CDMI

CENTER FOR DISRUPTIVE
MUSCULOSKELETAL INNOVATIONS

Biomechanics of Topping-Off the Fused Segment

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Background

- Lumbar spine fusion carried out in the patients with severe low back pain.

- Has relatively good results in appropriately selected patients

- Concerns:

1. Adjacent segment disease
2. Issues at multiple levels

Historical Dilemma

- Best management option for a minimal dysfunctional adjacent level

Approaches:

1. Fuse it ?

Too aggressive intervention!

Will it deteriorate ?

May shift risk to a level above it?

2. Leave it alone?

Outcome of fusion surgery!

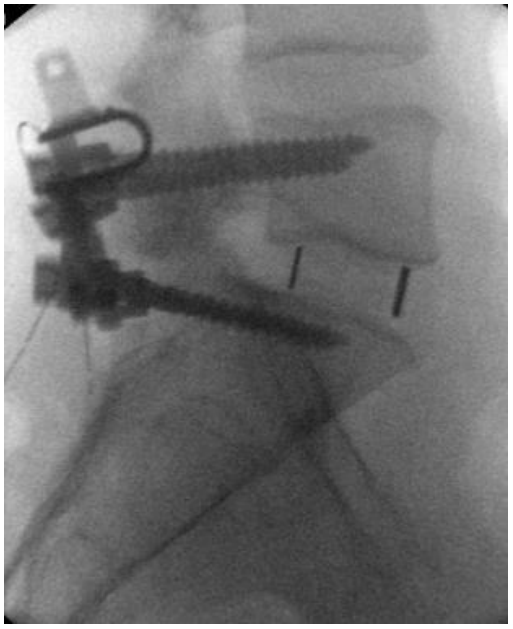
Would patient require further surgery later?

3. Combine fusion with non – fusion device?

Hypotheses

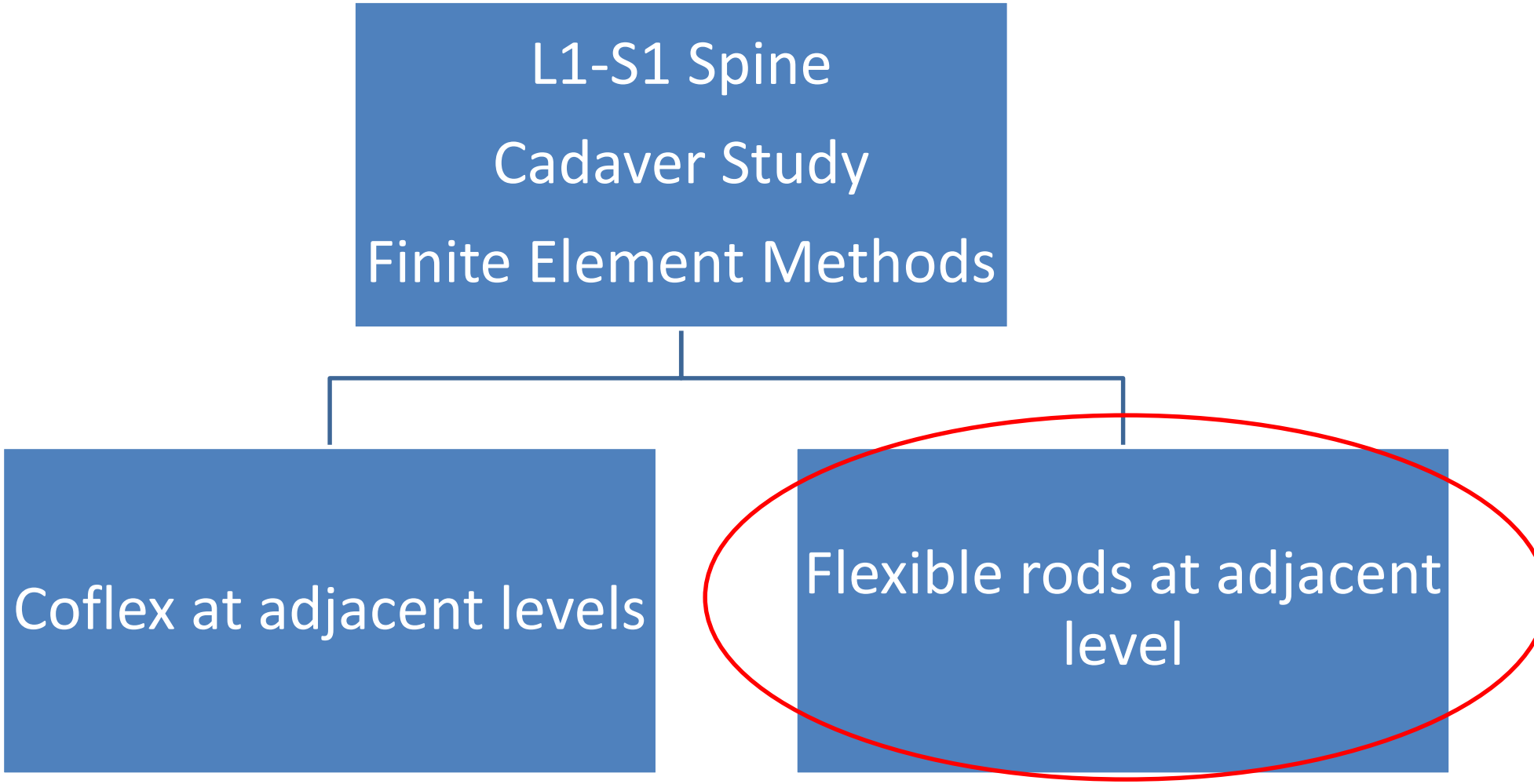
The use of dynamic system at the adjacent level may

- Produce a tapered increase of motion (in adjacent levels) as opposed to sudden increase
- Lower stresses at the adjacent levels

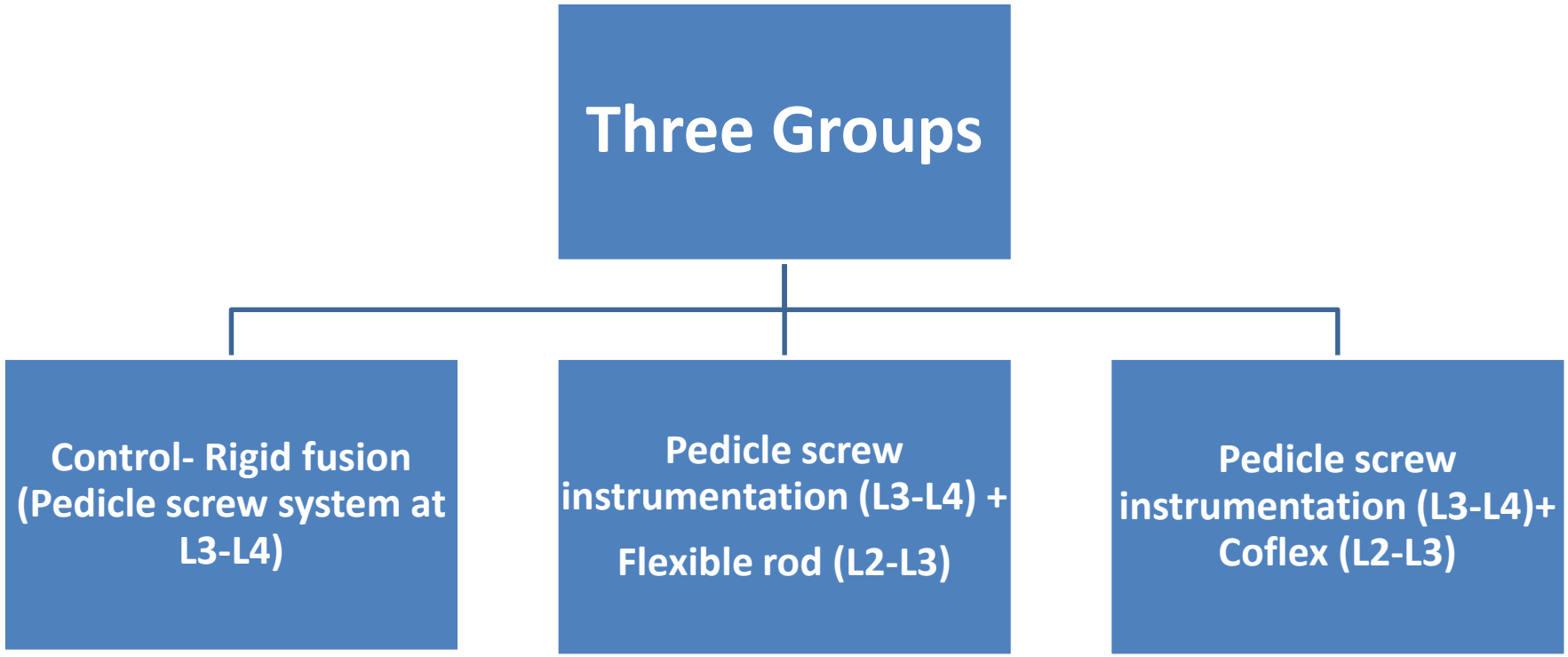


Courtesy: Dr. Agarwal's case pictures

Methods


L1-S1 Spine
Cadaver Study
Finite Element Methods
Coflex at adjacent levels
Flexible rods at adjacent level

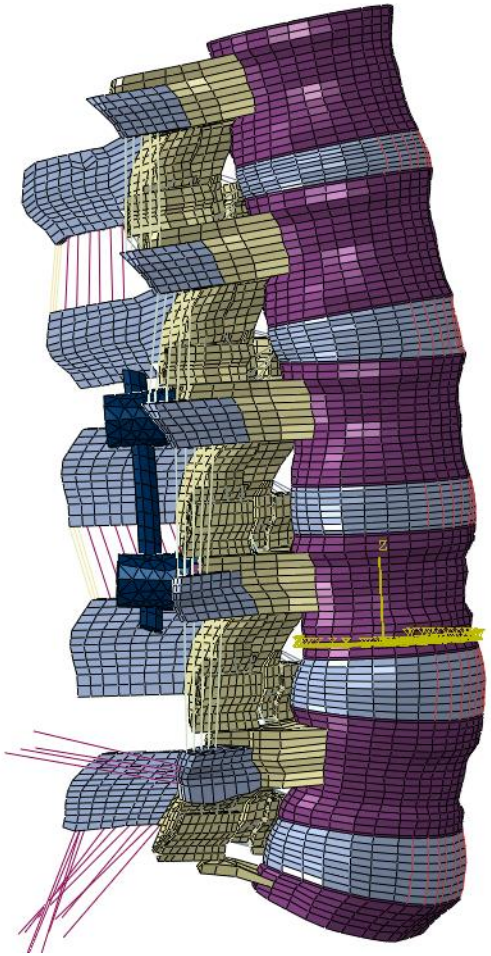
Methods-FEA


Three Groups
Control- Rigid fusion (Pedicle screw system at L3-L4)
Pedicle screw instrumentation (L3-L4) + Flexible rod (L2-L3)
Pedicle screw instrumentation (L3-L4)+ Coflex (L2-L3)

Methods

L1

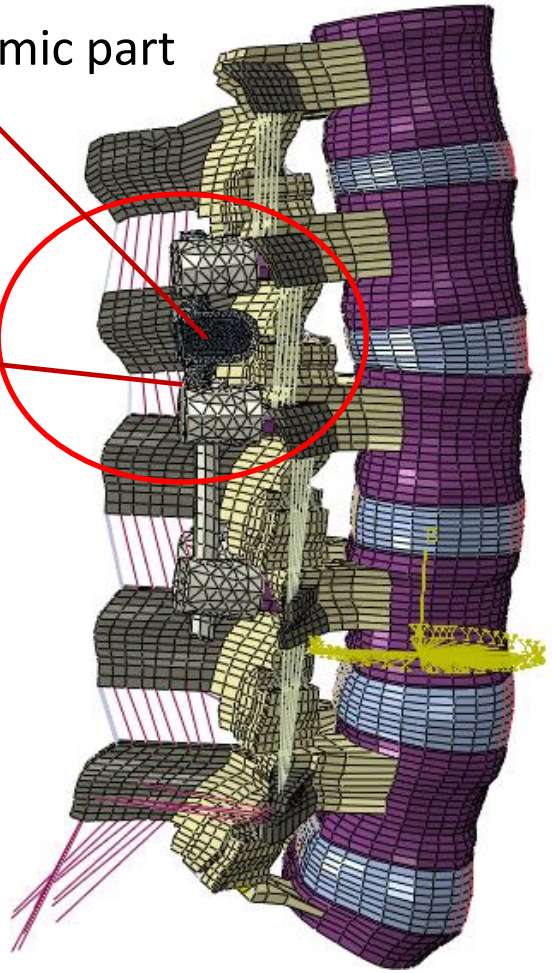
L5



Only PSS @L3-L4

Silicon-Dynamic part

PEEK



PSS+ Flexible rod @L2-L3

Methods-FEA

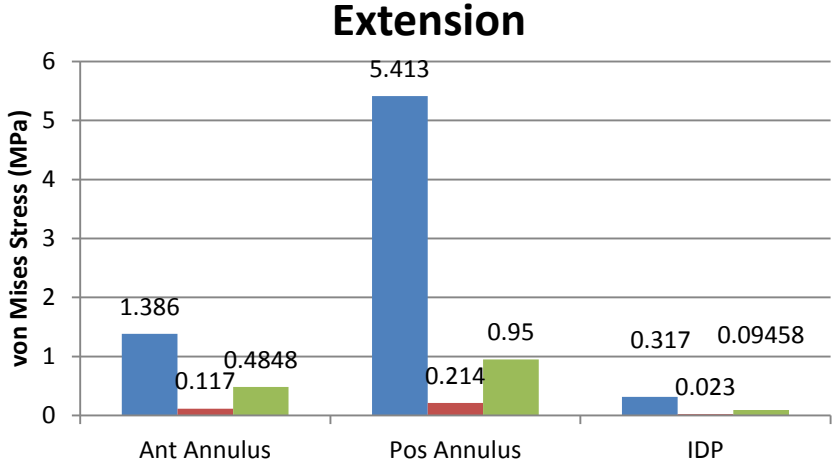
Simulation of Surgery

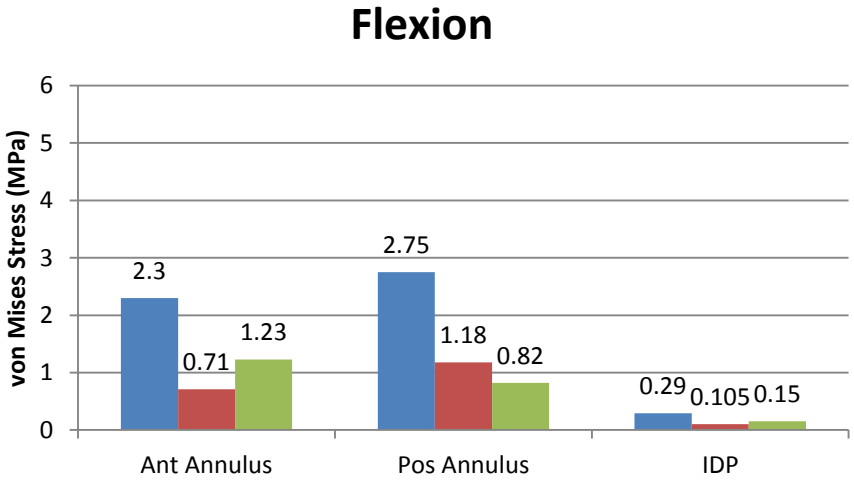
1. Flexible rod was placed at the proximal level
2. Application of follower load (400N)
3. 10 Nm moments to simulate extension, flexion, bendings and rotations

- Intra discal pressures (IDP) and the stresses at the anterior and posterior annulus were analyzed.

Results

Intradiscal pressures and stresses at the anterior and posterior annulus at L2-L3 for the Normal disc





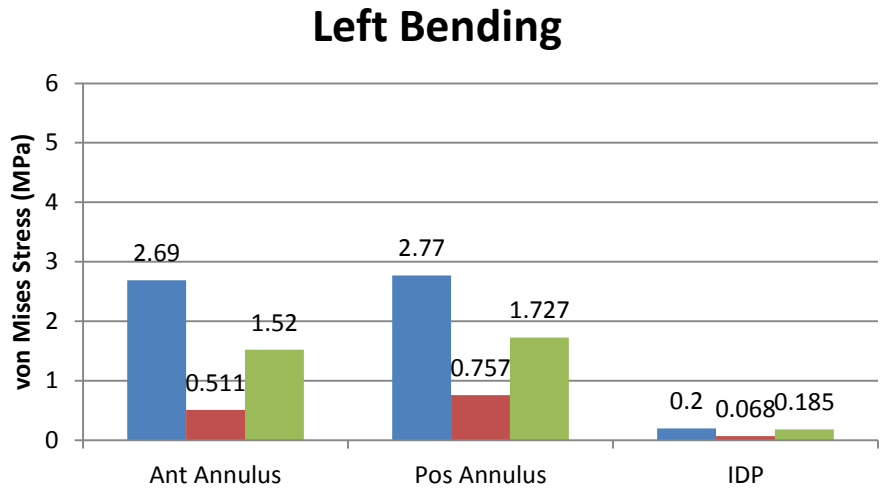
PSS @L3-L4

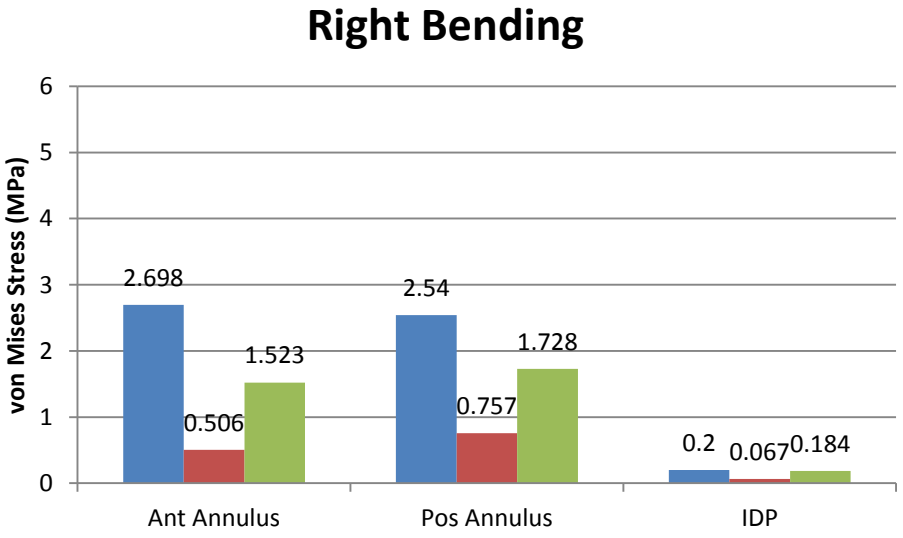
PSS+Flexible Rods@L2-L3

PSS+ Coflex @L2-L3

Results

Intradiscal pressures and stresses at the anterior and posterior annulus at L2-L3 for the Normal disc





PSS @L3-L4

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PSS+ Coflex @L2-L3

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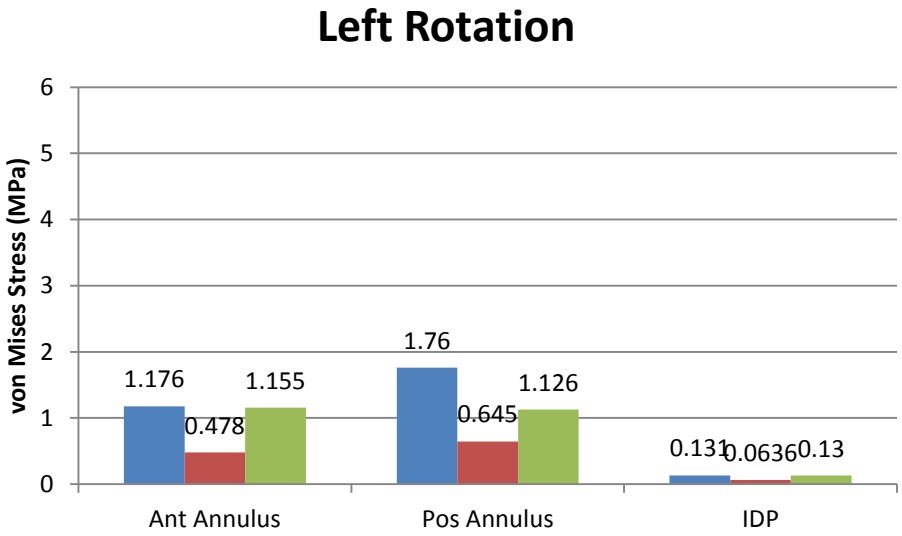
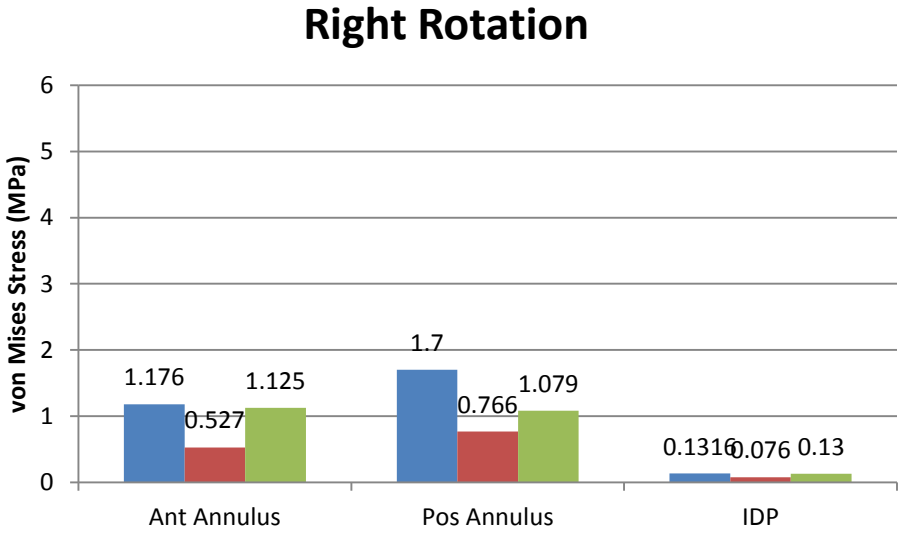




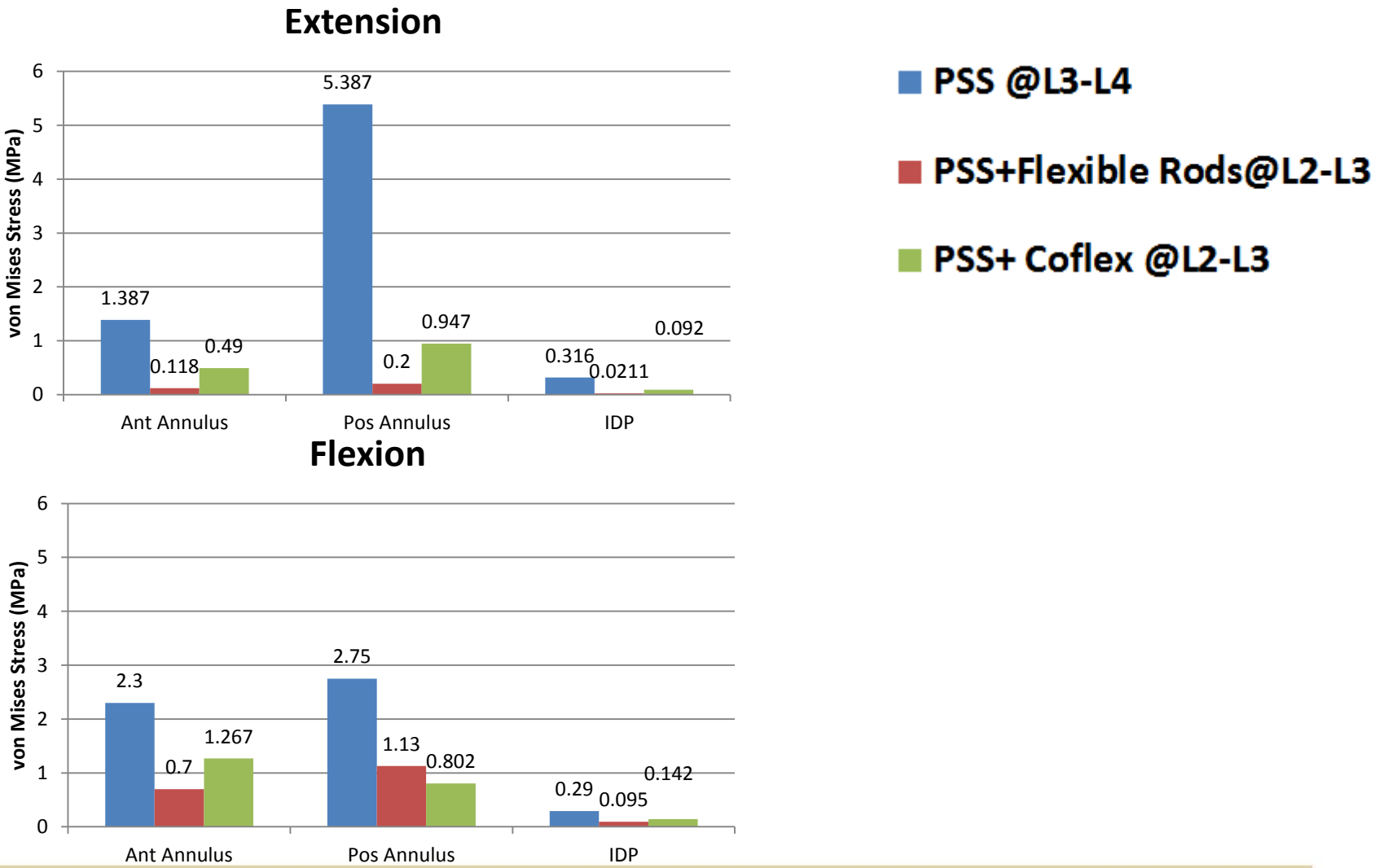
PSS @L3-L4

PSS+Flexible Rods@L2-L3

PSS+ Coflex @L2-L3

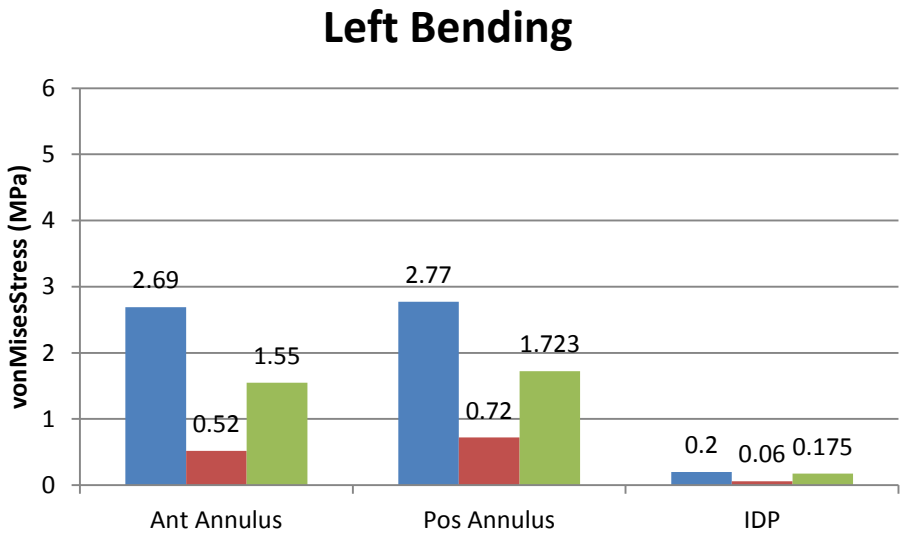
Results

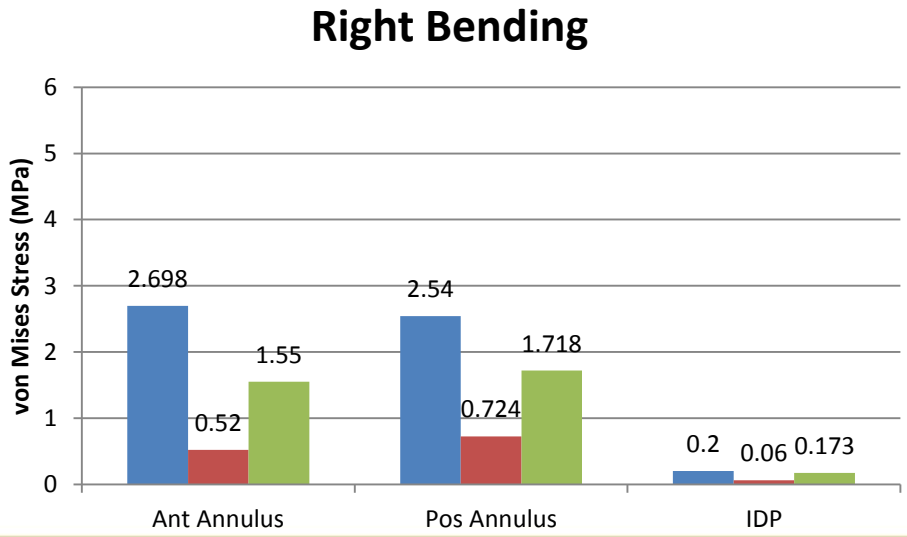
Intradiscal pressures and stresses at the anterior and posterior annulus at L2-L3 for the Type 2 degenerated disc



Results

Intradiscal pressures and stresses at the anterior and posterior annulus at L2-L3 for the Type 2 degenerated disc





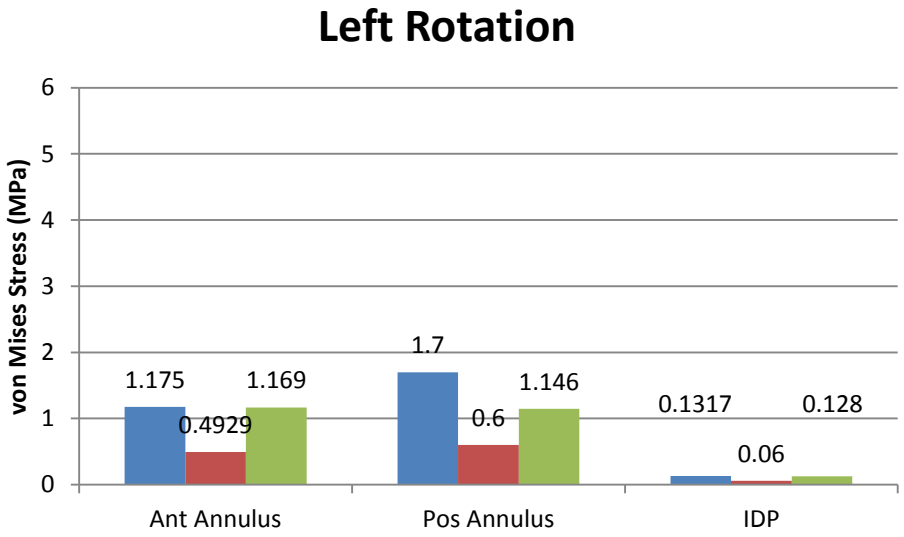
PSS @L3-L4

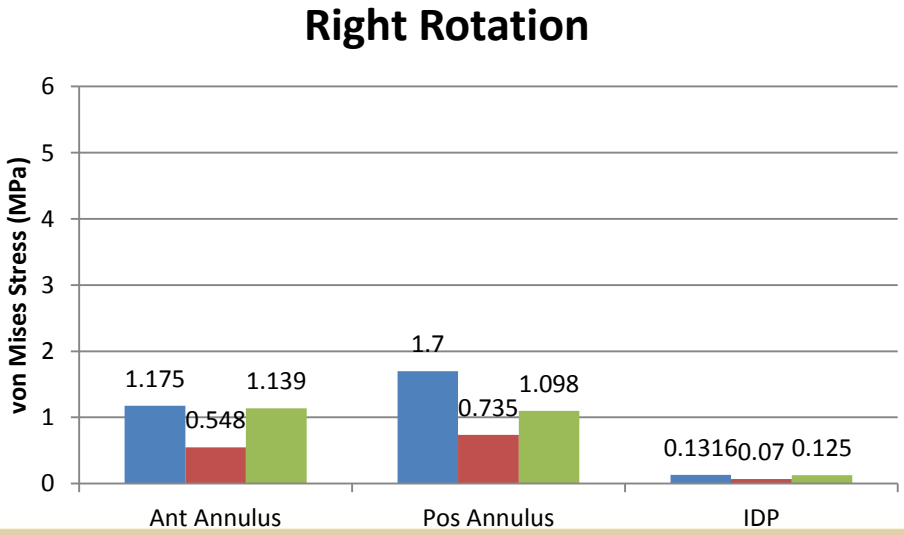
PSS+Flexible Rods@L2-L3

PSS+ Coflex @L2-L3

Results

Intradiscal pressures and stresses at the anterior and posterior annulus at L2-L3 for the Type 2 degenerated disc





PSS @L3-L4

PSS+Flexible Rods@L2-L3

PSS+ Coflex @L2-L3

Results- Summary

% Decrease in the Intradiscal pressures w.r.t. PSS for L2-L3 disc		
	PSS+ Flex Rod @L2-L3	PSS+ Coflex @L2-L3
Extension	93%	71.6%
Flexion	63.7%	48.27%
Left Bending	66%	7.5%
Right Bending	66.5%	8%
Left Rotation	51.5%	1%
Right Rotation	42.2	4.4%

Results- Summary

% Decrease in the stresses at the Anterior annulus w.r.t. PSS for L2-L3 disc		
	PSS+ Flex Rod @L2-L3	PSS+ Coflex @L2-L3
Extension	91.5%	65%
Flexion	69%	46.5%
Left Bending	81%	43.5%
Right Bending	81.2%	43.5%
Left Rotation	59.4%	1.8%
Right Rotation	55.2%	4.3%

Results- Summary

% Decrease in the Posterior annulus stresses w.r.t. PSS for L2-L3 disc		
	PSS+ Flex Rod @L2-L3	PSS+ Coflex @L2-L3
Extension	96%	82.4%
Flexion	57.1%	70.2%
Left Bending	72.6%	37.65
Right Bending	70.2%	32%
Left Rotation	63.4%	36%
Right Rotation	55%	36.5%

Results

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Intradiscal pressures and stresses at the discs for Extension

L1-L2			
	Ant Annulus	Pos Annulus	IDP
PSS @L3-L4	1.432	3.96	0.27
PSS+Flexible Rods @L2-L3	1.44	3.97	0.266
PSS+ Coflex @L2-L3	1.443	3.878	0.2637
L2-L3			
	Ant Annulus	Pos Annulus	IDP
PSS @L3-L4	1.386	5.413	0.317
PSS+Flexible Rods@L2-L3	0.117	0.214	0.023
PSS+ Coflex @L2-L3	0.4848	0.95	0.09458
L3-L4			
	Ant Annulus	Pos Annulus	IDP
PSS @L3-L4	0.25	0.26	0.028
PSS+Flexible Rods@L2-L3	0.2716	0.287	0.034
PSS+ Coflex @L2-L3	0.2639	0.26	0.033
L4-L5			
	Ant Annulus	Pos Annulus	IDP
PSS @L3-L4	0.536	1.282	0.109
PSS+Flexible Rods@L2-L3	0.548	1.35	0.113
PSS+ Coflex @L2-L3	0.5348	1.28	0.1089
L5-S1			
	Ant Annulus	Pos Annulus	IDP
PSS @L3-L4	0.536	1.282	0.109
PSS+Flexible Rods@L2-L3	0.548	1.35	0.113
PSS+ Coflex @L2-L3	0.5348	1.28	0.1089

Results

- Intradiscal pressures for L1-L2, L3-L4 and L5-S1 were similar for the all the groups.

- The intradiscal pressures were similar for the type 1 disc degeneration and type 2 disc degeneration, both were mildly degenerated discs with the loss of incompressibility of the nucleus.

- There was a higher reduction of the stresses with the flexible rods implanted at the proximal level (L2-L3) compared to the implantation of coflex.

- The stresses at the posterior annulus was higher with the implantation of flexible rods only for the flexion movement.

Discussion

- Intradiscal pressures and the stresses at the annulus reduced significantly with the implantation of flexible rods and coflex at the proximal junction for all the motions.

- However, there was a higher reduction of the stresses with the flexible rods implanted at the proximal level compared to the implantation of coflex.

- These dynamic systems provided the topping off the fused segment and allowed a smooth load transition, providing a better outcome.

- This may lead to the decrease in the adjacent segment disease.

Timeline

More FEA Simulations	September, 2017
Complete the project, prepare manuscript(s), and final report	September, 2017

Thank you for your attention

Research, Product Development
and Evaluation: Partnership with Industry