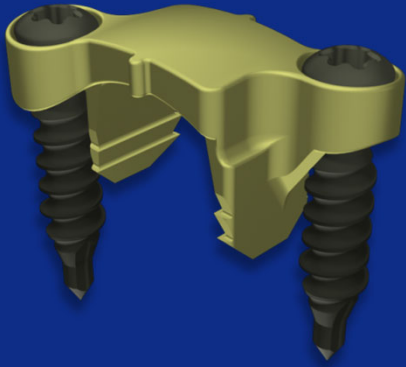


Anterior Flexible Staple



Eric Wall, MD

Donita Bylski-Austrow, PhD

Joseph Reynolds, BSME, MBA

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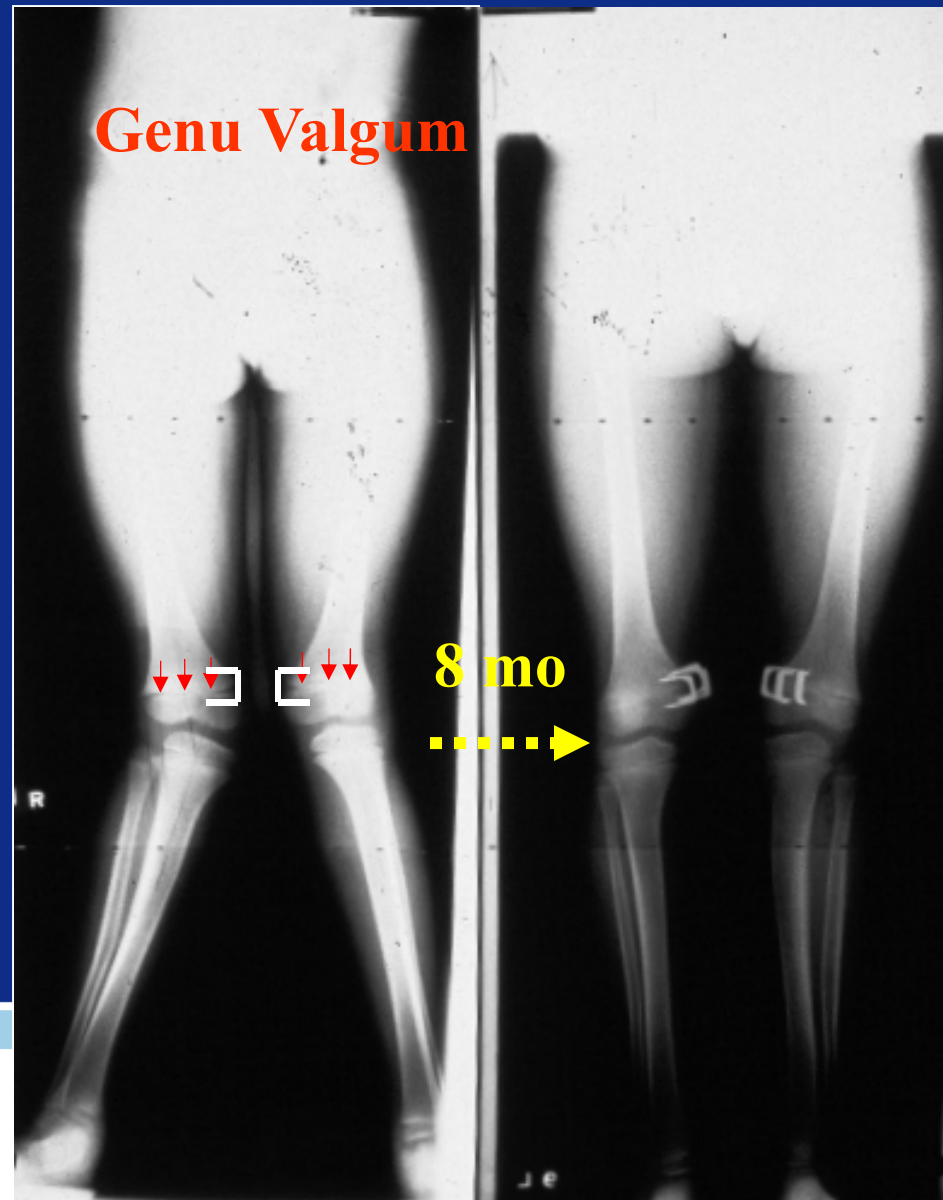


Disclosure



- Royalty Agreement
- Founder's Equity
- Ownership Shares

HEMIEPIPHYSEAL STAPLING IS HOT!



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Huter-Volkman Law

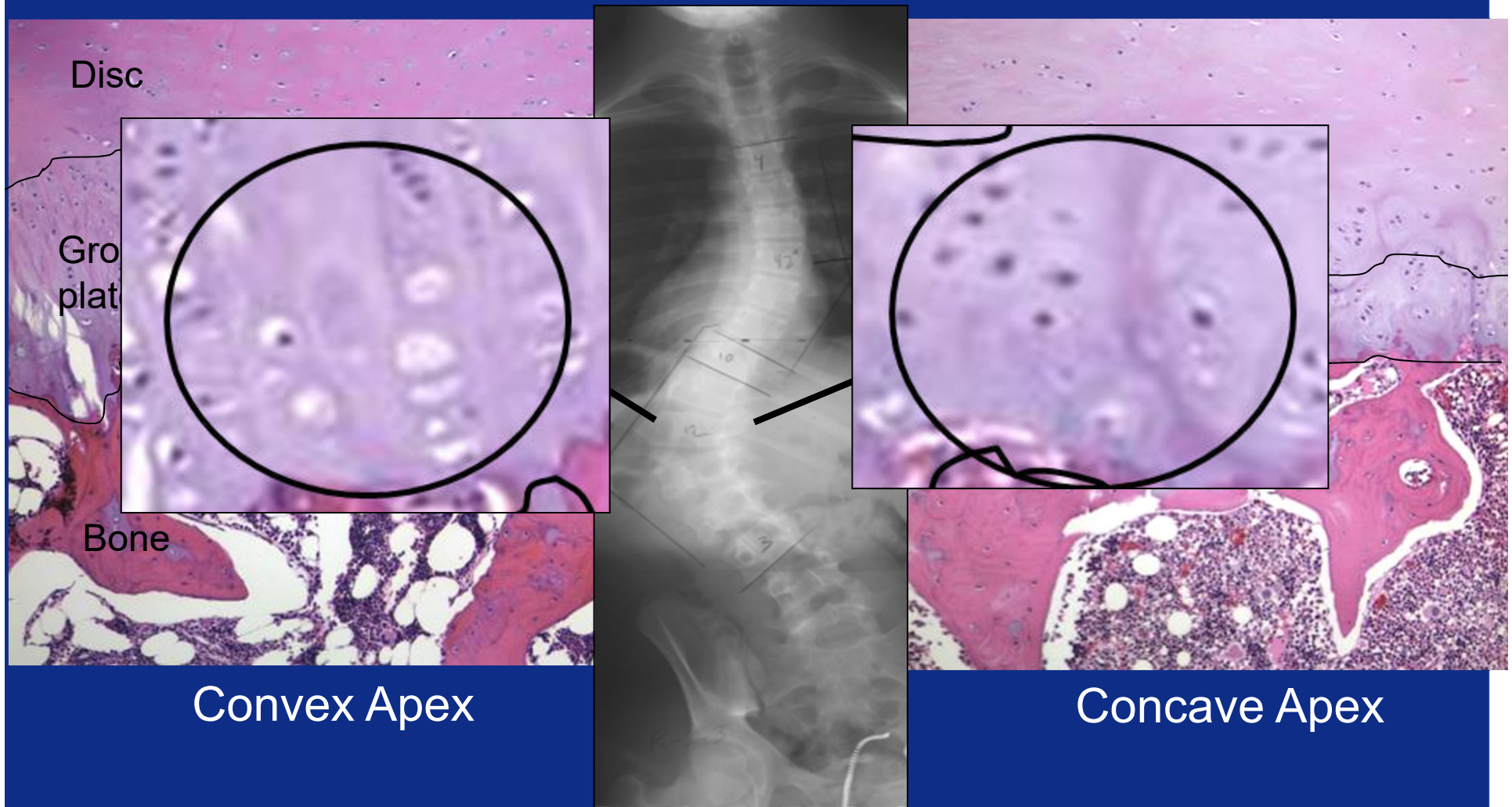


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Rivas & Shapiro JBJS 2002

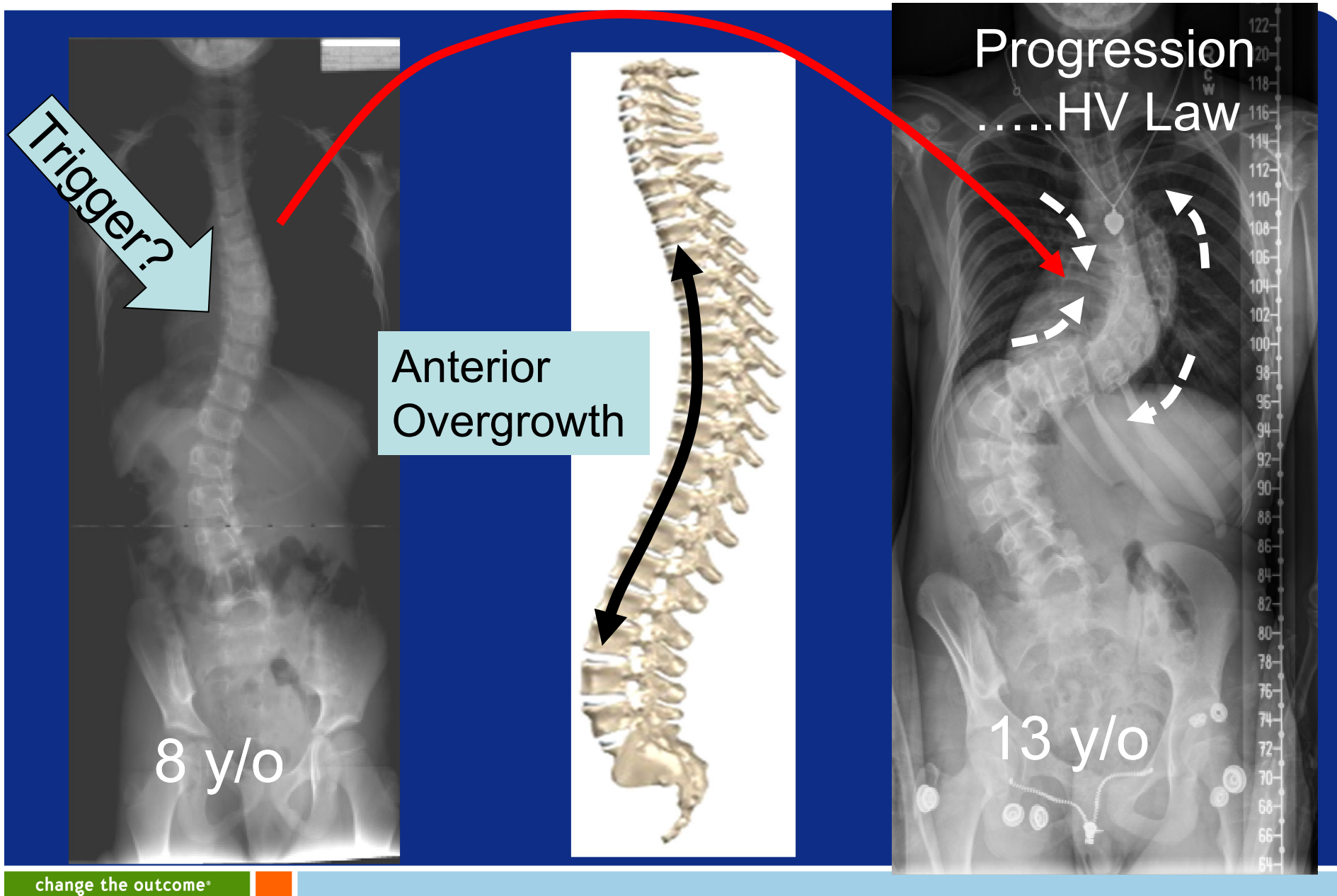
Human Scoliosis?



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Male, 12 years, 74°

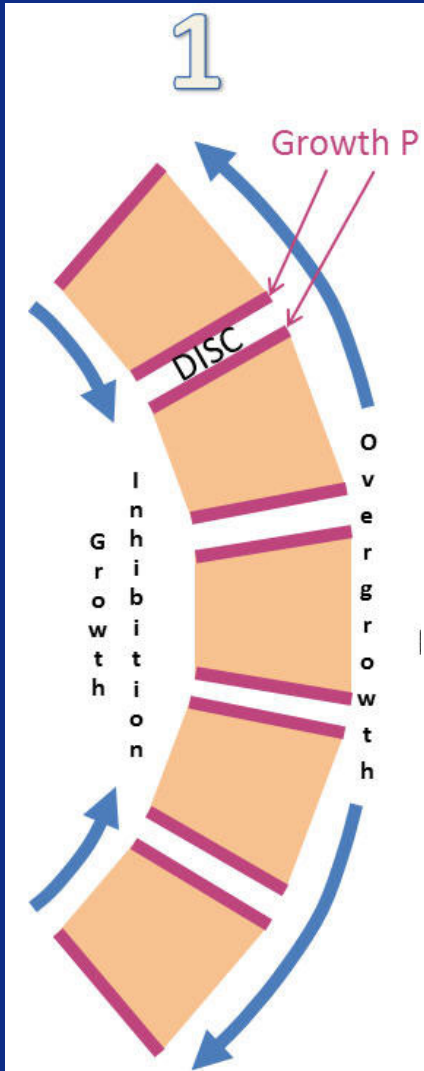


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JC Cheng
JBJS Br '03





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DOGS

FAILED

Incision

W. Nachlas
JBJS, 1951

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3 Humans

No reports results

FAILED?

A. Smith
JBJS, 1954

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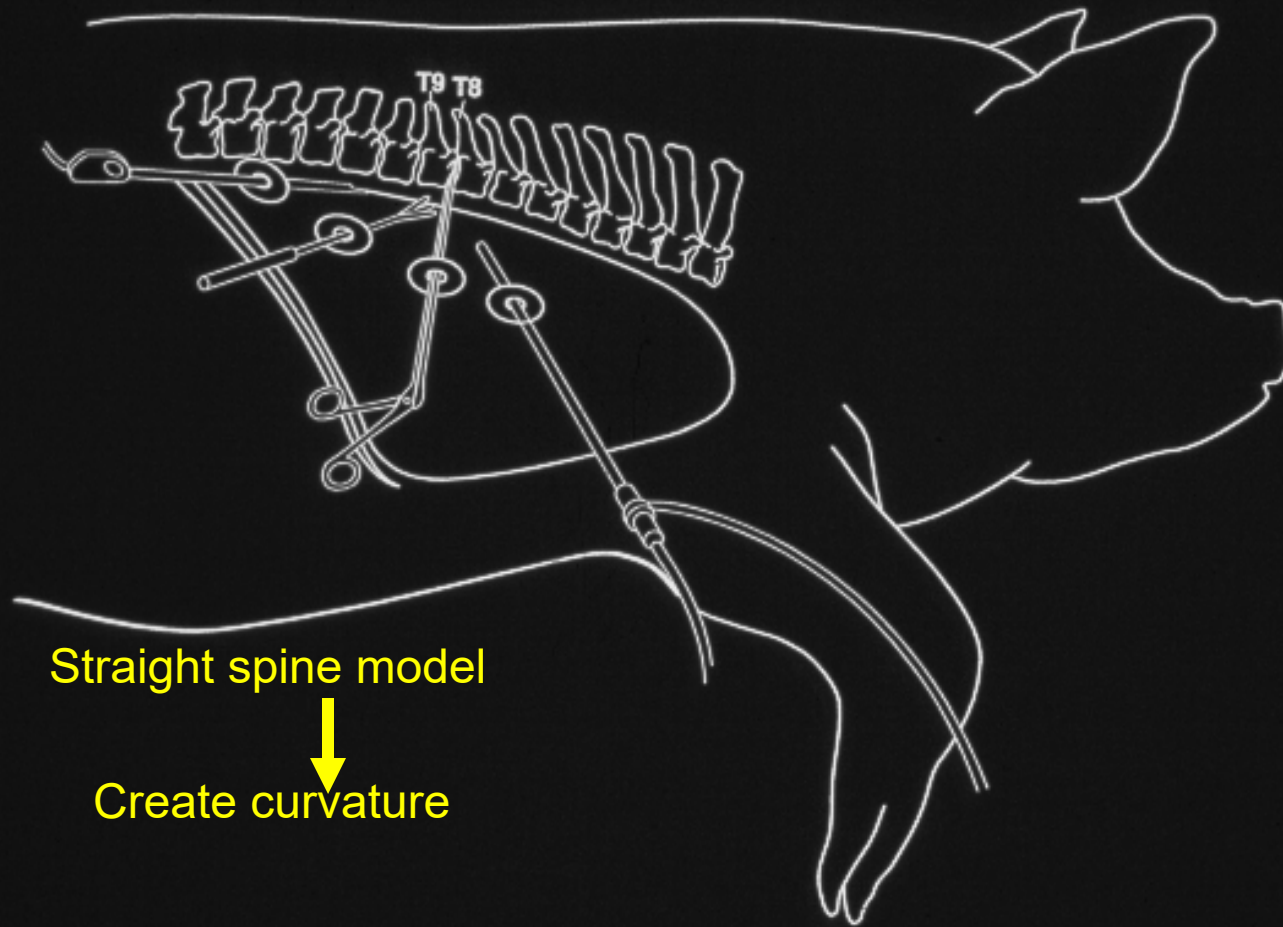
No reports on the failure mechanism

- “Knowing why it failed is as important as knowing why it worked”

Donita Bylski-Austrow

Always ENDOSCOPIC

Pigs

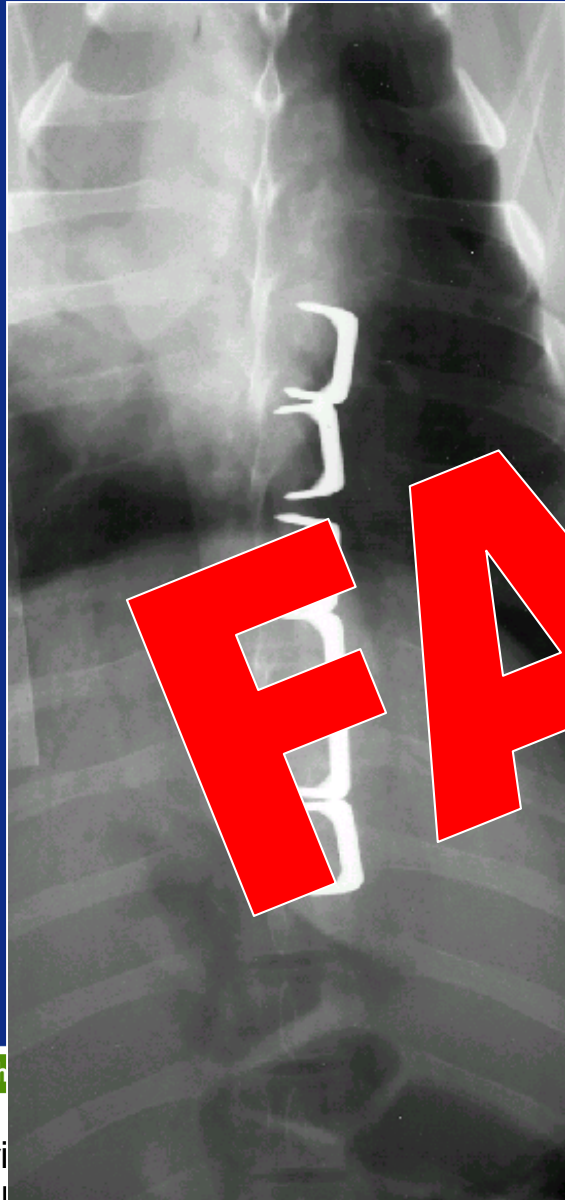


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Cincinnati
Children's

Time = 0



Time = 6 weeks



change th

Er
ICLOS 10NOV2011

Failure due to disc motion



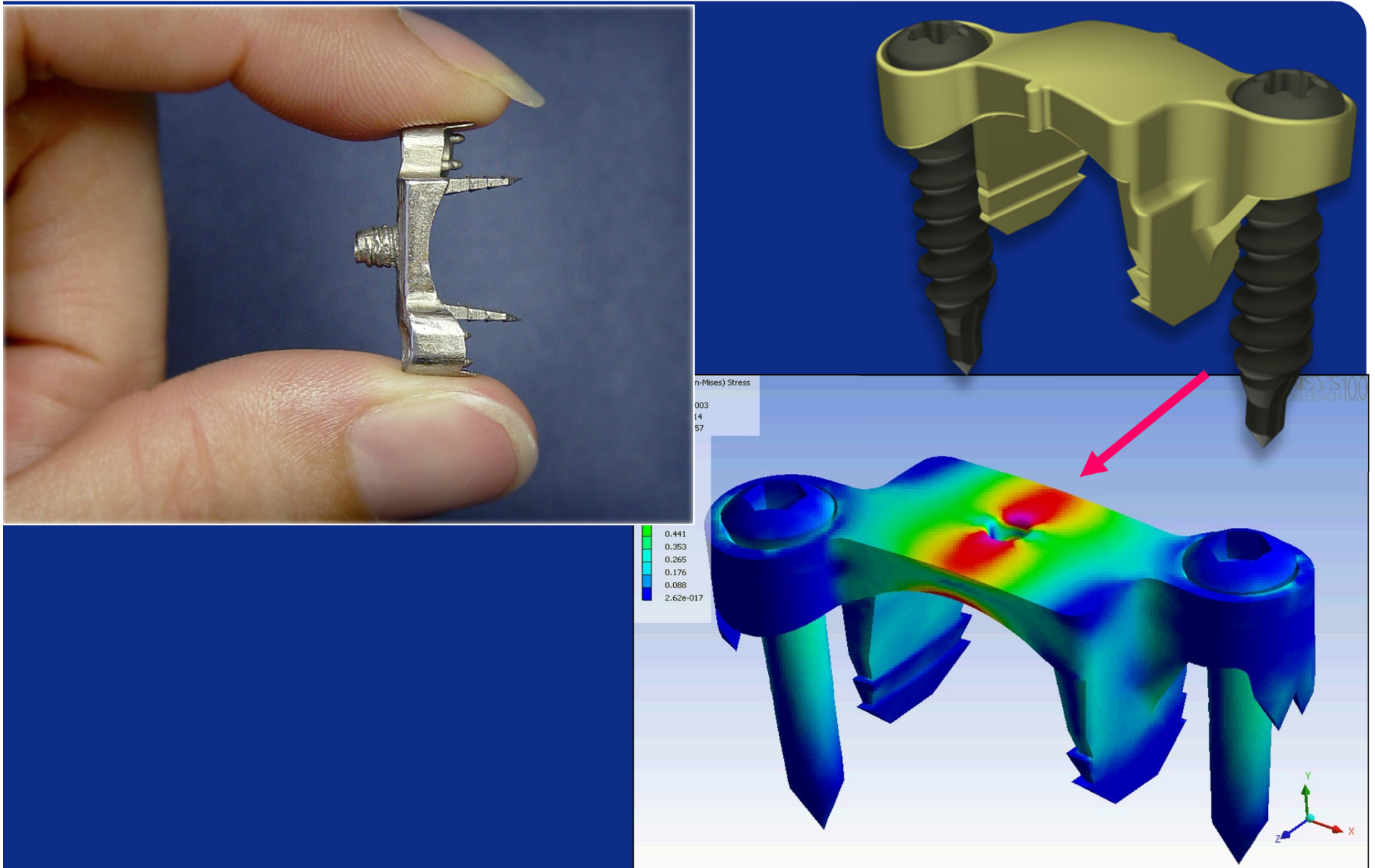
Courtesy of Tushar Patel, MD

Pig



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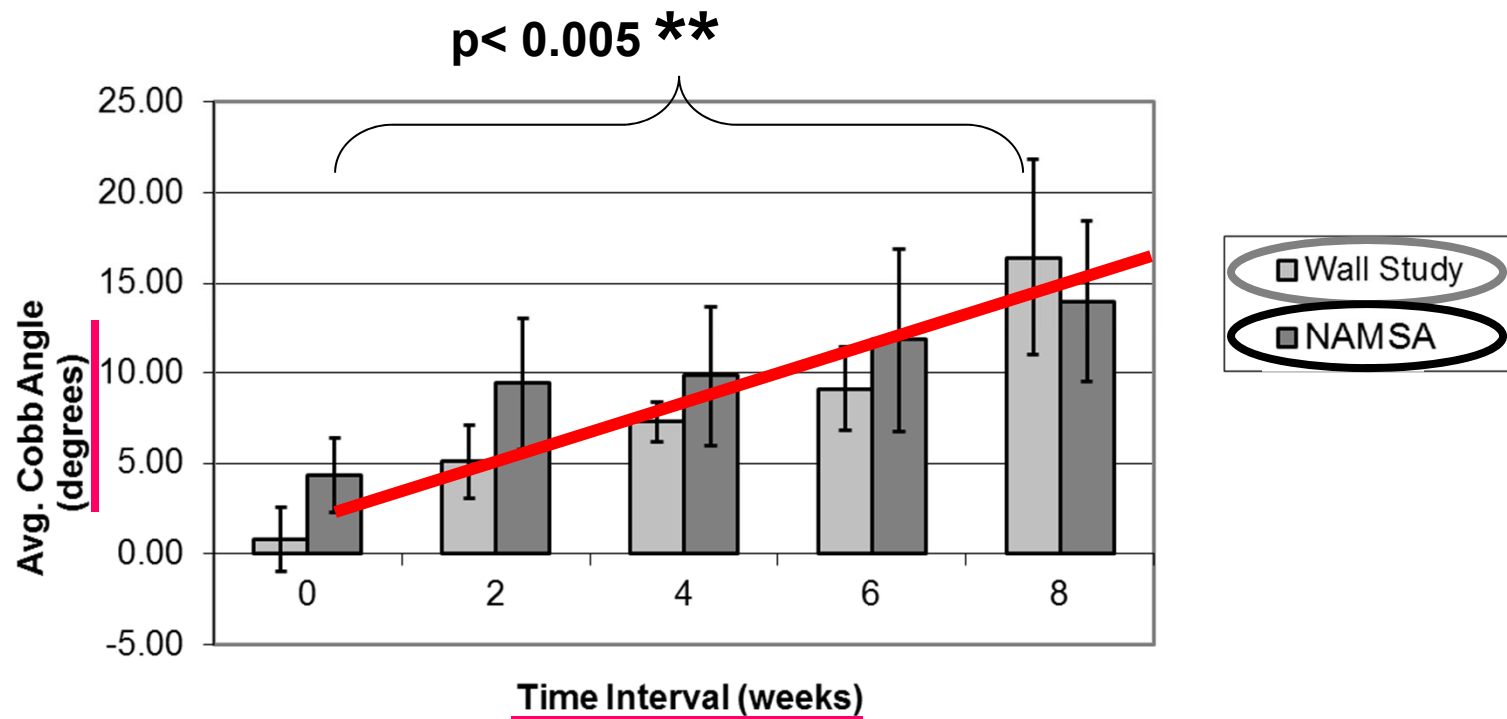


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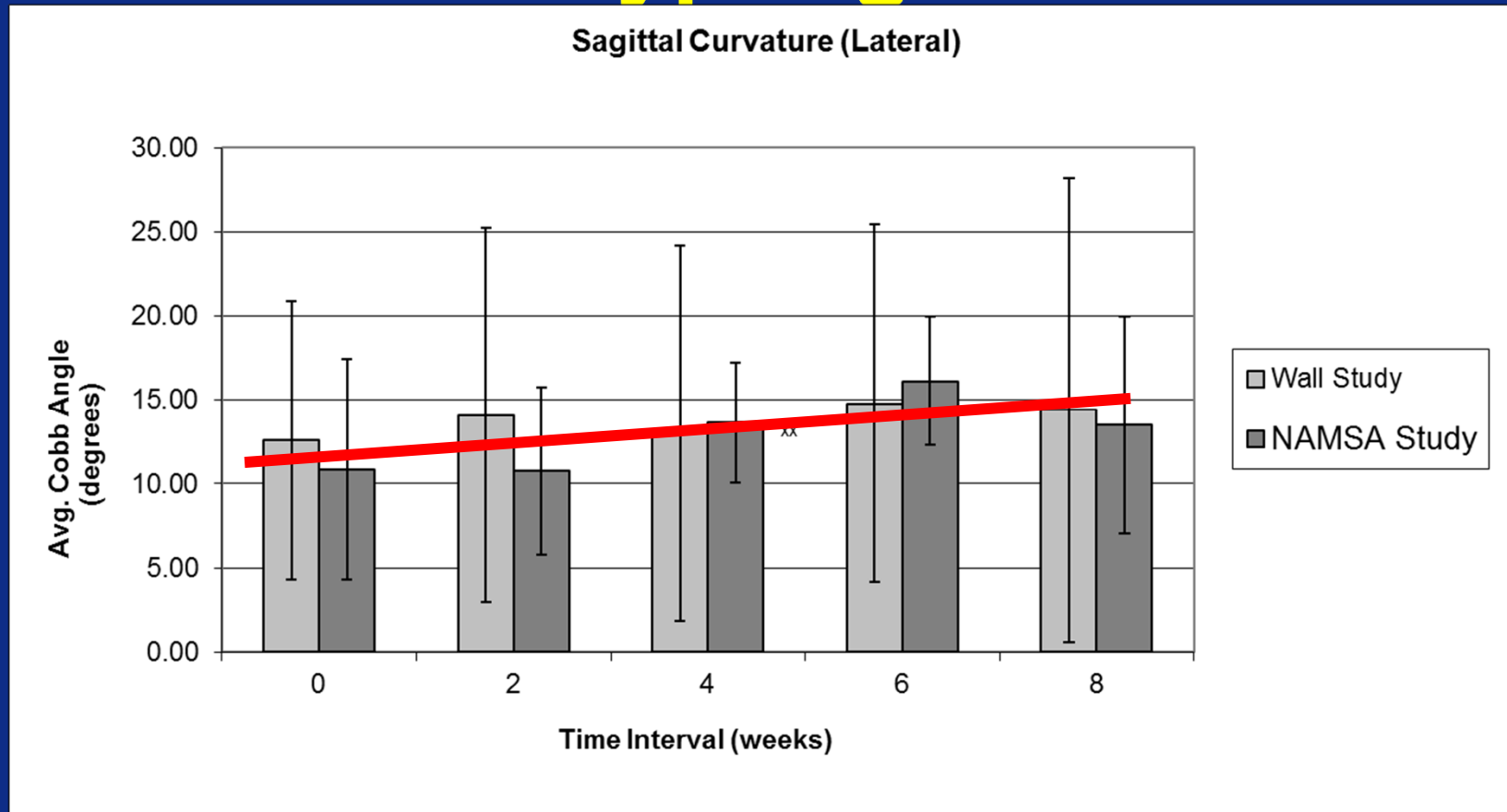
Cobb Angle vs. Time

2 Pig Studies (n=14)

Coronal (VD) Curvature Comparison of Wall et al. and NAMSA



Sagittal Plane: Not Kyphogenic

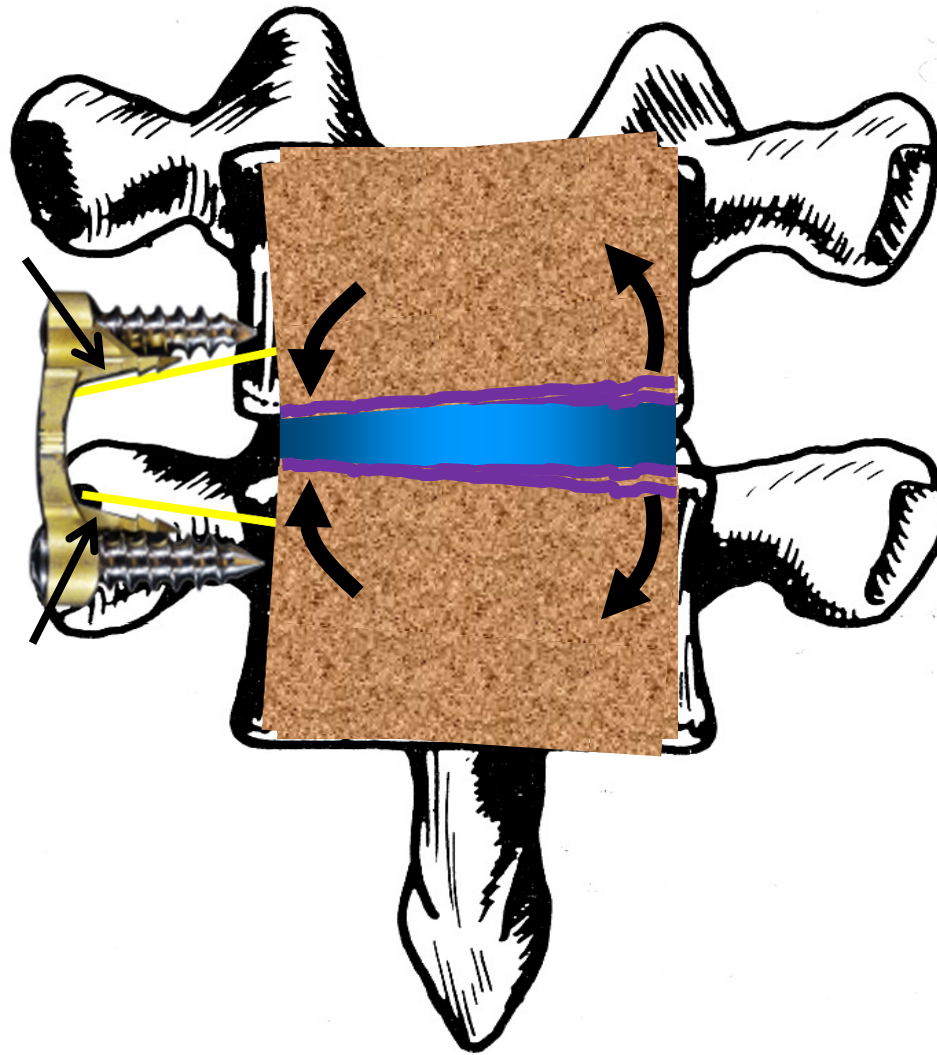


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Device Failure?

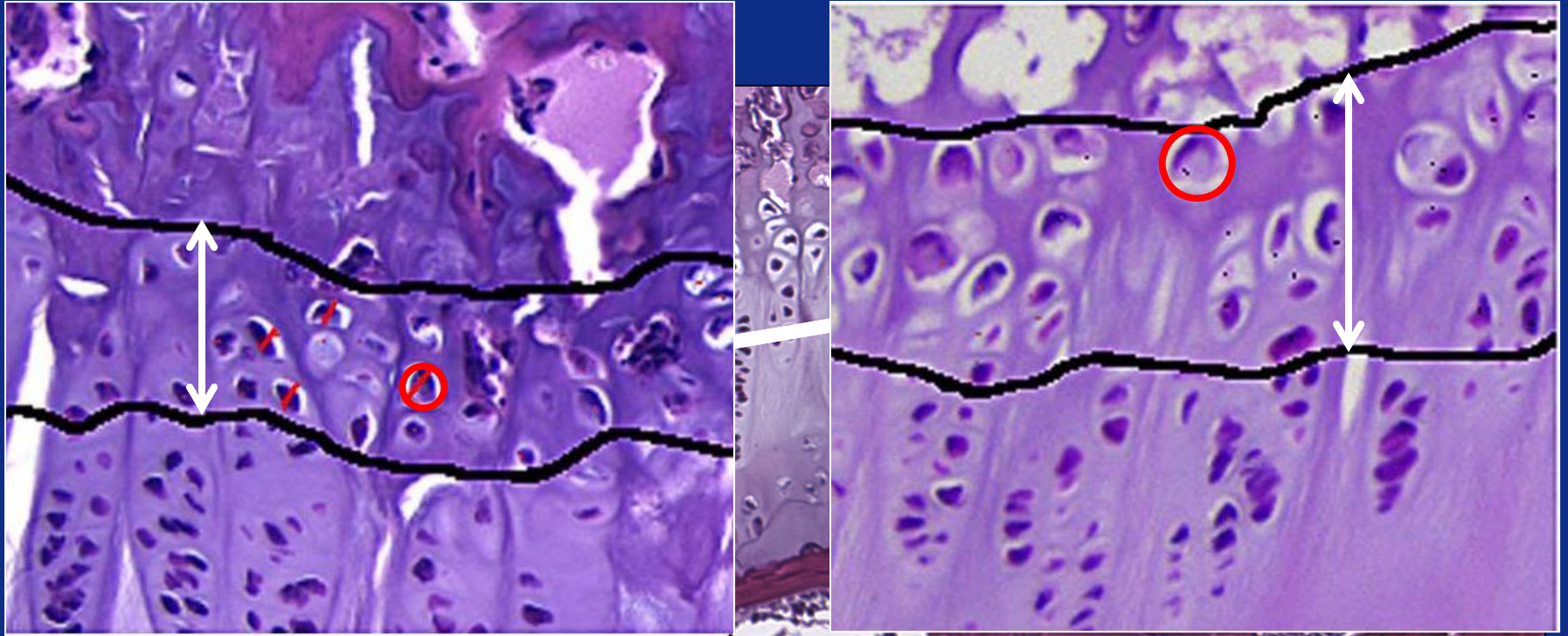
- Plough 0%
- Migration 0%
- Screw Back Out 0%
- Breakage 0%



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Staple Heuter-Volkman?



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Eric Wall, MD
Keio University 9.27.10

Bylski-Austrow, JBJS 2008



Disc Degeneration?

- Proteoglycan content, synthesis
- H₂O content
- Thymidine Sulfur incorporation
- Molecular assay TUNEL, Capase-3



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Problem

- We want to know if disc changes are painful.
- Animal models not helpful

What kills a disc?

- Too much pressure
- No motion



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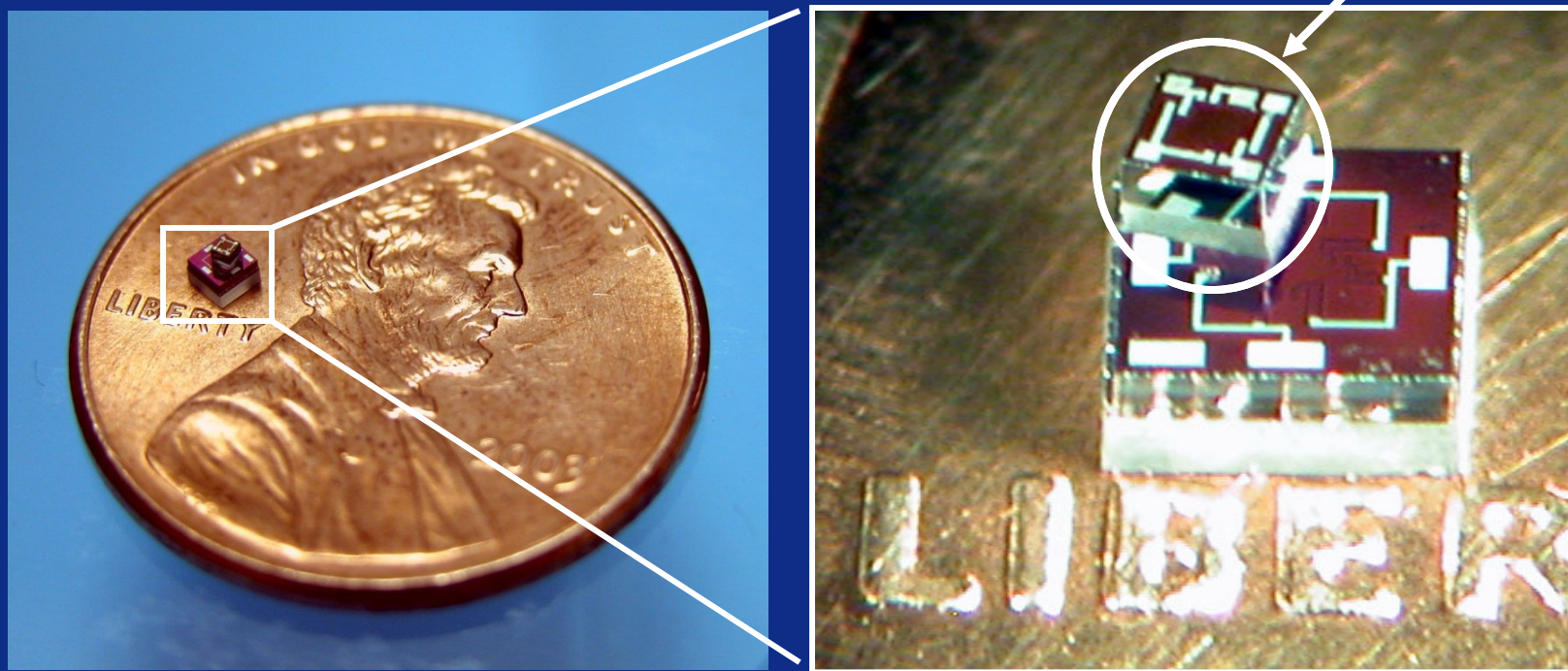
Are disc forces under staple physiologic?

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MEMS Pressure Sensors Implanted in Disc/Annulus



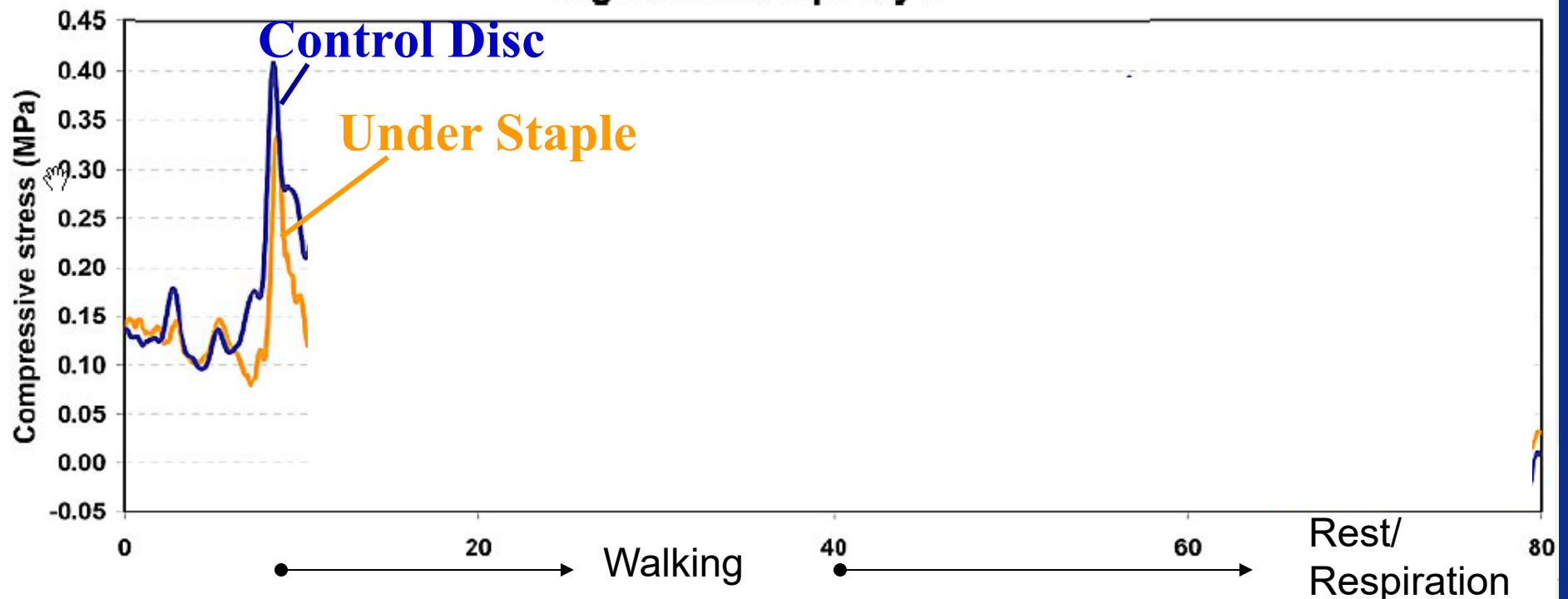
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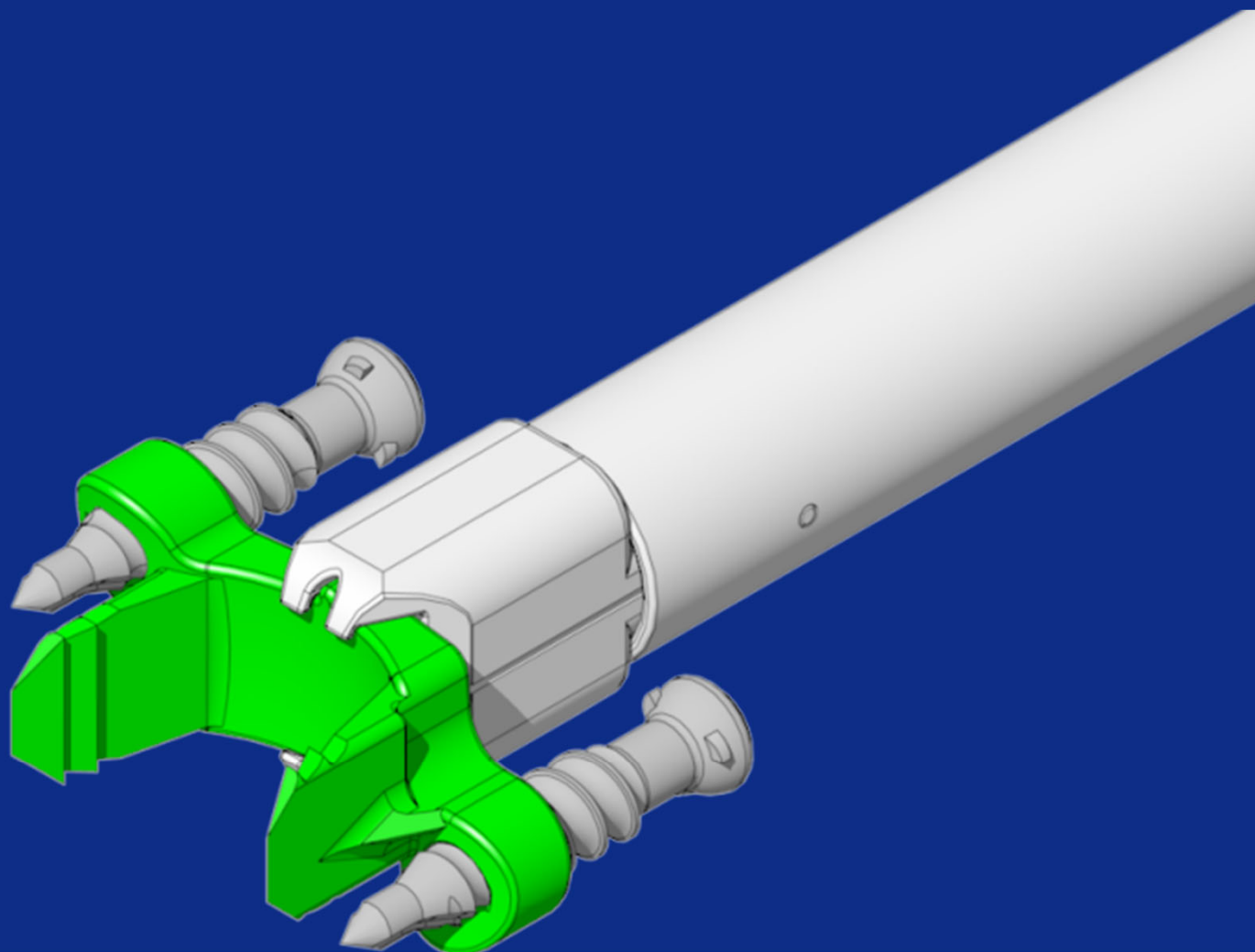


Disc Pressure with Motion

Pig101 Post-Op Day 5



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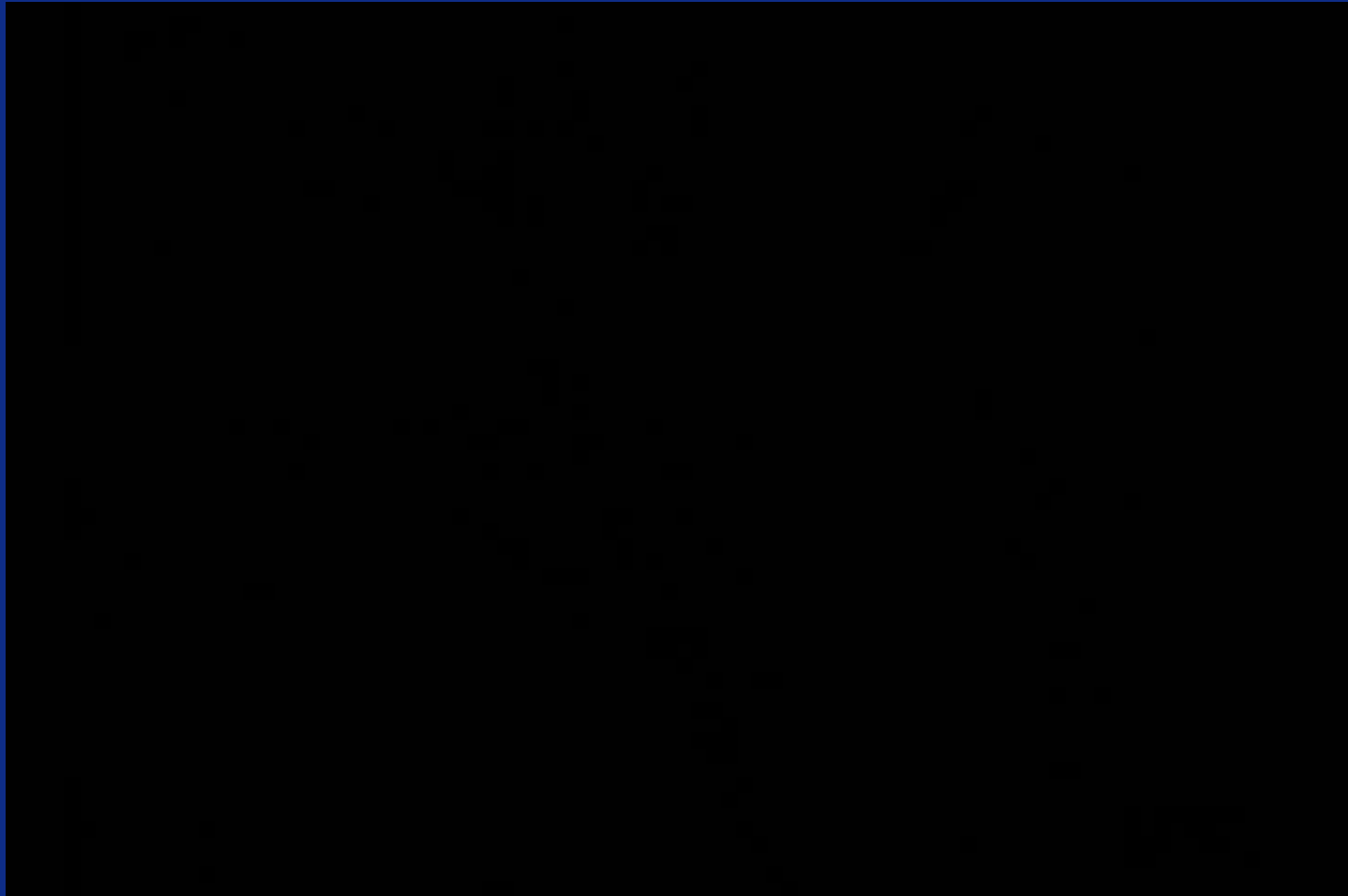


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Staple Attractiveness

- Minimally invasive
- Minimal spine or pleural dissection
- Simple technique for all spine surgeons

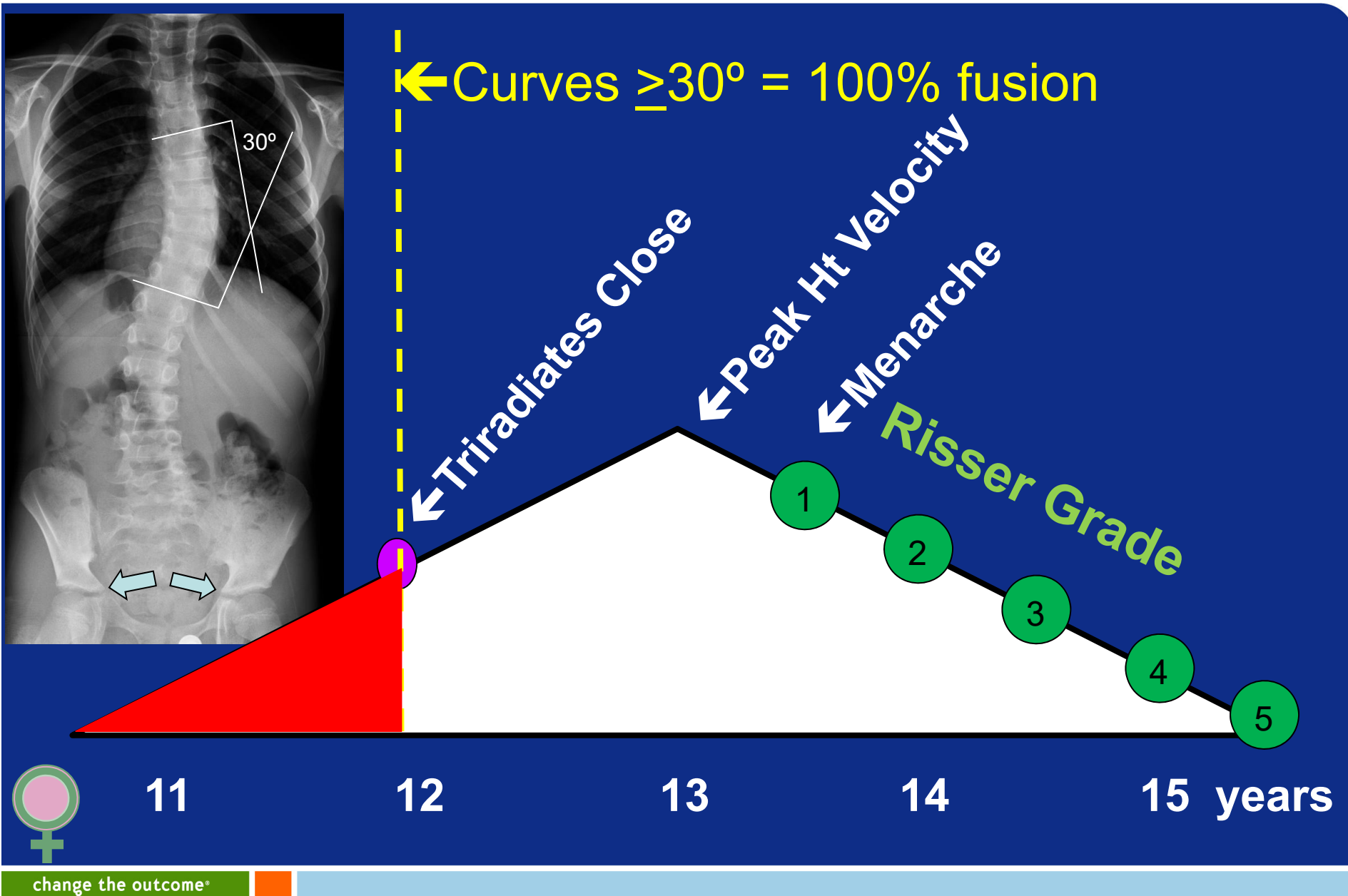
**Now US FDA Approved
for Human Study**

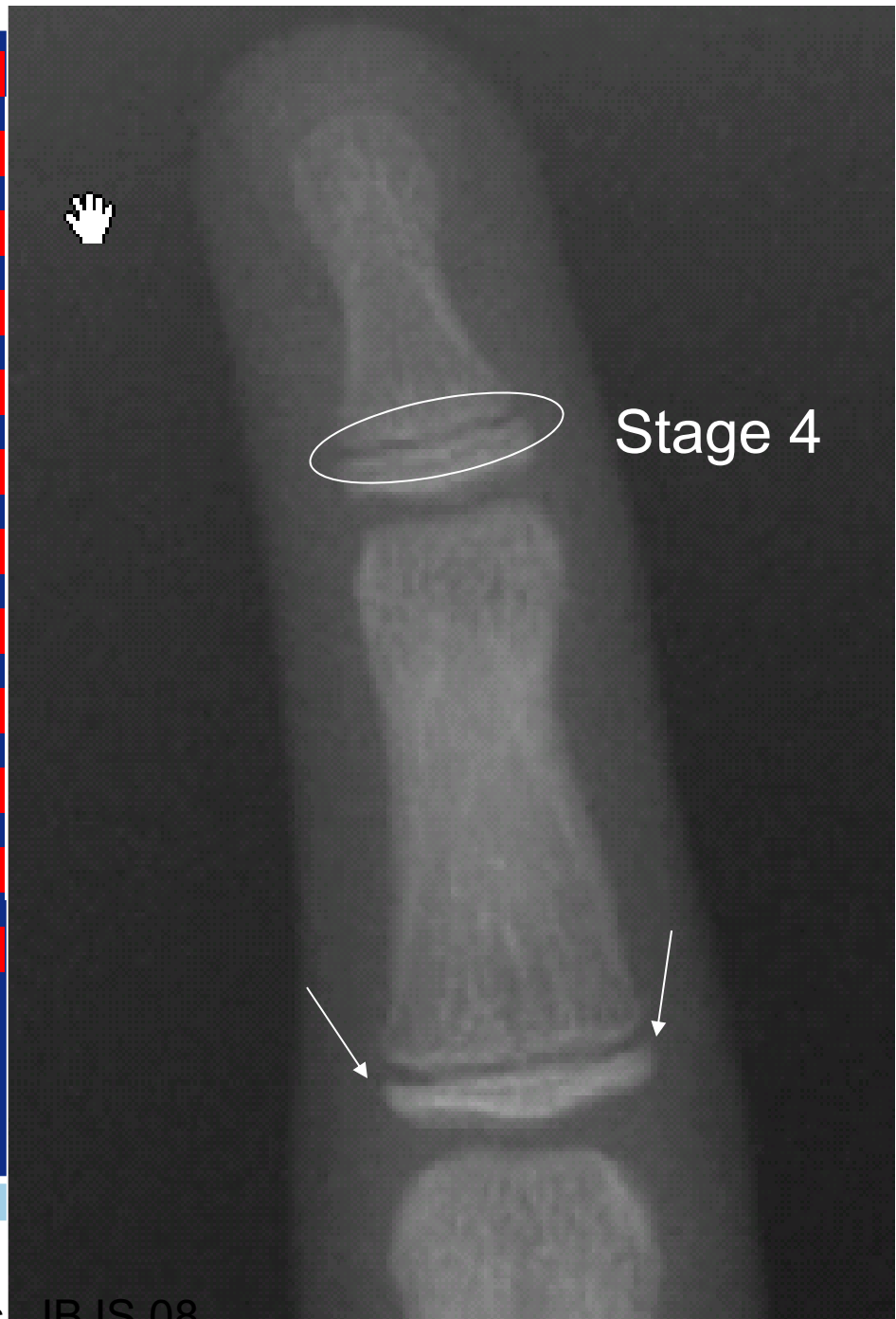
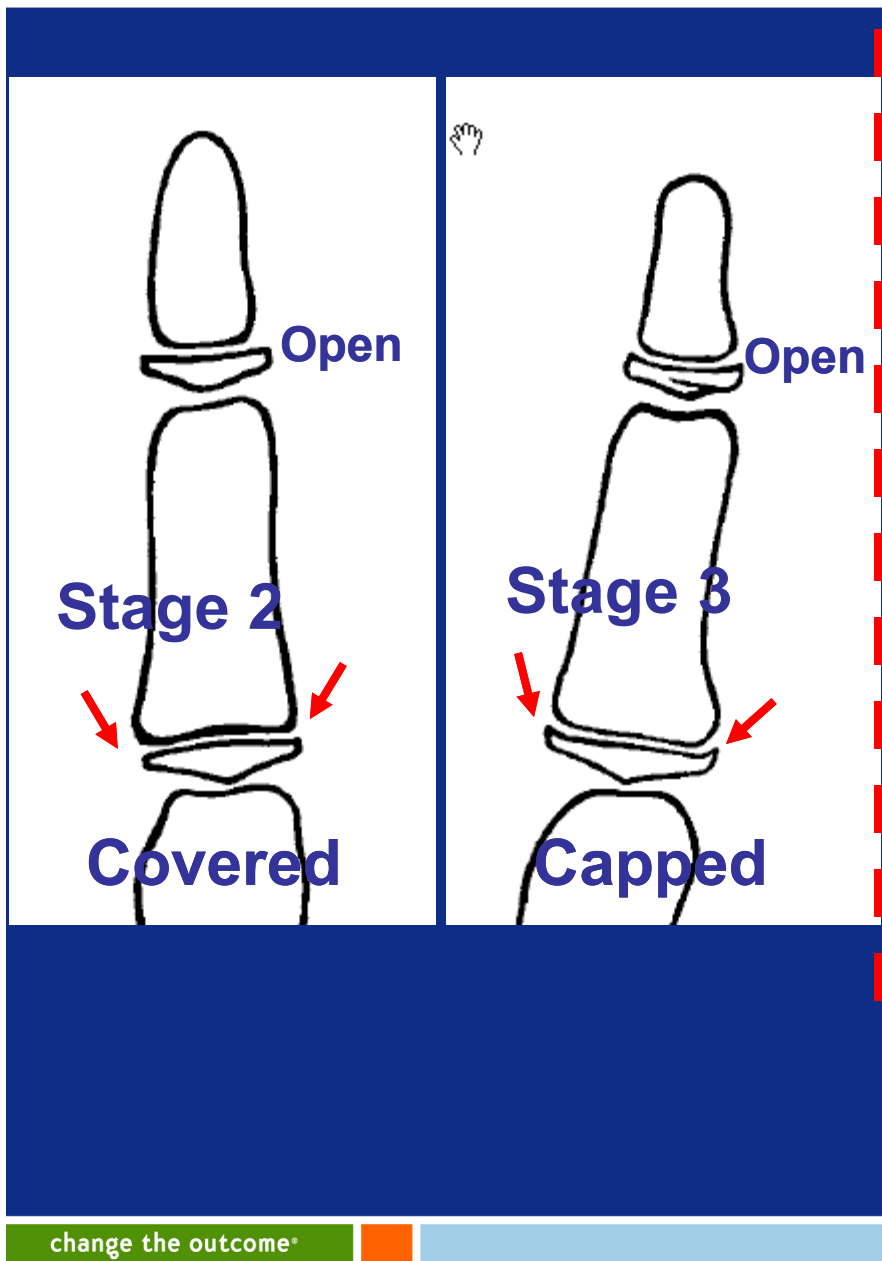
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Update 2011

“The ideal time to use a growth tethering procedure is before peak growth velocity, before menses, and before closure of the tri-radiate cartilage”

Aaronson & Stokes, JPO, 2011





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James Sanders, JBJS 08

ati
Children's

“Reality Check”

Sanders JPO 2011

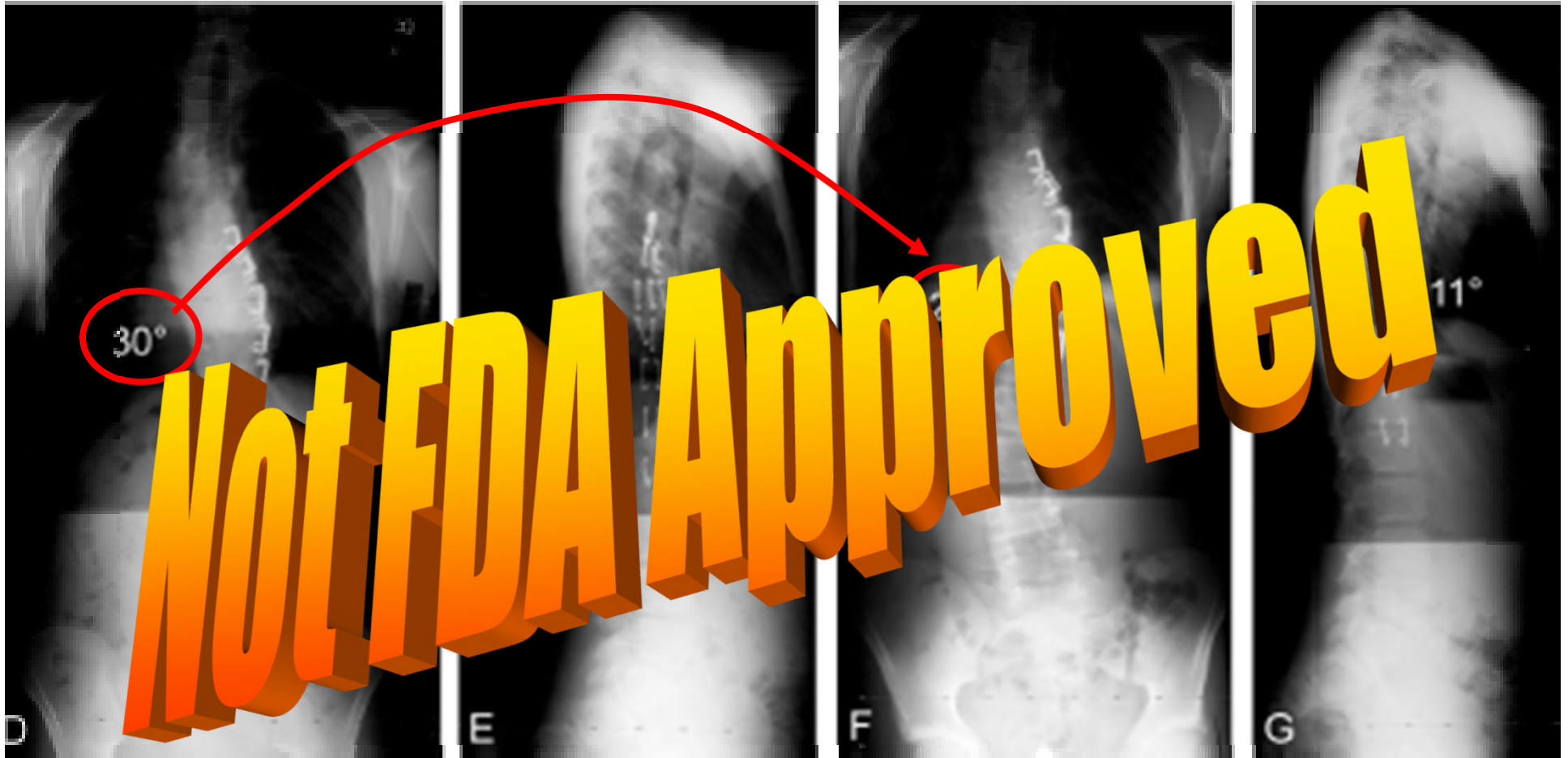
TABLE III Logistic Projection of the Probability of Lenke Type-1 and Type-3 Curves Progressing to Surgery Assuming a $>50^\circ$ Threshold*†

Curve	Stage 1	Stage 2	Stage 3	Stage 4	Stage 5	Stage 6	Stage 7, 8
10°	2% (0% to 40%)	0% (0% to 15%)	0% (0% to 0%)	0% (0% to 0%)	0% (0% to 0%)	0% (0% to 0%)	0% (0% to 1%)
15°	74% (4% to 69%)	11% (1% to 58%)	0% (0% to 1%)	0% (0% to 0%)	0% (0% to 0%)	0% (0% to 0%)	0% (0% to 7%)
20°	84% (40% to 98%)	92% (56% to 99%)	0% (0% to 14%)	0% (0% to 1%)	0% (0% to 1%)	0% (0% to 1%)	0% (0% to 26%)
25°	99% (68% to 100%)	100% (92% to 100%)	29% (3% to 84%)	0% (0% to 5%)	0% (0% to 5%)	0% (0% to 2%)	0% (0% to 64%)
30°	100% (83% to 100%)	100% (98% to 100%)	100% (47% to 100%)	0% (0% to 27%)	0% (0% to 22%)	0% (0% to 11%)	0% (0% to 91%)
35°	100% (91% to 100%)	100% (100% to 100%)	100% (89% to 100%)	0% (0% to 79%)	0% (0% to 65%)	0% (0% to 41%)	0% (0% to 98%)
40°	100% (95% to 100%)	100% (100% to 100%)	100% (98% to 100%)	15% (0% to 99%)	0% (0% to 94%)	0% (0% to 83%)	0% (0% to 100%)
45°	100% (98% to 100%)	100% (100% to 100%)	100% (100% to 100%)	88% (2% to 100%)	1% (0% to 99%)	0% (0% to 98%)	0% (0% to 100%)

Risk of progression to $\geq 50^\circ$ (to fusion)!!!

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Betz Nitinol Staple



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50% Nickel



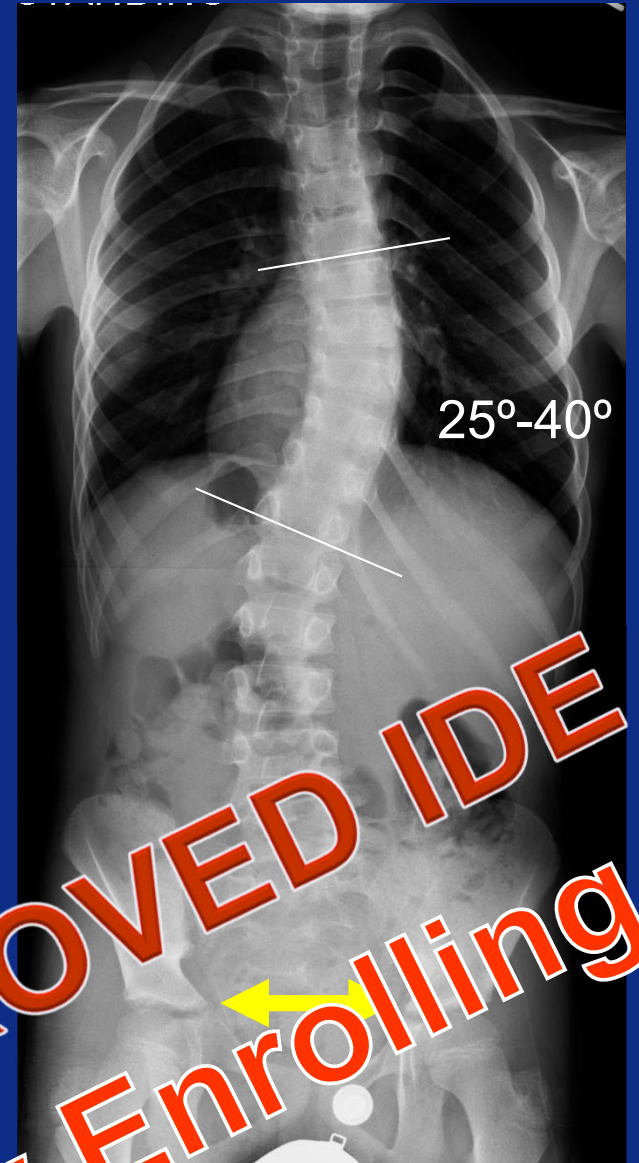
Questions

- Need well designed human clinical trial to prove safety and effectiveness

Human Study

- Lenke 1A, 1B Thoracic
- T3-L1
- Ages 10+
- Risser 0, **Open Tri-radiate**
- Cobb 25°-40°
- Bone Age <13 girls, <15 boys

Near 100% predicted fusion



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FDA APPROVED IDE
Now Enrolling



Thank You

Volunteerism

George Thompson

Alain Dimeglio

Greg Redding

Jose Herra-Soto

Viral Jain

Tim Hresko

Peter Sturm

Alvin Crawford

Bob Campbell

Courtney Brown

Rick McCarthy

Muharrem Yazici

Jo-Chen Son Hing

Behrooz Akbarnia

Laural Blakemore