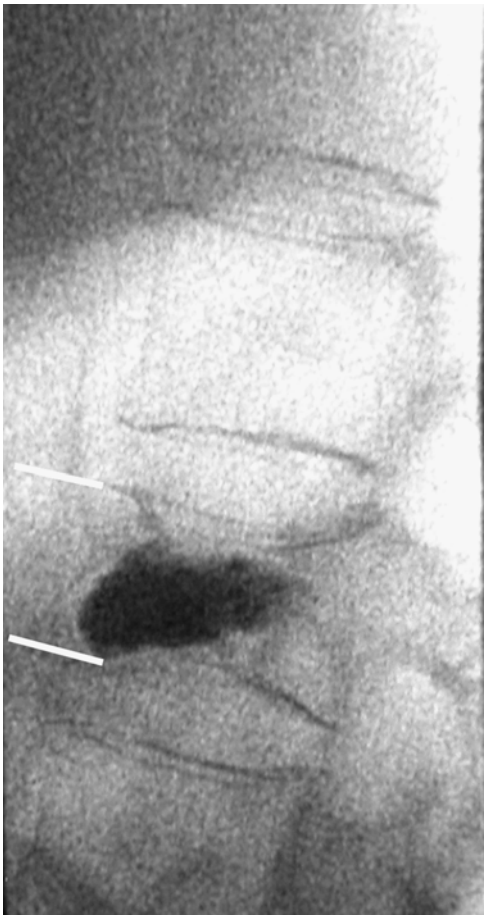

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Figure 9.3. (A) Compression fracture with anterior cleft prior to KP. Endplates are marked with white arrows. The height is estimated at 50% of the height of the adjacent level above. **(B)** Fluoroscopic image showing balloon inflation during KP. **(C)** After cement injection the height gain is approximately 4 mm or 25% of a vertebral height (when compared with the adjacent level above). There was essentially no kyphosis to start with, and this vertebra had a cleft originally and therefore would be expected to be a good candidate for height restoration with either KP or PV. (White bars indicated upper and lower vertebral margins.)

relatively late after fracture, and many of these patients could have experienced partial fracture healing prior to KP. Although these reports are anecdotal, it does seem that VCFs treated closer to their date of incidence tend to experience more height restoration (22). While the average height restoration in a clinical setting ranges from 2.5 to 3.5 mm (35), no clinical trials are available that help us select those patients who will predictably get maximum height restoration with KP. Pain relief seems less sensitive to "time since fracture." Pain relief in the series of Lieberman et al. (22) was not adversely affected by treatment delay or the amount of height restoration achieved and was similar to that seen with PV.

Vertebral height restoration reported in some KP studies has been linked to correction of associated kyphotic deformity of the spine (23,36). Theodorou and coworkers (23) reported an average kyphosis correction of 62.4% ± 16.7%; however, patients who are pain free following VP or KP usually experience less muscle spasm and tend to stand straighter with the elimination of spine pain. Mathis (33) demonstrated this effect in a PV case with 50% kyphosis reduction after PV alone (Figure 9.4). Teng et al. (37) reported kyphosis improvement

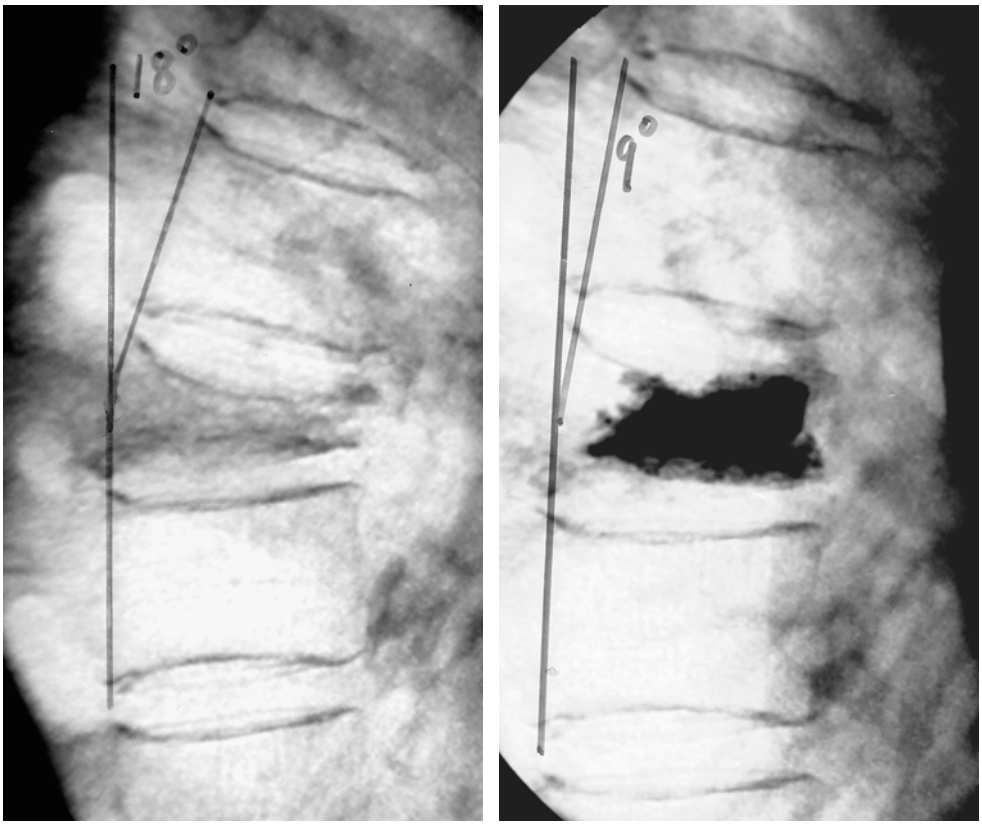

Figure 9.4. (A) Radiograph of a compression fracture and 18° of kyphosis. **(B)** Following PV there is modest height gain estimated at 3–4 mm and a reduction in kyphosis to 9°. (From Mathis [33], with permission.)

following PV in 45 of 53 patients, with 49% having a kyphotic angle reduction of 5° or more. Studies on the secondary benefits of kyphosis correction, such as improved pulmonary function, are not yet available. Obviously, this is another place where the corrections of both PV and KP need to be compared with control to determine the relative difference between the therapies.

What has often been neglected in the controversy regarding height restoration with KP is that PV can, in selected patients, also restore vertebral body height (Figure 9.4). Hiwatashi et al. (38) have shown that vertebral body height can be augmented by an average of 2.2 mm with PV simply by hyperextending the affected spinal segment. Similarly, McKiernan et al. (39) demonstrated dynamic fracture mobility in 35% of 65 VCFs that they treated with PV. When they used PV alone, they found that the "average anterior vertebral height increased 106% compared with initial fracture height (absolute increase, 8.41 ± 0.4 mm)" in patients with these mobile fractures. Their kyphotic angle reduction was 40% (39). If some height restoration can be expected from PV alone, then the meager height recovery found in a series like that of Lieberman et al. (22) may be partially measuring the effect due to prone positioning rather than that due to the balloon inflation.

Kyphon touts KP as providing a safer procedure than PV. There are no direct comparison studies to prove or disprove this claim. However, using data accumulated by the FDA (on their Web site devoted to medical devices and related complications), Nussbaum et al. (40) found that the permanent complication rates for KP were approximately 20–30 times higher on a per basis case than those reported for PV. Although not from a perfect source, the finding disputes the claim for improved safety with KP. Without question, both procedures are capable of producing permanent neurologic injury. This is usually associated with cement leaks into the spinal canal (Figure 9.5). These large cement leaks should be avoidable if good imaging equipment is used by prudent physicians.

Death is a rare complication and was equal in KP and PV, occurring in about 1/50,000 cases. Death may occur in either procedure related to severe cement allergy or cardiopulmonary failure created by the procedure (usually in those with severe chronic obstructive pulmonary disease).

Authors' Opinions

Without doubt, both PV and KP need additional trials that conclusively establish the effectiveness of each compared with conservative medical therapy and to each other. Attempts to perform these types of studies have been stymied by poor patient enrollment in the control arm of each trial. This occurs due to the positive public awareness about these augmentation techniques and the dramatic benefit that previously treated patients have experienced. Few patients are willing to accept the chance of undergoing a sham procedure when the available treatments seem reliably safe and effective. A randomized comparison of

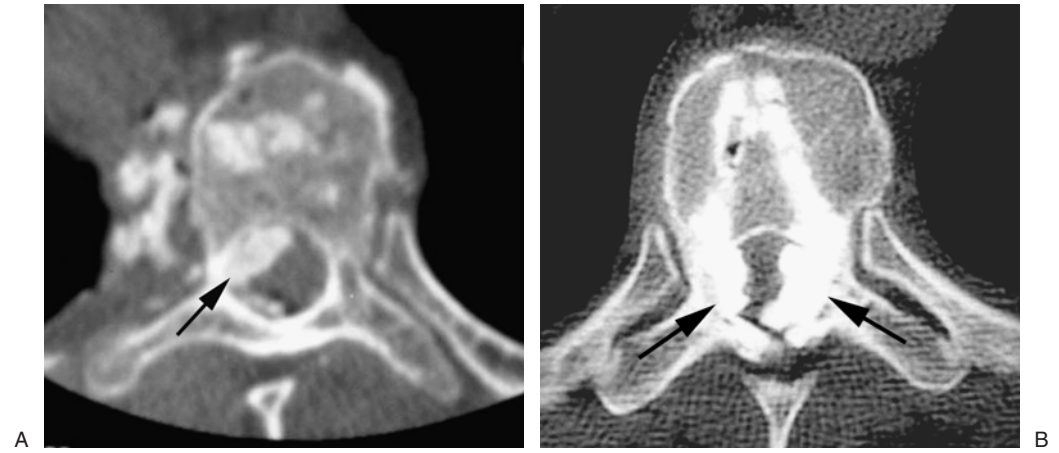

Figure 9.5. (A) Computed tomography image postvertebroplasty that shows a large cement leak into the spinal canal (black arrow) that resulted in permanent neurologic injury. **(B)** Computed tomography following kyphoplasty demonstrating a large cement leak into the spinal canal (black arrows). The complications resulted in cord compression and permanent paralysis.

PV and KP would also help establish patient selection criteria and individual procedure advantages, allowing physicians to better utilize these procedures to the patients' benefit. Until these data are available, we will likely continue to hear considerable jargon and relentless marketing claims about the relative safety and therapeutic advantages of each procedure.

The authors believe that both procedures relieve pain and can be performed with acceptable complication rates by prudent, well-trained physicians. We do note the large differential in cost of the procedures. If KP is going to be worthwhile, it should reliably produce significantly more height restoration than does PV. In our practices, we employ KP differently but agree to its use when we think that height restoration (beyond that usually achieved by PV) is feasible and would be beneficial. Our implementation of KP is driven by the "time since fracture" and is markedly different within our own ranks. One extreme requires fractures of 3 weeks or less (J.M.M.), and another tack includes fractures of less than 3 months (O.O.). Even with these guidelines, we are unable to ensure large height restoration in all patients.

At present, we recommend that both procedures be available in the treatment armamentarium of all operators, thus allowing the physician, not the marketplace, to determine patient selection criteria.

All VCFs are not the same, and certain fracture subtypes may be more amenable to one or the other procedure. Regardless of which procedure is chosen, safety depends on operator experience, excellent imaging equipment, and adequate cement opacification. Complications that have occurred with either procedure most often have been a result of poor operator judgment or experience or of inadequate anatomic and cement visualization. Time and accumulated data will

tell whether the promise of reliable height restoration with KP is realistic. Until then, careful use of either procedure should successfully relieve the pain associated with vertebral compression injury.

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