Biomechanical analysis of vertebral body load-to-failure after cement augmentation with polymethylmethacrylate cement augmentation performed using two different techniques

By

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Abstract

Introduction

Cement augmentation is a commonly performed procedure by spine surgeons as well as interventional radiologists. The ultimate goal of cement augmentation is to aid a vertebral body in resisting axial stresses. Understanding the difference between traditional and modern techniques in cement augmentation is therefore important in providing the best possible augmentation technique.

Objective: To compare the traditional technique of using a cannulated needle to introduce cement followed by a non-cannulated, non-fenestrated screw against introduction of cement through a cannulated, fenestrated screw.

Materials and Methods: Eight cadaveric spines were used. The T8-L1 vertebrae were dissected, divided into their respective groups, potted in a resin, augmented and subjected to increasing axial loading.

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Chapter 1: Introduction

There are around 1.62 million instrumented spinal surgeries performed per year in the US (Dyrda, April 5, 2019) and approximately 1.5 million vertebral compression fractures that occur annually in the US (Alexandru & So, 2012). Both require the use of cement augmentation via one of several techniques. Polymethylmethacrylate cement augmentation of vertebral bodies is performed for a variety of reasons in clinical practice. Surgeons and interventional radiologists currently utilized cement augmentation for multiple clinical goals. Prevention of vertebral body fracture or collapse is a common reason cement may be used. In spinal deformity patients undergoing surgery, cement augmentation may be utilized to prevent a vertebral body fracture at the upper level of instrumentation or the levels just proximal to this.

Different methods for introducing cement into the cancellous portion of the vertebra exist and include the use of a cannulated needle for direct injection or alternatively using a fenestrated, cannulated screw that allows cement injection and extravasation through multiple holes in the screw. Each technique utilizes different insertion devices and produces different intra-body cement spread patterns. To our knowledge, no study has analyzed the biomechanical differences between the different cement injection techniques and how this impacts the prevention of vertebral body collapse or fracture.

The purpose of the study is to better understand the clinical relevance of cement augmentation techniques commonly used in spinal deformity surgery and whether biomechanical differences exist between augmentation techniques. This will be accomplished by performing cement injection in vertebral bodies using two commonly used techniques and then biomechanically test the strength and load to failure between the samples.

Chapter 2: Literature Review

2.1 Vertebral Compression Fractures

A vertebral compression fracture (VCF) is due to an axial/compressive load with resultant biomechanical failure of the bone and presents in a bimodal distribution with younger patients, secondary to high energy mechanisms, and with older patients secondary to osteoporosis(C. J. Donnally, 3rd et al., 2019; Maempel & Maempel, 2019). By definition, a VCF involves the anterior column and therefore is a failure of the anterior vertebral body and the anterior longitudinal ligament (ALL). This is how they are differentiated from a burst fracture which results in disruption of the anterior and posterior osseous components. Approximately 60-75% of VCFs occur at the thoracolumbar junction. The thoracolumbar region, specifically the T10-L2 vertebrae, is the most common region of the spine to be affected by trauma. This is due to the transition from a rigid thoracic spine to a more flexible caudal spine (I. C. Donnally, DiPompeo, & Varacallo, 2021; Fernandez-de Thomas & De Jesus, 2021).

Experiencing a VCF leads to a kyphotic deformity of the spine which may result in future fracture of adjacent vertebrae or progressive deformity due to the altered biomechanics (I. C. Donnally et al., 2021). For this reason, surgical options may be considered based on fracture characteristics, particularly if indications of an unstable fracture are present. This includes identifying ≥30 degrees of traumatic kyphosis and a 50% vertebral body height loss, though these standards are changing. Rarely would instrumentation be required, as the most common surgical interventions are vertebroplasty or kyphoplasty. While kyphoplasty has shown marginally lower rates of cement extravasation (McCall, Cole, & Dailey, 2008; Schmidt et al., 2005), vertebroplasty is still widely performed. The vertebroplasty procedure involves the introduction of a shank, such as a Jamshidi, into the vertebral body. This is commonly achieved through the transpedicular approach (see Figure 1). Cement augmentation such as this should be considered in patients who have failed a trial of conservative management or are hospitalized due to pain and decreased function (Savage, Schroeder, & Anderson, 2014). Prophylactic cement augmentation in osteoporotic vertebrae has been demonstrated to maintain stiffness significantly better than vertebroplasty post-fracture (Furtado, Oakland, Wilcox, & Hall, 2007) and, similarly, Kurutz et. al. concluded that prophylactic cement augmentation of non-fractured adjacent vertebrae may be advantageous to avoid subsequent fractures after post-fracture vertebroplasty (Kurutz, Varga, & Jakab, 2019). An earlier study by Kinzl et. al. demonstrated that endplate-to-endplate cement augmentation yielded a stronger and stiffer vertebral body (Kinzl, Benneker, Boger, Zysset, & Pahr, 2012). These studies all point towards the benefits of prophylactic cement augmentation in the setting of vertebral body fracture, particularly in patients with osteoporosis.

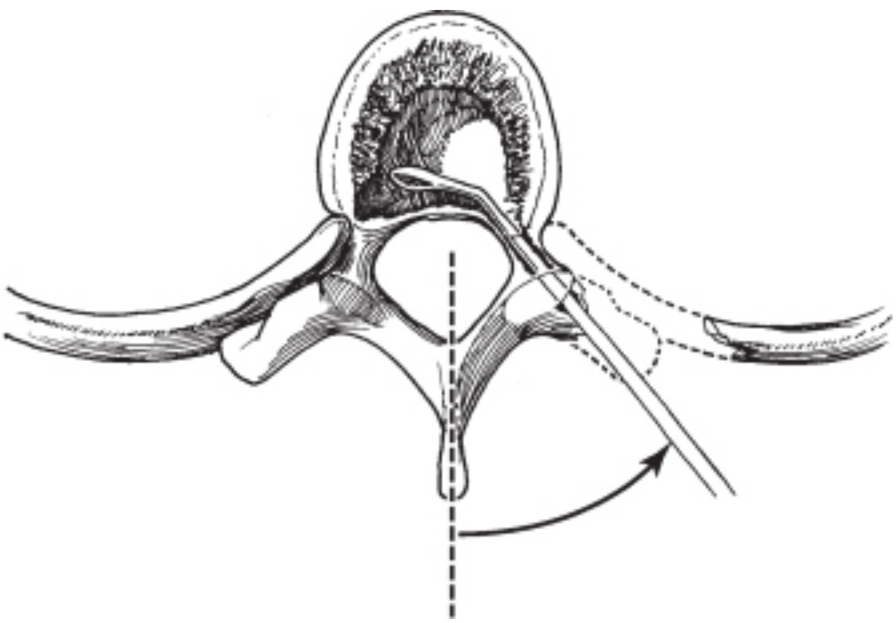

Figure 1. Transpedicular Approach

2.2 Cement Augmentation in Deformity Cases

Screw cement augmentation is also considered in the setting of deformity cases where instrumentation is required. A major concern in deformity surgery after long-segment instrumentation is the development of proximal junctional kyphosis (PJK). PJK is considered to be present when the sagittal Cobb angle between the upper instrumented vertebrae (UIV) and two supra-adjacent vertebrae exceeds 10°. Risk factors for PJK include patients with osteoporosis, prior history of VCF and history of fusion to the pelvis (Koike, Kotani, Terao, & Iwasaki, 2021). Screws placed in the upper or lower portions of the constructs may be augmented with cement to enhance pullout strength (Zapalowicz, Kierzkowska, & Ciupik, 2018). The use of 2-level cement augmentation has been associated with a decreased rate of acute proximal junctional fractures and associated revision surgeries, though a causal relationship has yet to be demonstrated (Theologis & Burch, 2015). This association was seen with cement augmentation of the uppermost instrumented vertebra (UIV) and the vertebrae one level proximal to the UIV. Between solid screws and more expensive and complex fenestrated screw, evidence suggests comparable screw stability in pull-out testing (Leichtle et al., 2016). We can see that while there has been research completed on the torsional/pull-out strength of fenestrated screws, there has not been research into how a fenestrated screw's cement distribution may impact load bearing as compared to more traditional methods.

2.3 Cement and Cement Distribution

The most used cement for the purpose of augmentation in spinal surgery is polymethylmethacrylate (PMMA). PMMA was first introduced operatively for joint arthroplasty including those of the hip and knee. It is usually supplied as two components being a powder and a liquid. PMMA can vary in viscosity, typically being categorized into low, medium and high viscosity cements. High viscosity cements are comprised of PMMA with no methylmethacrylate-styrene-copolymer content. Dealing with PMMA involves four main phases: mixing, waiting (2-3 min), working (5-8 min) and setting time (8-10 min) (Rajesh Kumar Ranjan, 2017). The reaction that occurs after mixing the liquid and powder components is quite exothermic and therefore care must be taken to ensure it does not irritate surrounding tissues. For this reason, as well, cement extravasation is a concern. Extravasation in the vertebral arteries can lead to arterial damage due to the exothermicity as well as the production of an iatrogenic thrombus and possible embolization (Makary, Zucker, & Sturgeon, 2015).

Cement distribution within the vertebral body is an area of research that has only received attention within recent years. In a study from Frankl et. al, the spread of polymethylmethacrylate was analyzed and a classification system was created to determine the type of spread; however, this study was performed using balloon kyphoplasty instead of our intended use of vertebroplasty (Frankl et al., 2016). Yuan et. al. compared targeted percutaneous vertebroplasty to traditional percutaneous vertebroplasty in the treatment of osteoporotic VCF's. They found that precise puncture and injection of small doses of cement at the fracture line results in a lower incidence of cement leakage and adjacent vertebral body fracture (Yuan et al., 2020). Cement extravasation is an important consideration to surgeons when performing these procedures and therefore understanding how volume and techniques impact this is key.

Chapter 3: Methods

3.1 Overview

This study was completed at the University of Kansas Medical Center in the Orthopaedic Research and Education Lab. The lab was equipped with a dissection room to handle cadaveric specimens, a heavy machinery shop capable of producing tools and molds that we required as well as a Material Testing System (858 Mini Bionix II, see Figure 1) able to perform the necessary controlled axial loading. The principal investigators were two orthopaedic spine surgeons.

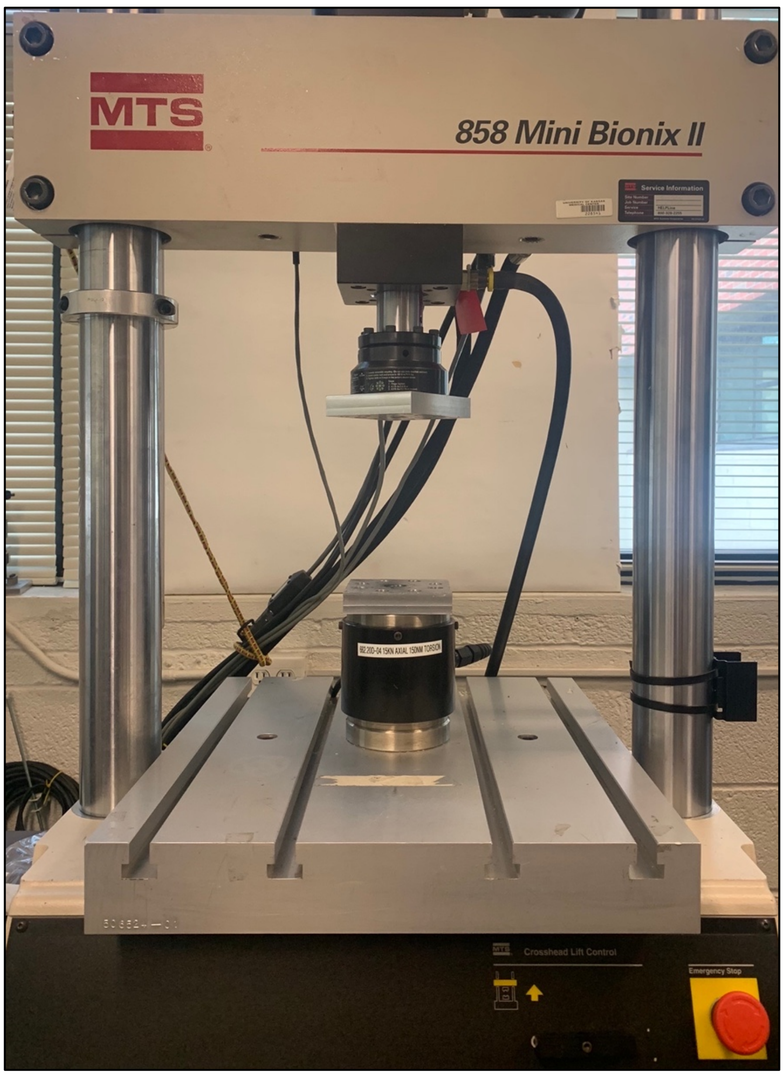

Figure 2. Materials Testing System

3.2 Specimens

Cadaveric spines were sourced from the available spines at the Orthopedic Research and Education Center (OREC) of Kansas University Medical Center (KUMC). Initial screening for fractures, previous surgery/hardware or any other defects was completed using fluoroscopy. Ten spines were selected, and computed tomography was then used to measure the Hounsfield units of the vertebral bodies to confirm the specimens were osteoporotic. All spines met the classification of osteoporosis based on Hounsfield units. Measurements were also taken to determine optimal screw shank length and diameter. Vertebral height and width were also recorded.

Soft tissue, including muscle, ligaments and tendons were removed from around the spine. The T8-L1 vertebrae were then disarticulated from the spines and intervertebral discs removed. Two spines were excluded, one due to end plate damage during dissection and one due to vertebral body fracture not previously identified on fluoroscopy. The T9 and T12 vertebrae in each spine served as the internal control for the T8-T10 and T11-L1 groups respectively. Within each spine, the T8, T10 and T11 and L1 vertebrae were sorted in their respective test groups (see Table 1). Each specimen received 2.0cc of Confidence cement through each pedicle for a total of 4.0cc in each vertebral body.

Table 1. Breakdown of Groups

NO CEMENT	CEMENT	
Control	Traditional (Jamshidi®)	Fenestrated Screw (CREO®)
16 vertebrae (T9 and T12)	16 vertebrae (T8 and T11)	16 vertebrae (T10 and L1)

The vertebrae were potted in Bondo® with the inferior endplate parallel to the base of mold. Each vertebra was potted in the fixture that would be used on the MTS to minimize variability. The ratio used for the Bondo was 260g of Bondo® to 4g of hardener. This ratio was determined after prior testing to make sure there was ample time to manipulate the vertebrae with in the hardening Bondo® such that optimal positioning could be obtained. The vertebrae were held in place by a three-pronged, adjustable clamp (see Figure 1) and the Bondo® was allowed 30 minutes to cure before removing from the fixture.

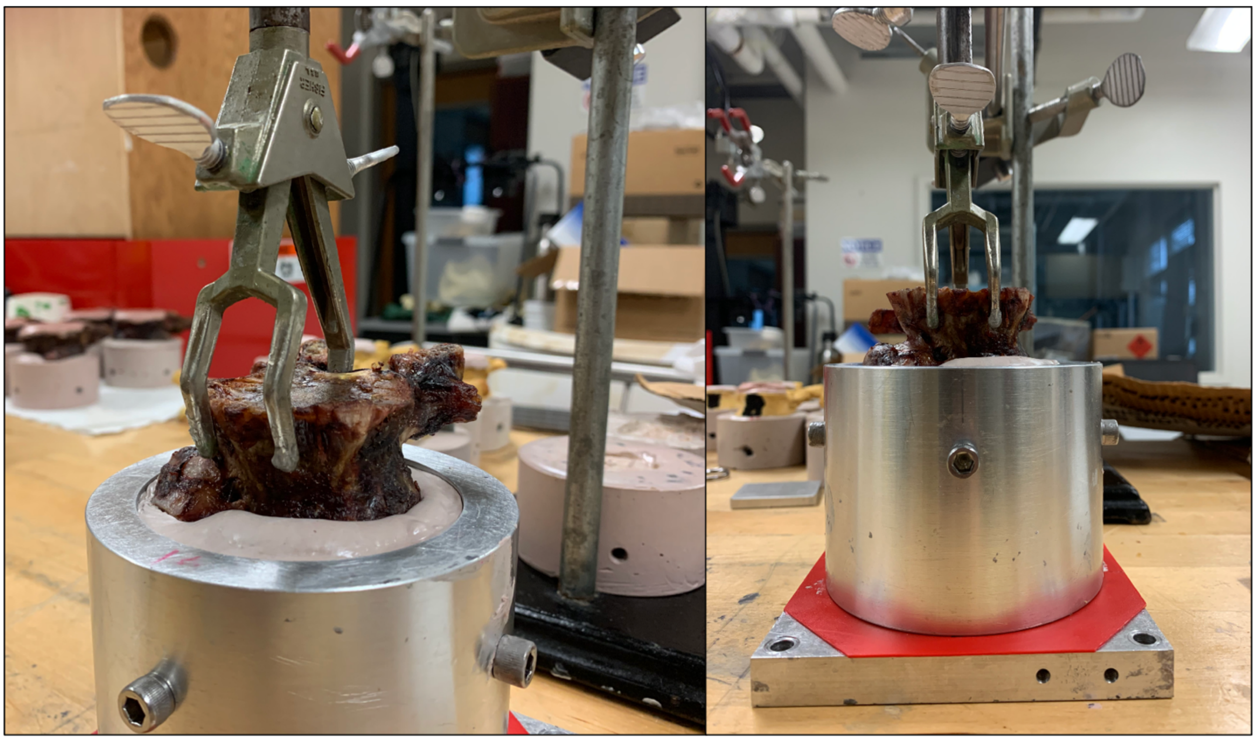

Figure 3. Potting Mechanism
Two views of the jig used to hold the vertebrae in place while allowing the Bondo® to cure.

The superior endplate and any anterior osteophytes had Bondo® applied which was flattened such that the force of the actuator would be evenly distributed along the surface of the superior endplate (and the osteophytes if present). This was also allowed 30 minutes to cure.

Figure 4. Vertebrae Potted in Bondo®
Top left shows an anterior view. Bottom left demonstrates how the posterior elements were not potted. Right demonstrates how the Bondo® was only applied the superior endplates and not to any posterior structures.

3.3 Intervention

As previously mentioned, the vertebrae were kept in groups based on the spine they were retrieved from. The T9 and T12 vertebrae of each spine remained the internal control for each spine. The T8 and T11 vertebrae in each group received intervention via the Jamshidi® Needle and Bone Void Filler followed by a non-cannulated, non-fenestrated screw. The T10 and L1 vertebrae in each group received intervention via the CREO® Fenestrated Screw System. Each vertebra received a total of 3.0cc of CONFIDENCE® High Viscosity Spinal Cement (1.5cc in through each pedicle). The vertebrae were once again imaged with computed tomography to ensure there was no extravasation of the cement and to assess cement distribution.

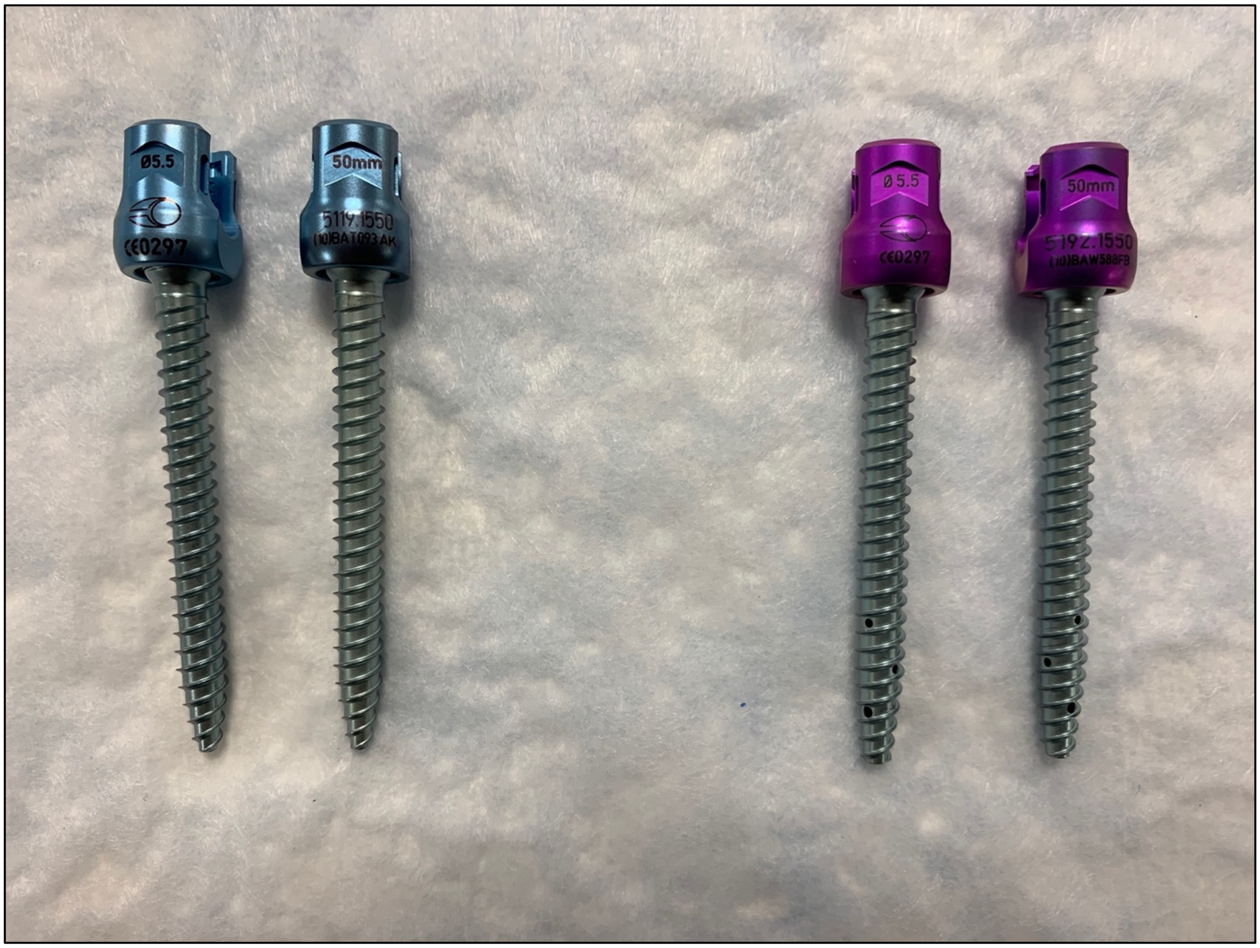

Figure 5. Screws
CREO® Solid Shank Screw (Left) and CREO® Fenestrated Screw (Right)

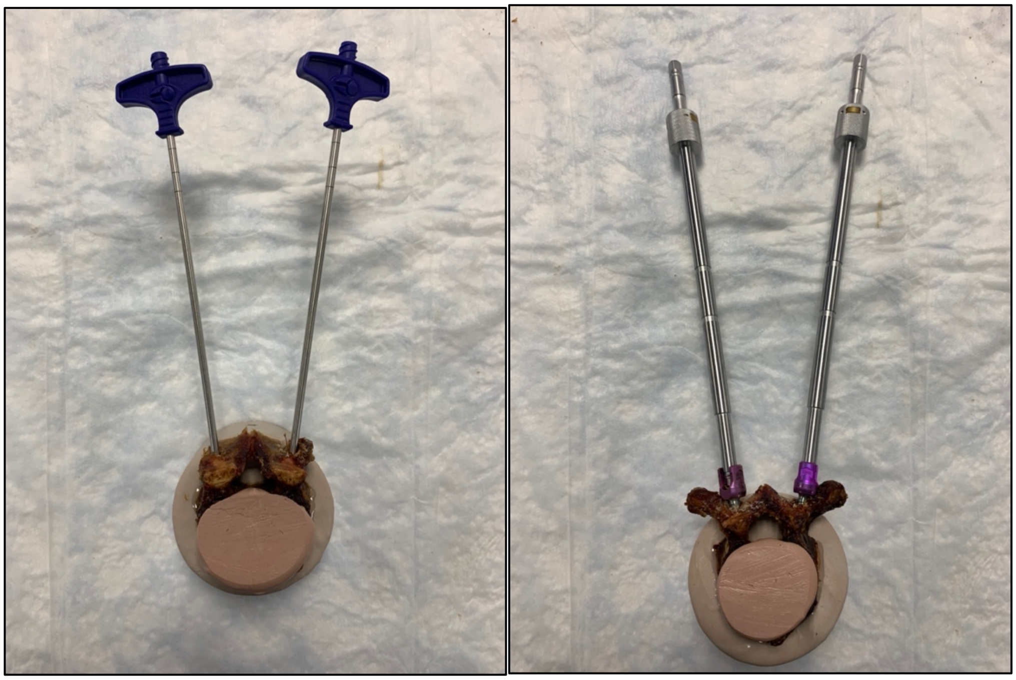

Figure 6. Cement Delivery Methods
Jamshidi® Cannula (Left) and CREO® Cement Delivery System (Right)

3.4 Testing

A jig was created to be attached to the loading cell of the MTS. This included a hinge adjustable in the anterior-posterior directions relative to the vertebral body. Each potted vertebra was loaded in the fixture and then locked in place such that the axis of rotation about the hinge would always be at the midpoint of the spina canal. This therefore allowed for use to calculate the necessary displacement that the actuator must travel to ensure 50% reduction in height for each vertebra (as seen in FIGURE).

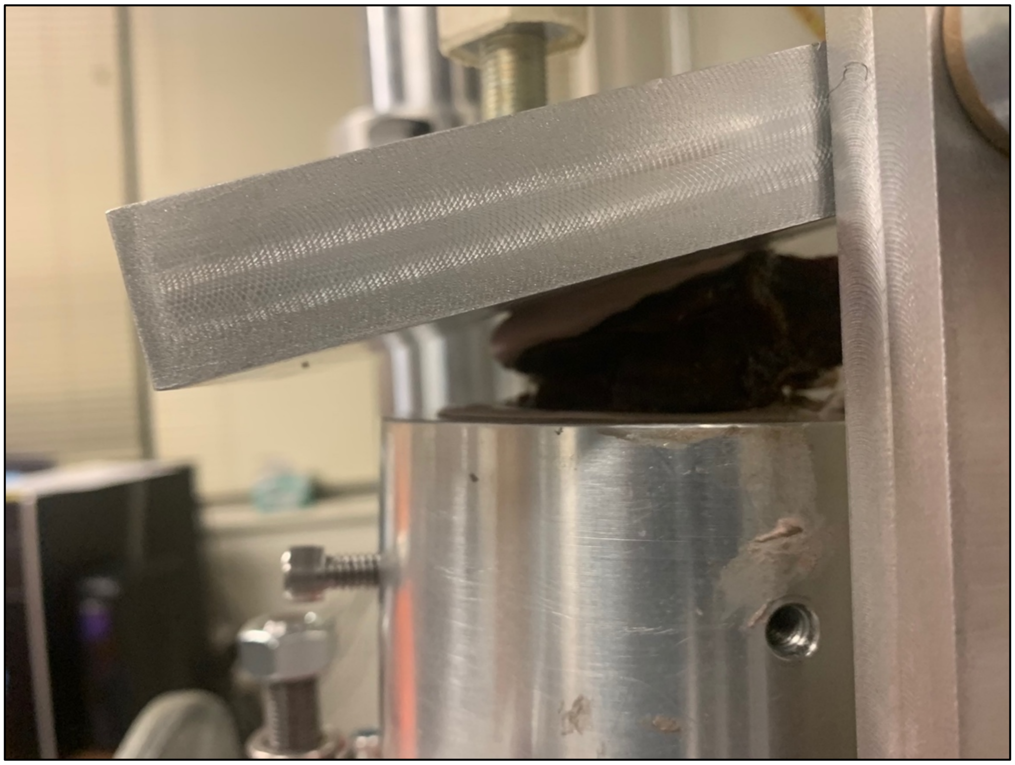
Figure 7. Hinge Action Example

The MTS was set to load at a rate of 5mm/min and the vertebrae were loaded until failure defined as fracture noted on the stress-strain curve within the necking phase (see Figure 3) of the curve. The stress at the maximal or ultimate strength of the augmented vertebrae as we all the stress at the time of fracture were recorded. Proper calibration was completed in between the loading of each vertebra to ensure consistent results.

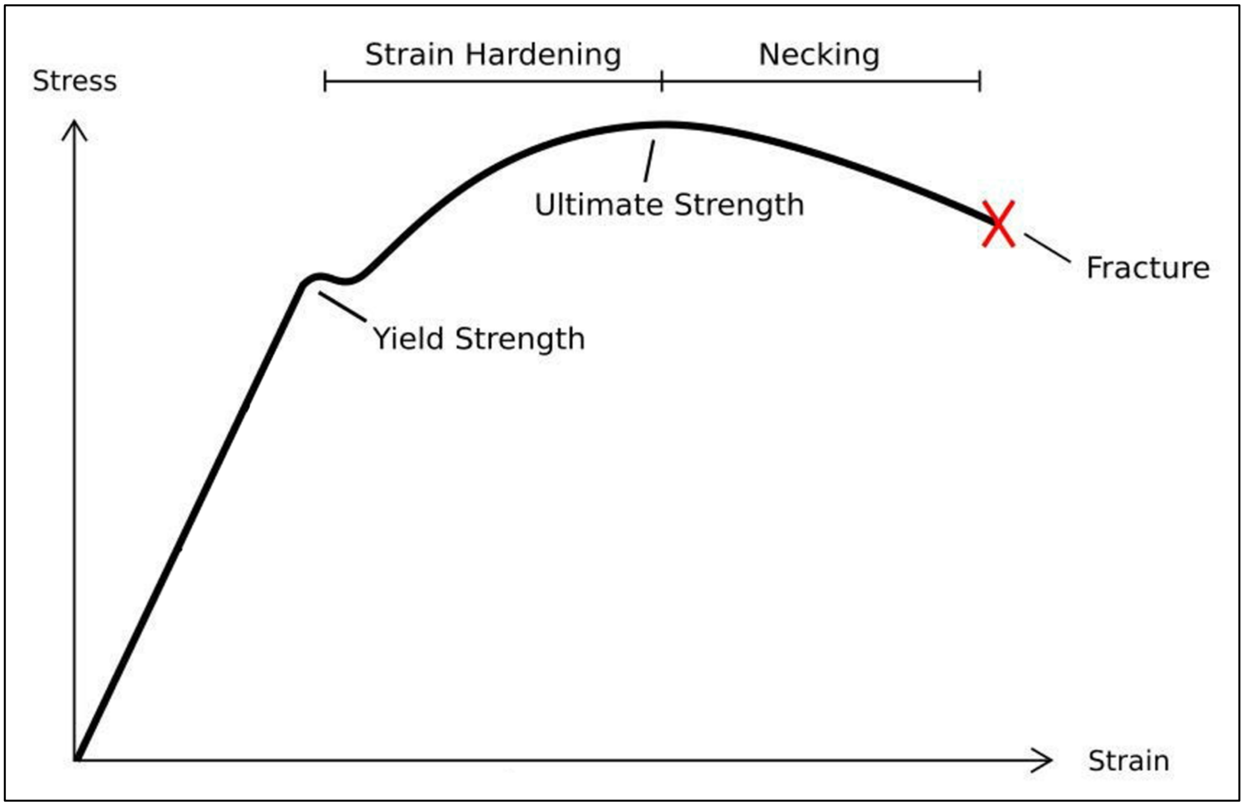

Figure 8. Example of Stress-Strain Curve

3.5 Data Analysis

The data will be analyzed by the investigation team and SPSS will be used to complete to the analysis. The data will be tested for normality and homogeneity of variance prior to determining statistical testing methods and parametric and non-parametric tests will be used as appropriate. This will most likely involve both paired T-tests and ANOVA. The primary outcome variable is differences in load to failure between groups. Differences in means (medians) will be calculated between technique groups within the same volume group for loads-to-failure values. Tests will be conducted with the following null hypotheses in mind:

<u>Null hypothesis 1:</u> There is no difference in load to failure when adding cement augmentation compared to no cement augmentation.

Null hypothesis 2: There is no difference in load to failure value between cement augmentation with Jamshidi or fenestrated screws using the same cement volume.

Additional subgroup analysis will be performed as deemed possible. Potential subgroups include vertebral body size vertebral body height.

Chapter 4: Results

4.1 Preliminary Results

Preliminary intervention and testing were completed on a set of 6 vertebra from the same spine that were deemed unfit for use in the proper test. On subsequent fluoroscopy shown in FIGURE 9 of two vertebrae that were augmented with the Jamshidi/solid screw method (left) and CREO® Fenestrated Screw System we can see that the traditional Jamshidi methods resulted in a greater anterior distribution of cement as anticipated. The cement delivered via the fenestrated screw system resulted in a more radially and concentrated dispersion of cement around the screws.

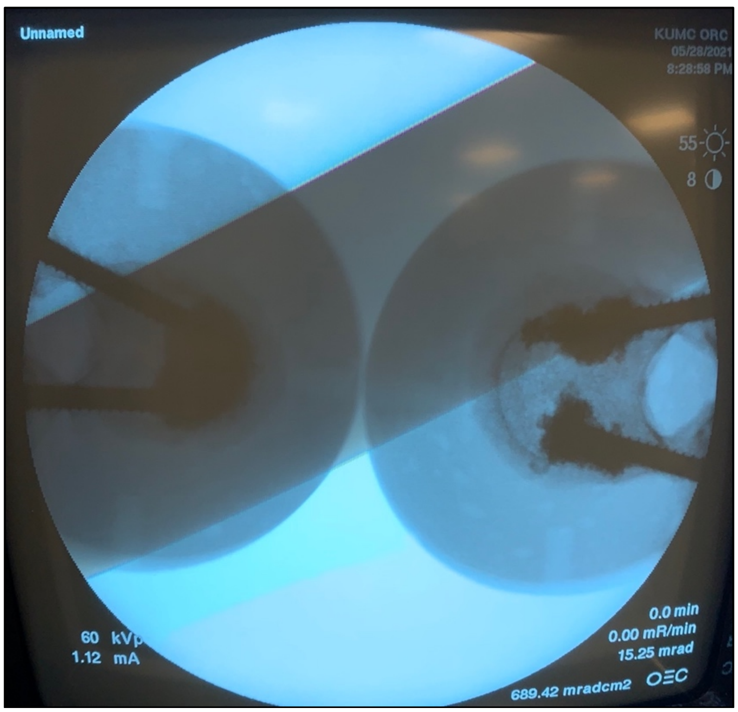

Figure 9. Cement Spread Pattern

4.2 Statistical Results

Statistics

		T8_Force	T9_Force	T10_Force
N	Valid	15574	15017	16258
	Missing	3799	4356	3115
Mean		3168.47395	2793.33045	2774.06273
Median		2936.15270	2446.78860	2167.68075
Std. Deviation		2734.96571	2818.18949	2930.32456
Minimum		5.10299160	-2.8967459	-9.0987806
Maximum		9765.35740	11295.3050	12912.8350

Table 2. T8, T9, T10 Summary Statistics

Statistics

		T11_Force	T12_Force	L1_Force
N	Valid	17294	18574	19153
	Missing	2079	799	220
Mean		3497.40168	2921.67822	3199.72191
Median		3174.49220	1784.39000	2319.51390
Std. Deviation		3062.14909	2944.32671	2824.93787
Minimum		3.21286440	5.06634900	2.93807510
Maximum		11897.8230	13139.5020	12649.5160

Table 3. T11, T12, L1 Summary Statistics

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.[a,b]	Decision
1	The distributions of T11_Force, T12_Force and L1_Force are the same.	Related-Samples Friedman's Two-Way Analysis of Variance by Ranks	.000	Reject the null hypothesis.

a. The significance level is .050.

b. Asymptotic significance is displayed.

Table 4. T8, T9, T10 Friedman's

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.[a,b]	Decision
1	The distributions of T8_Force, T9_Force and T10_Force are the same.	Related-Samples Friedman's Two-Way Analysis of Variance by Ranks	.000	Reject the null hypothesis.

a. The significance level is .050.

b. Asymptotic significance is displayed.

Table 5. T11, T12, L1 Friedman's

As the data is nonparametric, ANOVA was used to analyze the data of the spines together within 2 groups, being the T8, T9 and T10 subgroup and the T11, T12 and L1 subgroup with T9 and T12 serving as internal controls in their respective groups. A significant difference ($p < 0.05$) was found in the force required to load-to-failure. A significant difference between the two techniques and the control was demonstrated, as seen by our p-value < 0.001 (see TABLE 4 and TABLE 5) when utilizing a Friedman's Two-Way ANOVA by Ranks. In conclusion, we believe that our data indicates a difference in the two techniques and that further analysis and testing will be needed to determine to true effect of the Jamshidi and fenestrated screw techniques.

References

Alexandru, D., & So, W. (2012). Evaluation and management of vertebral compression fractures. *Perm J, 16*(4), 46-51. doi:10.7812/tpp/12-037

Donnally, C. J., 3rd, Rivera, S., Rush, A. J., 3rd, Bondar, K. J., Boden, A. L., & Wang, M. Y. (2019). The 100 most influential spine fracture publications. *J Spine Surg, 5*(1), 97-109. doi:10.21037/jss.2019.01.03

Donnally, I. C., DiPompeo, C. M., & Varacallo, M. (2021). Vertebral Compression Fractures. In *StatPearls*. Treasure Island (FL).

Dyrda, L. (April 5, 2019). Surgeons perform 1.62M instrumented spinal fusions per year in the US: 5 things to know. Retrieved from https://www.beckersspine.com/spine/item/45273-surgeons-perform-1-62m-instrumented-spinal-fusions-per-year-in-the-us-5-things-to-know.html#:~:text=Careers%20at%20Becker's-,Surgeons%20perform%201.62M%20instrumented%20spinal%20fusions%20per%20year,US%3A%205%20things%20to%20know&text=There%20are%20more%20than%201,to%20an%20iData%20Research%20report.

Fernandez-de Thomas, R. J., & De Jesus, O. (2021). Thoracolumbar Spine Fracture. In *StatPearls*. Treasure Island (FL).

Frankl, J., Sakata, M. P., Choudhary, G., Hur, S., Peterson, A., & Hennemeyer, C. T. (2016). A Classification System for the Spread of Polymethyl Methacrylate in Vertebral Bodies Treated with Vertebral Augmentation. *Tomography, 2*(3), 197-202. doi:10.18383/j.tom.2016.00196

Furtado, N., Oakland, R. J., Wilcox, R. K., & Hall, R. M. (2007). A biomechanical investigation of vertebroplasty in osteoporotic compression fractures and in prophylactic vertebral reinforcement. *Spine (Phila Pa 1976), 32*(17), E480-487. doi:10.1097/BRS.0b013e31811ea2ee

Kinzl, M., Benneker, L. M., Boger, A., Zysset, P. K., & Pahr, D. H. (2012). The effect of standard and low-modulus cement augmentation on the stiffness, strength, and endplate pressure distribution in vertebroplasty. *Eur Spine J, 21*(5), 920-929. doi:10.1007/s00586-011-2119-5

Koike, Y., Kotani, Y., Terao, H., & Iwasaki, N. (2021). Risk Factor Analysis of Proximal Junctional Kyphosis after Surgical Treatment of Adult Spinal Deformity with Oblique Lateral Interbody Fusion. *Asian Spine J, 15*(1), 107-116. doi:10.31616/asj.2019.0341

Kurutz, M., Varga, P., & Jakab, G. (2019). Prophylactic vertebroplasty versus kyphoplasty in osteoporosis: A comprehensive biomechanical matched-pair study by in vitro compressive testing. *Med Eng Phys, 65*, 46-56. doi:10.1016/j.medengphy.2019.01.004

Leichtle, C. I., Lorenz, A., Rothstock, S., Happel, J., Walter, F., Shiozawa, T., & Leichtle, U. G. (2016). Pull-out strength of cemented solid versus fenestrated pedicle screws in osteoporotic vertebrae. *Bone Joint Res, 5*(9), 419-426. doi:10.1302/2046-3758.59.2000580

Maempel, J. F., & Maempel, F. Z. (2019). The speedboat vertebral fracture: a hazard of holiday watersports. *Scott Med J, 64*(2), 42-48. doi:10.1177/0036933018760226

Makary, M. S., Zucker, I. L., & Sturgeon, J. M. (2015). Venous extravasation and polymethylmethacrylate pulmonary embolism following fluoroscopy-guided percutaneous vertebroplasty. *Acta Radiol Open, 4*(8), 2058460115595660. doi:10.1177/2058460115595660

McCall, T., Cole, C., & Dailey, A. (2008). Vertebroplasty and kyphoplasty: a comparative review of efficacy and adverse events. *Curr Rev Musculoskelet Med, 1*(1), 17-23. doi:10.1007/s12178-007-9013-0

Rajesh Kumar Ranjan, M. K., Rakesh Kumar and Md Farman Ali. (2017). Bone cement. *International Journal of Orthopaedics Science*(4). doi:10.22271/ortho.2017.v3.i4b.12

Savage, J. W., Schroeder, G. D., & Anderson, P. A. (2014). Vertebroplasty and kyphoplasty for the treatment of osteoporotic vertebral compression fractures. *J Am Acad Orthop Surg, 22*(10), 653-664. doi:10.5435/JAAOS-22-10-653

Schmidt, R., Cakir, B., Mattes, T., Wegener, M., Puhl, W., & Richter, M. (2005). Cement leakage during vertebroplasty: an underestimated problem? *Eur Spine J, 14*(5), 466-473. doi:10.1007/s00586-004-0839-5

Theologis, A. A., & Burch, S. (2015). Prevention of Acute Proximal Junctional Fractures After Long Thoracolumbar Posterior Fusions for Adult Spinal Deformity Using 2-level Cement Augmentation at the Upper Instrumented Vertebra and the Vertebra 1 Level Proximal to the Upper Instrumented Vertebra. *Spine (Phila Pa 1976), 40*(19), 1516-1526. doi:10.1097/BRS.0000000000001043

Yuan, L., Bai, J., Geng, C., Han, G., Xu, W., Zhang, Z., . . . Zhu, X. (2020). Comparison of targeted percutaneous vertebroplasty and traditional percutaneous vertebroplasty for the treatment of osteoporotic vertebral compression fractures in the elderly. *J Orthop Surg Res, 15*(1), 359. doi:10.1186/s13018-020-01875-4

Zapalowicz, K., Kierzkowska, A., & Ciupik, L. F. (2018). In vitro simulation of intraoperative vertebroplasty applied for pedicle screw augmentation. A biomechanical evaluation. *Neurol Neurochir Pol, 52*(1), 64-69. doi:10.1016/j.pjnns.2017.12.001