CDMI

CENTER FOR DISRUPTIVE MUSCULOSKELETAL INNOVATIONS

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

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Background

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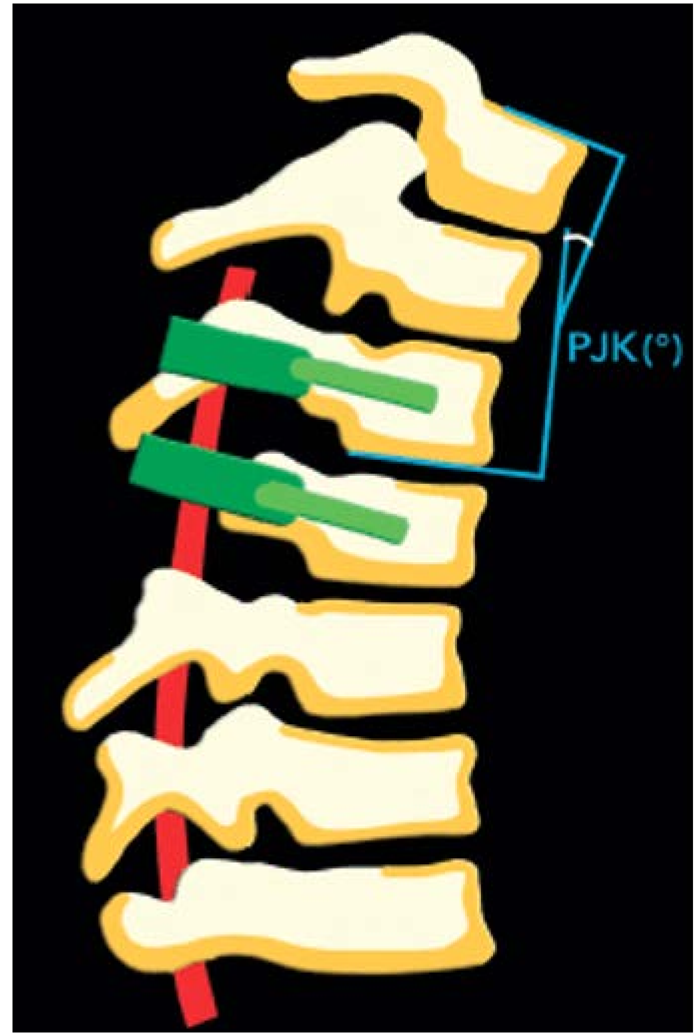
- Proximal Junction Kyphosis (PJK):

  Long thoracolumbar fusion
  PJK

- Abnormal PJK:
  - Proximal Junctional Cobb Angel > Pre-op angle by +10 degrees



Clinical Need and Industrial Relevance

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i. PJK range from 6% to 41%, appears shortly following surgery

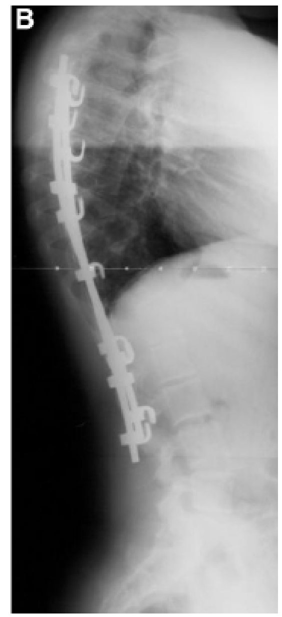
ii. PJK is well known and acknowledged.

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

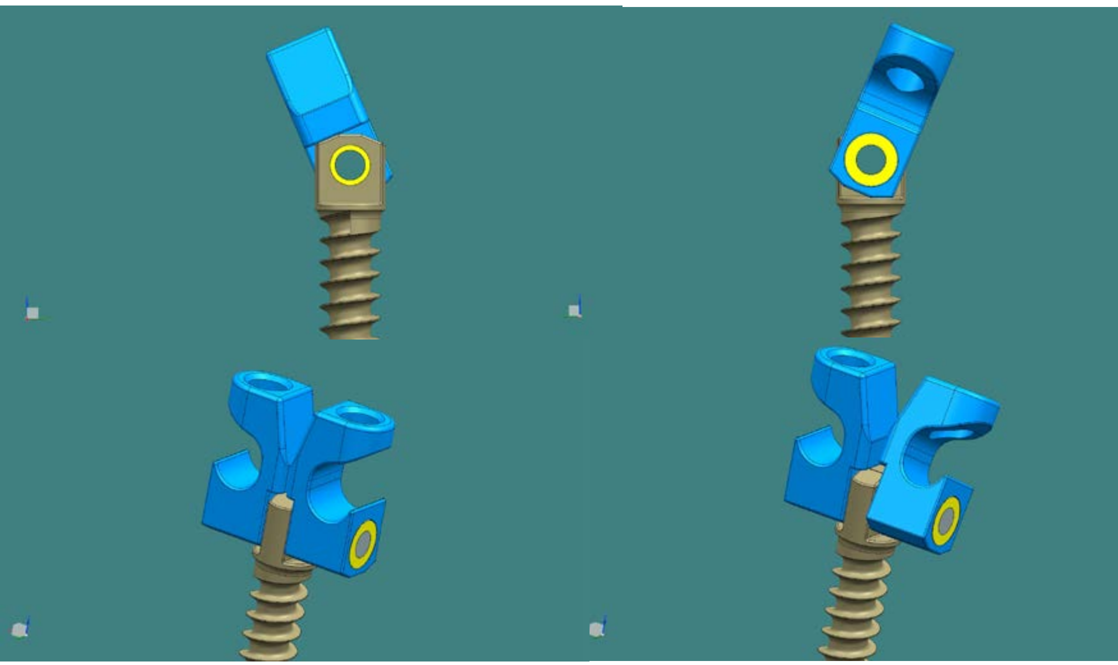
iv. Further research needed to reduce incidence.

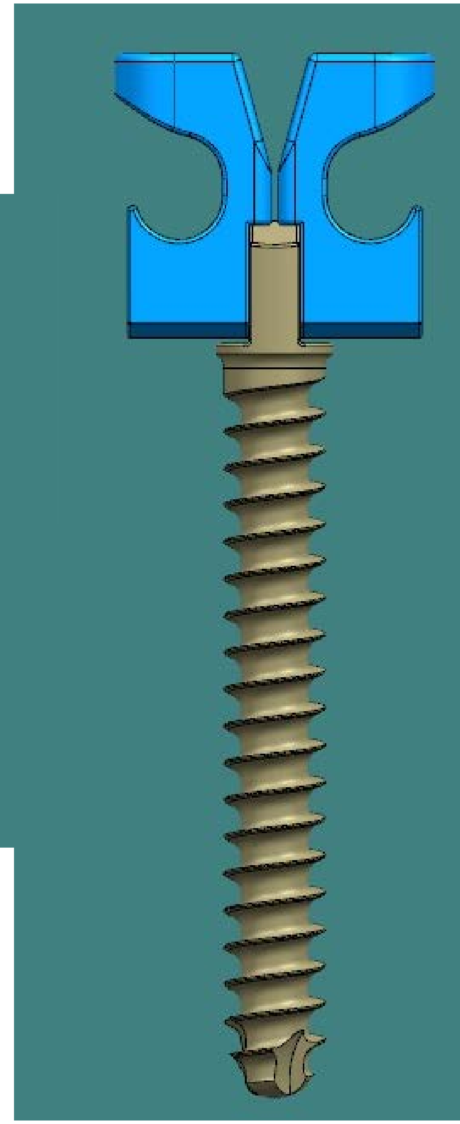
v. A new double-headed semi-rigid pedicle screw device might help reduce the incidence.



- 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





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

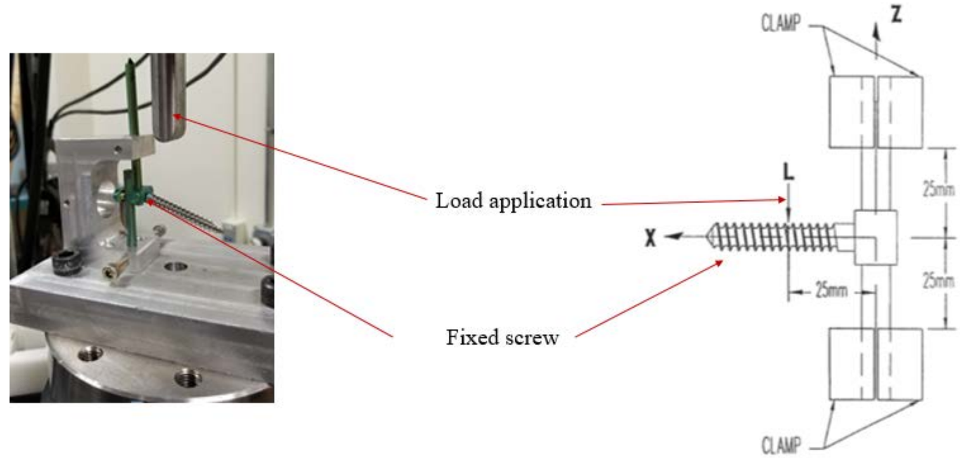
A. Optimization of double-headed pedicle screw design using a CAD software
B. Manufacture the optimized prototypes
C. Evaluate the design using FEA and compare with others on the market
D. Mechanical testing (Dynamic) of the device according to ASTM/ISO standards.
E. In vitro testing of the optimized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

Previously – Static testing

1 - Flexion-Extension moment test - F1798

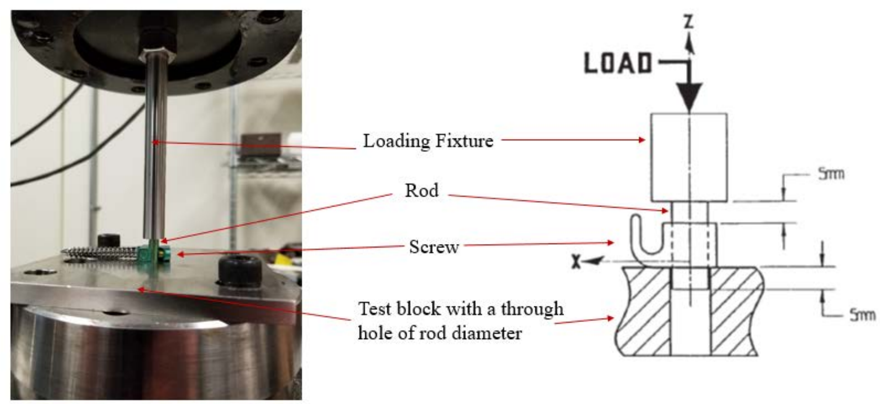
2 - Axial grip test - F1798

Specimen ID	Maximum Load (N)	
S1	934	-
S2	811	-
S3	907	-
S4	825	-
S5	955	-
S6	870	-
Mean	884	504
Standard Deviation	58	56



Reference: F1798 Standard

Specimen ID	Maximum Load (N)	Literature
S1	615	-
S2	726	-
S3	695	-
S4	648	-
S5	745	-
S6	622	-
Mean	675	1042
Standard Deviation	55	99



Reference: F1798 Standard

Fatigue testing – ISO 12189:2008(E)

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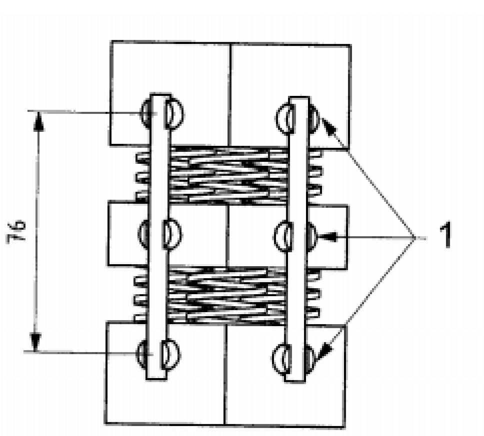
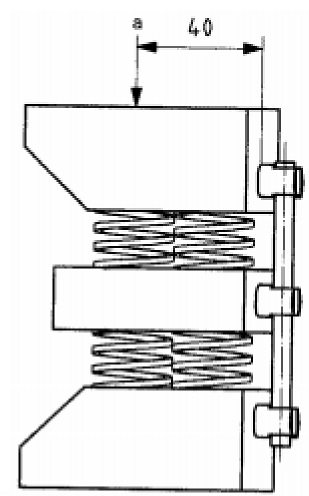
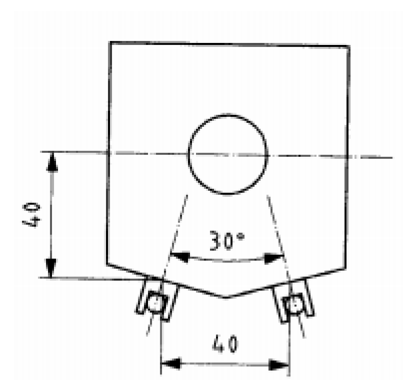
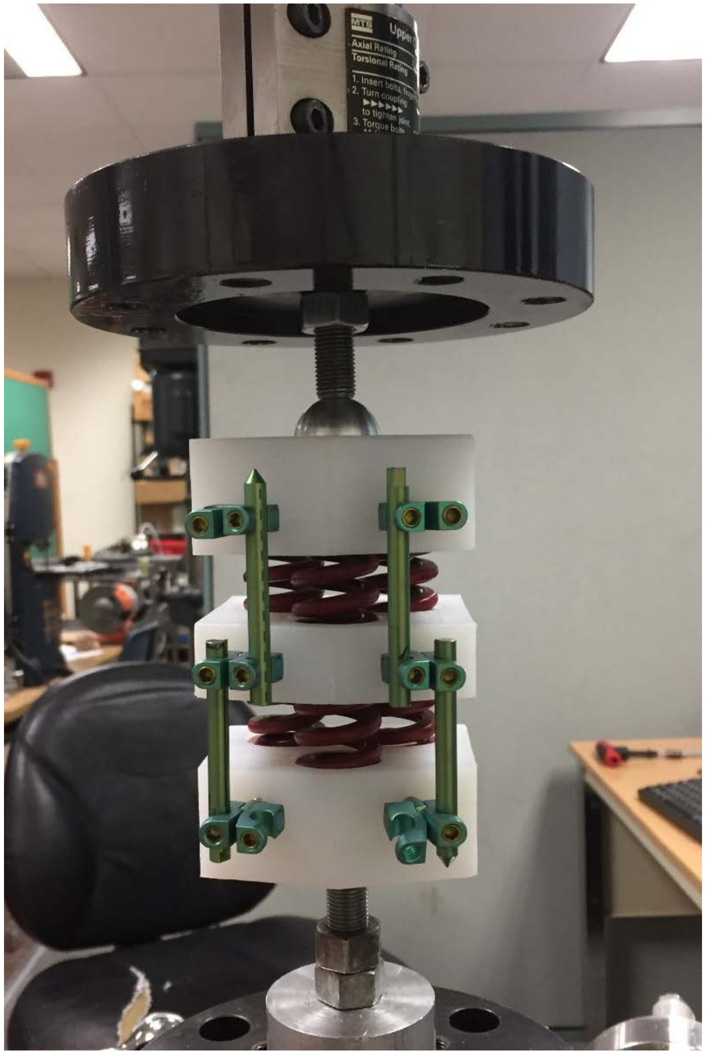
ISO 12189:2008(E)
Construct was built per ISO 12189 standard. 6 Springs of stiffness 375 N/mm were used in between the test blocks.
Dynamic testing was conducted under load control.
Cyclic loads of 2000 to 600 N were applied in compression.
Frequency:5 Hz
Cycles:5 million



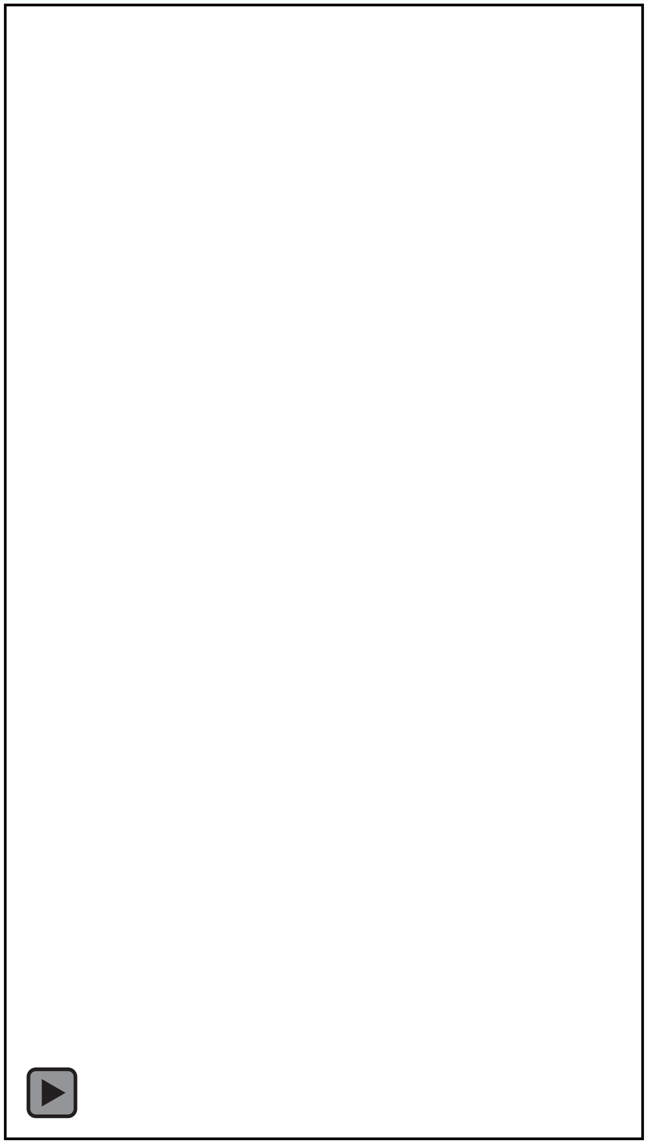


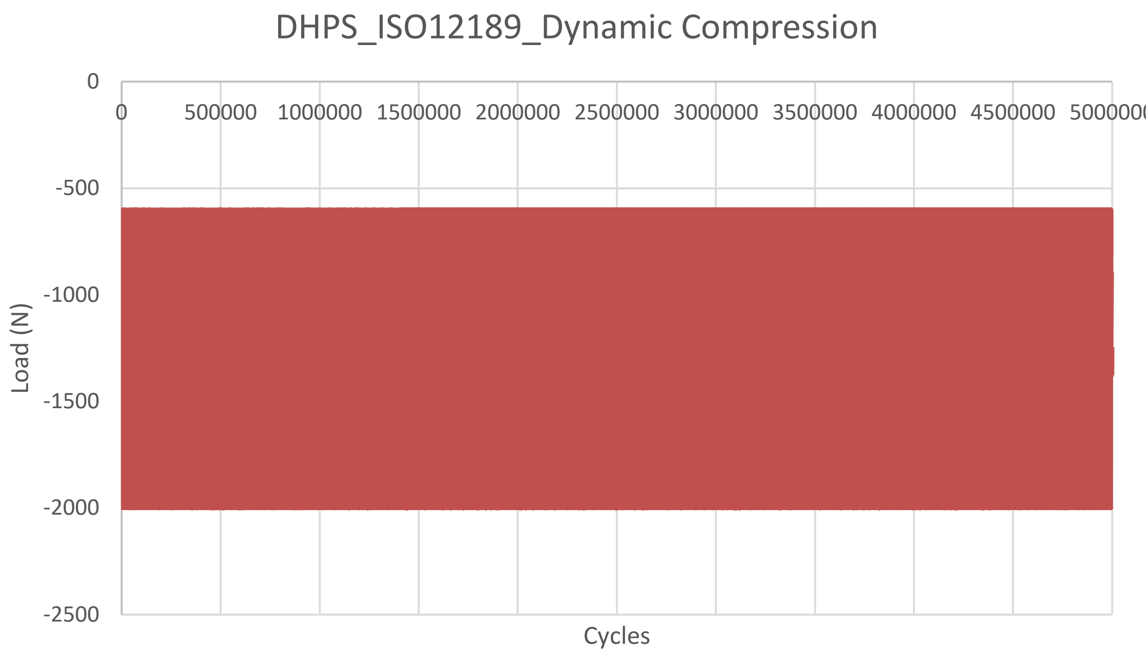


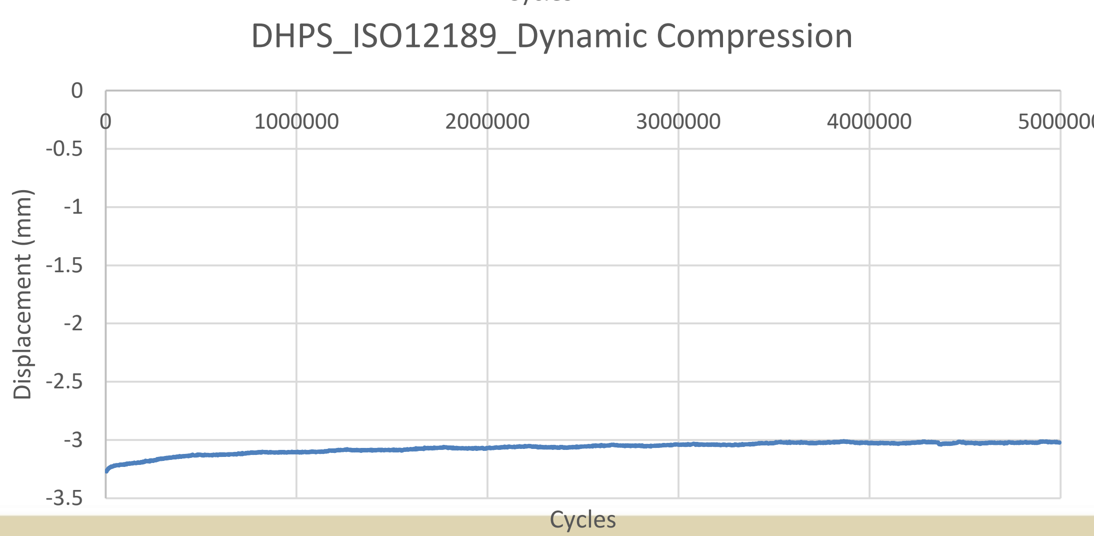
Test Setup – ISO 12189:2008 (E)



Results

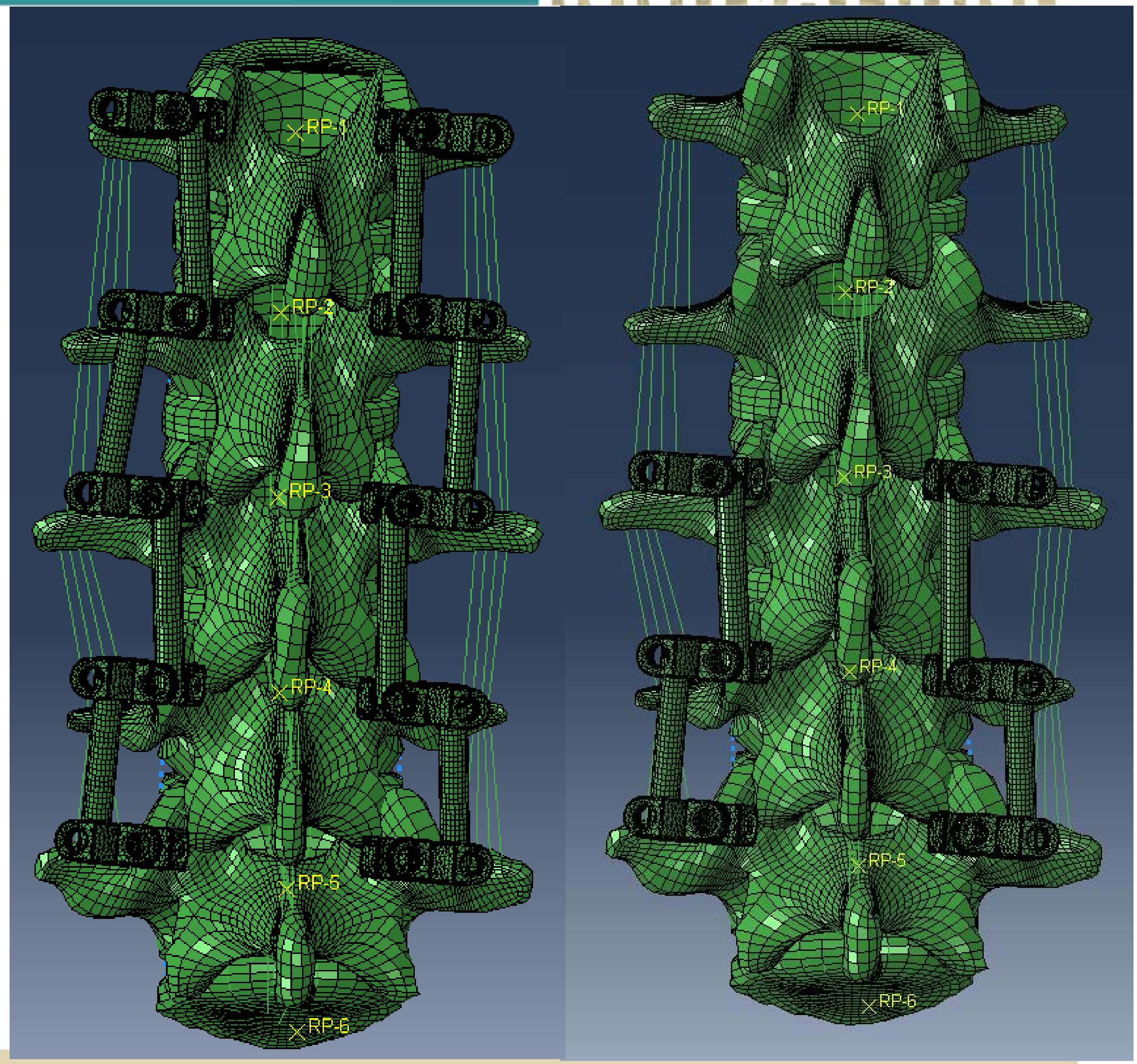



DHPS_ISO12189_Dynamic Compression
Load (N)
0
-500
-1000
-1500
-2000
-2500
0
500000
1000000
1500000
2000000
2500000
3000000
3500000
4000000
4500000
5000000
Cycles


DHPS_ISO12189_Dynamic Compression
Displacement (mm)
0
-0.5
-1
-1.5
-2
-2.5
-3
-3.5
0
1000000
2000000
3000000
4000000
5000000
Cycles

FE Analysis

- L1-L5 Lumbar model – 57405 elements
- Implanted level
    a) L1-L5 – 202975 elements – nodes 325969 nodes
    b) L3-L5 – 143757 elements – 226086 nodes
- Interaction btw head and screw shaft – surface to surface with 0.01 friction coefficient
- Flex, Ext, LB, AR moment – 10Nm
- Follower load – 400N



Conclusions

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i. Initial mechanical dynamic testing was carried. FE model was prepared and will be presented

ii. Pedicle screw tested under dynamic fatigue test – ISO 12189:2008(E) No damage. No visible wear particles (needed to be investigated)

i. The proposed design might address to PJK by allowing some motion at UIV and UIV+1 (to be compared with other techniques.)

Milestones & Timeline

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

Thank you