Comparison of Nonnavigated and 3-dimensional Image-based Computer Navigated Balloon Kyphoplasty

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abstract

Balloon kyphoplasty is a common treatment for osteoporotic and pathologic compression fractures. Advantages include minimal tissue disruption, quick recovery, pain relief, and in some cases prevention of progressive sagittal deformity. The benefit of image-based navigation in kyphoplasty has not been established. The goal of this study was to determine whether there is a difference between fluoroscopy-guided balloon kyphoplasty and 3-dimensional image-based navigation in terms of needle malposition rate, cement leakage rate, and radiation exposure time. The authors compared navigated and nonnavigated needle placement in 30 balloon kyphoplasty procedures (47 levels). Intraoperative 3-dimensional image-based navigation was used for needle placement in 21 cases (36 levels); conventional 2-dimensional fluoroscopy was used in the other 9 cases (11 levels). The 2 groups were compared for rates of needle malposition and cement leakage as well as radiation exposure time. Three of 11 (27%) nonnavigated cases were complicated by a malpositioned needle, and 2 of these had to be repositioned. The navigated group had a significantly lower malposition rate (1 of 36; 3%; \( P = .04 \)). The overall rate of cement leakage was also similar in both groups (\( P = .29 \)). Radiation exposure time was similar in both groups (navigated, 98 s/level; nonnavigated, 125 s/level; \( P = .10 \)). Navigated kyphoplasty procedures did not differ significantly from nonnavigated procedures except in terms of needle malposition rate, where navigation may have decreased the need for needle repositioning. [Orthopedics. 2015; 38(1):17-23.]
Balloon kyphoplasty, a minimally invasive procedure conventionally performed with 2-dimensional fluoroscopy, is an accepted treatment option for painful osteoporotic and pathologic compression fractures. Encouraging results have been obtained in pain relief, with a quicker recovery period. However, this technique relies mainly on fluoroscopy, which exposes both the surgeon and the patient to substantial ionizing radiation. Furthermore, needle introduction may be complicated by difficulty in visualizing the pedicular margins of an already deformed osteoporotic vertebra.

Computer-navigated kyphoplasty with 3-dimensional imaging is a recent advancement that potentially may decrease radiation exposure time because navigation with 3-dimensional data does not require real-time fluoroscopic imaging. It also has been reported to result in improved accuracy of needle placement and thus decreased cement leakage rate.

Reported rates for accuracy of instrument placement in the spine, including pedicle screws and kyphoplasty needles, are largely dependent on the evaluation method. Sun et al evaluated the accuracy of needle placement indirectly by noting bone cement leakage on postoperative radiographs. Schils investigated cement leakage and the accuracy of needle placement in kyphoplasty using intraoperative 3-dimensional imaging without computer navigation. Findings included a 17% asymptomatic cement leakage rate in a series of 54 consecutive patients (76 levels). Most studies are preliminary case series with no comparison group; therefore, the benefit of image-based navigation in kyphoplasty has not been fully established.

The goal of this study was to determine whether there is a difference between fluoroscopy-guided conventional balloon kyphoplasty and 3-dimensional image-based navigation in terms of needle malposition rate and cement leakage rate (as determined by intraoperative 3-dimensional scanning) as well as radiation exposure time.

**Materials and Methods**

A retrospective comparative study was conducted between balloon kyphoplasty procedures performed with the assistance of 3-dimensional image-based navigation and those performed with conventional 2-dimensional fluoroscopic imaging. Institutional review board approval was obtained before study initiation. All procedures were performed by 3 fellowship-trained spine surgeons (J.N.S., D.W.P., and E.R.G.S.) between February 2007 and April 2009. In both groups, 3-dimensional scans were obtained after needle placement and again after cement injection to assess the accuracy of needle placement and to assess cement leakage, respectively. The O-arm (Medtronic Navigation, Louisville, Colorado), a new-generation mobile intraoperative computed tomography (CT) scanner, was used for 3-dimensional imaging.

In the navigation group (21 patients, 36 levels), intraoperative 3-dimensional images were linked to the Stealth comput-
er navigation system (Medtronic) to allow 3-dimensional image navigation during percutaneous transpedicular needle placement for kyphoplasty. The group included 12 men and 9 women, with a mean age of 64.2 years (range, 42-86). Average body mass index (BMI) was 28.3 kg/m², and approximately half of the patients (11 of 21) were obese (BMI>30 kg/m²). Twenty-two thoracic and 14 lumbar procedures were performed (Table 1).

In the nonnavigation group (9 patients, 11 levels), needles were placed with conventional fluoroscopic 3-dimensional imaging. The group included 6 men and 3 women, with a mean age of 55.1 years (range, 29-96). Average BMI was 24.2 kg/m²; no obese patients were included. Six thoracic and 5 lumbar procedures were performed (Table 1).

Operative levels were likewise grouped according to anatomic region (T3-T8, T9-T12, or L1-L5) as well as severity of fracture collapse (mild, moderate, or severe) (Figure 1; Table 1). Fractures with less than 25% collapse compared with adjacent nonfractured vertebrae were considered mild. Those with greater than 25% collapse were considered moderate, and those with greater than 50% collapse were considered severe.

The following factors were compared: (1) needle malposition rate, (2) cement leakage rate, and (3) radiation exposure time.

**Operative Technique (Conventional 2-dimensional Fluoroscopy)**

Patients were placed in the prone position after induction of general anesthesia. Localization of the involved vertebrae and proper needle positioning were done with anteroposterior and lateral fluoroscopic views. Cannulation of the vertebrae, insertion of inflatable balloon tamps, and injection of cement were performed in accordance with standard kyphoplasty technique.6,9 However, 3-dimensional scans were obtained after needle placement and again after cement injection.

**Operative Technique (3-dimensional Image-based Navigation)**

Patients were placed in the prone position after induction of general anesthesia. Lateral and anteroposterior fluoroscopy views were used to localize the involved vertebrae. The dynamic reference frame with reflective markers for navigation was attached to a spinous process exposed through a small midline incision (n=13), attached to the posterior iliac crest percutaneously (n=1), or taped to the skin (n=7) (Figure 2). Another frame was attached to the kyphoplasty needle. An intraoperative 3-dimensional scan was obtained, and the images were automatically transferred to the navigation system. Images were collected and calibrated to form a virtual image of the...
spinal anatomy and the instruments to be used.

The location of the pedicle was determined using the images provided by the navigation system. The skin incision site was determined by aligning a virtual extension of the needle with the desired transpedicular trajectory to ensure minimal need for realignment of the needle against soft tissue during insertion. The kyphoplasty needle was introduced and docked onto the bone. Needle position and trajectory were adjusted based on images on the navigation screen. These included axial, sagittal, and coronal images showing the position of the needle in relation to the bony anatomy (Figure 3). The needle was then introduced by tapping with a mallet. Once the needle was past the level of the posterior vertebral body wall, another 3-dimensional scan was obtained to verify its position. Repositioning was performed as needed. Once the position was acceptable, the rest of the balloon kyphoplasty procedure was performed in standard fashion, similar to the procedure used for the nonnavigated group. After cement was injected, a final 3-dimensional scan was obtained to evaluate cement leakage into the disk space, paravertebral soft tissue, vascular system, or spinal canal (Figure 4).

### Assessment of Needle Malposition, Cement Leakage, and Radiation Exposure

An independent review of 3-dimensional images after needle placement was conducted to evaluate needle malposition, regardless of whether the needle was revised. A modification of the grading system used by Gertzbein and Robbins for pedicle screw evaluation was used, including optimal (no breach), acceptable (<2-mm breach), and unacceptable (>2-mm breach). Needles with optimal and acceptable positioning were considered well positioned; unacceptable needle placement was deemed malpositioned (Figure 5; Table 2). The final 3-dimensional images after cement injection were evaluated to assess for leakage. Cement leakage was either intradiscal, intraspinal, paravertebral, or circulatory (Figure 6). Radiation exposure time was measured by adding the 2-dimensional fluoroscopy time and the 3-dimensional scan time. The O-arm has 2 settings for 3-dimensional scans: standard and high-definition. A standard-definition scan lasts for 13 seconds, and a high-definition scan lasts for 26 seconds. The decision on which setting to use was based on surgeon discretion.

### Statistical Analysis

Needle placement and cement leakage data were compared between groups using Fisher’s exact test. Radiation exposure time between the 2 groups was analyzed with the Mann-Whitney U test. P<.05 was considered statistically significant for both tests.

### RESULTS

Navigated kyphoplasty had a lower needle malposition rate (3%; 1 of 36 levels) than nonnavigated kyphoplasty (27%; 3 of 11 levels); this difference was significant (P=.035) (Table 2). The overall cement leakage rates of the navigated group (22%; 8 of 36) and the nonnavigated group (27%; 3 of 11) were similar. Radiation exposure time was comparable between the 2 groups, with a mean of 14 seconds for the navigated group and 15 seconds for the nonnavigated group.

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**Table 2**

<table>
<thead>
<tr>
<th>Malposition and Cement Leakage</th>
<th>Navigated Level (n=36), No.</th>
<th>Nonnavigated Level (n=11), No.</th>
<th>Fisher’s Exact Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trocar needle malposition</td>
<td>1 (3%)</td>
<td>3 (27%)</td>
<td>P=.035</td>
</tr>
<tr>
<td>Intradiscal leak</td>
<td>1 (3%)</td>
<td>1 (9%)</td>
<td>P=.417</td>
</tr>
<tr>
<td>Circulatory leak</td>
<td>0</td>
<td>0</td>
<td>N/A</td>
</tr>
<tr>
<td>Intraspinal leak</td>
<td>1 (3%)</td>
<td>1 (9%)</td>
<td>P=.417</td>
</tr>
<tr>
<td>Paravertebral leak</td>
<td>6 (17%)</td>
<td>2 (18%)</td>
<td>P=.729</td>
</tr>
<tr>
<td>Overall cement leak</td>
<td>8 (22%)</td>
<td>4 (36%)</td>
<td>P=.285</td>
</tr>
</tbody>
</table>

Abbreviation: N/A, not applicable.
group (36%; 4 of 11) were not significantly different ($P=0.285$). Table 2 shows the distribution of cement leakage by location. The most common is paravertebral, occurring in 17% (6 of 36 levels) of the navigated group and 18% (2 of 11 levels) of the nonnavigated group.

The 1 malpositioned needle in the navigated group occurred at L3, with severe fracture collapse, in a nonobese male. The 3 needle malpositions in the nonnavigated group occurred at T6, L1, and L4. All 3 fractures had moderate collapse; no patient was obese.

One patient in the navigated group who had osteoporotic compression fracture of T4 and T6 had right lower-extremity weakness on waking from the procedure. Needle position could not be adequately assessed based on intraoperative 3-dimensional scans because of poor bone density and significant surrounding soft tissue (obesity). Paravertebral cement leakage occurred at both operative levels. The patient underwent emergency laminectomy, regained partial strength of the right lower extremity, and was able to ambulate independently with a walker at the time of hospital discharge.

Mean radiation exposure time per level was not significantly different for the navigated group (98 seconds) and the nonnavigated group (125 seconds) ($P=0.104$) (Table 3). In the navigated group, the overall decrease in 2-dimensional fluoroscopy time was offset by the increased 3-dimensional scan time. In the nonnavigated group, although significantly more 2-dimensional fluoroscopy time was required, fewer 3-dimensional scans were obtained.

**DISCUSSION**

The growing number of kyphoplasty procedures has increased clinicians' awareness of the potential dangers to both surgeons and patients. Concerns have been raised about the amount of ionizing radiation exposure incurred during the procedure as well as the accuracy of needle placement and the incidence of cement leakage. Theoretically, computer navigation can address these matters, and recent reports addressed these concerns. The goal of the current study was to determine the difference between navigated and nonnavigated kyphoplasty in needle malposition rate, cement leakage rate, and radiation exposure time.

Assessment of the accuracy of needle placement in computer-navigated procedures is only as accurate as the evaluation device. Use of a new-generation intraoperative CT scanner to obtain 3-dimensional scans for all patients in this study greatly improved the authors' ability to assess needle placement and cement position because the vertebra can be visualized in 3 planes. Sun et al. noted that 7 of 21 patients who underwent conventional kyphoplasty required several readjustments to achieve the desired position. Although results are usually satisfactory, repeated readjustments cause...
increased surgical time, greater radiation exposure, and increased likelihood of operative mistakes. The main advantage of image-guided navigation is that it allows “virtual-time” viewing of needle insertion through the pedicle with computer-generated images. Moreover, the setup of the system provides enough room for the surgeon to work in a comfortable position compared with the setup for conventional kyphoplasty, where the surgeon must work around fluoroscopy units.

The current study showed no difference in cement leakage rates between the navigated and nonnavigated groups. A number of factors affect cement leakage during kyphoplasty, regardless of whether computer navigation is used. These factors include cement viscosity at the time of injection, cement volume, fracture pattern, and the criteria used for cement leakage. This may explain why the cement leakage rate was unaffected by navigation. Navigation was used only for needle placement, and cement injection was performed similarly, using regular 2-dimensional fluoroscopy imaging in both the navigated and nonnavigated groups. Kaso et al\(^5\) noted that epidural accumulation of bone cement was closely correlated with needle tip position during injection. They do not recommend routine use of computer navigation in vertebroplasty but rather reserve its use for severely deformed fractures.

Although navigation led to decreased 2-dimensional fluoroscopy time, it also required at least 1 additional 3-dimensional scan at the beginning of the procedure for image registration. However, this difference may lead to less radiation exposure for the surgical team because 3-dimensional scans are taken with the surgical team stepping into a substerile room or behind lead-impregnated shields.

In this study, mean radiation exposure time using computer navigation was comparable to published data (Table 4). The 2-dimensional fluoroscopy time was notably less than in other studies. Variation in surgeons’ use of intraoperative imaging may account for this disparity. For instance, the authors do not use continuous fluoroscopy during balloon inflation and cement injection, whereas others may do so.

Limitations of the study include the small sample size and the use of radiation exposure time as a surrogate measure of radiation exposure. The limited sample size, although larger than many published reports, may still be too small to provide a valid statistical comparison. However, the data suggest that the accuracy of needle placement is markedly improved with the use of computer navigation in kyphoplasty.

Radiation exposure time is not a direct measurement of the amount of radiation acquired by the surgeon or patient. A more accurate way to document the radiation dose would be with the use of dosimeter badges. The authors, however, concede that CT radiation dose varies not only as a function of total fluoroscopy time and number of scans but also based on the position of the image intensifier, the machine settings, and the scanning protocol. These data were not routinely recorded.

### Table 3

<table>
<thead>
<tr>
<th>Fluoroscopy</th>
<th>Navigated</th>
<th>Nonnavigated</th>
<th>Mann-Whitney U test</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-dimensional</td>
<td>45±25</td>
<td>34±25</td>
<td>(P = .187)</td>
</tr>
<tr>
<td>2-dimensional</td>
<td>52±25</td>
<td>91±25</td>
<td>(P = .017)</td>
</tr>
<tr>
<td>Total (2-dimensional+3-dimensional)</td>
<td>98±63</td>
<td>125±69</td>
<td>(P = .104)</td>
</tr>
</tbody>
</table>

### Table 4

<table>
<thead>
<tr>
<th>Study</th>
<th>Navigated</th>
<th>Nonnavigated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Izadpanah et al(^2)</td>
<td>99±38 s/case</td>
<td>175±82 s/case</td>
</tr>
<tr>
<td>Villavicencio et al(^4)</td>
<td>81 s/case</td>
<td>293 s/case</td>
</tr>
<tr>
<td>Current study</td>
<td>98±63 s/level</td>
<td>125 s/level</td>
</tr>
</tbody>
</table>
Finally, the single case of neurologic injury in the authors’ series occurred in the navigated group. Although a single event in a relatively small number of cases does not suggest statistical correlation, this finding should be enough to dampen enthusiastic conclusions favoring navigation. More than 1 fracture level (T4 and T6) occurred in this case, and the patient was both obese and very osteopenic. It is not certain whether the same complication would have occurred or whether the surgeon would have abandoned the procedure for lack of clear visualization without navigation. However, the most important concerns for the authors’ surgical team were where and how to place the reference frame of the navigation system. Before this case, the reference frame was simply taped over the skin with strips of antimicrobial surgical incise drape (Ioban; 3M, St. Paul, Minnesota) in most navigated cases (7 of 9). This was done to avoid making a longer additional skin incision for what was supposedly a percutaneous procedure. After this single and serious complication, the authors abandoned the “skin taping” technique because they believed that this may have affected the accuracy of the navigation. All subsequent navigated procedures were performed with the reference frame either clamped to a spinous process or fixed to the iliac crest with a percutaneous pin.

**Conclusion**

Navigation may be able to reduce needle malposition rates compared with standard fluoroscopy, obviating the need for needle repositioning. However, this study did not show the significance or clinical benefit of improved needle malposition rates. Further studies are warranted before routine use of navigation can be recommended for kyphoplasty procedures.

**References**