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ABSTRACT

Background: As the prevalence and associated health care costs of osteoporosis continue to rise in our aging population, there is a growing need to continue to identify methods to predict spine construct integrity accurately and cost-effectively. Dual-energy x-ray absorptiometry (DEXA) in both anterior to posterior (AP) and lateral planes, as well as computed tomography (CT) Hounsfield units (HU), have all been investigated as potential preoperative predictive tools. The purpose of this study is to determine which of the 3 bone density analysis modalities has the highest potential for predicting pedicle screw biomechanics.

Methods: Lumbar spine specimens (L2, L3, and L4) from 6 fresh frozen cadavers were used for testing. AP-DEXA, lateral-DEXA, and CT images were obtained. Biomechanical testing of pedicle screws in each vertebrae was then performed including pullout strength and fatigue testing. Statistical analysis was performed.

Results: Pullout strength was best predicted by CT HU, followed by AP-DEXA, then lateral-DEXA ($R^2 = 0.78$, $0.70$, and $0.40$, respectively). Fatigue testing showed a significant correlation of relative rotation between HU value and AP-DEXA bone mineral density ($R^2 = 0.54$ and $R^2 = 0.72$, respectively), and there was a significant correlation between relative translation and HU value ($R^2 = 0.43$). There was a poor correlation between relative rotation and lateral-DEXA ($R^2 = 0.13$) as well as a poor correlation between relative translation and both AP- and lateral-DEXA ($R^2 = 0.35$ and $R^2 = 0.02$).

Conclusions: CT is the only modality with a statistically significant correlation to all biomechanical parameters measured (pullout strength, relative angular rotation, and relative translation). AP-DEXA also predicts the biomechanical measures of screw pullout and relative angular rotation and is superior to lateral-DEXA. CT may provide an incremental benefit in assessing fatigue strength, but this should be weighed against the disadvantages of cost and radiation.

Clinical Relevance: The results of this study can help to inform clinicians on different bone density analyses and their implications on pedicle screw failure.

INTRODUCTION

Pedicle screw fixation is now a widely accepted means of internal fixation for fusion surgery in patients with thoracolumbar pathology.1,2 Osteoporosis is a known risk factor for increased clinical complications after posterior spinal fusion including delayed fusion, hardware loosening, and hardware failure.3–5 Biomechanically, decreased bone mineral density (BMD) has been shown to correlate with reduced cutout force, pullout force, and maximal insertional torque.6 As the prevalence and associated health care costs of osteoporosis continue to rise in our aging population,7,8 there is a growing need to continue to identify methods to predict spine construct integrity accurately and cost-effectively.

The gold standard for measuring BMD is dual-energy x-ray absorptiometry (DEXA) in the anterior to posterior (AP) plane.9 Lateral-DEXA has also been explored in an attempt to better isolate the BMD of the vertebral bodies without contribution from the posterior elements.10 Computed tomography (CT) is now being used to calculate BMD by measuring the attenuation of radiation at the midvertebral body in Hounsfield units (HU).11,12 Quantitative CT uses software to automate these measurements.11
Biomechanical studies have correlated AP-DEXA BMD with pedicle screw pullout strength and fatigue endurance.\textsuperscript{13} CT HU have also been clinically correlated with screw loosening and have been shown to be more accurate than T-scores at clinically predicting screw loosening.\textsuperscript{12,14,15} To the authors’ knowledge, these comparisons have not been directly made in a biomechanics lab, and no study has evaluated lateral-DEXA as a predictor of pedicle screw biomechanics. The purpose of this study is to determine which of the 3 bone density analysis modalities has the highest potential for predicting pedicle screw biomechanics. Our hypothesis is that CT-based BMD analysis has the highest correlation with pedicle screw pullout and fatigue strength followed by lateral-DEXA and AP-DEXA.

METHODS

Specimens

Lumbar spine specimens (L2, L3, and L4) from 6 fresh frozen cadavers of mean age 65.2 (SD 9.4) years were used for testing. The L2-L4 vertebral bodies were dissected from the cadaver en bloc and labeled. Next, all muscle, neural tissue, and disc material were sharply excised from the bony surfaces leaving the bony vertebrae intact. The resulting 18 vertebrae were imaged using CT and DEXA. A compression fracture resulted in the exclusion of one L2 vertebra. The remaining 17 vertebrae (5 L2, 6L3, and 6 L4) underwent biomechanical testing.

Computed Tomography

All scanning was performed using a G.E. Discovery 750 HD 64 slice CT scanner. Specimens were placed in anatomic position and scanned with standard lumbar spine protocol in helical CT mode with internal phantom calibration. A region of interest (ROI) was selected over the body of each vertebra at 5 different levels (figure), and the mean HU value of the ROI was recorded. The 5 levels were axial slices corresponding to (1) the most cranial axial slice of cancellous bone in the vertebral body just caudal to the superior endplate, (2) the most cranial aspect of the pedicle, (3) midpedicle, (4) the most caudal aspect of the pedicle, and (5) the most caudal axial slice of cancellous bone just cranial to the inferior end plate. The mean of these 5 values was recorded as the HU value for that vertebra (Figure 1).

Dual-Energy X-Ray Absorptiometry

All scanning was performed using a Hologic (Hologic Inc., Bedford, MA) fan beam densitometer with rotating C-arm functionality. Specimens were sealed in clear plastic bags and scanned in anatomic position using a matched AP-lateral supine scan in array scanning mode. After scanning, standard analysis of the AP scan was performed according to standard lumbar spine protocol described by Hologic with resulting areal BMD values in g/cm\textsuperscript{2} recorded for each vertebra. For the lateral scan, the machine’s C-arm rotated to a lateral orientation without changing the specimen positioning.
Lateral scan analysis was performed by manually defining the superior and inferior endplates on a lateral view. The anterior border was defined by the anterior margin of the vertebral body, while the posterior border was defined by the junction between the vertebral body and the posterior elements (Figure 2). The resulting lateral-DEXA areal BMD values in g/cm² corresponding to each vertebra were recorded.

**Biomechanical Testing**

All L2-L4 spinal segments were separated into individual vertebrae after completing imaging. Seventeen vertebral specimens were instrumented using 7.5 × 45 mm pedicle screws (K2M, Leesburg, VA). Screw entry points were selected according to established principles. Pedicles were cannulated under direct visualization, and screw paths were tapped with a 5.5 mm tap. Screws were advanced until all threads were inserted into the bone. Two identical pedicle screws were placed in each vertebral body, and each screw (right and left) was randomly assigned to either direct pullout or pullout following fatigue testing. All vertebrae were then embedded in a polyester resin (Bondo/Mar-Hyde Corp., Atlanta, GA) at the vertebral body, keeping the posterior elements and screws free from resin. Next, specimens were secured to a universal materials testing machine (Instron, Canton, MA) via an adjustable vise.

**Pullout Strength**

The specimen was aligned such that the axis of the screw was in line with the loading axis. The screw was attached to the load cell via a steel wire and pulled axially at a rate of 5 mm/minute (Figure 3). The test was stopped when gross pullout of the screw was noted, and the highest load value was recorded as the pullout load.

**Fatigue Testing**

The specimen was secured into the testing machine via the vise keeping the pedicle screw parallel to the ground. A spinal rod was attached to the pedicle screw at one end and linked to the load cell via a fixture at the other end. The fixture was designed such that the vertical motion of the machine’s crosshead was converted to planar rotation through a hinged joint. At the neutral position, the adapter and pedicle screw were parallel to the ground, and the connecting spinal rod was vertical and 30 mm offset from the axis of motion of the crosshead. Two sets of reflective markers were attached firmly to the pedicle screw head and pars region to detect relative motion (translation and rotation) between
bone and screw using a motion analysis system (Vicon, Oxford, UK).

Starting from ±100 N, yielding a 3 Nm bending moment at the pedicle screw head, the specimen was loaded at increments of 50 N for 2000 cycles at 2 Hz at each load level until 300 N (9 Nm) or 6° of relative motion was achieved. The maximum translation (mm) and rotation (°) were recorded.

Due to fixture failure during testing, 6 specimens were eliminated from the analysis. The remaining 11 specimens were able to complete fatigue testing. Eight of these specimens achieved maximum loading (300 N) at 10,000 cycles, and 3 specimens achieved the maximum relative motion (6°).

STATISTICAL METHODS

For all statistical tests, the significance level was set at $P = 0.05$.

Pullout Strength

Univariate linear regression analysis was used to model the relationship between maximal pullout load and AP-DEXA BMD, lateral-DEXA BMD, and CT HU value. Steiger’s Z test for dependent samples was used to determine if these correlations, as measured by $R^2$ values, for each of the 3 linear regressions were statistically different.
Fatigue Testing

At the end of each test, relative motion (translation and rotation) at the bone-screw interface and total cycle count was recorded. A cross-correlation analysis was performed using all bone quality parameters (HU value, AP-DEXA, lateral-DEXA, T-score, and age) and biomechanical parameters (relative translation, relative rotation, and maximum pullout strength).

We repeated statistical analyses using normalized relative motion data with total cycle count, but the results did not change. Therefore, we report only non-normalized data.

RESULTS

Pullout Strength

The regression models between the 3 types of imaging modalities and maximum pullout strength were all significant ($P < 0.05$) with positive slopes indicating a correlation between bone quality (BMD and HU value) and pullout strength.

Pullout strength was best predicted by HU value measurement on CT as indicated by a larger coefficient of determination ($R^2 = 0.78$) (Figure 4). BMD as measured on AP-DEXA also showed a similar ability to predict pullout strength ($R^2 = 0.70$) (Figure 5). BMD as measured on lateral-DEXA showed a decreased ability to predict pullout strength ($R^2 = 0.40$) (Figure 6) (Table 1).

The coefficient of determination for “HU value vs pullout strength” was significantly larger than that of “lateral-DEXA BMD vs pullout strength” ($P = 0.009$). Similarly, the coefficient of determination for “AP-DEXA BMD vs pullout strength” was significantly larger than that of “lateral-DEXA BMD vs pullout strength” ($P = 0.032$). The coefficient of determination of “HU value vs pullout strength” was larger than that of “AP-DEXA BMD vs pullout strength” (0.78 vs 0.70); however, this difference did not reach statistical significance ($P = 0.120$) (Table 2).

Fatigue Testing

Two variables measuring relative motion were recorded during fatigue testing, translation (mm), and rotation (degree).

The regression models of relative rotation resulted in a statistically significant correlation with the HU value and AP-DEXA BMD ($R^2 = 0.54$ and $R^2 = 0.72$, respectively). There was a poor correlation between rotation and lateral-DEXA BMD ($R^2 = 0.13$), and this was not statistically significant.

The regression models of relative translation resulted in a statistically significant correlation with the HU value ($R^2 = 0.43$). There was a poor correlation between relative translation and BMD.
measured on AP- and lateral-DEXA ($R^2 = 0.35$ and $R^2 = 0.02$).

**Age**

When comparing age with measurements of bone quality and biomechanical strength, a statistically significant correlation was noted with pullout strength ($R^2 = 0.24$) and relative rotation ($R^2 = 0.43$).

**T-Score**

T-score was found to have a statistically significant correlation with all the variables measured in our study: HU value, AP-DEXA BMD, lateral-DEXA BMD, pullout strength, relative translation, and relative rotation. The association was particularly strong between T-score and AP-DEXA BMD ($R^2 = 0.88$), as expected, and between T-score and HU value ($R^2 = 0.86$).

**HU Value and AP-DEXA BMD**

A very strong correlation was noted between HU value and AP-DEXA BMD ($R^2 = 0.92$ and $P < 0.000$).

**Pullout Strength vs Fatigue Strength**

Statistically significant correlation was noted between pullout strength and relative rotation ($R^2 = 0.60$) or relative translation ($R^2 = 0.49$).

**DISCUSSION**

Preoperative knowledge of bone quality is an important factor influencing clinical decision-making. The decisions to use a greater number of screws, alternative fixation techniques/implants, or augmentation with cement are based on the surgeon’s confidence in the strength of the pedicle screw-bone interface. Different methods of improving fixation in osteoporotic bone have been explored. Cement augmented pedicle screws have increased pullout strength compared to solid screws alone. Expansive pedicle screws with or without cement augmentation have also been shown to improve pullout strength in osteoporotic bone. At severely osteoporotic levels, fixation has been shown to remain poor even after these augmentation methods. This further emphasizes the difficulty of treating osteoporotic patients and the importance of understanding methods of preoperative BMD screening.

DEXA remains the gold standard for the evaluation of osteoporosis given its low cost, availability, and low radiation exposure. BMD measurements from DEXA images are classified according to a T-score that is an SD compared to a young, healthy reference population. A T-score of $-1$ to $-2.5$ is defined as osteopenia, while a T-score $< -2.5$ is defined as osteoporosis. There has been some debate in the literature about the utility of AP-DEXA when compared to lateral-DEXA. The theoretical benefit of a lateral DEXA image is a better assessment of the trabecular bone without overlapping the posterior elements. Lateral-DEXA was shown to be correlated more closely to quantitative CT when compared to AP-DEXA, and lateral-DEXA was more often identified in patients with osteopenia. However, AP-DEXA has remained the predominant screening tool as other studies have failed to show lateral-DEXA superiority when compared to AP-DEXA. This study found a strong correlation between pullout strength and AP-DEXA but only a fair correlation between pullout strength and lateral-DEXA. On fatigue testing, AP-DEXA showed a good correlation to relative angular rotation ($R^2 = 0.72$, $P < 0.005$); however, there was no correlation found with relative translation. Lateral-DEXA BMD did not have a statistically significant correlation with either of the fatigue parameters measured. The inclusion of the superimposed posterior elements in the calculation of AP-DEXA BMD is likely the reason for the stronger correlation with predicting pedicle screw biomechanics.

CT HU has been investigated as an alternative method of assessing BMD. This has been shown to be a reliable
method of assessing BMD and has been demonstrated to be a better predictor of pedicle screw loosening.\textsuperscript{11,12,15} Several HU thresholds have been proposed to define osteoporosis. While no consensus has been established, a recent meta-analysis has proposed a threshold of 135 HU.\textsuperscript{27} Limitations included cost, availability, and radiation exposure.\textsuperscript{13} Opportunistic use of CT images that are often obtained during routine preoperative investigation negates these disadvantages and adds utility equivalent to AP-DEXA without the expenditure of patient time or cost. The ROI selected for this study’s HU value calculations also excludes contributions from the posterior elements, similar to lateral-DEXA. Despite this, the correlation between HU value and pedicle screw pullout strength is as strong as with AP-DEXA (with a trend toward a stronger). HU value showed a statistically significant correlation with both measurements of fatigue, angular rotation ($R^2 = 0.54$ and $P < 0.05$), and translation ($R^2 = 0.43$ and $P < 0.05$), while AP-DEXA only showed a statistically significant correlation to relative angular rotation.

HU measurement is taken from manually created ROIs, which include an element of measurement bias. Previous investigations have used 1 to 3 ROIs per vertebral body.\textsuperscript{11,28} In our study, we chose to use an average of 5 ROIs with 3 of those ROIs located at the pedicle level to give additional weight to bone located in the path of pedicle screws and to minimize measurement bias.

Limitations of this study include the loss of 6 samples during the testing process, decreasing the total vertebræ available for testing to 11 and decreasing the power of the correlations. Our method for assessing fatigue strength may not reproduce in vivo failures. A new method of measuring bone quality (vertebral bone quality score) using magnetic resonance imaging has more recently been described since the initiation of this study and so was not able to be included.\textsuperscript{29,30} Magnetic resonance imaging on cadavers in the biomechanics lab is also not likely to provide clinically accurate results, limiting future possibilities of investigating vertebral bone quality score in this type of study.\textsuperscript{31}

**CONCLUSION**

CT is the only modality that exhibits a statistically significant correlation to all biomechanical parameters measured (pullout strength, relative angular rotation, and relative translation). AP-DEXA is as good as CT in predicting pedicle screw pullout strength. Lateral-DEXA has a poor correlation to all biomechanical parameters measured. AP-DEXA is a low radiation, low cost, and widely accessible modality for assessing bone quality prior to lumbar pedicle screw instrumentation. CT may provide an incremental benefit in assessing fatigue strength, but this should be weighed against the disadvantages of cost and radiation. CT provides the advantage of avoiding erroneously elevated AP-DEXA BMD values due to errors caused by midline vascular calcifications and can provide a bone quality assessment of any potential instrumented vertebra. Measurements taken from previously obtained CT images avoid the aforementioned limitations while providing high-quality information regarding bone strength that is equal or superior to AP-DEXA.

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Predicting Pedicle Screw Pullout and Fatigue Performance


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