Robot-Assisted Vertebral Body Augmentation

A Radiation Reduction Tool

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Study Design. Retrospective.
Objective. To assess radiation exposure time during robot-guided vertebral body augmentation compared with other published findings.

Summary of Background Data. Rising incidence of vertebral compression fractures in the aging population result in widespread use of vertebral body cement augmentation with significant radiation exposure to the surgeon, operating room staff, and patient. Radiation exposure leads to higher cancer rates among orthopedic and spine surgeons and patients.

Methods. Thirty-three patients with 60 vertebral compression fractures underwent robot-guided vertebral body augmentation performed by 2 surgeons simultaneously injecting cement at 2 levels under pulsed fluoroscopy. The age of patients was in the range from 29 to 92 (mean, 67 yr). One to 6 vertebrae were augmented per case (average 2). Twenty-five patients had osteoporotic fractures and 8 had pathological fractures. Robotic guidance data included execution rate, accuracy of guidance, total surgical time, and time required for robotic guidance. Radiation-related data included the average preoperative computed tomographic effective dose, radiation time for calibration, registration, placement of Kirschner wires, and total procedure radiation time. Radiation time per level and surgeon's exposure were calculated.

Results. Kyphoplasty was performed in 15 patients (1 sacroplasty), vertebroplasty in 13, and intravertebral expanding implants in 5. The average preoperative computed tomographic effective dose was 50 mSv (18–81). Average operative time was 118 minutes (49–350). Mean robotic guidance time was 36 minutes. Average radiation time per level was 46.1 seconds per level (33–160). Average exposure time of the surgeons and the operating room staff per augmented level was 37.6 seconds. The execution rate was 99%, with an accuracy of 99%. Two complications (hemothorax and superficial wound infection) occurred.

Conclusion. The radiation exposure of the surgeon and the operating room staff in a series of robot-assisted vertebral body augmentation was 74% lower than published results on fluoroscopy guidance and approximately 50% lower than the literature on navigated augmentation.
Key words: radiation exposure, radiation reduction, robot-assisted spine surgery, vertebral body cement augmentation.

Level of Evidence: 4


Modern orthopedic and spine surgeons strive to minimize surgical exposure and increase precision in implant placement. This trend has led to greater use of fluoroscopic guidance, resulting in increased exposure to ionizing radiation for patients, surgeons, and operating room (OR) staff. Radiation exposure is a growing concern among orthopedic surgeons and OR staff.1–3 Vertebral augmentation is a minimally invasive procedure aimed at reducing pain caused by osteoporotic and pathological vertebral compression fractures. Vertebroplasty was introduced in 1983 and kyphoplasty in 1995.4,5 Other systems for vertebral augmentation have been introduced more recently.6–8 Vertebral augmentation is typically performed under fluoroscopy guidance, exposing the surgeon and the OR staff to significant radiation.9

The estimated cancer incidence among surgeons who perform fluoroscopically assisted percutaneous vertebroplasty is 0.025%,9 and the estimated incidence of fatal thyroid cancer is 0.0025%, 25 times higher than the general population.9 Average annual exposure to the eye lens is close to 8% of the 150-mSv threshold radiation dose needed to develop radiation-induced cataracts. Skin exposure during augmentation is up to 10% of the annual effective dose limit recommended by the International Commission on Radiological Protection.9

Robot-assisted spine surgery is routinely performed in the authors’ institution for a variety of indications such as degenerative conditions, trauma, tumors, infections, and deformity correction.10 The objective of this study was to compare...
radiation exposure time during robot-guided vertebral body augmentation to published results for similar surgical procedures conducted under fluoroscopic guidance.

PATIENTS AND METHODS

Thirty-three consecutive patients underwent robot-guided vertebral body augmentation for vertebral compression fractures in a total of 60 vertebrae. The demographic details, surgical indications, operated levels, and methods of augmentation are summarized in Table 1. All patients who underwent vertebral augmentation were included; all patients who had contraindications for augmentation were excluded. In 2 procedures, technical issues prevented robotic guidance (faulty cable in 1 case and failed fluoroscopy equipment in the second). These cases were excluded from analysis (2 vertebrae, 2 trajectories).

This retrospective analysis was performed under a waiver of informed consent from our institutional review board (HMO 289-11). All patients had signed informed consent forms for surgery. The use of robotic guidance was discussed with all patients before surgery. Because the robotic device has Food and Drug Administration and European Conformity approval and the technique is in routine clinical use, the institutional review board does not require modification to the informed consent form used for vertebral augmentation procedures.

Preoperative CT examinations were performed in all patients with a 16-slice MDCT system (LightSpeed; GE Healthcare, Milwaukee, WI), cranio-caudally, according to the robot manufacturer’s instructions, using the following parameters: 140 kVp, 200 mA, 0.625-mm slice thickness, a pitch of 0.5, and a 512 × 512 matrix.

Intraoperative fluoroscopy examination was performed with a GE OED 9000 12 inch fluoroscopy unit (GE Healthcare). The total filtration of the radiograph tube was 4.6-mm aluminum, the focus-to-image intensifier distance was 90 cm, and the input field was 23 cm in diameter. Exposure parameters were determined by means of an automatic brightness control. The radiograph unit was equipped with a permanent dose-area-product meter and a beam-on timer.

Robotic Guidance

SpineAssist (Mazor Surgical Technologies, Caesarea, Israel) is a miniature robot, which can be mounted on bone using 1 of 3 platforms (Red Mount Device [Mazor Surgical Technologies], Hover-T Bridge [Mazor Surgical Technologies], Clamp [Mazor Surgical Technologies]). It is a semi-active system offering surgical tool guidance while leaving performance of the actual surgical operation, such as the drilling, in the surgeon’s hands.

The robotic procedure, consisting of 6 steps, has been described elsewhere and is summarized briefly in the text hereafter:

1. Preoperative planning: CT scan-based planning to determine the optimal tracts for insertion of the augmentation needle.

2. Platform attachment: The optimal robotic platform is attached to the patient’s bony anatomy.

3. Image acquisition and registration: Targets for image acquisition are connected to the robotic platform, and AP anteroposterior and 60° oblique fluoroscopic images are semi-automatically registered to the preoperative CT images.

4. Robot assembly and motion: The robot is attached to the mounting frame. It then moves and locks into position so that a guiding tube at the distal end of its arm is aligned with the planned screw/tool trajectory. Then the guiding tube is inserted through a small skin incision and gently tapped into the bony anatomy of the patient.

5. Trajectory execution: Drilling through the guiding tube along the planned trajectory is performed percutaneously. A hollow tube is then placed through the working channel and advanced into the pedicle and through the posterior vertebral wall. A Kirschner wire (K-wire) is then placed into the vertebral body and the hollow tube is withdrawn. This procedure is repeated until trajectories are drilled and K-wires are placed at all levels to be treated. At this point, robotic guidance is complete. The mounting system remains attached to allow a repeat robot-guided approach in case 1 of the trajectories is lost.

6. Vertebral body augmentation: In vertebroplasty, venous channels are blocked with slurry made of saline-contrast-gelfoam media, a bone marrow biopsy needle is introduced over the K-wire into the vertebral body, and a designated augmentation polymethyl methacrylate cement is injected with 2.5-mL syringes. In balloon kyphoplasty, the kit’s introducer is placed over the K-wire and the procedure is performed according to the manufacturer’s protocol. When intravertebral expandable devices are used, the kit’s introducer is placed over the K-wire and the procedure is performed according to the manufacturer’s protocol.

Cement is injected simultaneously by 2 surgeons into 2 ports at the same level or into 2 vertebrae in multilevel augmentation, with unilateral approaches with pulsed fluoroscopy monitoring for each 0.25 mL of injected cement.

After the augmentation procedure, patients are allowed to walk freely. They are observed overnight and discharged home the next day.

Data Collection

Clinical data included patient demographics, indications for surgery, the number of operated levels, and the method of augmentation used.

Robotic data included the platform chosen for each patient from 3 available platforms, rate of execution (executed/planned trajectories), success of guidance (i.e., rate of K-wire placement on the planned trajectory, as confirmed on intraoperative fluoroscopy), and robotic guidance time. In addition, intraoperative and postoperative challenges and perioperative complications were noted.
The effective radiation dose (mSv) from preoperative CT data was recorded for each patient. This parameter was calculated from the dose length product that is routinely reported for every CT examination performed in our scanner. The K conversion value was 0.015. Radiation exposure for OR personnel was calculated on the basis of duration of intraoperative fluoroscopy required for calibration, registration, confirmation of K-wire placement within the vertebra, needle placement, and vertebral augmentation. This data were routinely collected during all robotic procedures. Effective doses were not recorded during surgery. Because of the retrospective nature of this study, we could not capture this data. On the basis of the literature, 80 seconds of intraoperative fluoroscopy delivers a radiation dose that is comparable with standard MDCT scan of the lumbar spine.

**Statistical Analysis**

Descriptive statistics were prepared to present the data and compared with published results describing fluoroscopy-guided and navigation-assisted vertebral augmentation.

**RESULTS**

Between January 2008 and March 2010, 33 patients, including 24 females (72%) and 9 males (27%), with an average age of 67 years (range, 29–92 yr) underwent robot-guided vertebral augmentation. The series included 85 robot-assisted trajectories in 60 augmented vertebrae. A range of 1 to 6 vertebrae were augmented per patient, with a mean of 2. Augmentation was performed in 22 thoracic vertebrae from T5–T12 (27 trajectories), 38 lumbar vertebrae from L1–L5 (56 trajectories), and 1 sacral vertebra (2 trajectories). In 25 patients (76%), augmentation was performed because of osteoporotic fractures; 8 (24%) experienced pathological fractures due to multiple myeloma or metastatic disease. Kyphoplasty was performed in 15 patients (46%), including 1 sacroplasty; vertebroplasty in 13 (39%), and an intravertebral expanding implant was used in 5 (15%).

The average procedure time was 118 minutes (range, 49–350), with variation according to the number of levels augmented and the need for surgical decompression or tumor debulking. Robotic guidance took an average of 33.8 minutes per case (range, 10–93). Average radiation time per level (reflecting the patient’s exposure to radiation) was 41.6 seconds (range, 33–160 s). Radiation exposure time for surgeons and OR staff per augmented level was 34.1 seconds on average (range, 13–117 s). The average preoperative CT effective dose in this study was 50 mSv (range 18–81). It is worth noting that the CT protocol that formed the basis for this study has been substantially revised as a result of this study. The current protocol delivers a dose that is a 75% reduction from this dose.

The number of planned trajectories was in the range from 1 to 8 (mean, 2.7). The robot was mounted on a bed-mount device in 29 patients (88%), on the Hover-T Platform (Mazor Surgical Technologies) in 3 patients (9%), and on a clamp in 1 patient (3%).

The mean execution rate (executed vs. planned trajectories) was 99% (range 83%–100%). One trajectory was aborted because it was out of the field of the fluoroscopy images taken for registration in a patient undergoing augmentation at nonconsecutive 6 levels. The surgeon opted to perform augmentation on this level manually instead of repeating the registration procedure. Mean accuracy was 98.8%. One trajectory was missed laterally (the K-wire insertion felt wrong and the check fluoroscopic images confirmed). The trajectory was corrected manually under fluoroscopic guidance. The missed trajectory did not result in any clinical complication.

A loosened connection between the K-wire and the Hover-T Bridge was observed in 2 cases. This resulted in motion of the bridge with respiration. The loose connections were noticed in both cases. The connection was secured, new fluoroscopy images were acquired, and the trajectories were properly executed.

There were 2 complications in the series. One patient developed a hemothorax 9 days after augmentation of T12 with an expandable intravertebral implant. A chest drain was inserted and the hemothorax resolved. Another patient undergoing combined open L3–L4 decompression and L3 vertebral body augmentation developed a superficial wound infection, which healed with administration of intravenous antibiotics and local care.

**DISCUSSION**

Osteoporotic vertebral compression fractures occur in up to 20% of the elderly population. As the world population ages and life expectancies for patients with many cancers continue to increase, the frequency of vertebral compression fracture and vertebral augmentation procedures is rising. As a result, patients, surgeons, and OR staff members are exposed to increasing levels of radiation related to vertebral augmentation procedures. In addition, up to 40% of patients with cancer develop spinal metastases, which often lead to compression fractures.

The relative risk for cancer among orthopedic surgeons is 5.37 compared with the general population. Malignancies in exposed personnel range from cancers of solid organs (i.e., thyroid and pancreas) to skin and hematopoietic cancers. In female orthopedic surgeons, the standardized prevalence ratio for all cancers is 1.9 \( (P = 0.0021) \), and the ratio is 2.88 for
breast cancer (P < 0.0001), when compared with the general population.1

The estimated radiation exposure to patients during large C-arm procedures is 12 to 14 mSv (1200–1400 mrem) per minute, and for mini C-arm use it is 1.2 to 4 mSv (120–400 mrem) per minute.3 The annual whole-body limit for occupational exposure is 50 mSv (5 rem).9 Annual occupational limits are 150 mSv (15 rem) for eye exposure, 300 mSv (30 rem) for thyroid exposure, and 500 mSv (50 rem) for other organs.3

In the literature discussing radiation exposure in vertebral body augmentation, the use of navigation systems has been shown to reduce exposure time from 175 ± 23 seconds per level in fluoroscopy-guided procedures to 74 seconds per level under 2-dimensional imaging guidance and 99 seconds per level under 3-dimensional imaging guidance.16 In the radiological literature, radiation exposure time reached 10 minutes per level in some vertebroplasty and kyphoplasty procedures.17

In this series of patients, the average operative radiation exposure time was 41.6 seconds per level. During calibration and registration, the surgeon and OR staff are protected behind lead walls, and when this time is eliminated exposure time is further reduced to 34.1 seconds per level. The robotic method described here reduces exposure time by approximately 50% when compared with the shortest published results16 (Table 2).

Cannulation of the vertebrae requires both AP and 60° oblique fluoroscopic images for registration, 2 fluoroscopic images to verify K-wire position prior to needle insertion, and 2 to 4 fluoroscopy images to verify positioning of the needles, for a total of 6 to 8 fluoroscopic images. The use of pulsed fluoroscopy, with 1 image taken for every 0.25 to 0.5 mL of cement injected through a port, with 2 surgeons working simultaneously on 2 ports, also reduces the amount of radiation. The use of pulsed fluoroscopy while cementing the vertebrae is safe, as long as cement is injected carefully and at the proper viscosity, thus preventing leakage and uncontrolled cementation. In this series of patients, no cementation-related complications occurred.

The robot reduces the need for radiation exposure to the surgical staff by guiding the surgeon along a previously planned trajectory. In a prior report from our group11 the accuracy of the surgical robot in guiding pedicle screws was 89.3%. In the current series, the accuracy of robotic guidance was 99%. This difference can be explained by the additional experience gained since the initial publication. Moreover, the planned entry points in vertebral augmentations were on a straight surface, on top of the ascending articular process. This entry point is less prone to skiving when compared with the entry point of a pedicle screw, near the mammillary process.

In addition to the risk for hospital staff, 1 must take into consideration patients’ exposure. The robotic guidance technique requires a preoperative CT scan. The protocol was set according to the manufacturer demands and includes a high-kV study with very thin slices and slice overlap. As a result, the radiation dose is relatively high compared with conventional CT examination of the spine. With the goal of reducing this dose, we initiated discussions with the robot manufacturer, which led to improvements in algorithms run by the robot software and the volumetric CT acquisition technique. These changes enable us to perform the preoperative CT using thicker slices and higher pitch values, with retrospective reconstruction of thinner slices from raw data. Currently, the dose is approximately 75% lower than exposure using the initial protocol, which was the basis for analysis in this study. Newer CT machines with sophisticated dose reduction software will probably permit further reductions of radiation exposure with acceptable or even improved image quality. This assumption warrants a prospective analysis. Patients with severe osteoporosis present a challenge, and may require the protocol suggested by the robot manufacturer. The field of view should be limited to the region of interest, enabling further reduction in radiation exposure to the patient.

Reducing radiation exposure is especially important when treating young healthy patients, especially female patients, because their longer life expectancies increase the risk that radiation-induced malignancies could develop.17 Most of the patients in this series were older than 60 years or patients with cancer. In these patients, the accuracy achieved by robotic guidance seems to justify the radiation exposure caused by the preoperative CT scan.

<table>
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<tr>
<th>Technique</th>
<th>Radiation Exposure per Level</th>
<th>Reference</th>
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<tbody>
<tr>
<td>Freehand</td>
<td>175 ± 23 s</td>
<td>Izadpanah et al9</td>
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<td></td>
<td></td>
<td>(2009)</td>
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<tr>
<td>Freehand</td>
<td>10.1 min ± 22 s</td>
<td>Perisinakis et al7</td>
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<td></td>
<td></td>
<td>(2004)</td>
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<tr>
<td>Computer navigation</td>
<td>74 ± 27 s in 2D mode/lumbar</td>
<td>Izadpanah et al9</td>
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<td></td>
<td></td>
<td>(2009)</td>
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<tr>
<td>Robot-assisted</td>
<td>Patients’ exposure,</td>
<td>Current patient series</td>
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<td></td>
<td>41.6 s</td>
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<td>Surgeon and OR staff</td>
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<td>exposure, 34.1 s</td>
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According to this comparison, more than 50% reduction in radiation exposure to the surgeon can be achieved when using robotic guidance when compared with the best published results in navigation-assisted augmentation.

OR indicates operating room.
Key Points

- Vertebral body cement augmentation is associated with significant radiation exposure to the patient and the operating staff.
- Occupational radiation exposure is associated with increased cancer risk.
- A retrospective analysis of a series of robot-guided vertebral cement augmentation was conducted.
- Robot-guided vertebral body cement augmentation performed by 2 surgeons, simultaneously injecting cement under pulsed fluoroscopy reduces radiation exposure to the surgeon and OR staff when compared with the published results on freehand and navigation-assisted augmentation.

References