Kyphoplasty Techniques

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Scott A. Vincent, Emmett J. Gannon, and Don K. Moore

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Abstract

Galibert and Deramond performed the first percutaneous vertebral cement augmentation in 1984 for the treatment of painful vertebral hemangiomas. Over the next decade, its use became more widespread and modifications to the technique led to the development of kyphoplasty. Currently, both kyphoplasty and vertebroplasty are most commonly used in the USA for the treatment of painful osteoporotic

S. A. Vincent (✉) · E. J. Gannon
Department of Orthopaedic Surgery and Rehabilitation, University of Nebraska Medical Center, Omaha, NE, USA
e-mail: scott.vincent@unmc.edu; emmett.gannon@unmc.edu

D. K. Moore
Department of Orthopaedic Surgery, University of Missouri, Columbia, OH, USA

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vertebral compression fractures. More than 50 million people in the USA have osteoporosis or low bone density and this number is projected to only increase with the aging population. Osteoporotic vertebral compression fractures are one of the most common manifestations of the disease, with more than 1.4 million occurring worldwide each year. These vertebral compression fractures can be a source of substantial morbidity and disability. Other common uses of vertebroplasty and kyphoplasty include the treatment of vertebral body pain or fracture secondary to metastatic disease or primary bone tumors. There have been numerous studies investigating the utility of their use. Despite the large volume of research, there is still debate on the exact role and efficacy of both vertebroplasty and kyphoplasty. Prior to recommending or performing percutaneous vertebral augmentation, physicians should weigh the potential benefits andcomplications for each individual being considered for treatment.

Keywords

Kyphoplasty · Vertebroplasty · Osteoporosis · Vertebral compression fracture · Kyphoplasty technique · Percutaneous vertebral augmentation

Introduction

Percutaneous vertebral body augmentation was first performed in France by Galibert and Deramond who percutaneously injected acrylic cement into the vertebral body for treatment of painful hemangiomas in 1984 (Galibert et al. 1987). This technique was given the name vertebroplasty and was eventually used in the USA in the early 1990s where its main use has been in the treatment of osteoporotic vertebral body compression fractures (VCFs). Kyphoplasty was later developed with the added potential of deformity correction due to the addition of an inflatable bone tamp. The bone tamp is theoretically able to improve the vertebral height and decrease the amount of kyphosis that resulted from the VCF, while also creating a cavity for the cement to be injected. Since its development, the use of kyphoplasty has had widespread use for the treatment of VCFs. In 2007, 130,000 patients with VCFs were treated with either vertebroplasty or kyphoplasty (Mauro 2014). A majority of these VCFs occur in patients with osteoporosis, however, they can also occur in other patient populations including those with hemangiomas, multiple myeloma, and metastatic lesions (Wang et al. 2015). In the USA alone, the estimated number of adults in 2010 with osteoporosis and low bone mass was greater than50 million (Wright et al. 2014). By the year 2020, it was expected that the total number of patients with severe osteoporosis will exceed 14 million (National Osteoporosis Foundation 2002). Due to the aging population, it is predicted that greater than three million osteoporotic fractures will occur in 2025, with more than one-quarter of these affecting the vertebral column (Burge et al. 2007). Osteoporotic VCFs have been shown to significantly affect a patient's quality of life, both mentally and physically. The risk of mortality is also significantly increased after an osteoporotic VCF, with a mortality risk 25% higher than after hip fracture (Cauley et al. 2000). In addition to the significant long-term effect on morbidity and mortality, VCFs can also have an immediate impact on a patient's health. In many cases, narcotics are used as a primary means to attain adequate pain control. Unfortunately, these medications carry a significant risk of serious side effects. Their use for treatment among the commonly affected elderly patient is of particular concern as the geriatric population routinely experiences more severe complications with opioid use. Bed rest is another commonly used treatment modality for patients with painful VCFs. Like narcotics, bed rest can have a substantial impact on an individual in a very short period of time. Bed rest can not only lead to extensive deconditioning, but it has been shown to have an almost immediate detrimental effect on bone quality (Kortebein et al. 2008). Therefore, the risk of short- and long-term consequences can begin to increase immediately after sustaining a 9ol compression fracture severity and complexity varies greatly, and therefore treatment decisions and management strategies should be individualized based on the clinical exam and fracture morphology. Treatment usually begins with medical and nonoperative management; however, in some cases percutaneous vertebral augmentation should be considered. Due to the significant pain some patients experience with VCFs, many physicians believe vertebral augmentation is an excellent option in the treatment pathway, as conservative treatment options fail to provide symptomatic relief. There have been numerous studies investigating the efficacy of vertebroplasty and kyphoplasty that have showed varying degrees of efficacy. Two of the more popular studies that demonstrated no benefit of vertebroplasty were published in the *New England Journal* in 2009, in which both found no difference in outcomes between vertebroplasty and a sham procedure in treatment of osteoporotic VCFs (Kallmes et al. 2009; Buchbinder et al. 2009). A significant benefit, however, was found in well-regarded articles published in the *Lancet* journal, supporting the use of vertebroplasty and kyphoplasty (Klazen et al. 2010; Wardlaw et al. 2009; Clark et al. 2016). The inconsistent findings have led to no general consensus among physicians on the role of percutaneous vertebral augmentation in the treatment of VCFs. The most recent American Academy of Orthopaedic Surgeons (AAOS) clinical guidelines for treatment of osteoporotic VCFs recommend against the use of vertebroplasty (McGuire 2011). In addition, according to the AAOS guidelines, kyphoplasty is considered an option for patients with osteoporotic VCFs with a limited strength of recommendation. Therefore, when considering using percutaneous vertebral augmentation for treatment of a VCF, a physician must consider the risks and benefits of the procedure for each individual.

Indications

The most common indication for the use of kyphoplasty is in the treatment of an unhealed vertebral compression fracture with persistent pain despite conservative therapy. Commonly accepted failures of medical therapy include inadequate relief with analgesic medications, adverse side effects with their use (namely narcotics), and hospitalization secondary to uncontrolled pain. Other medications that have been used include the initiation of osteoporotic-specific medications to prevent future fractures, namely bisphosphonates and teriparatide. Other forms of conservative care that are often used include bed rest and bracing. Much like narcotic therapy, these nonoperative methods are often poorly tolerated by the elderly population. Bed rest leads to deconditioning and has detrimental effects on bone quality, while bracing can be uncomfortable and may restrict pulmonary function. Therefore, the inherent risks and benefits of various conservative treatment modalities should be weighed based on inherent patient factors.

For those failing conservative management, kyphoplasty can be considered. The exact length of time for conservative management is still unclear. Many would consider 3–6 weeks as a reasonable time period of trialing nonoperative care and then considering cement augmentation in those that do not respond. In addition, there is advocacy for earlier utilization of vertebral augmentation in those with incapacitating pain and the inability to tolerate mobilization. The advocacy for earlier utilization of kyphoplasty in select cases is supported by the high mortality rate with VCFs and how commonly nonoperative modalities can be poorly tolerated or cause detrimental effects.

Osteoporosis is the leading cause of painful VCFs that necessitate consideration for treatment. In addition to osteoporosis, other causes of VCFs that may benefit from kyphoplasty include metastatic disease, secondary osteoporosis (i.e., steroid-induced osteoporosis), or multiple myeloma. Kyphoplasty can also be considered in patients without a vertebral fracture that exhibit a painful vertebra secondary to primary bone tumors, like a hemangioma or giant cell tumor, or in those with metastatic disease. In addition, it can be considered in patients with Kummell disease, which is the development of a vascular necrosis of the vertebral body due to a VCF nonunion. Special consideration should be taken in those with metastatic disease and primary tumors of the spine. The timing and treatment plan is very much dependent on tumor type and stage of disease. Collaboration with medical oncologists is warranted in order to determine appropriateness of treatment. It is also important to consider timing of the treatment in regards to specific chemotherapy and radiation therapy plans. There is currently no consensus on the best timing of treatment, whether before, during, or after chemotherapy or radiation treatment. There is a theoretical risk of tumor dissemination after the injection of pressurized cement, leading some physicians to recommend its use after radiation therapy in certain circumstances. The timing of cement augmentation depends largely on the tumor tissue type and planned medical or radiation treatment. For example, multiple myeloma can be treated with cement augmentation at any time as the surgical trauma is minimal and the risk of wound complication in the setting of ongoing or prior radiation therapy is extremely low.

Contraindications

There are both relative and absolute contraindications to the use of kyphoplasty. Absolute contraindications include resultant neurologic injury secondary to the fracture, active spinal or systemic infection, bleeding diatheses, and cardiopulmonary or other health compromise that would impede undergoing the necessary general anesthesia or sedation safely. Allergy to the bone filler/cement or opacification agents is also considered an absolute contraindication. Relative contraindications include instances where the risks and difficulty of performing kyphoplasty are substantially increased. These include disruption of the posterior cortex of the vertebral body, extension of a tumor into the epidural space, significant canal stenosis, and extensive loss of the vertebral height (>70%). Most of these instances result in a significantly increased risk of spinal cord or nerve root injury due to cement leakage. With advanced vertebral collapse, placement of the cannula can become significantly more challenging. Some physicians also recommend against performing kyphoplasty on more than three levels during a single procedure due to the potential risk of developing a cardiopulmonary injury secondary to cement, fat, or marrow embolization to the lungs. The presence of radiculopathy is also considered to be a relative contraindication to the use of kyphoplasty. As a result of the increased risk of complications in patients with these relative contraindications, physicians should proceed with caution and these cases should only be performed by experienced practitioners (Herkowitz and Rothman 2011; Mauro 2014) (Fig. 1).

Initial Workup

History and Examination

Obtaining a full and detailed history is essential in the initial assessment of a patient with a known or suspected VCF. Patients with an acute VCF will typically present with new onset midline back pain that is commonly worsened with standing and motion, especially flexion. Most osteoporotic vertebral compression fractures will present without a history of a fall or trauma (Savage et al. 2014). Key elements of the history include timing of symptom onset, pain severity, individual risk factors including history of previous cancer, diagnosis of osteoporosis, or signs or symptoms concerning for infection. Attempted treatments and their efficacy, including any improvement in symptoms or adverse side effects, are also very important to document. In addition, patients should be inquired on whether they have had any radicular-type symptoms or perceived neurologic changes in sensation, strength, coordination, or bowel and bladder control. Physicians should also inquire about the patient's functional status, past medical history, and use of anticoagulation therapy. Assessing the patient's overall state of health is vital in determining appropriate treatment options and strategy.

The physical examination is another essential piece in the evaluation of a patient with a VCF. Typically, patients will have tenderness to

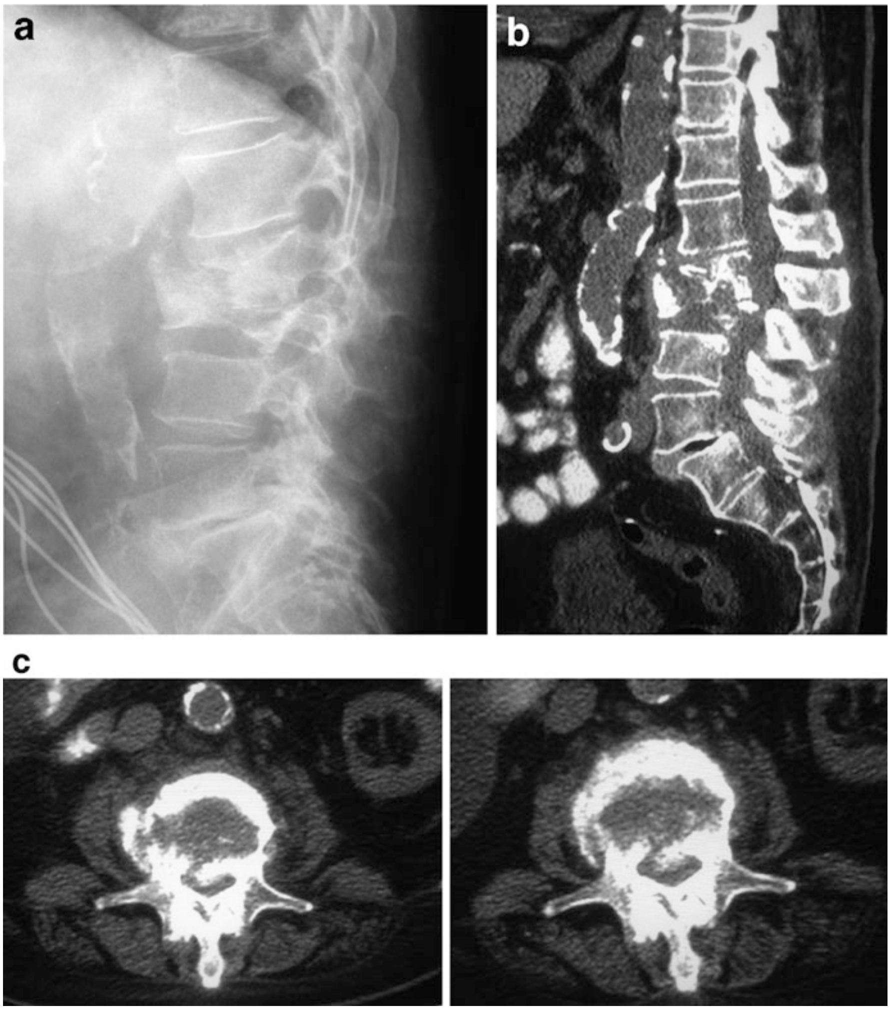

Fig. 1 Sagittal fluoroscopic (**a**) and sagittal (**b**) and axial (**c**) computed tomography images of a burst fracture. There is retropulsion of fracture fragments into the spinal canal and the posterior cortex is also noted to be compromised. These findings would be contraindications to the use of vertebral cement augmentation

palpation over the affected level's spinous process. It is critical to ascertain the level at which the patient is having symptoms, which is especially true in patients with multiple VCFs. The clinical exam and its correlation with imaging findings will then assist in determining which level(s) may benefit from intervention. It is also important to note that tenderness to palpation may not always be present in a patient with an unhealed VCF. Therefore, a lack of localizable pain with palpation should not preclude treatment. In these cases, the patient's history and imaging correlation is imperative in identifying a symptomatic VCF. In addition, a thorough neurologic assessment is the cornerstone of a complete examination and should be done in all patients. This preoperative neurologic assessment will not only identify patients that can potentially worsen with vertebral augmentation, and should be excluded from consideration, but will also aid in detecting any postoperative changes or complications.

Imaging

For every case, imaging of the spine is obtained in order to establish a diagnosis by correlating imaging results with a patient's clinical symptoms and examination findings. Imaging will not only identify potential candidates for intervention, but will also identify those in which cement augmentation would be contraindicated. Comparison to previous imaging is very beneficial in detecting new fractures and lesions or progression of those that had been previously identified. The diagnosis of a new VCF can be confirmed through either magnetic resonance imaging (MRI), serial radiographs, or bone scintigraphy.

Plain radiographs of the spine should be the first imaging modality obtained when evaluating a patient with a suspected VCF. It is an easily attainable assessment of the spine and also an excellent resource for comparison to previous or future radiographs. In addition to the wide accessibility, plain radiographs are a considerably more cost-effective source of initial evaluation when compared to more advanced imaging modalities. Furthermore, standing radiographs of the spine supply an excellent assessment of a patient's coronal and sagittal alignment and stability. This is of special importance when assessing the common kyphotic deformity that can result from a VCF, as well as any potential instability of the vertebral column.

Magnetic resonance imaging (MRI) is another useful adjunct when imaging a patient with known or suspected VCF. An important role of MRI is determining the acuity of VCFs. This can be helpful in patients without previous radiographs or in patients with a history of multiple fractures and equivocal exam findings. In these situations, having the ability to distinguish between new, symptomatic fractures and chronic fractures is essential to guide appropriate treatment when considering kyphoplasty. Findings consistent with an acute fracture include an increased signal on the short tau inversion recovery (STIR) and T2-weighted sequences, and decreased intensity on the T1-weighted sequence. Chronic fractures, which typically are not responsive to kyphoplasty, will not have an increased signal on STIR or T2-weighted sequences. For cases in which the cause of a pathologic fracture is unknown, a MRI is very useful in establishing a differential diagnosis and identifying patients that may require further diagnostic workup. Visualization of cord or nerve root compression from retropulsed fracture fragments, tumors, or other pathology is also best accomplished with a MRI.

Computed tomography (CT) can also be a beneficial resource in the preoperative evaluation of a patient with VCF or pathologic compromise of the vertebral body. A CT is most useful in assessing the integrity of the posterior cortex of the vertebral bodies. When the posterior cortex is compromised, injection of cement can lead to cement leakage or further displacement of the compromised bone posteriorly into the spinal canal. Therefore, a CT is especially valuable in patients in which the integrity of the posterior cortex is in question. It is also the imaging modality of choice for identifying other osseous injuries, and evaluation of the spine in patients involved in high-energy trauma. A CT is also useful in patients that cannot undergo a MRI safely, such as those with a pacemaker.

Bone scintigraphy is another imaging modality that can be used to differentiate between healed and unhealed fractures in patients that cannot undergo MRI. In patients with acute or unhealed fractures, a higher metabolic activity will lead to an increased uptake of technetium-99m. Although bone scintigraphy has a high sensitivity, it has a low specificity as it can continue to show increased uptake for greater than 1 year after a significant amount of healing has occurred (Savage et al. 2014). Another disadvantage of bone scintigraphy is the inability to directly visualize the spinal cord and nerve roots and the lack of spatial resolution. Single photon emission computed tomography (SPECT) is a form of bone scintigraphy that allows for improved fracture localization and characterization due to the improved spatial resolution. A MRI is still preferred over bone scintigraphy, as it is more reliable in assessing the chronicity of a fracture and provides improved visualization of the spinal cord, nerve roots, and surrounding soft tissues (Figs. 2 and 3).

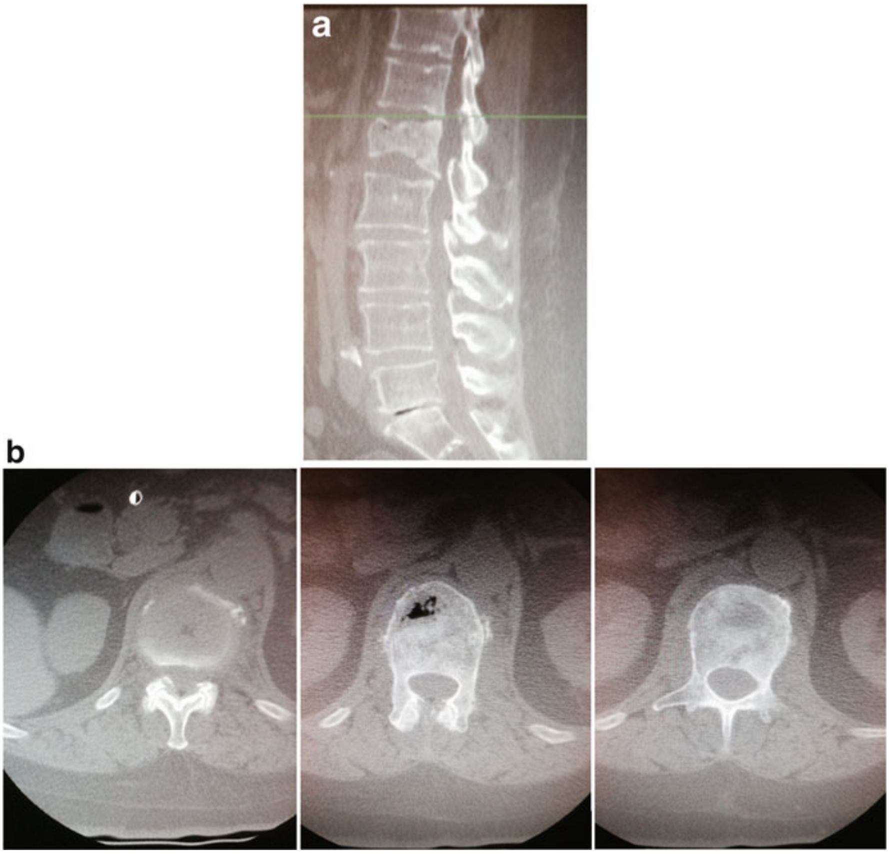

Fig. 2 Sagittal (**a**) and axial (**b**) computed tomography images of a L1 compression fracture secondary to metastatic colon cancer. No retropulsion of fracture fragments into the spinal canal noted. The integrity of the posterior cortex of the vertebral body is noted to be intact

Preoperative Testing

If a patient is considered a candidate for kyphoplasty, there are several laboratory tests that should be routinely obtained prior to proceeding. These include coagulation studies, a basic metabolic panel, and a complete blood cell count. In some instances, further testing may be warranted, such as inflammatory markers, an electrocardiogram, or a chest radiograph. Determining the necessary preoperative testing should be done on a case-by-case basis and should be based on specific patient risk factors. Ideally, this should be accomplished through a team approach that involves the physician performing the procedure, anesthesiologist, hospitalist, and in some circumstances, other medical subspecialists. It is critical to ensure a patient is medically optimized prior to the procedure in order minimize the risk of intraoperative or postoperative complications. Early involvement with referral and establishment of care with a specialist in metabolic bone disease in order to help formulate a postoperative treatment plan to prevent future osteoporotic fractures is also beneficial. Recently, the American Orthopaedic Association developed the Own the Bone program to address the need for comprehensive care of patients with metabolic bone disease. This national postfracture, system-based, multidisciplinary fragility fracture prevention initiative is designed to address physician and patient behavior in an effort to reduce the incidence of further fragility fractures.

Fig. 3 Sagittal magnetic resonance image demonstrating a L2 compression fracture with accompanying increased signal within the vertebral body, indicating it is most likely an acute fracture

Technique

Before a definitive decision is made on the treatment plan and utilization of the vertebral cement augmentation, a well-informed discussion with the patient regarding the risks and benefits and alternative treatments should occur. Once a patient is determined optimized, they are brought to the operating room or radiology suite and general anesthesia or sedation is initiated. In contrast to vertebroplasty, which is generally performed under local anesthesia, kyphoplasty is usually performed under general anesthesia at most institutions. In patients with a significantly increased risk of medical complications with general anesthesia, the procedure can be performed with intravenous (IV) analgesia and sedation only, as demonstrated by Mohr et al. (2011). The decision between general anesthesia or intravenous sedation should be made in conjunction with the anesthesia provider. Adequate anesthesia should routinely be attained prior to positioning, as required movement and maneuvering can be exceedingly painful for patients with VCFs. The patient is then placed in the prone position and cushion support or chest and pelvic boosters are properly positioned to allow for spine extension. Proper positioning with adequate spine extension will facilitate reduction of the typical kyphotic deformity. The arms should also be placed toward the head of the bed to facilitate fluoroscopic visualization during the procedure. In patients with suspected limited shoulder motion, a preoperative exam testing the range of motion of both shoulders can be beneficial in anticipating lack of abduction and externals needed for positioning. In these cases, the arms may need to be placed in line with the spine. A significant portion of the patient's undergoing kyphoplasty will have underlying osteoporosis, therefore care should be taken during the transferring and positioning of the patient to prevent additional fragility fractures such as rib or sternal fractures.

After attaining adequate anesthesia and positioning of the patient, the next step is identifying the affected level(s) with fluoroscopy. Fluoroscopy is used throughout the procedure and some physicians find the use of simultaneous biplanar fluoroscopy to be beneficial. It is imperative for the correct vertebral level to be treated and close attention to preoperative and intraoperative imaging is critical in ensuring this is accomplished. For both thoracic and lumbar levels, it is helpful to count from sacrum up to the vertebral body to be addressed. Identifying transitional vertebra or anatomic variations preoperatively is very useful in order to correctly correlate with intraoperative fluoroscopic images. Obtaining both thoracic and lumbar X-rays preoperatively is imperative whenever treating thoracic level pathology in order to ensure consistency when counting from the sacrum up to the thoracic level to be treated. It can be helpful to have a discussion with the radiologist preoperatively in advance so in order to ensure the correct levels are labelled and identified prior to surgery. These steps are especially useful in cases in which the thoracic vertebral fractures reduce with positioning, which can lead to increased difficulty in identifying the correct level intraoperatively. Obtaining repetitive fluoroscopic images with a radio-opaque metallic instrument used as reference point while the counting is being done can also be extremely helpful. Placing a sterile marker such as a spinal needle adjacent to the spinous process of the vertebral body can provisionally identify the correct level. If using local anesthesia or IV sedation, a local anesthetic can be delivered via a 22-gauge needle into the skin and periosteum prior to the insertion of the larger needle and cannula. An additional benefit of this step is the ability to make adjustments to the insertion site and trajectory prior to insertion of the larger-gauge needle. A size of 11- or 13-gauge needle is sheathed in a cannula and a Jamshidi needle is then inserted. Prior to this step, a small incision can be made to allow for easier insertion and trajectory adjustments. There are two specific approaches to the vertebral body that can be utilized. These include a transpedicular approach or an extrapedicular approach. The transpedicular approach begins with needle insertion at the posterior aspect of the pedicle, followed by subsequent cannulation through the length of the pedicle and into vertebral body. The extrapedicular approach entails the needle traveling along the lateral aspect of the pedicle and then inserting into the vertebral body at the junction of the pedicle and vertebral body. One benefit of the extrapedicular approach is that it allows for a more medial tip placement of the needle in the vertebral body which may allow more centralized cement placement. This can be difficult to attain with the transpedicular approach as the path is limited by the anatomic configuration of the pedicle. An advantage of using the transpedicular approach is the utilization of an intraosseous path that protects against soft tissue structure penetration and potential neurologic injury. A general guideline for both approaches, to decrease the risk of accidental spinal canal or neural foramen penetration, is to keep the needle superior to the inferior cortex of the pedicle on the lateral fluoroscopic image and lateral to the medial cortex of the pedicle on the AP view. Advancement of the needle is done under fluoroscopic guidance, ensuring proper trajectory. A mallet or orthopedic hammer can be used to assist in needle advancement. Once the needle is advanced into the vertebral body, just anterior to the junction of the pedicle and the body, the stylet is removed and a working channel through the cannula is utilized for advancement of the balloon tamp. If necessary, biopsy needles can be used at this point to obtain samples prior to balloon tamp and cement insertion. The cannula is then brought back posteriorly to the junction of the pedicle and the vertebral body. Kyphoplasty can be performed through either a bipedicular or unipedicular approach. If the bipedicular approach is used, the Jamshidi needle or needle and cannula placement on the contralateral side is done at this time. The balloon bone tamp is then inserted and advanced within the vertebral body. The balloon tamp is then inflated under intermittent fluoroscopic visualization and pressure monitoring via a digital manometer. When inflating the balloon, inflation is stopped once the fracture has been adequately reduced; the balloon tamp reaches maximal pressure or volume, or cortical contact occurs. After one of these objectives is

Fig. 4 Example of an operating room setup used for performing a kyphoplasty procedure. In this example, utilization of simultaneous biplanar fluoroscopy is accomplished with the use of two C-arms

attained, the balloon is then deflated and removed. The cement, most commonly polymethyl methacrylate (PMMA), is then injected through the cannula until the cavity created by the balloon tamp is filled. A radio pacifier is required to appropriately visualize cement administration fluoroscopically. Most commercially available PMMA formulations contain either barium sulfate ($BaSO_4$) or ziroconium dioxide (ZrO_2) as a radiopacifier. Radiopaque cement is necessary to monitor for extravasation and ensure adequate filling of the cavity formed by the balloon tamp. In addition to the inclusion of a radiopacifier attaining an appropriate level of viscosity prior to its injection is critical. This will assist in preventing extravasation and also facilitate cement travel through the cannula. According to Lieberman et al., cement with a low viscosity or longer liquid phase is preferred for vertebroplasty, while cement with high viscosity or longer working phase is more ideal for kyphoplasty (Lieberman et al. 2005). The patient is then left in the supine position until the cement has cured. The cement plungers are inserted into the working cannula after the delivery of the cement as close as possible to the end of the cement filler. This prevents leaving a cement column that may harden inside the cannula and thus remain in the soft tissue after the cannulas are removed. Once it has cured, the cannulas are removed, dressings are applied, and the patient is transported back to their hospital bed. (Herkowitz and Rothman 2011; Mauro 2014) (Fig. 4).

Postoperative Care

After the patient is safely transported back to the hospital bed, the patient is brought to the post-anesthesia care unit for routing postoperative monitoring. Some physicians recommend obtaining a routine postoperative chest X-ray in patients undergoing thoracic kyphoplasty to rule out iatrogenic pneumothorax. Select patients may benefit from an overnight observational stay, while most patients are safe for discharge later the same day. Most of the care postoperatively focuses on assessing for any neurologic changes and attaining adequate pain control. For the same reason kyphoplasty may be indicated, avoidance or minimized use of narcotics should be a priority when formulating a sufficient analgesic regimen in order to avoid their deleterious side effects. If the patient develops neurologic deficits, or other concerns for cement extravasation, CT imaging should be obtained urgently. Physicians must also be cognizant of the potential for pulmonary embolism, particularly if multiple levels were addressed. A chest X-ray to rule out pulmonary edema should be considered for patients with postoperative dyspnea.

Establishing appropriate follow-up is necessary for these patients as many will require treatment for their underlying cause of fracture. Most frequently, patients will require management of their underlying osteoporosis and it is important to make the appropriate referrals for necessary testing and treatment of underlying metabolic bone disease. Furthermore, many patients will be at high risk of subsequent fractures, and education regarding future risk of fracture is essential. In follow-up, if signs or symptoms of subsequent fractures occur, providers should obtain new imaging as appropriate. Routine follow-up radiographs should also be obtained and can be useful for comparison if further fracture or deformity occurred (Fig. 5).

Complications

Complications following percutaneous vertebral augmentation are generally rare; however, they can be a cause of significant morbidity. Complications that do occur are commonly a result of cement extravasation, subsequent fracture, or embolization. Other potential complications include infection, pneumothorax, nerve or spinal cord injury, pain exacerbation, hematoma formation, and intraoperative fractures (pedicle, vertebral body, and rib). The type of fracture being treated also plays an important role in risk of complications as malignancy-related fractures result in a higher complication rate compared to osteoporotic VCFs (Mathis et al. 2001; Barragan-Campos et al. 2006). When comparing kyphoplasty and vertebroplasty, the rate of procedure-related complications is significantly lower with kyphoplasty (Lee et al. 2009). Cement extravasation is a common occurrence for both kyphoplasty and vertebroplasty, but it is rarely symptomatic. In some circumstances, however, cement extravasation can lead to neurologic deficits, which may necessitate decompression and reconstruction (Savage et al. 2014). Lee et al. reported the rate of symptomatic cement extravasation is significantly lower in kyphoplasty compared to vertebroplasty (Lee et al. 2009). The study found the rate of symptomatic cement extravasation was 1.48% after vertebroplasty and 0.04% following kyphoplasty. If there is concern for complications related to cement extravasation, a CT scan is the imaging modality of choice to best visualize cement leakages. Embolization is another potential complication that is commonly asymptomatic; however, it may have severe cardiopulmonary consequences. The rate of cement embolization following percutaneous vertebral augmentation varies between 2.1% and 26% (Wang et al. 2012). The incidence appears to be lower following kyphoplasty compared to vertebroplasty. This is likely a result of the creation of a cavity that leads to the cement being injected under lower pressure. The emboli can either be from the bone marrow fat or the cement as a small fragment or as monomer that is later polymerized at a distant location. Regardless of cause, this may lead to cardiopulmonary embolism, which can be fatal in very rare cases. Clinical manifestations of cardiopulmonary embolization include patient complaints of chest pain or tightness, palpitations, and shortness of breath. Examination of the patient may reveal tachypnea, hypotension, oxygen desaturation, cyanosis, or cardiac arrhythmias with the potential development of acute respiratory distress syndrome or cardiac arrest. Physicians should be cognizant of the early signs and symptoms of cardiopulmonary embolization, as early diagnosis and treatment is critical. The development of subsequent fracture is common following vertebral augmentation. Most patients being treated will commonly have an underlying condition that already carries an increased risk of future fractures. Treatment with vertebral augmentation, however, does not appear to be an individual risk factor. A meta-analysis done by Anderson et al. demonstrated no significant difference in secondary fractures between those treated with vertebroplasty and those treated with conservative management. In this analysis, both groups had approximately 20% of patients developing a new fracture between 6 and 12 months after the procedure (Anderson et al. 2013). Because of this high rate of subsequent

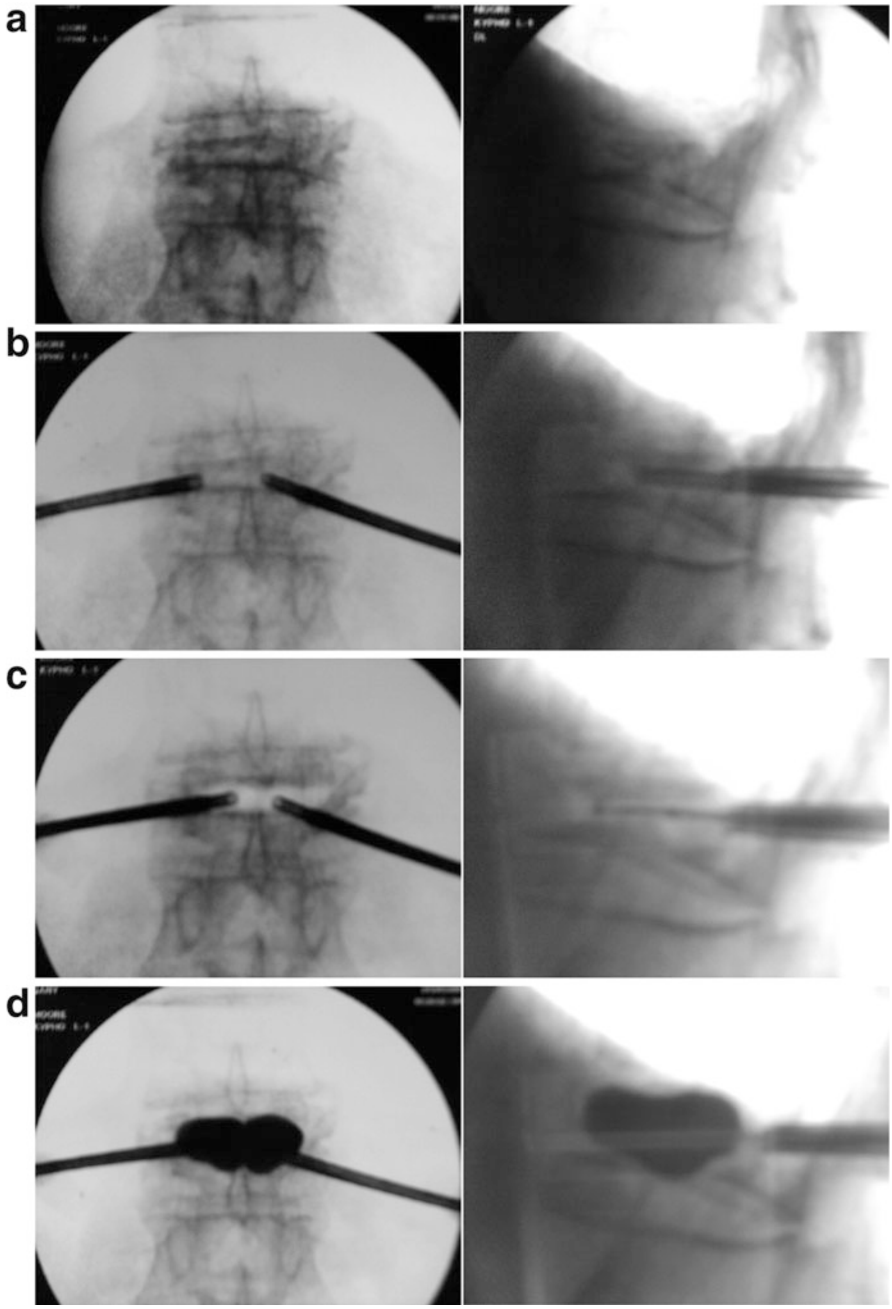

Fig. 5 (continued)

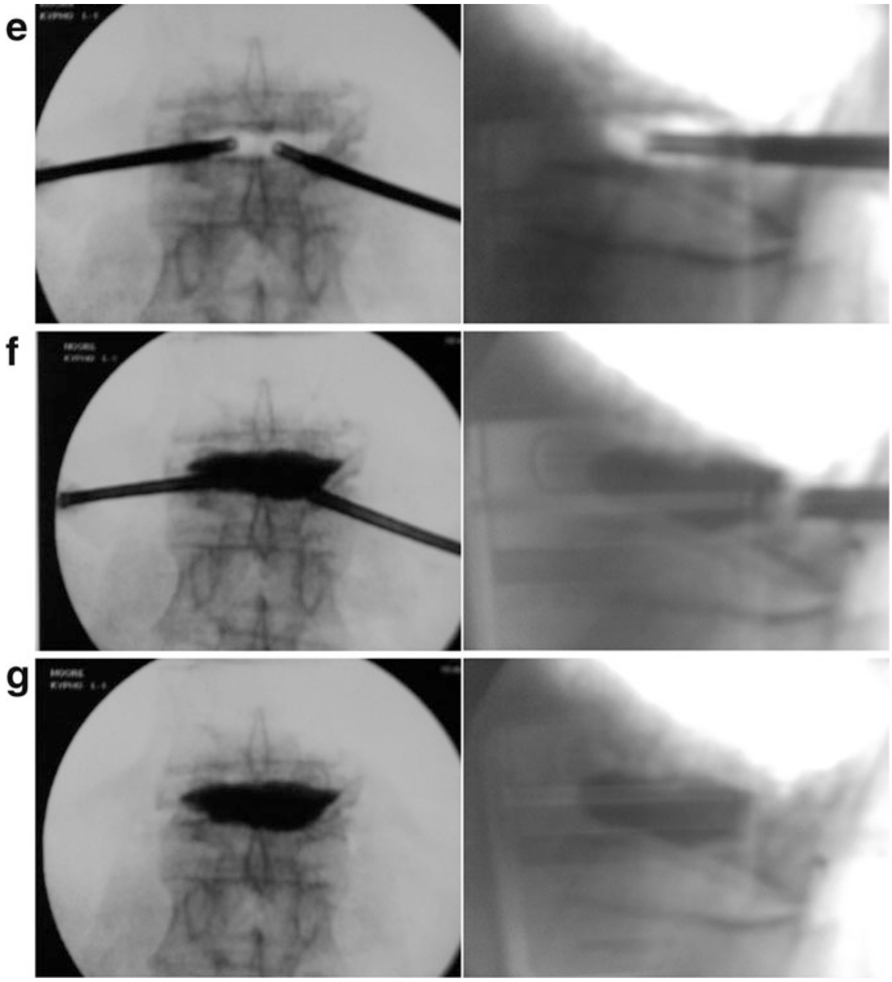

Fig. 5 Biplanar fluoroscopic images of a kyphoplasty being performed using a bilateral approach for treatment of vertebral compression fracture. (**a**) Vertebral compression fracture. (**b**), Insertion of the starting needles into the vertebral body. (**c**) Insertion of the balloon bone tamps. (**d**) Inflation of the balloon bone tamps. (**e**) Residual cavity formation noted after deflation of the balloons. (**f**), Injection of PMMA cement into the cavity. (**g**) Final AP and lateral fluoroscopic images following cement augmentation with mildly improved sagittal alignment and vertebral height

fracture, physicians should be weary of future fractures and attempt to decrease the risk by establishing appropriate treatment for underlying diseases. Although the development of an adjacent or new spinal level vertebral fracture is more common, it is also possible for patients to have a re-fracture or progression at a previously treated level. This should be of concern in patients that have no improvement, increasing pain, or worsening pain after an initial improvement period after treatment. Patients at an increased risk of re-fracture or progression include those with inadequately filled fractures or with fluid-filled vertebral fracture clefts (Jacobson et al. 2017). For these patients, a MRI or fine cut CT can assist in determining the cause for lack of improvement or early deterioration. Treatment with either observation or revision should be formulated based upon the patient's clinical status and imaging findings. Overall, complications are rare following vertebral augmentation. Treating physicians, however, should be aware of the signs and symptoms of the potential complications as late recognition may lead to significant morbidity and poor outcomes.

Outcomes

There have been numerous studies investigating the efficacy of vertebral augmentation. Despite the extensive volume of data, debate still exists regarding its effectiveness. Since the late 2000s, a number of prospective randomized controlled trials (RCTs) have been published investigating the efficacy of vertebral augmentation for treatment of osteoporotic VCFs. Wardlaw et al. published a prospective RCT in which kyphoplasty was compared to nonoperative management of VCFs (Wardlaw et al. 2009). In this study a significant improvement in the Short-Form-36 (SF-36) physical component summary scores were found in the kyphoplasty group compared to the nonoperative group at 1 month. Another prospective RCT done by Klazen et al. found beneficial results when comparing vertebroplasty to medical management of VCFs (Klazen et al. 2010). In this study there was a significant improvement found in pain scores and in secondary outcome measures in those that underwent vertebroplasty. Similar to other prospective RCTs that demonstrated beneficial results with vertebral augmentation, both studies by Klazen et al. and Wardlaw et al. did not blind the treatment and control groups. The absence of blinding has been considered a major limitation of these and similar studies as the efficacy of vertebral augmentation may be overestimated secondary to a placebo effect. In 2009, two articles, by Kallmes et al. and Buchbinder et al., were published in the *New England Journal of Medicine* in which both the treatment and control group were blinded (Kallmes et al. 2009; Buchbinder et al. 2009). In both of these prospective RCTs, vertebroplasty was found to have no beneficial effect compared to a sham procedure in the treatment of osteoporotic VCFs. Although these studies addressed a major limitation of similar RCTs, there has been concern regarding the selection criteria for patients involved in these studies. One concern entails the inclusion of patients with fractures that were up to 12 months old. The involvement of a sham procedure instead of traditional medical management has also led many to question the impact these articles should have on practice management. The RCTs by Kallmes et al., Buchbinder et al., Klazen et al., and Wardlaw et al. were subsequently utilized in a meta-analysis performed by Anderson et al. (2013). In addition to these four RCTs, two additional studies met inclusion criteria and were used to compare vertebral augmentation with conservative management in patients with osteoporotic VCFs. The study revealed a significant improvement in pain relief, functional recovery, and health-related quality of life with vertebral augmentation compared to nonoperative management or sham procedures. This significant difference was noted at early (less than 12 weeks) and long-term follow-up (6–12 months). In 2016, Clark et al. published results on a multicenter, double-blinded, prospective RCT in which 44% of patients that underwent vertebroplasty had a numeric rated pain score below 4 out of 10–14 days compared to only 21% in the control group (Clark et al. 2016). In this study, the control group underwent a process to simulate vertebroplasty in order to control for the placebo effect. Unlike the sham procedures performed in the studies done by Kallmes et al. and Buchbinder et al., there was no local anesthetic or needle infiltration of the periosteum as lidocaine use was limited to subcutaneous administration only. Following the procedure, patients were then treated by their primary physicians with standard medical care. Inclusion criteria for this study also required that the patient's painful vertebral fractures were less than 6 weeks old. This article, in addition to the meta-analysis done by Anderson et al., support the use of vertebral cement augmentation in carefully selected patients with painful VCFs (Clark et al. 2016; Anderson et al. 2013). There have also been studies comparing the results of kyphoplasty with vertebroplasty. In a systematic review done by Han et al., the authors concluded that vertebroplasty had improved short-term pain relief while kyphoplasty demonstrated better intermediate-term functional improvement (Han et al. 2011). There was found to be no difference, however, between the two in long-term pain relief or functional status. In a study done by Omidi-Kashani et al., both kyphoplasty and vertebroplasty demonstrated significant improvement in pain scores and outcome measures (Omidi-Kashani et al. 2013). Those that underwent kyphoplasty showed improved kyphosis with an average of 3.1° of correction. This study did not find a significant difference between the two in regards to pain and functional outcomes. As mentioned previously, complications have been shown to be more commonly seen with vertebroplasty, especially cement extravasation. The most recent AAOS guidelines recommend against the use of vertebroplasty and kyphoplasty carried a limited recommendation in the treatment of painful osteoporotic VCFs. Since this recommendation, there have been multiple articles published supporting the use of both vertebroplasty and kyphoplasty. With the substantial amount of data investigating the use of vertebral augmentation, physicians should make an effort to understand the strengths and limitations of the current literature in order to formulate the optimal treatment plan for each patient.

Special Considerations and Topics

Antibiotic Prophylaxis

For percutaneous vertebral augmentation, antibiotic prophylaxis can be accomplished one of two ways, via IV administration or by mixing with the PMMA during cement preparation. Although there is no data to support its use in this procedure, most practicing providers use at least one type of antibiotic prophylaxis due to the potential morbidity associated with infection (Moon et al. 2010). As with many other procedures, the most common infection-causing bacteria are *Staphylococci* and *Streptococci*species. For that reason, the most frequently used IV antibiotics include cefazolin, cefuroxime, and clindamycin. When using antibiotic impregnated cement, 1.2 g of tobramycin is ordinarily used and mixed with the PMMA cement. Both impregnated cement and IV administered antibiotics are considered appropriate as no evidence demonstrates superiority of one technique over the other. Theoretical disadvantages include increasing antibiotic resistance and the individual side effects that accompany their use. Based on the Surgical Care Improvement Project (SCIP) guidelines, the authors recommend intravenous antibiotics given within 1 h prior to surgical incision (Rosenberger et al. 2011).

Bilateral Transpedicular Versus Unilateral Transpedicular Approach

Kyphoplasty has been traditionally been performed using a bilateral transpedicular approach. This requires bilateral insertion of the balloon bone tamp and simultaneous inflation to create the cavity. Some studies, however, have shown that it can be done using a unilateral approach without negatively affecting outcomes. Chen et al. and Yılmaz et al. both demonstrated no significant difference in pain relief, kyphotic angle, and vertebral height restoration between the unilateral and bilateral approaches (Chen et al. 2014; Yılmaz et al. 2017). Both studies also found that the unilateral approach required a significantly shorter operative time and less cement. Hu et al. reported similar success with the use of a unilateral approach and, like many other authors, recommended a more medial trajectory to attain a midline position within the vertebral body (Hu et al. 2005). Yılmaz et al., however, questioned the necessity of a midline position when using the unilateral approach (Yılmaz et al. 2017). In their study, the needle trajectory was not altered from their typical trajectory and placement with the bilateral approach and, therefore, no additional effort was made to obtain a more medial start point or final midline position. This approach led to no difference in outcomes or decreased deformity correction when compared to other studies. The baseline position of needle placement in this study, however, was not reported, and therefore it is difficult to assess the significance of these findings. It does appear, however, that the unilateral approach can be used safely in kyphoplasty without negatively affecting outcomes. A recent analysis of registry data evaluated the effect of cement volume on pain relief in balloon kyphoplasty. In their analysis, they found that cement volumes greater than 4.5 ml independently predicted pain relief in patients with vertebral compression fractures (Röder et al. 2013). This data may explain why a unilateral approach may be as successful as a bilateral approach, simply by restoring the mechanical property of the cemented vertebral body. Advantages of the bilateral approach include the ability to more easily access the contralateral portion of the vertebral body for cavity formation and the facilitation of cement injection using bilateral cannulas. The shorter operative time and the avoidance of the risks associated with placing an additional needle are both benefits of the unilateral approach. Some physicians also believe attaining a more midline position when utilizing the unilateral method, which is easier to obtain using an extrapedicular approach to the vertebral body. An insertion needle with a flexible tip to allow for a modifiable curve is also currently available and may aid in obtaining a more midline position within the vertebral body. Overall, the outcomes of both the bilateral and unilateral approach appear to be similar and the decision on which approach is utilized should be based on the performing physician's experience and comfort (Fig. 6).

Metastatic or Primary Bone Tumor Cases

There are a few special considerations when pathologic fractures involve metastatic or primary bone tumors. An essential part of ensuring improvement following vertebral augmentation with these types of cases is differentiating pain related to the fracture versus the tumor. This is critical, as pain originating from the tumor is typically not improved with vertebral augmentation (Savage et al. 2014). Clinical features that would be more consistent with a painful fracture include pain that increases with load-bearing activities, such as walking, sitting, or standing. Whereas pain that is secondary to the tumor will typically be present at rest and when lying supine, patients may also experience the classic worsening of symptoms at night. If a patient is having tumor-related pain, this is most often treated more successfully with radiation therapy. Patients with pain secondary to fractures with metastatic disease or primary bone tumors, such as giant cell tumors, may benefit from vertebral augmentation. First line treatment for these types of fractures, much like that for osteoporotic VCFs, consists of medical management and appropriate analgesia. The goal for treatment of painful metastatic or primary bone tumors of the vertebral body is to attain pain control and preserve function. Radiation, chemotherapy, and bisphosphonate therapy are all options that should be discussed and considered as reasonable treatment options (Gralow and Tripathy 2007). As previously discussed with VCFs, goals of treatment and timing of intervention should be addressed utilizing a team approach and individualized based on fracture pattern and underlying pathology. If vertebral cement augmentation is indicated, special care should be taken to ensure the risk of potential complication is minimized. Careful review of pertinent imaging is important for minimizing the potential risk of complication. Important aspects of the imaging include visualization of the integrity of the posterior cortex of the vertebral body, and any potential spinal cord or nerve root compression as a result of the tumor. In addition, a biopsy may be necessary in some cases and this should be known prior to proceeding. Outcomes in the treatment of cancer-related VCFs with kyphoplasty have been promising. In a randomized-control study, Berenson et al. found a significant improvement in pain relief and overall function at 1 month postoperatively compared to the control group (Berenson et al. 2011). Dudeney et al. also showed favorable results with the use of kyphoplasty in patients with osteolytic VCFs secondary to multiple myeloma (Dudeney et al. 2002). In their study, patients experienced a significant improvement in SF-36 scores, pain, and in physical and social function compared to preoperatively. With the main goals in treatment being pain relief and maintaining function, kyphoplasty is a viable option for certain patients with primary bone tumors or metastatic disease.

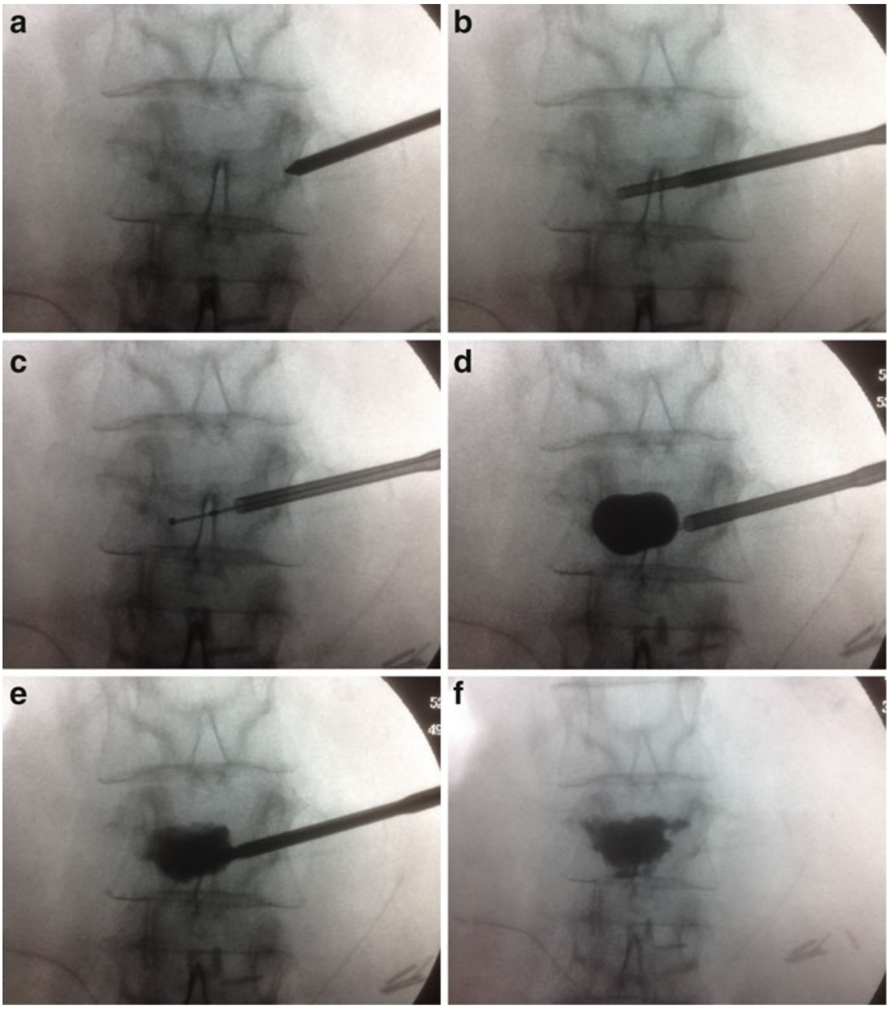

Fig. 6 Sequential intraoperative fluoroscopic images of a kyphoplasty being performed using a unilateral approach. (**a**) Initial insertion of the starting needle into the vertebral body. (**b**) Advancement of the needle utilizing a medial trajectory in order to attain a more midline final position. (**c**) Insertion of the balloon bone tamp. (**d**) Inflation of the balloon bone tamp. (**e**) Injection of PMMA cement into the cavity created by the balloon tamp. (**f**) Final AP fluoroscopic image following kyphoplasty performed via an unilateral approach

Conclusions

Despite the large volume of literature, there is still no consensus on the role of vertebral cement augmentation. Furthermore, the ideal timing of performing kyphoplasty or vertebroplasty remains controversial. Based upon the current available literature, cement augmentation should be considered for patients that meet a general set of criteria. The ideal patients being those that fail conservative management with persistent, debilitating pain, limited mobility, and an acute VCF. The length of time dedicated to conservative treatment is of debate, but generally 3–6 weeks is a commonly used time frame. Earlier consideration for patients that poorly tolerate nonoperative care, particularly narcotics and bed rest, seems to be appropriate. The use of vertebral augmentation for treatment of chronic symptomatic VCFs, metastatic disease, and primary bone tumors has also shown promise and can be considered in certain situations. Physicians should be cognizant of the potential benefits and complications of kyphoplasty and vertebroplasty when considering treatment with vertebral augmentation. In addition, it is vital for practitioners to have a solid grasp on the current literature in order to hold well-informed discussions with patients when making an individualized treatment plan.

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