

Project: Tapered reduction of cement volume in the proximal vertebrae adjacent to the fused segment may translate into a decreased rate of Posterior Junctional Kyphosis – PJK (Continutaion – effect of cyclic loads)

Site: University of Toledo	
Site Director: Vijay Goel, PhD	
PI's name: Vijay K. Goel, PhD	Proposed Budget: (including 10% indirects): \$50,000
Phone: 419-530-8035	E-mail : Vijay.Goel@utoledo.edu
<p>Need and Industrial Relevance: Proximal Junctional Kyphosis (PJK) and Proximal Junctional Failures (PJF) are complications observed in long posterior thoracolumbar spinal fusions. The vertebral compression fractures (VCF) at the adjacent proximal junction are correlated to PJK. Prophylactic vertebroplasty for the treatment of VCF reduces the rate of immediate adjacent segment fractures but it shifts the level of failure one level up. To mitigate upper level fractures, we hypothesize that a vertebroplasty technique involving tapered reduction of cement volume in the proximal vertebrae adjacent to the fused segment may translate into a decreased rate of PJK.</p>	
<p>Project Goals: Our goals are to undertake a cadaver study to investigate the failure of adjacent segments in a stabilized long construct as a function of the amount of cement injected in the adjacent segments under cyclic loads. We will then subject these specimens to failure as per the previous protocol for quasi-static testing and compare the outcomes of specimens with and without cyclic loading.</p>	
<p>Objectives:</p> <ul style="list-style-type: none"> • In consultation with the Industrial Advisory Board and faculty, build upon the previous testing protocol to investigate the effect of cyclic loads on the outcome <ul style="list-style-type: none"> • Formulate the group comprising at least one graduate student, an undergraduate student, a post-doctoral fellow, and a senior faculty for the project. The group will interact with Industry clients and a team of surgeons to ensure that research is clinically relevant and will yield clinically relevant data. • Undertake various steps listed below in the Approach Section. 	
<p>Approach (Research Methods): 24 fresh-frozen human thoraco-lumbar cadaveric spines T6-S1 will be inspected by fluoroscopy to exclude fractures, tumors, malformations, and pre-existing deformity. The spines will be carefully dissected, preserving the posterior ligament-complex, facet joints, and anterior longitudinal ligament. The spines will be stored in freezer bags and stored at -20° C. Prior to testing, the spines will be thawed at room temperature for 24 hours, and then evaluate for bone mineral density via dual energy x-ray absorptiometry (DEXA). The specimens will be stratified based on DEXA score and will be assigned to 1 of 4 treatment groups to insure roughly equivalent DEXA scores across the 4 groups. The groups will be as follows: Group 1: instrument T10 with bilateral pedicle screws (Control group). Group 2: instrument T10 with bilateral pedicle screws and place 2 cc of cement in each pedicle screw pilot hole prior to placing T10 screws (4 cc total per T10 vertebra). Group 3: instrument T10 with screws and place 2 cc of cement in each side prior to placing T10 screws (4 cc total per T10 vertebra), and place 2 cc of cement in each side at T9 (4 cc total per T9 vertebra). Group 4: instrument T10 with screws and place 2 cc of cement in each side prior to placing T10 screws (4cc total</p>	

per T10 vertebra), place 1.5 cc cement in each side at T9 (3 cc total per T9 vertebra), and place 1 cc cement in each side at T8 (2 cc per T8 vertebra) (Study group). We will keep four specimens for pilot testing to develop the protocol for cyclic tests

All specimens will be instrumented with pedicle screws and rods from T10 to S1 using standard surgical techniques. In the 3 vertebroplasty treatment groups, Jamshidi needles will be inserted up to the midpoint of the all vertebral bodies for cement placement. All T10 pedicle screws will be inserted approximately 60 seconds after the cement injection. All T10 pedicle screws will be similar in diameter and screw lengths so the tip of the screw ended at the midpoint (50%) of the corresponding T10 vertebral body. After insertion of all of the screws, the specimens will be checked with radiographs and direct inspection in order to verify that the pedicle screws are contained within the vertebral body. The posterior rods will be attached after cement hardening.

The cephalad and caudal vertebral bodies of the construct will be embedded into the test fixtures ensuring parallel orientation of the outer surfaces of the fixtures to the vertebral endplates. The construct will be mounted on the axial loading deck of a materials testing machine (MTS 858, Eden Prairie, MN). Axial compression in cyclic mode ranging from 0 N to 400 N (based on the failure data from the earlier study that ranged from 700 to 1200 N) for 10,000 cycles. These specimens will be tested by applying axial compression eccentrically (10-mm anterior offset) on the fixed cephalad end at 5 mm/min for 50 mm or until failure. Failure will be defined as a steep decrease in load with increasing compression.

The data will be recorded for comparison and statistical analyses. Correlations on the effect of cement augmentation relative to the VCF and the effects of the cement volume will be evaluated. The data will be compared with the earlier study to assess the effect of cyclic load on the specimen behavior. Differences at the level of $P < 0.05$ will be considered significant.

Milestones:

- Develop protocol and finish pilot testing – Nov 30, 2015
- Finish collecting all data – April 28, 2016
- Data Analyses, publications (abstracts and manuscripts) and report – July 30, 2016

Outcome/Deliverables:

Including:

- *Presentation Update* - beginning of 2016~~5~~ at the University of Toledo, Ohio
- *Final Report including results* - July~~ne~~ 30, 2016~~5~~

Impact: How the project may be transformative and/or benefit society:

The study will show that prophylactic vertebroplasty with gradually decreasing bone cement volume could reduce the risk of VCF, PJK and PJF.

Project Duration & General Budget Outline:	
Personnel	\$ 18,000
Supplies/Specimens	\$ 22,000
Imaging	\$ 5,000
Total Direct	\$ 45,000
Indirects (10%)	\$ 4,500
Total	\$ 49,500
Duration: 1 year	
Start Date: Oct 1, 2015	End Date: Sep30, 2016

Please send this document along with your *IP Checklist for Projects* to mark.fox@utoledo.edu (Univ of Toledo Patent Technology Associate) and dezba.coughlin@ucsf.edu (CDMI Managing Director)