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Fatigue Performance of Cortical Bone Trajectory Screw Compared to Standard Trajectory Pedicle Screw

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ABSTRACT

Study Design

Cadaveric biomechanical study.

Objective

To determine fatigue behavior of cortical bone trajectory (CBT) pedicle screws.

Summary of Background Data

Cortical bone trajectory screws have been becoming popular in spine surgery; however, the long-term fatigue behavior of the new CBT screws still remains understudied and limitations not well-defined.

Methods

Twelve vertebrae from 6 cadaveric lumbar spines were obtained. After bone mineral density (BMD) measurements, each vertebral body was instrumented with screws from each group, i.e., CBT (4.5 x 25 mm) or standard pedicle screw (6.5 x 55 mm). A load (± 4 Nm sagittal bending) was applied under displacement control at 1 Hz. Each construct was loaded for 100 cycles or until 6° of loosening was observed. After fatigue testing, the screws were pulled out axially at 5 mm/min.

Results

The standard pedicle screw showed better resistance against 100 cycle loading compared to the CBT screws (P<0.001, 6.9°±4.8° vs 15.2°±5.5°, respectively). The standard pedicle screw testing usually required more than 100 cycles of loading to achieve the critical loosening (3592±4564 cycles) while the CBT screw never exceeded 100 cycles (84±24 cycles) (P=0.002). Increased BMD was significantly associated with a higher number of cycles and less loosening. The standard pedicle screw group had a higher post-fatigue pullout load than the CBT screw group (P=0.001, 776±370 N and 302±232 N, respectively).

Conclusions

The standard pedicle screw had a better fatigue performance compared to the CBT screw in vertebra with compromised bone quality. The proper insertion of the CBT screw might be prevented by the laminar anatomy depending on the screw head design. The CBT screw damaged the bone along its shaft by rotating around a fulcrum, located either at the pars, pedicle isthmus, or the junction of the pedicle and superior endplate, contingent upon the strength of the bone.

Key Words: Pedicle screw; Cortical screw; traditional trajectory; cortical bone trajectory; fatigue testing; pullout testing; biomechanics; strength

Level of Evidence: N/A

INTRODUCTION

Cortical bone trajectory (CBT) screws have been becoming popular in spine surgery because this new construct allows less soft tissue retraction than does the standard pedicle screw construct. Santoni et al found that CBT screws, which engage the pars and the medial and superior cortices of the pedicle isthmus, had a similar pullout resistance as the traditional pedicle screws[1]. In addition, the CBT screws seem to provide comparable stability to a single lumbar motion segment as the standard pedicle screw construct, which was shown by a cadaveric biomechanical study[2] .

Although these biomechanical studies showing favorable outcomes[1-3] are encouraging, the long-term fatigue behavior of the new CBT screws remains understudied and limitations not well-defined. In a recent study by Baluch et al, the authors investigated the cyclic fatigue performance of the CBT screws compared to the standard screws in a cadaveric model[4]. They tangentially cycled both types of screw, inserted into the pedicles of the same vertebra, by loading them at the screw head and compared the load and cycle number at which the screws failed. They showed that the CBT screws outperformed the standard pedicle screws in the cadaveric lumbar vertebrae, which had normal bone quality as detected by quantitative computed tomography.

In this study, we employed cadaveric specimens with less than ideal bone quality to assess the fatigue behavior of the CBT screws. We also used a new fatigue fixture for the testing of the bone-screw interface, which mimicked the ASTM F1717 setup designed for pedicle screw system fatigue testing. We believe that this new testing protocol will apply a bending moment to the screw that better simulates physiologic screw loading and motion than traditional method of loading the screw via a hinge-joint. The hypothesis of this study was that the standard pedicle screw would have a better fatigue performance than the CBT screw in a vertebra with less than ideal bone quality.

MATERIAL AND METHOD

Study Design:

In this study, the CBT and standard trajectory pedicle screws were inserted in the same vertebrae and cyclically loaded to failure under sagittal bending. The loosening at the bone-screw interface was monitored by means of reflective markers and infrared cameras. All screws were pulled out axially following the fatigue testing.

Specimen Preparation:

Six human cadaveric lumbar spines without any infectious and neoplastic disease were obtained. After scanning with dual-energy X-ray absorptiometry (DEXA) to quantify the bone mineral density (BMD), the spines were separated into single vertebral specimens by removing all soft tissue. Then each vertebral body was wrapped in saline soaked paper towels, heat-sealed in a plastic bag, and stored at -20°C until the night before the day of testing. Twelve vertebra from all lumbar spines were allocated for this study (N=12).

After thawing overnight in the fridge, each specimen was instrumented with pedicle screws from each group, i.e., CBT or standard pedicle screw. The vertebral levels and right and left pedicles were carefully assigned so that all lumbar levels were preferred and no screw type was inserted with a right/left side-bias. Specimens were embedded into a dental stone (Die Stone, Eti Empire Direct, Anaheim, CA).

Instrumentation:

On the traditional trajectory side, pilot holes were started at the junction of the mid-transverse process and the lateral aspect of the superior facet and extended using a high-speed surgical burr with a diameter of 1.7 mm (Midas Rex Legend, Medtronic, Minneapolis, MN) following the anatomical orientation of the pedicle. The hole was enlarged by using a gearshift probe. Then, a 6.5 x 55 mm polyaxial pedicle screw (NuVasive, San Diego, CA) was placed with pedicle screw driver until all threads were inserted into bone without tapping (Figure 1).

On the CBT side, the screw starting point was at the junction of the inferior borderline of the transverse process and the midline of the superior facet, which was approximately 2 mm medial to the lateral margin of pars interarticularis. The same surgical burr was used to start and extend the hole with a trajectory of approximately 25° cephalad and 8° lateral as described by Matsukawa et al[5]. After tapping, 4.5 x 25 mm polyaxial cortical screws (Nuvasive, San Diego, CA) were inserted using a driver. The screws were inserted until the tulip head of the screw contacted the pars and/or the lamina. Further advancement of the screw was hampered by resistance from the pars and lamina, which sometimes left a few proximal threads unengaged from the bone (approximately 4-5 mm form the bottom of the tulip head). This seemed to be a screw design and anatomy limitation of the CBT screw, which has never been documented previously and could not be eliminated without compromising the bone structure. The spinous process was removed during the insertion of the CBT as deemed necessary to achieve the desired trajectory.

The screw placements were confirmed with coronal and lateral x-ray images for all specimens (Figure 2).

Fatigue Testing:

Fixture Design: A new fatigue fixture was designed to homogenously load the screws in bending. The new fixture mimicked the ASTM F1717 setup, in which two opposite and equal forces generated pure bending moment acting on the spinal construct via two hinge-joints (Figure 3). This design helped eliminate the shear (pullout) forces that occur in commonly used fatigue fixtures in which the screw deflects via an axial load applied to the screw through a hinge-joint (REFs). The fixture had counterweights to balance the weight of the brackets that held the vertebra and top screw.

Testing Protocol: The specimen was secured to the bottom bracket with threaded rods with keeping the specimen centered and transverse processes parallel to the edge of the bracket. A 5.5x130 mm spinal rod was attached to the screw using a locking nut tightened with a torque wrench. The top end of the rod was attached to the top bracket through a pedicle screw inserted into an ultrahigh molecular weight polyethylene block, keeping the spinal rod vertical.

The relative motion of the bone - screw interface was measured with reflective markers and a motion analysis system (Vicon, Oxford, UK). Two K-wires were randomly bent after a black heat-shrink plastic tube was fitted to prevent any reflections from the wire surface. Four ~5 mm reflective markers were randomly attached to each wire with glue. The vertebral markers were inserted either to the lamina or superior facet as close to the screw as possible. The screw markers were glued to the screw head. The coordinate system was anatomically oriented such that the X-axis was in the medio-lateral plane, Y-axis was in the antero-posterior plane and parallel to the endplates, and Z-axis was in caudo-cephelad plane.

The loading was conducted under displacement control at 1 Hz. An adaptive control algorithm was selected where the loading (ie, displacement) was increased gradually until pre-determined minimum and maximum forces were achieved. The amount of force was determined by measuring the distance of the spinal rod to the plane of hinged-joints to produce a ± 4 Nm sagittal bending moment at the rod (i.e., screw head). Each construct was loaded for 100 cycles or until 6° of loosening (i.e., relative motion at the bone-screw interface) was observed in order to cause damage that could be detected by pullout test. If a 6° angle was not achieved by 10,000 cycles or the physical stroke limit of the testing machine was reached earlier than 100 cycles, indicating a marked loosening in fixation, the test was manually stopped. In addition to the marker data, the load and displacement data were also collected from the testing machine.

Pullout Testing:

After fatigue testing, the screws were pulled out axially to determine the post-fatigue holding power of the screws. Thus, each specimen was placed in an adjustable vice such that the screw was vertically oriented (Figure 4). Screw orientation inside the pedicle was estimated with the pedicle screwdriver, which could firmly attach to the screw shaft and its poly-axial tulip head. After securing the specimen into the vice, inline with the crosshead of the testing machine, the screw was pulled out at 5 mm/min by means of steel wire until several proximal threads were visible. The load and displacement data was collected. The maximum load was noted as the pullout load.

Statistical Analysis:

From the fatigue test, the relative angle at the 100th cycle and the end-point cycle number for each screw were recorded. Both screw types were compared with a paired t-test with a significance level set at 0.05. The post-fatigue pullout loads were compared using a paired t-test. If the data did not pass the Shapiro-Wilk normality test, a non-parametric t-test (Mann-Whitney) was preferred. Pearson cross-correlation analysis was run for age, bone density, end-point cycle number, relative angle at 100th cycle, and pullout load.

RESULTS

Bone Density:

The bone density information along with the demographics of the donors was presented (Table 1). The average age of the six donors was 87±5 yrs (4M/2F). The average lumbar (L1-4) T-score was -1.1±0.9 and average BMD of the specimens was 0.9±0.1 g/cm^2. Age was not significantly correlated with either T-score or BMD (P>0.05).

Fatigue Performance:

The standard pedicle screw showed better resistance against 100 cycle loading compared to the CBT screws (P<0.001, 6.9±4.8 degree vs 15.2±5.5 degree, respectively) (Table 2). The standard pedicle screw testing usually required more than 100 cycles of loading to achieve the critical loosening (3592±4564 cycles) while the CBT screw never exceeded 100 cycles (84±24 cycles) (P=0.002).

In CBT screw group, higher cycle numbers and less loosening were significantly associated with increased BMD (P<0.05). In standard pedicle screw group, increased BMD was significantly associated with increased cycle number required for critical loosening in the screw fixation (P<0.05).

Pullout:

The standard pedicle screw group had a higher post-fatigue pullout load than the CBT screw group (P=0.001). BMD was significantly and strongly correlated with pullout load in CBT screw group (P=0.003, r=0.85). In the standard group, there was a moderate association of BMD with pullout but it was not found to be significant (P=0.06, r=0.64).

Pullout load was strongly correlated with the amount of relative motion at the bone-screw interface after 100-cycle loading in the standard group (P<0.001, r=-0.87) but not in the CBT screw group (P=0.07, r=-0.53).

DISCUSSION

Supporting our hypothesis, this study showed that the standard pedicle screw had better fatigue performance than the CBT screw in vertebrae with compromised bone quality.

An observation of utmost importance from this study was related to the anatomical limitations of the CBT technique. In most of the screws, the tulip-head of the screw rested on the curvature of the junction of the spinous process and lamina, lamina, or inferior margin of the superior facet, preventing the full insertion of the screw. This was a significant problem that occurred to some degree in all spinal levels but most involved in the upper lumbar spine. Coercing the screw to full insertion in this situation would partially damage the lamina or pars or the bone-screw interface. Thus, in the CBT group, some screws were inserted 3-5 mm less than the full length. We did not quantify this but think that it could have added to the poor performance of the already small CBT screw. One might think that advancing the screw head to the laminar cortex will increase toggle resistance, however this was not the case in our study and has been previously shown to be not true[6].

There is only one study in the literature to date investigating the fatigue behavior of the CBT screw probably because it is a relatively new system on the market. Baluch et al found that the CBT screw had a superior performance against loosening through fatigue test when compared to the standard pedicle screw[4]. The results of the current study are not in agreement with this finding.

There could be several explanations to this conflict. First, in the previous study, the researchers used cadavers with normal bone quality. However, the spines in the current study had diminished bone quality. In contrast with the current belief that the CBT screws would maintain the mechanical advantage despite decreasing bone quality could not be confirmed by our study. Apparently, the cortical purchase was not sufficient to counteract the small length and diameter of the CBT screw in maintaining fixation under tangential cyclic loading in low density vertebrae. Secondly, the testing setup and loading methodology of two studies were different. In the previous study, the authors tangentially loaded the screws at the head by a vertical loading while pure bending moment was applied to the construct in the current study. Thirdly, in the previous study, the cyclic loading ended when sagittal displacement of the screw reached 2 mm as opposed to our loosening criterion, which caused significantly larger displacements at the screw head, especially when the angle reached 20°. The criterion of at least 100 cycles and 6° of loosening served the purpose of ensuring a marked damage at the bone-screw interface that could be detected by the subsequent pullout test. Otherwise, we could have run into the risk of not having sufficient number of cycles that would yield a “fatigue loosening”.

After the experiment, upon manual palpation and visual inspection of the vertebral cross-section along the screw hole on a few specimens with large loosening, we observed that screws showed a “windshield wiper” or “teeter-totter” motion defined for the standard pedicle screws [6, 7]. Screws purchased some of the four cortices, namely, the cortical bone at the pars, inferior and superior cortices of the pedicle isthmus, and the junction of the superior margin of pedicle and superior endplate. The form of the loosening depended on the strength of these components in each vertebra. Basically, the screw rotated about a fulcrum, which was close to the region providing the strongest support.

To our surprise, the DEXA measurements (T-score and BMD) did not reflect our expectations on the bone quality given the age of the donors, our tactile examination of the bone strength and post-test visual inspection of the internal structure of the vertebrae (Figure 5). This conflict cannot be explained by the scanning protocol because we followed the water-bath technique as usual[8]. We think that our BMD values might have been skewed in favor of better bone quality because of the degree of degeneration in the spine. The degenerated spine is not easy to scan and analyze with DEXA because of the abnormalities in the vertebral alignment (eg, wedge or compression fractures, osteophytes, scoliosis, collapsed disc space, etc). Osteoarthritis in the lumbar spine explains the 16 % and 22 % variance in BMD in women and men, respectively[9] . In clinical practice, femoral scans are preferred to avoid biased bone density measurement due to arthritis in the lumbar spine.

The results of the present study are limited to the cadaveric spine and low bone quality. The loading method was simplified to sagittal bending, which is obviously different from the complex loading mechanisms of an in-vivo construct. The current experiment did not take into account the load sharing occurring in the spine among the disc (or graft), facets, ligaments, and construct. Our protocol also did not consider the life style of a patient at the same age as our donors. The older patients might be more cautious and conservative in their daily activities after spine surgery, which might hamper or prevent fatigue loosening.

CONCLUSIONS

The standard pedicle screw had a better fatigue performance compared to the CBT screw in lumbar vertebrae with compromised bone quality. The CBT screw damaged the bone along its shaft by rotating around a fulcrum, located either at the pars, pedicle isthmus, or the junction of the pedicle and superior endplate, contingent upon the strength of the bone. The proper insertion of the CBT screw might be prevented by the laminar anatomy depending on the screw head design.

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Table Legends

Table 1: Specimens demographics and bone quality scores.

Donor	Level	Age	Gender	T-Score	BMD (g/cm^2)
1	**L3**	89	M	-2.0	0.941
	L4				0.978
2	**L2**	82	F	-0.5	0.941
	L4				1.145
	L5				-
3	**L2**	84	M	-2.1	0.828
	L3				0.846
	L5				-
4	**L5**	92	M	-0.5	-
5	**L3**	82	M	-0.1	1.177
	L4				0.840
6	**L1**	93	F	-1.5	0.771
	Mean	**87**		**-1.1**	**0.941**
	SD	**5**		**0.9**	**0.141**

Table 2: All specimen data regarding the relative motion (RM) at the bone-screw interface at the 100th cycle, the number of cycles at the end point of testing, and axial pullout load after fatigue testing were listed for both standard and cortical trajectory bone (CBT) screws. The standard pedicle screws had a superior performance against fatigue loading compared to CBT screws.

Donor	Level	RM @ 100th cycle		Cycle # @ end		Pullout (N)	
		Standard	CBT	Standard	CBT	Standard	CBT
1	**L3**	19.2	6.4	85	100	66	146
	L4	12	12	100	100	591	389
2	**L2**	4.9	16.5	649	100	982	220
	L4	2.8	13	10000	100	1062	459
	L5	3.9	15	10000	100	1118	136
3	**L2**	5.7	18.9	131	47	542	10
	L3	6.4	20	102	50	691	127
	L5	4.3	22	3330	77	893	384
4	**L5**	8.6	14.7	100	100	698	479
5	**L3**	2.1	6.7	10000	100	1420	848
	L4	3.7	13.1	8516	100	932	339
6	**L1**	9.5	24.3	100	40	322	81
	Mean	6.9	**15.2**	**3593**	**85**	**776**	**302**
	SD	4.8	**5.5**	**4565**	**24**	**370**	**232**

Figure 1: Screws that were used in experiment. (**bottom**) 6.5 x 55 mm polyaxial pedicle screw (NuVasive, San Diego, CA) and (**top**) 4.5 x 25 mm polyaxial CBT screw (NuVasive, San Diego, CA).

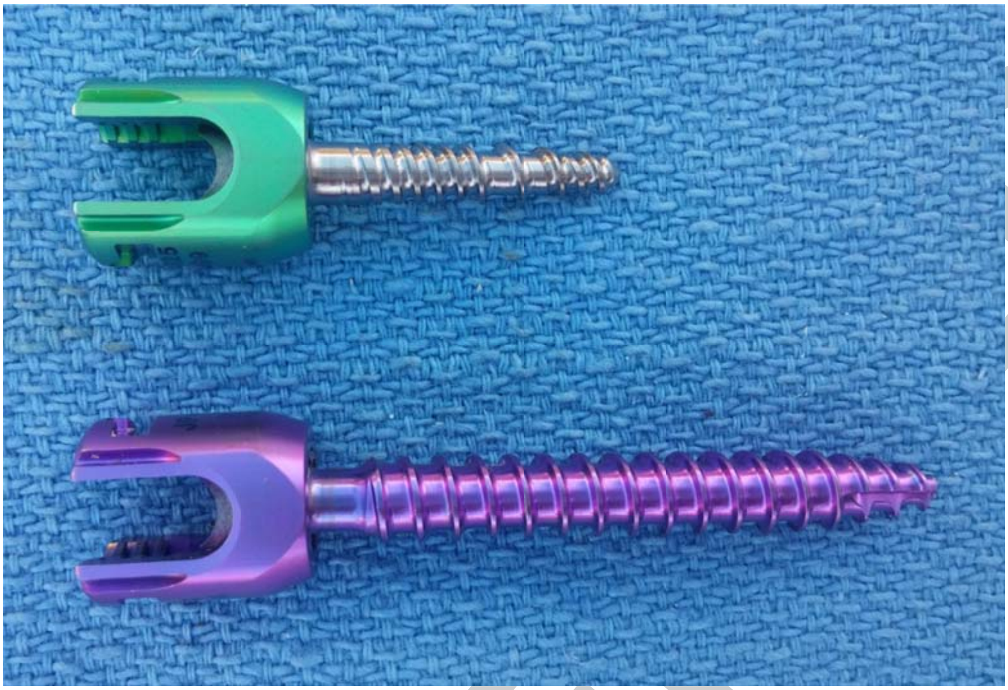

Figure 2: X-Ray image of a vertebra after instrumentation.

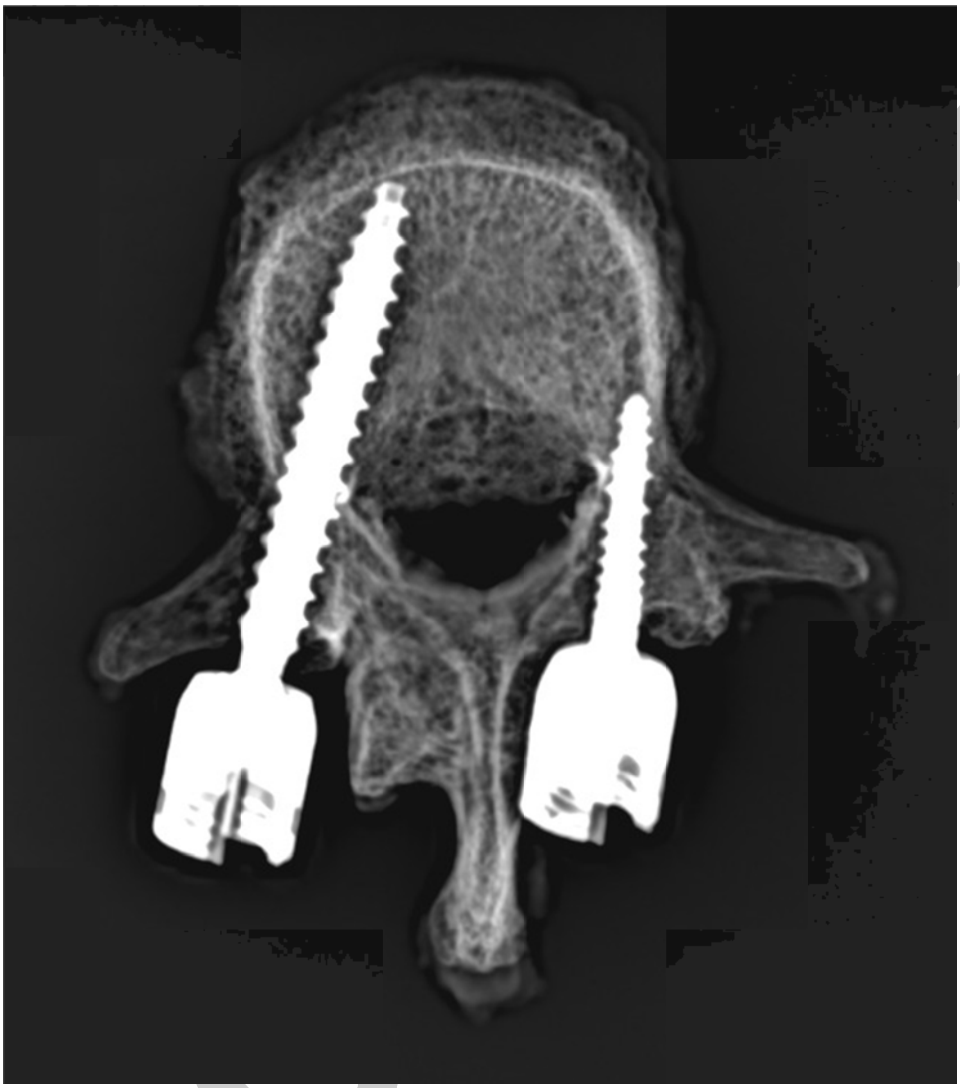

Figure 3: Fatigue testing setup. The instrumented specimen with reflective markers attached was held by the bottom fixture and polyethylene block - pedicle screw unit was held by the top fixture, both of which were able pivot around the pins as the crosshead of the machine moved up and down.

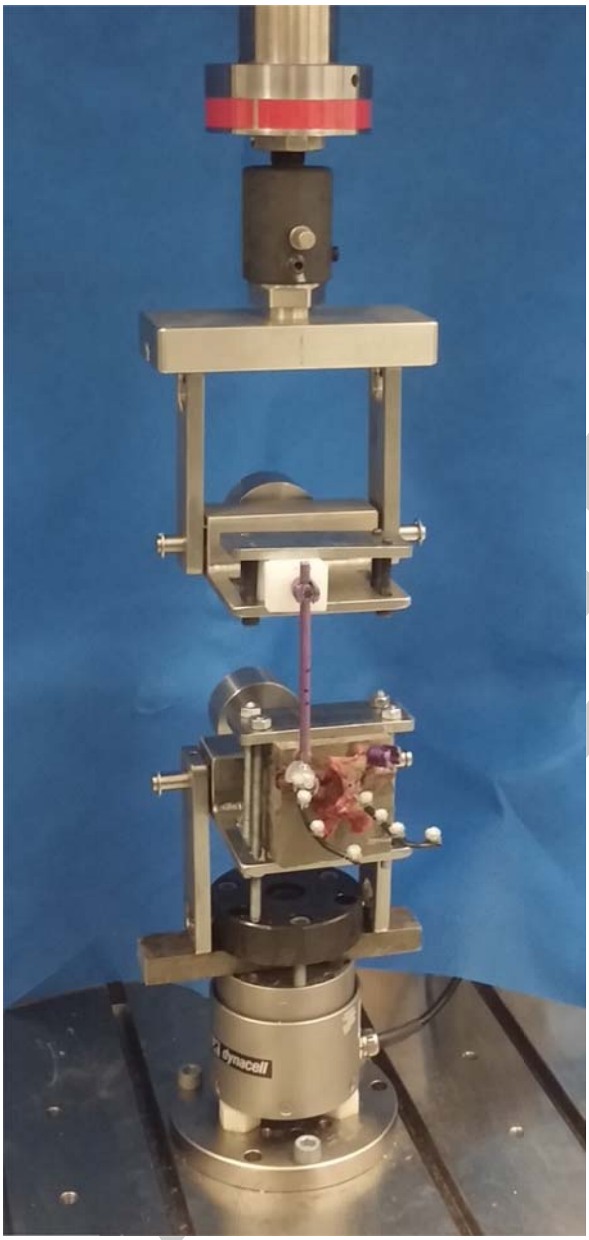

Figure 4: Pullout testing setup. The adjustable vice held the specimens such that the screw would be oriented vertically. A curved spinal rod was secured to the screw head. The rod was attached to top clamp via the steel wire.

Figure 5: Post-fatigue visual inspection of the vertebra and screw hole. (a) A pin with the same diameter with the CBT screw was toggled to illustrate the degradation in the screw hole after fatigue test. (b) The cross-sectional view of the vertebra through CBT screw trajectory. The CBT screw was placed on the screw track (the original insertion depth is unknown). The loosening was apparent along the screw hole with a large void at the proximal end of the screw. In addition, the fenestrations and thinning in the trabecular bone indicate compromised bone strength due to aging.

A

B