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MUSCULOSKELETAL INNOVATIONS

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

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Questions raised by the IAB

Question 1:

- What are boundary conditions for double headed screw?

Question 2:

- What does it accomplish?

Question 3:

- What difference does your screw make regarding control of PJK incidence compared to the traditional pedicle screw design?

Question 4:

- Will a low tightening torque of 2Nm cause any issues clinically?

Question 5:

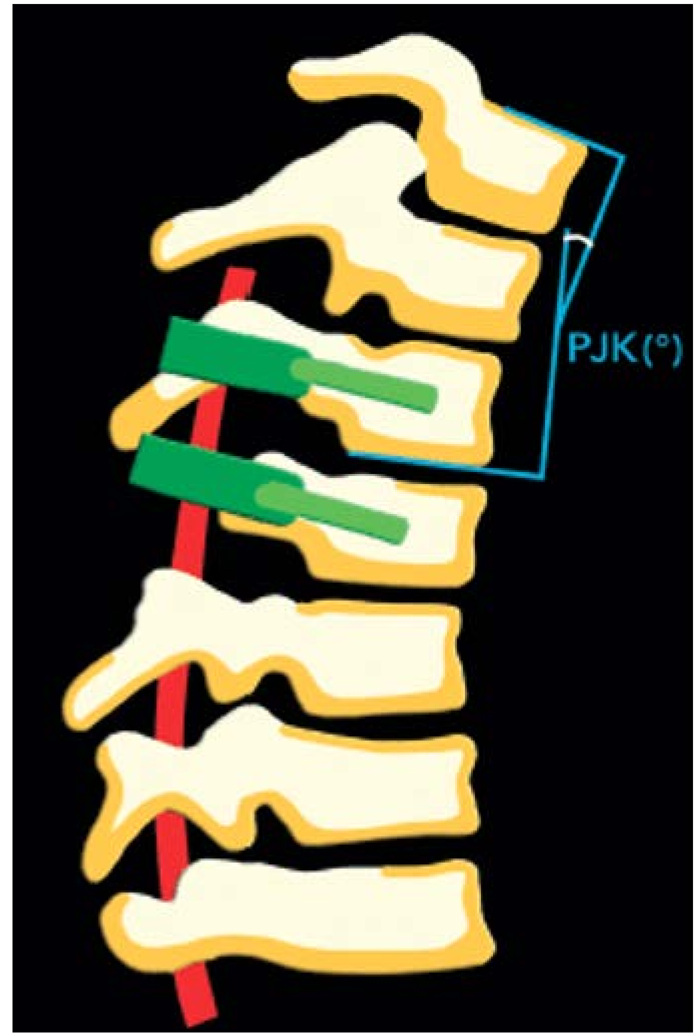
- Static issues, loosening between screw and rods

Background

- Proximal Junction Kyphosis (PJK):

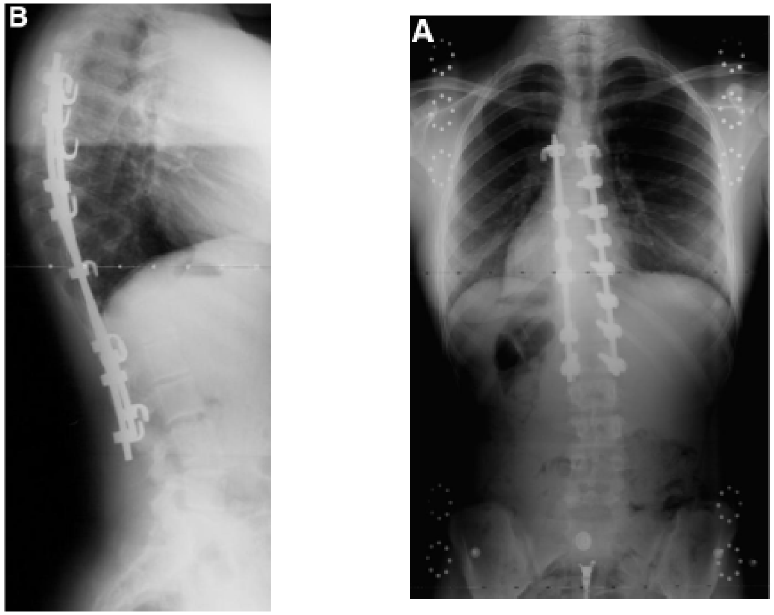
  Long thoracolumbar fusion
  PJK

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



Clinical Need and Industrial Relevance

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*

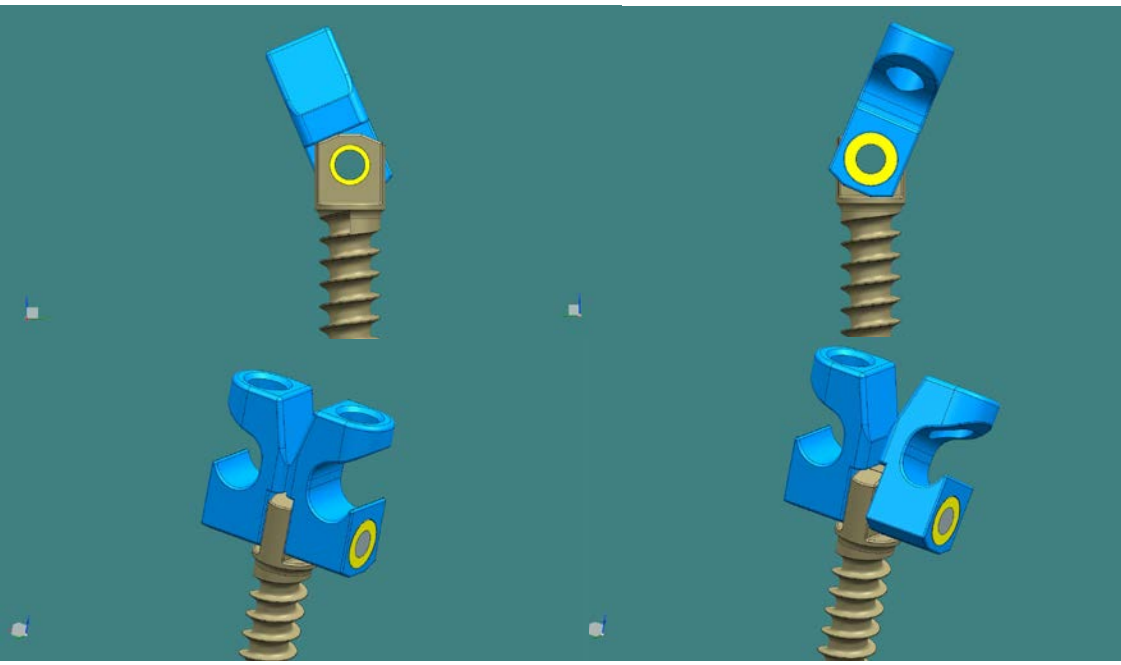
Double-Headed Screw Concept

Question 1:

What are boundary conditions for double headed screw?

Question 2:

What does it accomplish?



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

Question from the last meeting

Question 3:

What difference does your screw make regarding control of PJK incidence compared to the traditional pedicle screw design?

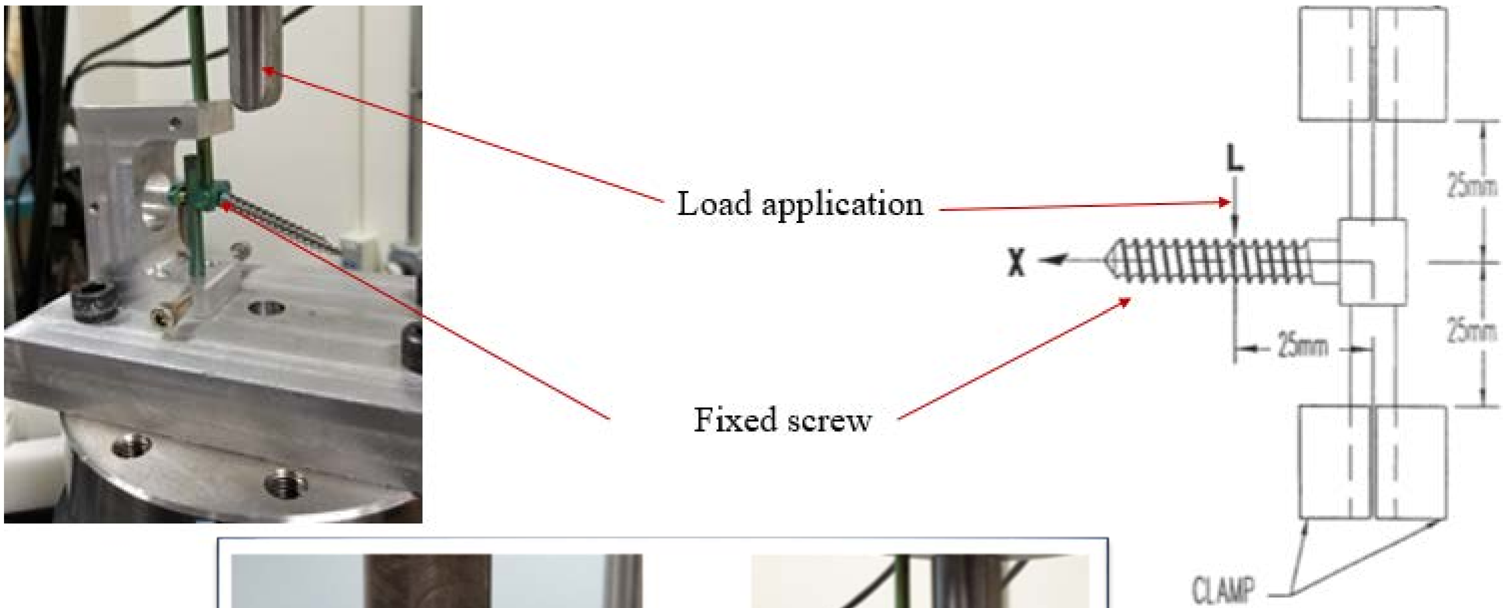
- It basically provides semi-dynamic stabilization to the segment to improve load sharing

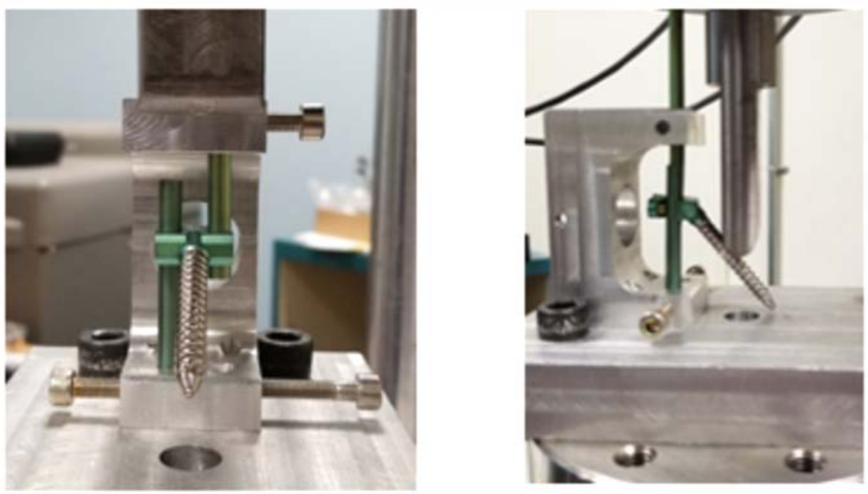
Methods

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

Prototype

Flexion – Extension Moment Test Setup





Before Test

After Test

Reference: F1798 Standard

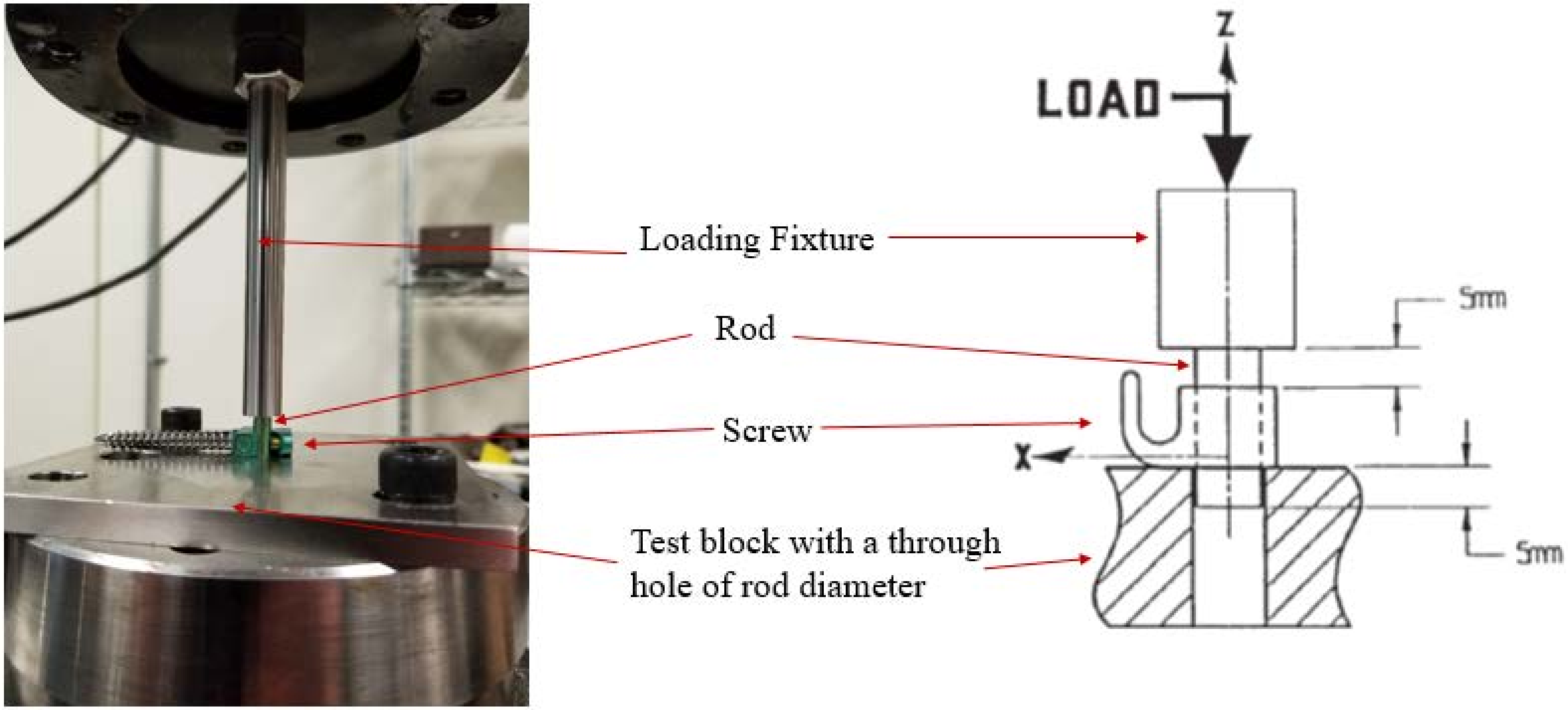
Mechanical Testing
Flexion-Extension Moment Test

- Standard followed: F1798
- No. of Specimens: 6 (2 Nm tightening torque).
- Both ends of the longitudinal rod were rigidly clamped and the set screw-pedicle screw interconnection centered on the longitudinal rod.
- Axial load was applied at a rate of **5 mm/min** at a distance of 25 mm from the axial center of the test assembly.
- Load displacement data was recorded and ultimate load was noted for each specimen.

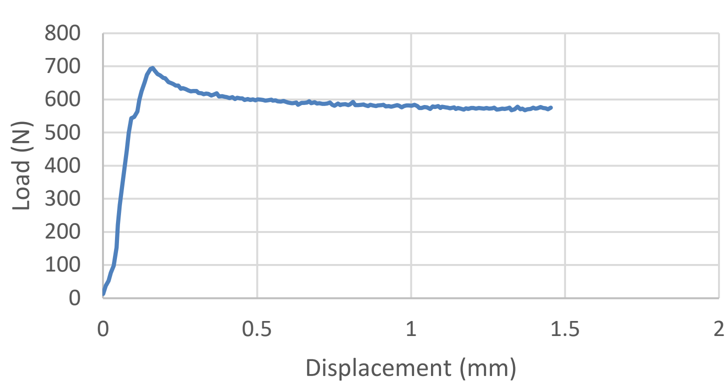
Results

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

Axial Grip strength Test



Reference: F1798 Standard



Axial Grip Test Procedure

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- Standard followed: F1798
- No. of Specimens: 6
- A 17.25 mm long rod of was tightly placed within in the tulip of pedicle screw using a set screw and tightened with a torque wrench at 2 Nm.
- A 5 mm rod-length was left on either side of the set screw-pedicle screw interconnection.
- The assembly was placed on the test block with a through hole of 5.5 mm diameter in the center.
- Axial load was applied at a rate of **5 mm/min** to the free end of the rod to push it through the interconnecting mechanism.
- Load displacement data was recorded.
- Axial grip capacity:

  The maximum applied load across an interconnection mechanism within the first 1.5 mm of displacement between the connected components was recorded.

Results

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

Conclusions

i. Initial mechanical testing was carried for design optimization purposes.
ii. Pedicle screw tested under axial force for grip strength- the mean force was 675 (58) N
iii. Pedicle screw tested under static Flexion/Extension (FE) bending showed a mean yield bending moment of 884 (58)N
iv. We have some data from literature to compare. FE moment test 504(56)N and Axial grip 1042 (99) N. (it is not from dynamic screws)

Question 4:

- Will a low tightening torque of 2Nm cause any issues clinically?
  - It might not affect the clinical outcome

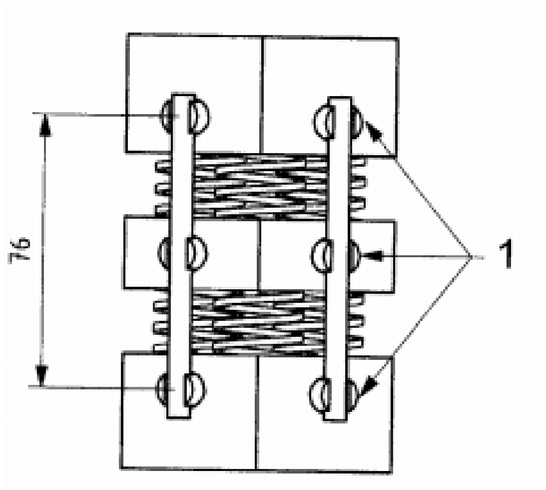
Question 5:

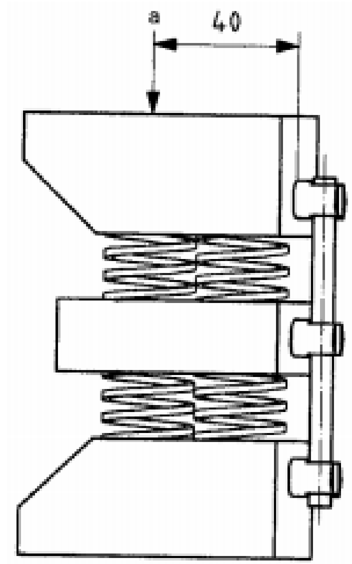
- Static issues, loosening between screw and rods
  - Dynamic stabilization and FE modeling

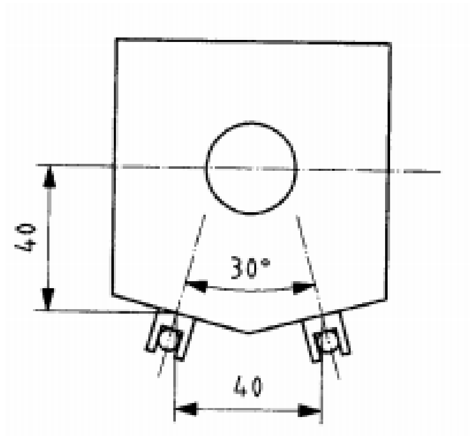
Suggestion about fatigue testing

ISO 12189:2008(E)

Implants for surgery – Mechanical testing of implantable spinal devices – Fatigue test method for spinal implant assemblies using and anterior support







Milestones & Timeline

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

Thank you