14 Osteoplastic Procedures for the Treatment of Vertebral Complications in Multiple Myeloma Patients

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Abstract Pain induced by vertebral fracture in multiple myeloma can be treated by an osteoplastic procedure. The magnitude of the pain reduction by the procedure depends on the presence of additional causes for pain as spondylosis deformans, osteochondrosis, stenosis of the spinal canal, or intervertebral nerve compression. To identify additional reasons for pain apart from a verterbal fracture-induced pain, a detailed preoperative analysis of the patients complaints is crucial for the outcome after an osteoplastic procedure. In addition, the technical aspects for performing the procedure and potential complications have to be considered as well as the stability of the cortical bone of the respective verterbal body. A complete collapse of the vertebra (vertebra plana) is an unfavorable situation for any osteoplastic procedure. In case of inflammatory or infetctious vertebral lesions (e.g. spondylodiscitis) osteoplastic procedures are contraindicated. An interdisciplinary discussion of the individual case among oncologists, radiotherpists, trauma/spien surgeons, radiologists, and osteologists/endocrinologists is a prerequisite for the identification of patients who will truly benefit from an osteoplastic procedure and to avoid overtreatment of the patient and economical expoitation of healthcare providers.

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14.1 Introduction

Pain induced by vertebral fracture in multiple myeloma can be treated by an osteoplastic procedure. The magnitude of the pain reduction by the procedure depends on the presence of additional causes for pain as spondylosis deformans, osteochondrosis, stenosis of the spinal canal, or intervertebral nerve compression. To identify additional reasons for pain apart from a vertebral fracture–induced pain, a detailed preoperative analysis of the patient's complaints is crucial for the outcome after an osteoplastic procedure. In addition, the technical aspects for performing the procedure and potential complications have to be considered as well as the stability of the cortical bone of the respective vertebral body. A complete collapse of the vertebra (vertebra plana) is an unfavorable situation for any osteoplastic procedure. In case of inflammatory or infectious vertebral lesions (e.g., spondylodiscitis), osteoplastic procedures are contraindicated. An interdisciplinary discussion of the individual case among oncologists, radiotherapists, trauma/spine surgeons, radiologists, and osteologists/endocrinologists is a prerequisite for the identification of patients who will truly benefit from an osteoplastic procedure and to avoid overtreatment of the patient and economical exploitation of health-care providers.

14.2 Osteoplastic Procedures

Osteoplastic techniques such as balloon kyphoplasty and vertebroplasty use a quickly solidifying resin (polymer from polymethylmetacrylate PMMA) or calcium phosphate cement. In malignoma-associated osteolytic lesions, only PMMA should be used. An important aspect of osteoplastic procedures is the immediate stability for the treated fractured vertebra. Usually osteoplastic procedures are performed at thoracic vertebrae 4–12 and lumbar vertebrae 1–5; cervical vertebral fractures due to pathological lesions of the spine are not a standard situation for osteoplastic techniques. During osteoplastic procedures, the patient is positioned horizontally (face down with pillows under shoulders and iliac crests) in a hyperlordotic position. Patients with an instable thorax, painful rib fractures, or instable cervical vertebral fractures should not be treated by osteoplastic techniques.

14.3 Balloon Kyphoplasty

In 1998, balloon kyphoplasty has been introduced for the stabilization of vertebral fractures (Garfin et al. 2001). Today it is an established osteoplastic procedure for routine therapy of vertebral fractures or lesions due to primary or secondary osteoporosis.

Usually balloon kyphoplasty is performed in general anesthesia after intubation of the patient. The balloon catheter is inserted into the fractured vertebral body via a trans- or extrapedicular approach. The balloon is then inflated using a contrast fluid under fluoroscopic control until it extends to the endplates of the vertebral body. The balloon is deflated and removed from the vertebra so that within the fractured vertebral body an empty void remains. Goal of the balloon expansion procedure is to restore the initial height of the vertebra. As muscle relaxation during general anesthesia and the positioning of the patient prevent any compressive forces on the spine that might cause a collapse of the space created by the balloon, the cavum remains even after removal of the balloon. Hyperlordosis as a consequence of the positioning of the patient and general anesthesia in complete muscle relaxation support the reheightening process of partially collapsed or fractured vertebrae.

As the amount of contrast fluid is known that was used to inflate the balloon, the volume of the

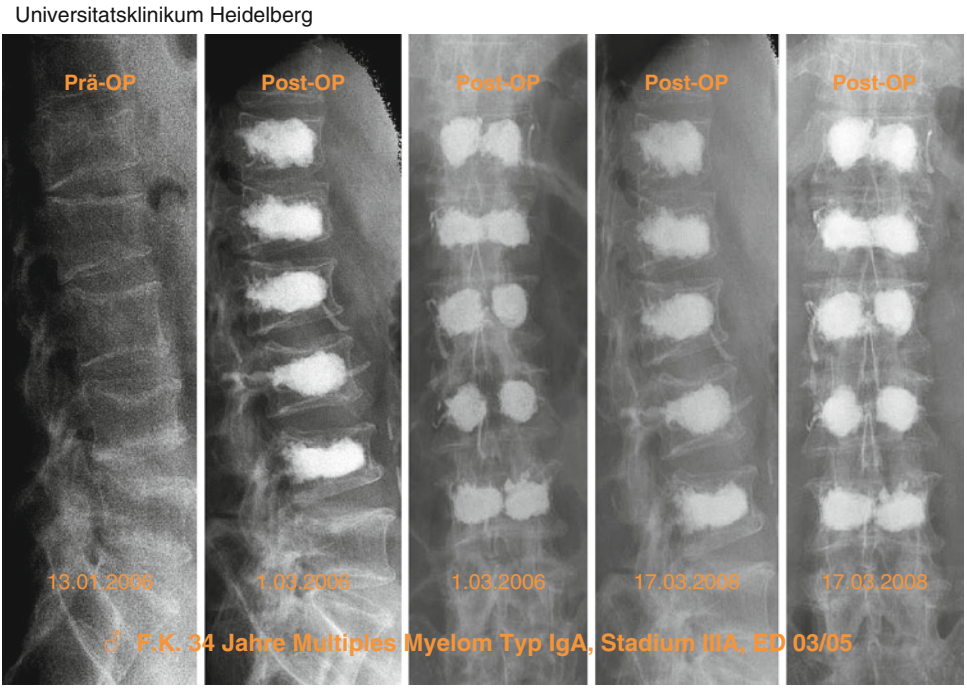

Fig. 14.1 Kyphoplasty in a 34-year-old patient was performed to improve severe lumbar back pain and to stop ongoing compression fracturing of all lumbar vertebrae due to myeloma. After 2 years, the X-rays demonstrate radio-morphologically a stable anatomical situation

balloon-created space is known and the same volume of PMMA plastic or other "cement" material is inserted into the void whereby only polymethylmetacrylate (PMMA) is used in malignoma-associated osteolytic lesions (Fig. 14.1). As PMMA and calcium phosphate cements solidify rapidly within the treated vertebral body, embolic events from PMMA or calcium phosphate cement are rare events.

14.4 Vertebroplasty

Vertebroplasty was established in 1984 for the internal stabilization of vertebral fractures and vertebral lesions (Galibert 1987; Gangi 1999). This technique is often applied by interventional radiologists in analgosedation under fluoroscopic or computer tomographic guidance.

Via a trans- or extrapedicular approach, a cannula is placed within the fractured vertebra and the PMMA plastic material is directly injected into the treated vertebra under fluoroscopic control.

In contrast to balloon kyphoplasty, vertebroplasty does not rely on the generation of a cavum of defined void within the treated vertebral body. Due to low viscosity of the PMMA plastic material and the overall technical procedure, a significant reheightening of the treated vertebra is not expected. The distribution of the PMMA plastic material within the treated vertebral body cannot be controlled; therefore, PMMA leakages are more frequent after vertebroplasty. A typical location for PMMA leakages after vertebroplasty is the venous plexus surrounding the

vertebrae which – for most cases – does not have any clinical consequences.

14.5 Comparison of Kyphoplasty and Vertebroplasty

The major technical difference between these two osteoplastic techniques is the usage of a balloon catheter for balloon kyphoplasty as described above in more detail. The balloon creates a void of defined volume within the fractured vertebra that is subsequently filled with plastic (or "cement") material of high viscosity to internally stabilize the fractured vertebral body. Leakages of the used plastic or cement material are therefore significantly less likely after balloon kyphoplasty. Another advantage for balloon kyphoplasty is the compression of spongious bone material during the intravertebral expansion of the balloon which creates a condensed spongiosa layer surrounding the void which may close possible cortical perforations of the vertebral body and allows bone repair to occur on the surface of the implanted plastic or cement material. In case of malignant disease and pathological osteolytic lesions, the malignant tissue is compressed and relocated to subcortical areas supporting local control, e.g., by radiation or chemotherapy.

The extent and the direction of dissemination of the PMMA material are less controllable in vertebroplasty leading to leakages mainly in venous plexus surrounding the vertebrae or into the muscle tissue. The direction of the dissemination is determined by areas within the vertebral body providing the lowest resistance which may predispose to leakages. Vertebroplasty may be more beneficial for the patient at an early time point when the vertebral body containing a pathological lesion shows signs of collapse (e.g., MRI bone edema) but has not lost much of its initial height, yet.

14.6 Indications and Contraindications

Osteoplastic techniques such as the balloon kyphoplasty or vertebroplasty should be considered if a patient suffers from severe-to-moderate pain due to a vertebral fracture or due to an osteolytic lesion which cannot be sufficiently controlled by pain medication. In addition, it should be considered if these minimally invasive procedures could potentially prevent future neurological complications due to instable vertebral bodies compromising the function of the spinal cord or spinal nerves. This situation occurs most often in secondary osteoporosis caused by malignant diseases such as multiple myeloma which destroys the biomechanical stability of the vertebral bodies.

In order to perform osteoplastic procedures, the cortical bone of the analyzed vertebral body should be intact – particularly the ventral and dorsal wall of the respective vertebral body – to prevent leakages of plastic or cement material into the spinal canal. Pedicular structures have also to be intact to apply the osteoplastic insertion instruments safely under fluoroscopic control. There should be no major degenerative changes of the spine that would compromise the fluoroscopic visibility of crucial vertebral structures and orientation by the surgeon during surgery.

Osteoplastic procedures are contraindicated in case of local or systemic infections. In particular, spondylodiscitis has to be excluded preoperatively as cause of a vertebral destruction. For most traumatic vertebral fractures without primary or secondary osteoporosis, osteoplastic procedures are not recommended because bone fragments will be dislocated such that neurologic complications may occur or the

morphological stability of the entire vertebral body may be jeopardized.

14.7 Randomized Controlled Studies of Osteoplastic Procedures for Vertebral Osteoporotic Fractures

No randomized, sham-controlled and blinded studies have so far been published on vertebral fractures and pain for malignancy-induced vertebral compression fractures. There is one randomized, controlled study in patients with multiple myeloma demonstrating a beneficial effect of kyphoplasty for at least 12 months as compared to non-standardized conservative management of painful vertebral fractures due to multiple myeloma (Berenson et al. 2009).

There are three randomized, controlled studies on osteoplastic procedures published for osteoporotic painful vertebral compression fractures.

The randomized FREE study (Wardlaw et al. 2009) investigated the balloon kyphoplasty in 300 patients with a mean age of 73 years. Ninety-five percent of the patients were diagnosed with primary and 5% with secondary osteoporosis. Patients had one to three vertebral fractures with a mean time interval between diagnosis of vertebral fracture and the kyphoplasty procedure of 5 weeks. All treated vertebrae had a minimum height reduction of 15% and a bone marrow edema in MRI. One hundred and thirty-eight patients treated with balloon kyphoplasty had postoperatively and also after 12 months a significant reduction in back pain and up to 6 months after kyphoplasty an improved mobility compared to the conservatively treated group. This study did not evaluate vertebral augmentation or a possible improvement of the kyphosis angle of the spine.

A double-blind randomized, sham-controlled study was published by Buchbinder et al. (2009) investigating vertebroplasty in 78 patients with a mean age of 76 years with painful osteoporotic vertebral fractures. Patients had one to two vertebral fractures not older than 12 months, and MRI confirmed bone marrow edema or fracture line. Thirty-five patients received vertebroplasty, and 36 patients underwent a sham procedure (local skin and periosteal anesthesia, synthetic material prepared to induce the PMMA smell in the operating room). In this study, no statistical difference of pain reduction between vertebroplasty and sham treatment group was noted postoperatively or 3 and 6 months after vertebroplasty.

Kallmes et al. (2009) investigated vertebroplasty in a randomized blinded, sham-controlled study in 131 patients at a mean age of 73 years with osteoporotic vertebral fractures. The patients were diagnosed with one to three vertebral fractures. The verum group ($n=68$) received mainly monopedicular vertebroplasty; for some vertebrae that did not contain "satisfactory amounts" of synthetic material, a bipedicular vertebroplasty was performed. A sham procedure was performed for control patients and a crossover of the patients was allowed after 1 month or at a later time point if pain reduction was not sufficient. Whereas the pain reduction was not significantly different between the two groups, more patients ($n=27$) in the sham-operated control group crossed over to verum. Only eight patients of the verum group crossed over to the alternative treatment.

In a competitive randomized study comparing balloon kyphoplasty to vertebroplasty (Liu et al. 2010), 50 patients per group at a mean age of 73 years were treated with vertebroplasty or balloon kyphoplasty. In the postoperative period as well as after 3 months, there was no significant difference in pain reduction between the two techniques. Vertebrae treated with balloon kyphoplasty were found to have a better vertebral augmentation and an improvement of the degree of the kyphosis.

In a non-randomized, controlled study ($n=40$), balloon kyphoplasty was compared to a standardized control treatment ($n=20$) for painful osteoporotic vertebral fractures. Balloon kyphoplasty was superior to conservative treatment regarding pain reduction over a period of at least 12 months and with regards to mobility in the first 6 months after kyphoplasty (Kasperk et al. 2005; Grafe et al. 2005). All vertebrae in the control group exhibited a progression of vertebral compression fracturing, whereas after balloon kyphoplasty a small but significant vertebral augmentation was recorded.

14.8 Studies Using Kyphoplasty and Vertebroplasty in Patients with Multiple Myeloma

Published reports on the outcome after minimal-invasive osteoplastic procedures (kyphoplasty and vertebroplasty) in patients with back pain due to multiple myeloma are based on prospective and retrospective, uncontrolled and unblinded cohort studies. In Tables 14.1–14.3, an overview on published trials utilizing kyphoplasty and vertebroplasty in patients with multiple myeloma is presented, including series with ≥10 patients with multiple myeloma.

In some of the published studies, the indication for an intervention is evaluated by an interdisciplinary team, and preoperative spine X-rays, MRI and CT scans are needed for this interdisciplinary assessment (Huber et al. 2009). Inclusion criteria for both kyphoplasty and vertebroplasty are localized painful vertebral fractures refractory to conservative treatment including opiate analgesia and/or physical therapy. In many cases, a desired more effective restoring of the height of a recently fractured vertebra leads to the selection of kyphopasty instead of vertebroplasty as the most appropriate procedure. Typical exclusion criteria for both interventions (kyphoplasty and vertebroplasty) include unstable fractures (i.e., with a destruction of the posterior wall of the vertebral body) or with retropulsed tumor tissue or bone fragments, epidural compression of neural elements, stenosis of the spinal canal, radicular pain, failure to localize symptomatic levels at the spine, intolerance to being positioned prone, significant medical contraindications (e.g., coagulopathy), or local or systemic infection. While kyphoplasty is typically performed in general anesthesia, vertebroplasty was usually conducted in local anesthesia in most patients. The treated levels by both kyphoplasty and vertebroplasty are mainly located in the thoracic and lumbar spines. There are few reports on vertebroplasty in cervical vertebral bodies (e.g., Pflugmacher et al. 2006b); however, cervical vertebral bodies are not treated routinely by osteoplastic procedures. The reported cement leakage rates are somewhat higher after vertebroplasty treatment (0–94%) compared to kyphoplasty (0–26%). In two retrospective studies, the included patients with multiple myeloma were treated either by kyphoplasty or by vertebroplasty (or both at different levels) (Fourney et al. 2003; Köse et al. 2006; Table 14.3). Köse et al. report a significantly better pain improvement after kyphoplasty compared to the vertebroplasty group after 6 and 12 months. However, due to the retrospective design and small group size as well as a possible selection bias by different indications for kyphoplasty and vertebroplasty, no direct comparison of efficacy and safety of both procedures is possible on the basis of these trials.

There is no randomized, blinded, sham-controlled clinical study to confirm the use of osteoplastic procedures in myeloma cases or other malignant entities causing osteolytic vertebral lesions. However, evidence from one randomized trial in myeloma patients (Berenson et al. 2009) and evidence provided from randomized trials in patients with primary osteoporosis are the current bases for the identification of myeloma patients most likely to benefit from osteoplastic procedures.

Table 14.1 Kyphoplasty in multiple myeloma patients

Author	Number of patients (mean age) Anesthesia	Number of levels treated	Follow-up	Outcome clinical[a]	Outcome radio-morphological	Complications
Prospective reports						
Pflugmacher et al. (2006a, b, 2007)	23 (63.5) GA	59	24 months	*64% pain reduction*VAS decreased from 8.6 to 2.4 (postoperatively) and to 3.1 (24 months) *57% improved disability* ODI improved from 78.1 to 37.3 (postoperatively) and to 33.6 (24 months)	Postoperative height improvement in 61% of vertebral bodies with height restoration of 3.5 mm (from 25 to 28.5 mm) After 2 years, slight height decrease by 1 mm Postoperative correction of kyphosis in 76.5% of patients by 8° After 2 years, slight loss of correction in 53.1% of patients by 3° Adjacent fractures in two patients	Cement leakage 10%
	20 (62.4) GA	48	12 months	*62% pain reduction*VAS decreased from 8.2 to 2.2 (3 days) and to 3.1 (12 months) *56% improved disability* ODI improved from 71.5 to 27.5 (3 days) and to 31.2 (12 months)	Postoperative height improvement in 64.5% of vertebral bodies with height restoration of 4.3 mm (47.3% of lost height) After 1 year, slight height decrease in 43.7% (21/48) of treated vertebral bodies by 1.1 mm Postoperative correction of kyphosis in 78.4% of patients by 6.3° After 1 year, slight loss of correction in 42% of patients by 1.8° One adjacent fracture after 2 weeks	Clinically asymptomatic cement leakage in 10.4%

(continued)

Table 14.1 (continued)

Author	Number of patients (mean age) Anesthesia	Number of levels treated	Follow-up	Outcome clinical[a]	Outcome radio-morphological	Complications
Lane et al. (2004)	19 (60.4) GA	46	3 months	*33% improved disability*ODI reduced from 48.9 to 32.6 Improvement in 84.2% (16/19 patients) No improvement with preoperative ODI <28	53.4% restoration of midvertebral height loss (in 42 of 46 levels) 37.8% restoration of anterior vertebral height loss (in 35 of 46 levels)	Cement leakage in 26.3%No clinical sequelae
Dudeney et al. (2002)	18 (63.5) No information on anesthesia	55	7.4 months (mean)	From SF36-questionnaire:Pain improved from 23.2 to 55.4 Physical function improved from 21.3 to 50.6	34% restoration of lost height	No major complications4% asymptomatic cement leakage
Retrospective reports						
Astolfi et al. (2009)	30 (63) GA [$n=13$]+LA [$n=17$]	45	4 years (median)	*56% pain reduction* VAS reduced from 8.7 to 2.8 (1 month), 2.1 (3 years), 3.8 (5 years) Complete pain relief in 59% Pain recurred in 10% between 3 and 12 months *58% improved disability* ODI improved from 87 to 45 (1 month), 21 (3 years), 37 (5 years) SF36 improved from 23 to 76.5 (1 month), 77.2 (3 years), 67.8 (5 years)	55% restoration of lost height, maintained to 5 years 6.8° correction of segmental kyphotic angle, decrease of 1.7° after 5 years Follow-up fractures in 14 patients (31.1%) after 18 months (mean)	Transiently increased back pain and pyrexia immediate postoperatively in two patients Two (4.4%) asymptomatic cement leakage No major complications

Table 14.2 Vertebroplasty in patients with multiple myeloma

Author	Number of patients (mean age)	Number of levels treated	Follow-up	Outcome clinical[a]	Outcome radio-morphological	Complications
Prospective reports						
Ramos et al. (2006)	12 (66) LA	19	3.2 years (median) [2–56 months]	*67% pain reduction* VAS reduced from 7.5 to 3.7 (1 day) and to 2.5 (3 years) 92% showed ≥75% pain reduction within 3 months *52% improved functional status* ECOG [0–4]reduced from 3.1 to 2.5 (1 day) and to 1.5 (3 years)	No further collapse of treated or neighboring vertebrae at last follow-up	Leakage in 94% (16/19) patients No clinical or neurological symptoms
Diamond et al. (2004)	7 (69) LA	14	6 weeks	*75% pain reduction*VAS [0–25] reduced from 19 to 4 After 1 day, six of seven patients (86%) had ≥50% decreased pain score *50–60% improved functional status* BI improved from 11.9 to 18.7 Of seven patients, three cease pain medication, three reduce analgesic >50% after 1 day	No information provided	No complications No paravertebral or foraminal leakages
Retrospective reports						
McDonald et al. (2008)	67 (66.2) LA + conscious sedation	114	12 months	Pain "at rest" improved from 3.9 to 2.7 (25%) (1 week) [69%] Pain "at activity" improved from 8.5 to 5.3 (48%) (1 week) [62%] RDQ improved from 19.5 to 11 (48%) (1 week) [56%] 70% of patients reported improvement in mobility after 1 week Clinical outcomes maintained for 1 year of follow-up Narcotics discontinued 16%, decreased 49%, increased 5%	No information provided	Twelve patients (17%) showed subsequent vertebral compression fractures, six within 12 months, Seven adjacent, five symptomatic treated with second VP 19% asymptomatic cement leakage

(continued)

Table 14.2 (continued)

Author	Number of patients (mean age)		Number of levels treated	Follow-up	Outcome clinical[a]	Outcome radio-morphological	Complications
Thang et al. (2008)	27 (65) LA: if 1 level treated GA: if >1 level treated	117	1 month (41 months)	1 month: *72% pain reduction* VAS reduced from 7.5 to 2.1 70–100% pain reduction in 70% 0–49% pain reduction in 16.7% *55% improved functional status* ECOG [1–5] reduced from 1.9 to 0.86 Opiate consumption interrupted in 59.3%, partially reduced in 22.2% 70.4% decrease in opiate dose		No evidence for progression at treated site after median follow-up of 41 months	No major complications One cement leakage L5 nerve root correlated with appearance of a transient sensory defect, which resolved within 3 weeks Eight clinically not relevant cement leakages (24%)
Shimony et al. (2004)	50 (62.7) Cancer patients 14 MM LA + conscious sedation	129	3 months (median)	Outcomes of myeloma subgroup not reported separately Pain reduction in 82% of patients Improved mobility in 52% of patients		No information provided	No major complications Increased pain in seven patients (with preoperative mild-to-moderate epidural involvement) (Immediately after VP in three patients, treated with epidural steroid injection of steroid infusion, after several weeks in four patients, treated by neuroforaminal epidural nerve root block)

Table 14.3 Reports including both kyphoplasty and vertebroplasty in patients with multiple myeloma

Author	Number of patients (mean age)Anesthesia	Number of levels treated	Follow-up	Outcome clinical[a]	Outcome radio-morphological	Complications
Retrospective reports						
Köse et al. (2006)[b]	34 KP: 18 (63.7) VP: 16 (62.2) LA + midazolam if needed	KP: 22 VP: 28	12 months	*KP: 73% pain reduction* KP: VAS [0–50] improved from 36 to 12.1 (6 weeks), 8.6 (6 months), 9.7 (12 months) *VP: 64% pain reduction* VP: VAS improved from 37.8 to 15.3 (6 weeks), 12.2 (6 M), 13.5 (12 months) → Significant better improvement after KP after 6 + 12 months compared to VP Decreased need of analgesics	Mean height restoration 54% No collapse of adjacent vertebrae	One superficial wound infection, resolved No neurologic or pulmonary complications No cement leakage
Fourney et al. (2003)[c]	56 (64) Cancer patients KP: 15 VP: 34 KP + VP: 7 (at separate levels) 21 MM: KP: 11 VP: 6 KP + VP: 4 KP: GA VP: GA or LA	97 KP: 32 VP: 65	4.5 months (median) [1 day–19.7 months]	Outcomes of myeloma subgroup not reported separately *Entire study group* VAS reduced from 7 to 2 Immediate pain improvement or complete relief after 84% of procedures (VP: 86%; KP: 80%) Maintained improvement through 1 year No significant functional improvement Decreased analgesic usage at 1 month	42% restoration of lost height and 4.1° improved kyphosis after kyphoplasty	9.2% (6/65) asymptomatic cement leakage after vertebroplasty No leakage after kyphoplasty No procedure-related clinical complications (2 patients subsequent spinal surgery not related to procedures)

(continued)

Table 14.3 (continued)

VAS Visual Analogue Score (Pain) [0–10]; differing ranges are indicated in brackets
ODI Oswestry Disability Index [0–100]
ECOG Eastern Cooperative Oncology Group scale [1–5] – functional status
BI Barthel Index, disability score [0 (worst disability) – 20 (no disability)]
RDQ Roland-Morris Disability Questionnaire [1–23]
SF36 Short Form 26 Health Survey [%]
MM Multiple myeloma
LA Local anesthesia
GA General anesthesia
KP Kyphoplasty
VP Vertebroplasty
[a]% Pain reduction and improved disability/functional status represents the percentage of change of the last reported follow-up compared to the preoperative value
[b]Indications for kyphoplasty: >50% loss of vertebral height vertebroplasty: <50% loss of vertebral height
[c]Indications for kyphoplasty: (1) kyphosis >20°, (2) disruption of posterior vertebral cortex, (3) significant vertebral collapse vertebroplasty: (1) severe vertebral collapse, when insertion of balloon device not possible, (2) GA or longer procedure time not tolerated

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