



CENTER FOR DISRUPTIVE
MUSCULOSKELETAL INNOVATIONS

Development of an innovative posterior pedicle-based screw device for multilevel semi-dynamic stabilization

PI: Dr. Deniz U. Erbulut
Co-PI: Prof. Vijay Goel
Co-PI Anand Agarwal, MD
Prof. Ali Fahir Ozer, MD

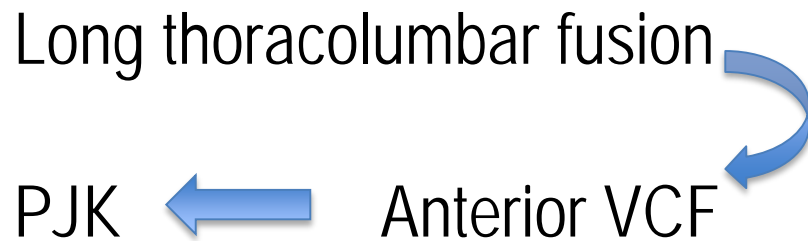
UNIVERSITY OF TOLEDO

WWW.NSFCDMI.ORG

Background

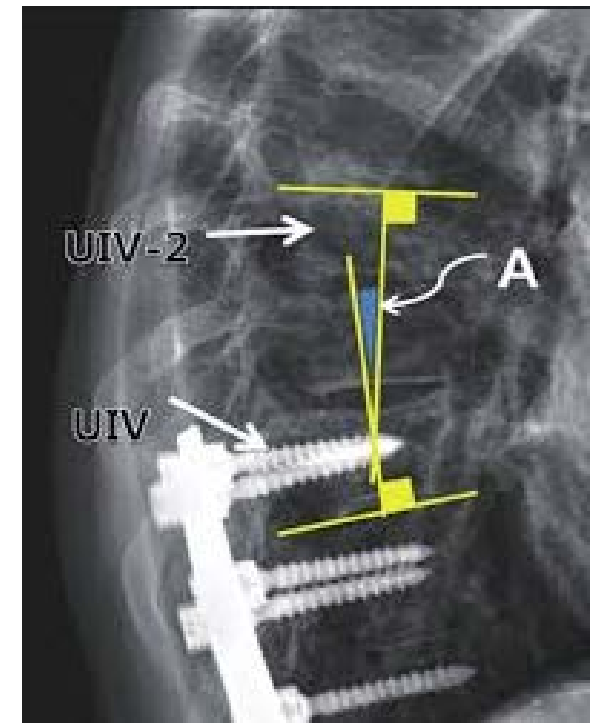
- Proximal Junction Kyphosis (PJK):

Long thoracolumbar fusion
PJK ← Anterior VCF



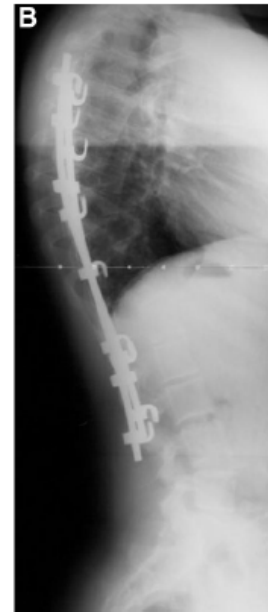
- Abnormal PJK:

- Proximal Junctional Cobb Angle > Pre-op angle by +10 degrees



Clinical Need and Industrial Relevance

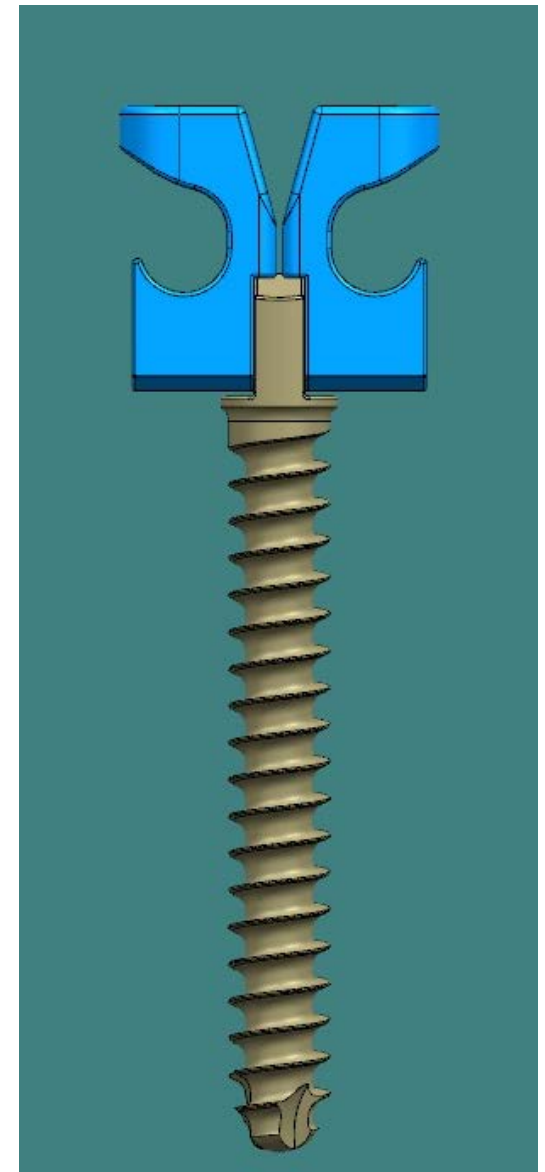
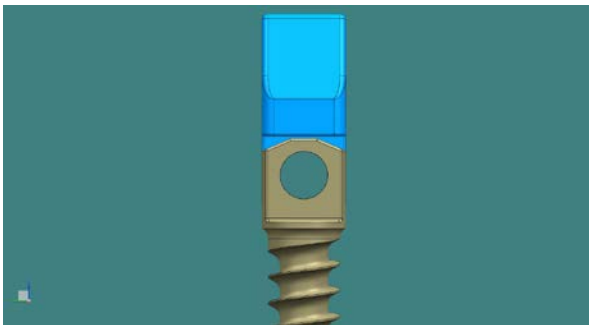
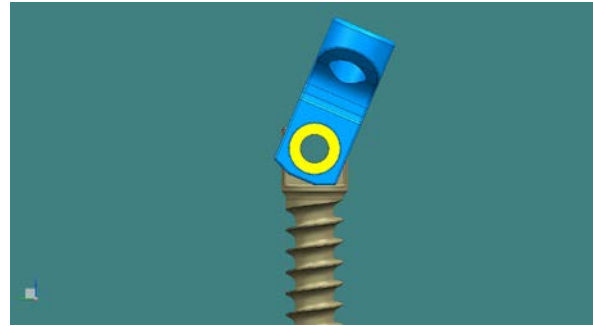
- i. PJK range from 6% to 41%, appears shortly following surgery
- ii. PJK is well known and acknowledged.
- iii. Current prevention techniques
 - a. Vertebroplasty
 - b. Using only hooks
 - c. Soft tissue consideration
 - d. Proper selection of UIV
 - e. Posterior ligament augmentation
 - f. Prophylactic rib fixation
- iv. Further research needed to reduce incidence.
- v. A new double-headed semi-rigid pedicle screw device might help reduce the incidence.



- Kebaish et al. *Spine J.* 2013 Dec; 13(12):1897-903
- Watanabe et al. *Spine.* 2010 Jan 15; 35(2):138-45.
- Cammarata et al. *Spine.* 2014 Apr 15; 39(8):E500-7.
- Smith et al. *Spine J.* 2015 Oct 1; 15(10):2142-8.
- Hart et al. *Neurosurg Clin N Am.* 2013 Apr; 24(2):213-8.
- Helgeson et al. *Spine.* 35-(2), pp 177-181

Double-Headed Screw Concept

CENTER FOR DISRUPTIVE
MUSCULOSKELETAL
INNOVATIONS



Project Aims

- Aim:
Develop a novel double-headed pedicle screw to reduce/prevent PJK and PJF
- Hypothesis:
Double-headed screw would decrease PJK/PJF compared to present approaches

Methods

- A. Optimization of double-headed pedicle screw design using a CAD software
- B. Manufacture the prototypes
- C. Evaluate the design using FEA and compare with others on the market
- D. Mechanical testing of the device according to ASTM/ISO standards.
- E. *In vitro* testing of the optimized design

Prototype



Mechanical testing -1

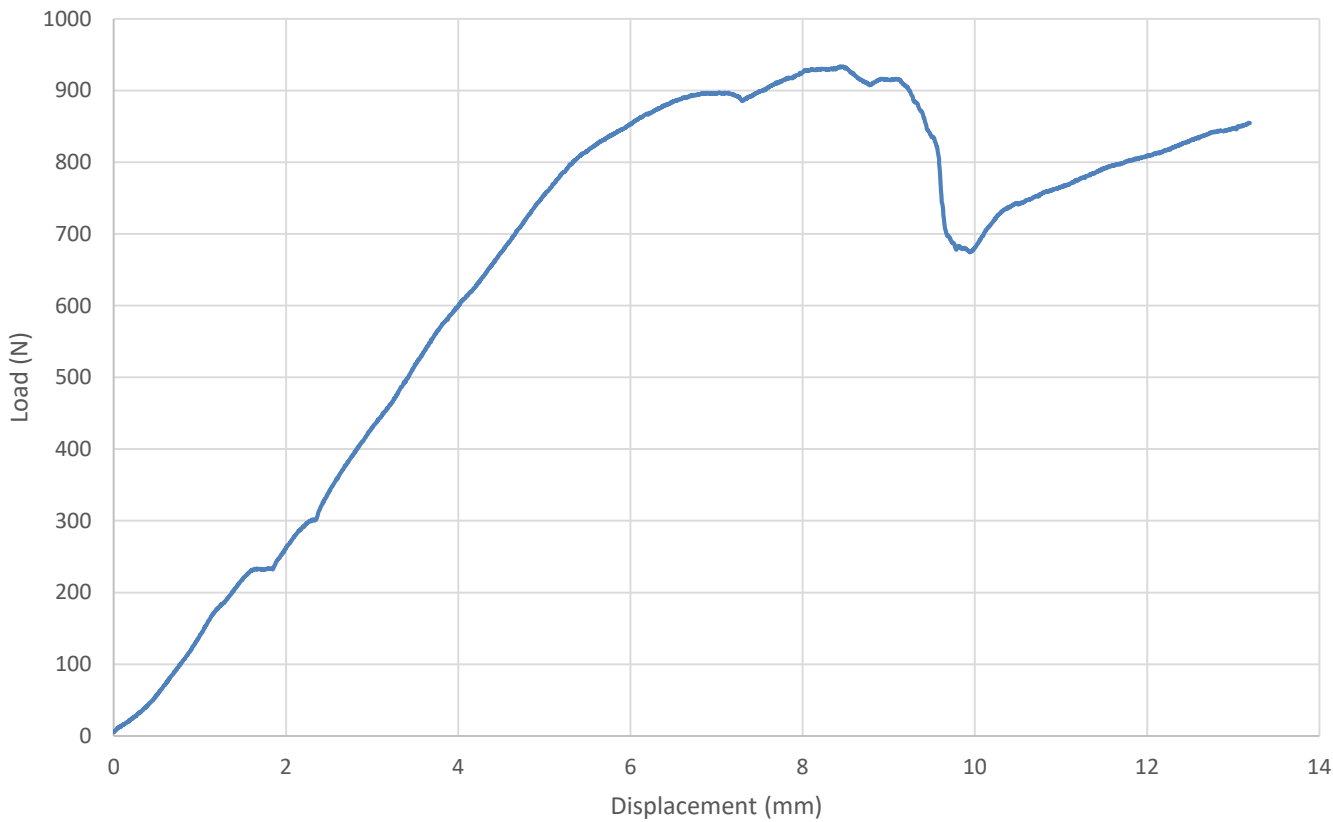


- Flexion/Extension moment - test set-up

Initial Mechanical Tests -1

- Flexion/Extension Moment

Dual Head Screw_Flexion-Extension Moment

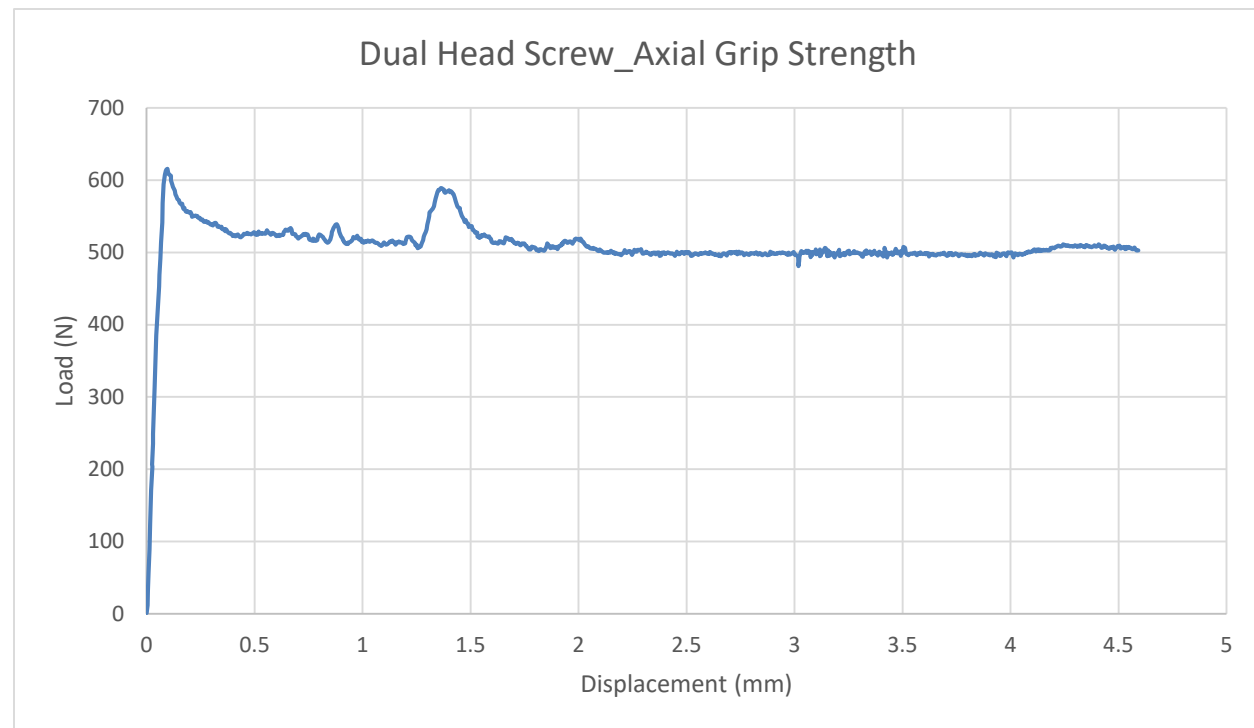
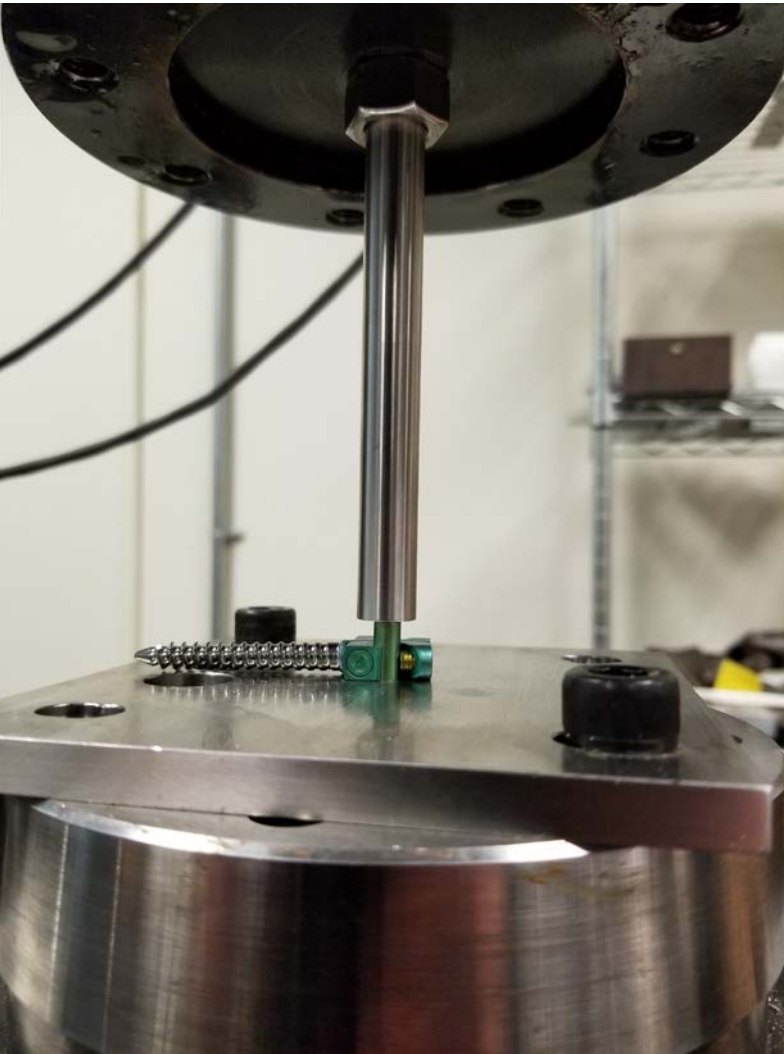


End of Test



Initial Mechanical Testing - 2

- Axial Grip strength



Conclusions

- i. Prototype of the first design draft was manufactured
- ii. Initial mechanical testing was carried for design optimization purposes.
- iii. Only 2Nm torque was applied on the locking cap – more than 5 Nm torque damaged the locking cap. Any comments are welcome
- iv. Pedicle screw tested under axial force for grip strength- the max force was around 600N
- v. Pedicle screw tested under static FE bending showed a mean yield bending moment of 800Nmm

Milestones & Timeline

- Finish design optimization and FE analysis – Feb 30, 2017
- Finish prototypes and mechanical testing – March 2018
- Finish *in vitro* testing – June 31 2018
- Finish collecting all data – Aug 31 2018
- Data analysis, publications and reports – Oct 2018

Thank you