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MUSCULOSKELETAL INNOVATIONS

Tapered reduction of cement volume in the proximal vertebrae adjacent to the fused segment may translate into a decreased rate of Proximal Junction Kyphosis (PJK) using Calcium phosphate cement - A biomechanical investigation

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Introduction

- Proximal Junctional Kyphosis (PJK) is a condition in which the Cobb angle between the upper instrumented vertebra (UIV) and adjacent vertebrae is >10 degrees.

- Incidence of PJK is 5% to 46% post adult spinal deformity surgery.

- Vertebral compression fractures (VCF's) are one of the causes of PJK.

Introduction

- Prophylactic vertebroplasty with the tapered bone cement dosage using PMMA showed reduced adjacent level fractures.

- A 5 year follow up clinical study by *Dr. Kebaish* demonstrated that prophylactic vertebroplasty using PMMA may minimize the risk for junctional failure in the early post operative period. However, it did not appear to decrease the incidence of PJK at 5 years.

- In this study, a novel calcium phosphate based bone cement reinforced with magnesium phosphate platelets will be used as a tapered dose for the prophylactic vertebroplasty and to compare with the results using PMMA.

Questions from Previous Update

- What will you evaluate in the in vitro study?
  - ➢ We are going to evaluate the effect of calcium phosphate with magnesium phosphate platelets as the tapered bone cement dosage for the prophylactic vertebroplasty and compare the results with PMMA

- Will you evaluate stiffness in the in vitro study?
  - ➢ Yes

- Can you evaluate the function of the cement volume?
  - ➢ Yes, by running multiple simulations using the FE model. I will show the results in the next update.

Objective

- To evaluate the effect of tapering dose of calcium phosphate with magnesium phosphate platelets at the adjacent segments in a spine stabilized with long construct using cadaver model and finite element analyses.

Project Outline

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1. Cadaveric Study

2. Finite Element Analyses

Group 1:

T10-Sacrum Instrumentation

Group 2:

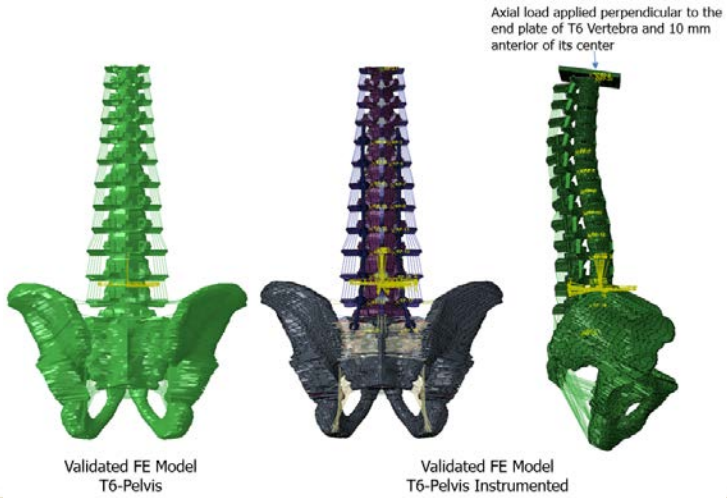
T10-Sacrum Instrumentation+ 4cc in T9 and T10 (n=5)

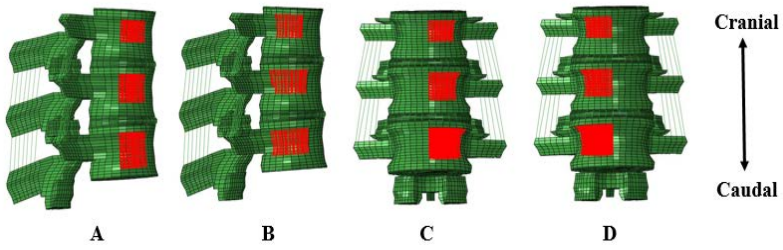
Group 3:

T10-Sacrum Instrumentation +4cc in T10+3cc in T9 +2cc in T8 (n=5)

Updates from Spring 2018 meeting

- In the previous update, the biomechanical evaluation of calcium phosphate bone cement was carried out using the osteoporotic finite element model
- Different placements of bone cement were evaluated and compared to the results from PMMA.
- The results showed a significant decrease in the endplate stresses of the injected vertebra for the anterior placement.
- The results were similar for PMMA and Calcium phosphate.
- However, due to the exothermic nature of PMMA, the resorbable calcium phosphate bone cement may provide a better clinical outcome.





Cadaveric Study

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Methods

Calcium Phosphate Bone Cement Evaluations

1. Setting Time
1. Strength Evaluation

Specimen Preparation

1. DEXA Scan
2. Preparation of Specimen
3. Potting of Specimen

Surgical Procedure

1. Insertion of Pedicle Screws
2. Injection of Cement

Monitoring continuously using X rays to ensure the proper placement

Biomechanical Testing

1. Loading on the MTS Machine using U- Joint and applying the load at the rate of 5mm/min up to 50 mm

Evaluation

1. CT scans
2. Data obtained from MTS machine

X-Ray Images

Group 1-Instrumentation

Group 2-Instrumentation +4cc Group

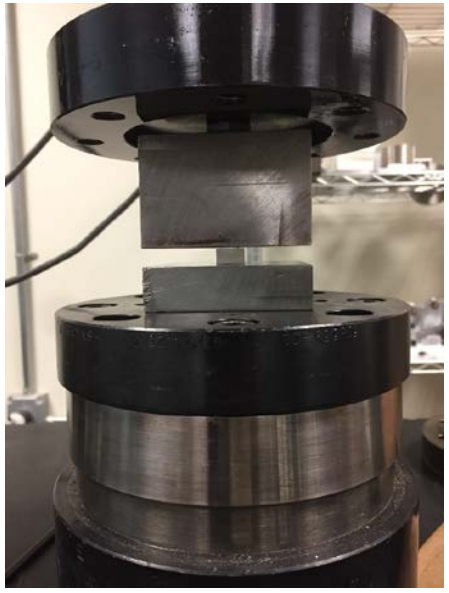
Group 3-Instrumentation +4cc+3cc+2cc

Calcium Phosphate Bone Cement Evaluations

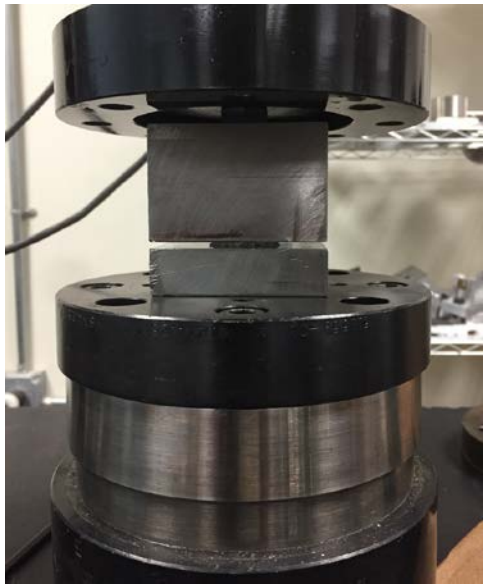
- The following tests were conducted on the Calcium Phosphate Bone Cement with magnesium phosphate platelets

1. Optimal Setting Time

- The mixed cement was placed in a mold to create cylindrical pellets of 12.5 mm diameter and height of 6.3 mm.
- The pellets were tested at 4 hour setting time , by applying compressive load using MTS test system at the rate of 5 mm/min.
- The cement was made in 10cc batches and individual pellets were created from it.
- The sample size of 6 pellets was tested and load vs displacement data was collected.



Before Compression



After Compression

Calcium Phosphate Bone Cement Evaluations

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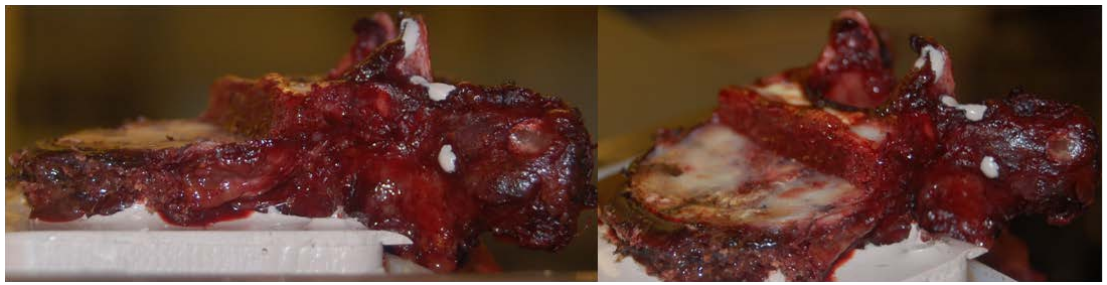
2. Strength Evaluation

- 5 vertebral bodies were cleaned without damaging the endplates. The height of each vertebra was recorded.
- The inferior endplate of each vertebra was wrapped with thin plastic sheet to avoid the infiltration of bondo into the endplate prior to potting using bondo.
- Fracture creation: A transverse slit was created using a hack saw, in the middle of the vertebral body and the potted specimen was placed on a fixture fixed in a 3 axes vice mounted on XY table on the MTS machine and each vertebra was loaded using compressive load at 10 mm anterior from the geometric center to create anterior compression fractures.

Transverse slit on vertebral body



Fractured vertebral body

Calcium Phosphate Bone Cement Evaluations

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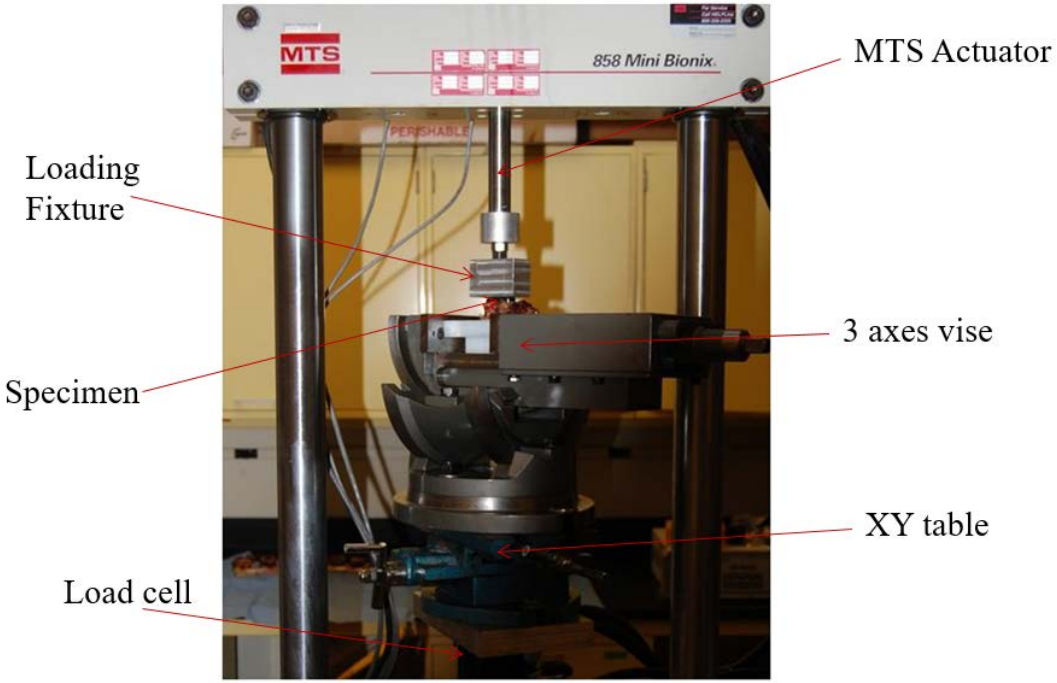
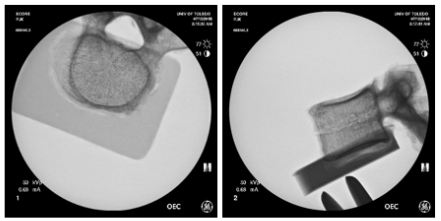
2. Strength Evaluation

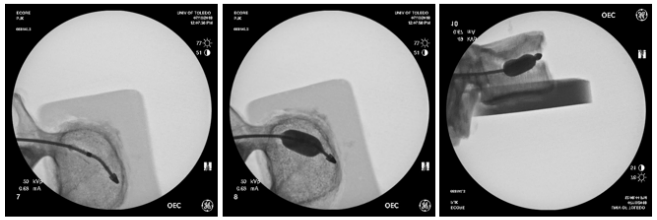
- The test was performed under displacement control at the rate of 5 mm/min.
- The fracture was reduced bilaterally using Kyphoplasty balloon and the CaP bone cement with magnesium phosphate platelets was injected bilaterally into vertebral body to stabilize it.
- Each cemented vertebra was loaded by applying compressive load similar to aforementioned procedure.



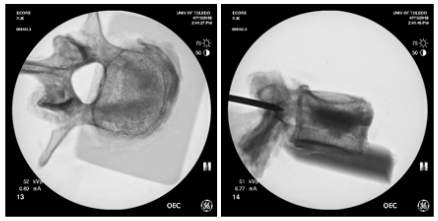


Pre Fracture

Fractured Vertebra



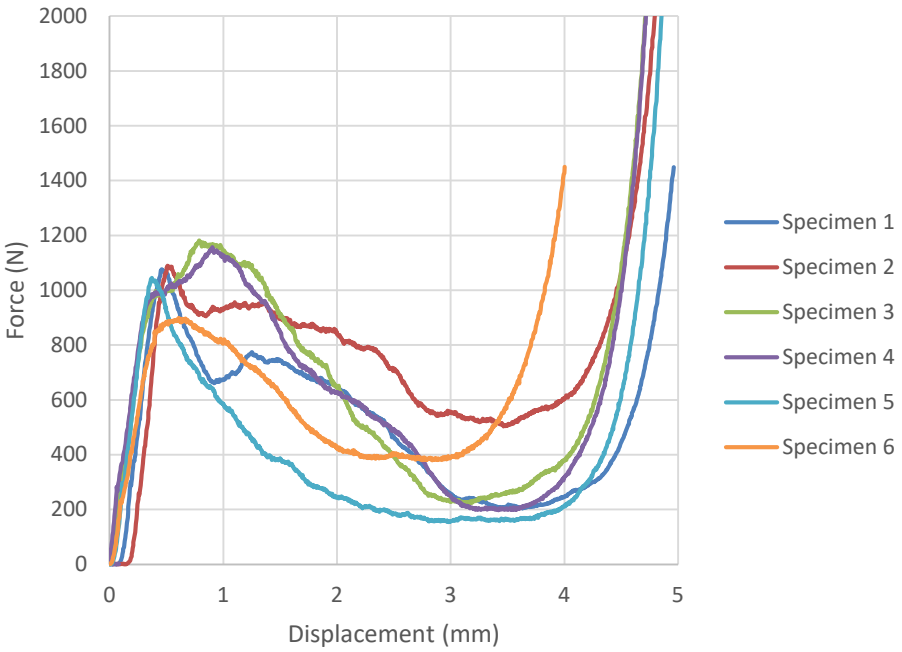
Fracture Reduction



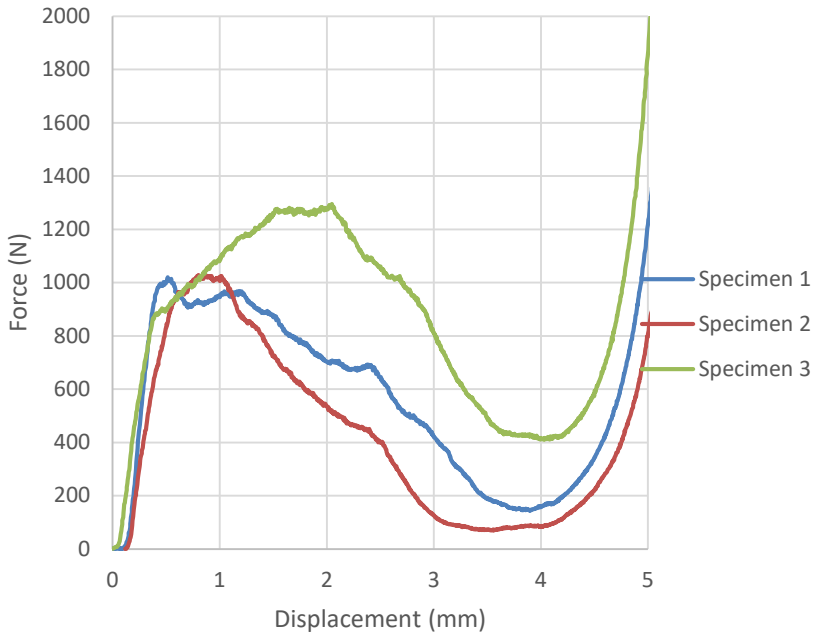
Post Cement injection

Results- Setting Time

Batch 1 - 4 Hours Data



Mean – 1074 N
SD – 100 N

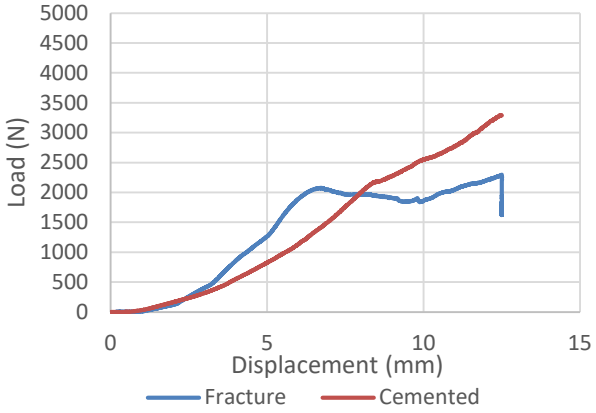


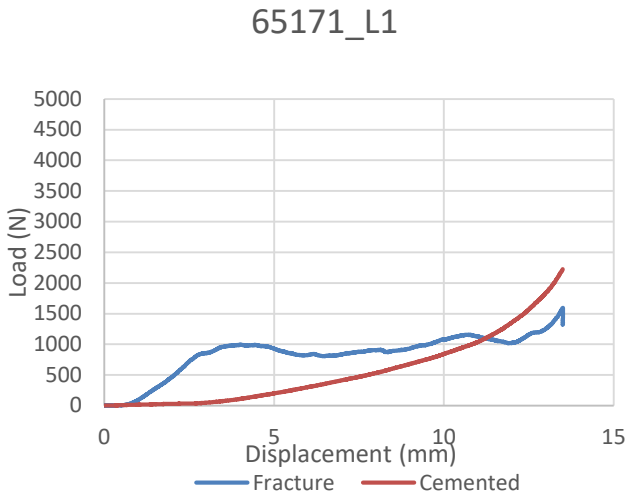
Mean – 1114 N
SD – 156 N

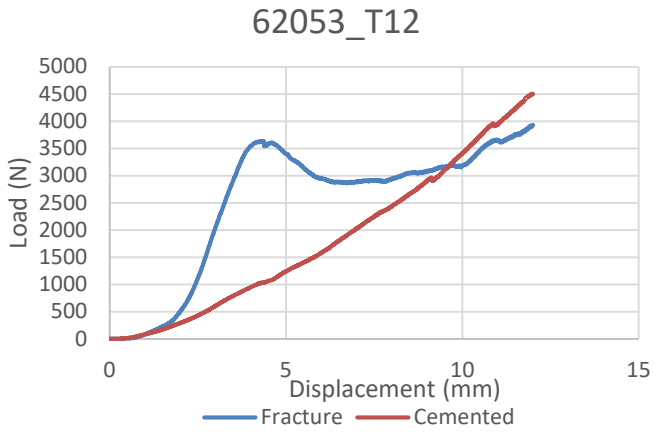
Specimen	1	2	3	4	5	6
1St Peak Load (N)	1076	1089	1182	1157	1045	898

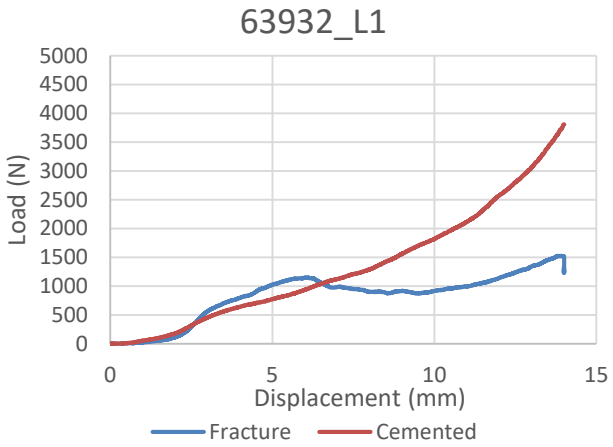
Specimen	1	2	3
1St Peak Load (N)	1019	1028	1295

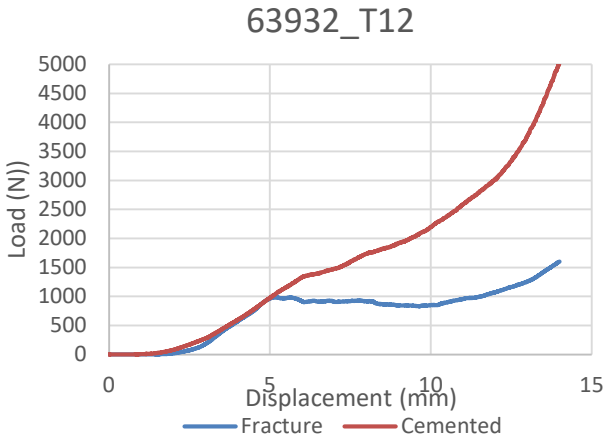
Results- Strength Evaluation





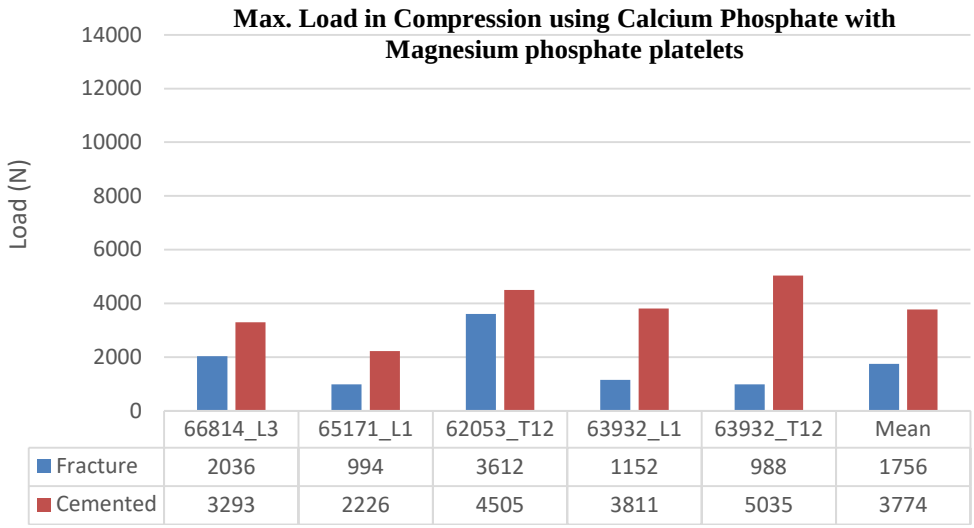




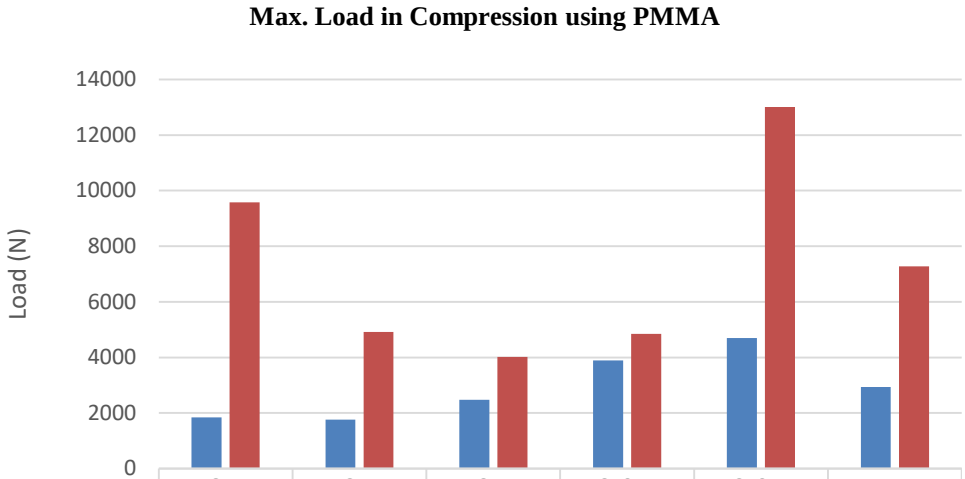


Results-Strength Evaluation

- The comparison between the max loads with the injection of calcium phosphate with magnesium phosphate platelets and PMMA bone cement.
- The mean BMD for the specimens injected with calcium phosphate is 0.66 and injected with PMMA is 0.64.



	66814_L3	65171_L1	62053_T12	63932_L1	63932_T12	Mean
Fracture	2036	994	3612	1152	988	1756
Cemented	3293	2226	4505	3811	5035	3774



	55651_L 1	55651_L 3	55651_L 4	56105_T 12	56105_L 2	Mean
Fracture	1839.62	1764.73	2475.88	3893.64	4693.68	2933.51
PMMA Cemented	9581.52	4919.62	4020.80	4846.03	13004.57	7274.51

Discussion

- The stiffness after the 4 hour setting time of the bone cement was fairly consistent for all the samples and was similar to the results from 6 hour data, so the 4 hour setting time was selected.
- Following the bone cement injection, the vertebra was rested for 4 hours before it was tested on the MTS machine.
- The biomechanical evaluations of the injected calcium phosphate bone cement with magnesium phosphate platelets and PMMA showed an increase in the stiffness of a vertebra significantly.
- The strength provided by the PMMA was higher than that of calcium phosphate based bone cement.

Discussion

- The FEA results showed the endplate stresses were similar for the injection of PMMA and calcium phosphate bone cement.
- These results show that the vertebrae may not need a bone cement as stiff as PMMA for the prophylactic vertebroplasty.
- Furthermore, the evaluations of in vitro testing from T6-pelvis cadavers using a tapered bone cement dosage prophylactic vertebroplasty of calcium phosphate bone cement with magnesium phosphate platelets will be used to understand the biomechanical comparison between PMMA and calcium phosphate based bone cement in long segment fusions.

TIMELINE

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Milestones	
Specimens Procuring, Preparation	May- June 2018
DEXA scans	July-August 2018
In vitro Testing using T6-Pelvis cadaver spines	July-August 2018
Data Collection and Statistical Analyses	July-August 2018
FE parametric analyses	July-August 2018
Prepare final report, abstracts/ manuscripts	August-September 2018

Acknowledgement

- Thanks CDMI and IAB.