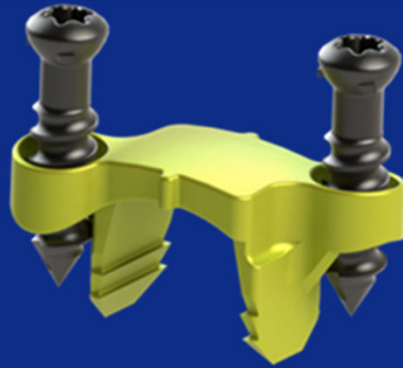




HemiBridge Spine Growth Modulation FDA Study: 18 Month Data

*Eric J. Wall, MD; Joseph E. Reynolds; Jain
V. Jain, MD; Donita I. Bylski-Austrow, PhD;
George H. Thompson, MD; Paul Samuels,
MD; Sean J. Barnett; Alvin H. Crawford, MD*

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Disclosure



Royalties
Investment
Medical Advisor



R01 Grant

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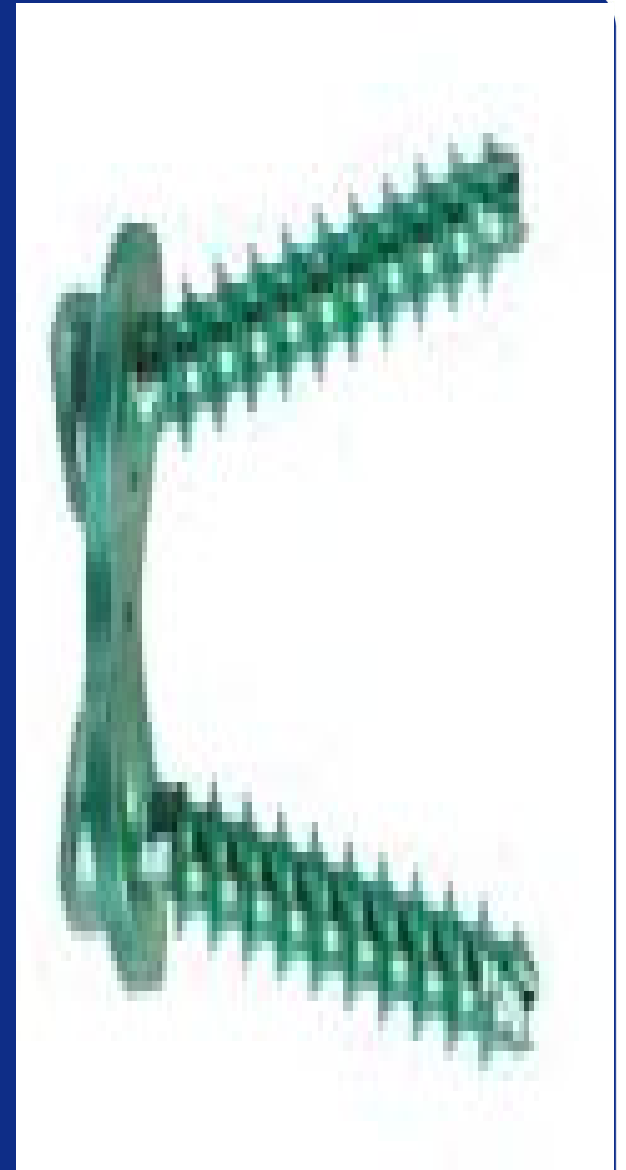
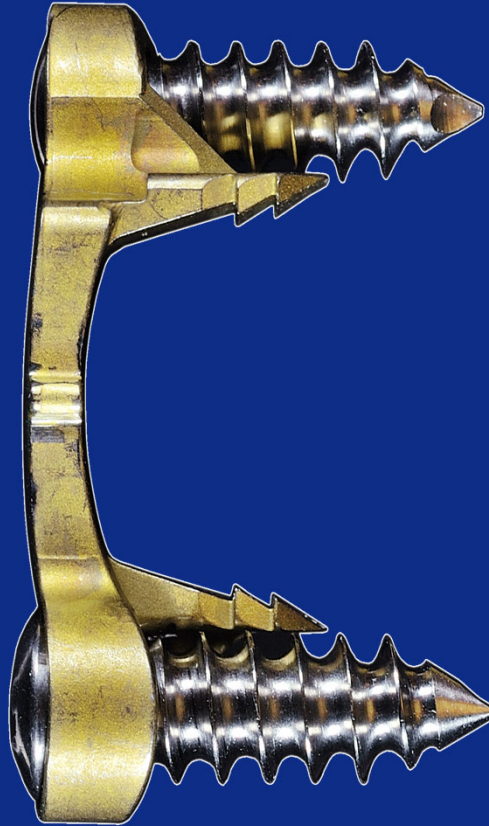


Failure due to disc motion



Courtesy of Tushar Patel, MD

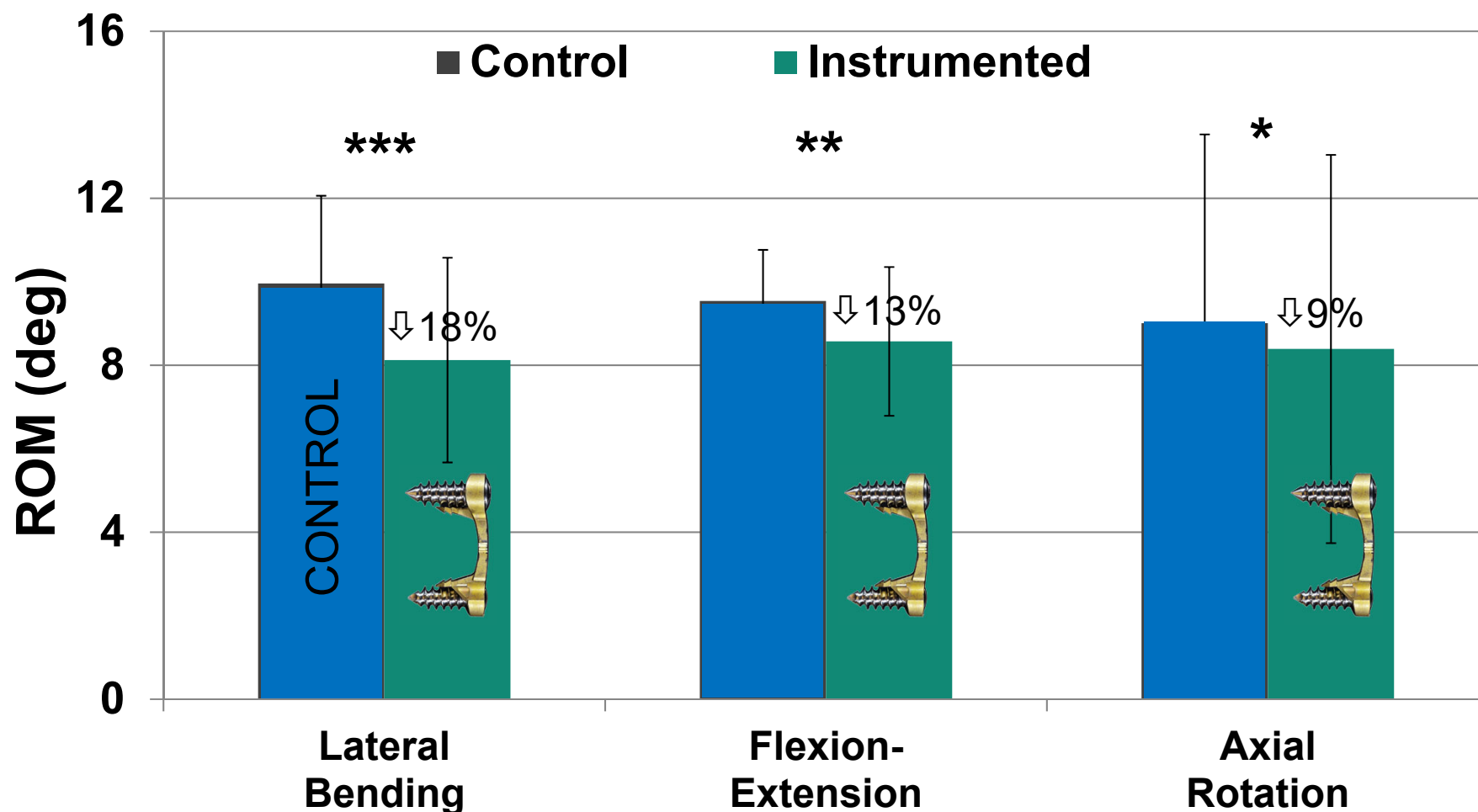
Clip/Screw



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Minimally Restricts ROM



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Coombs, MT, 2013, *Spine*

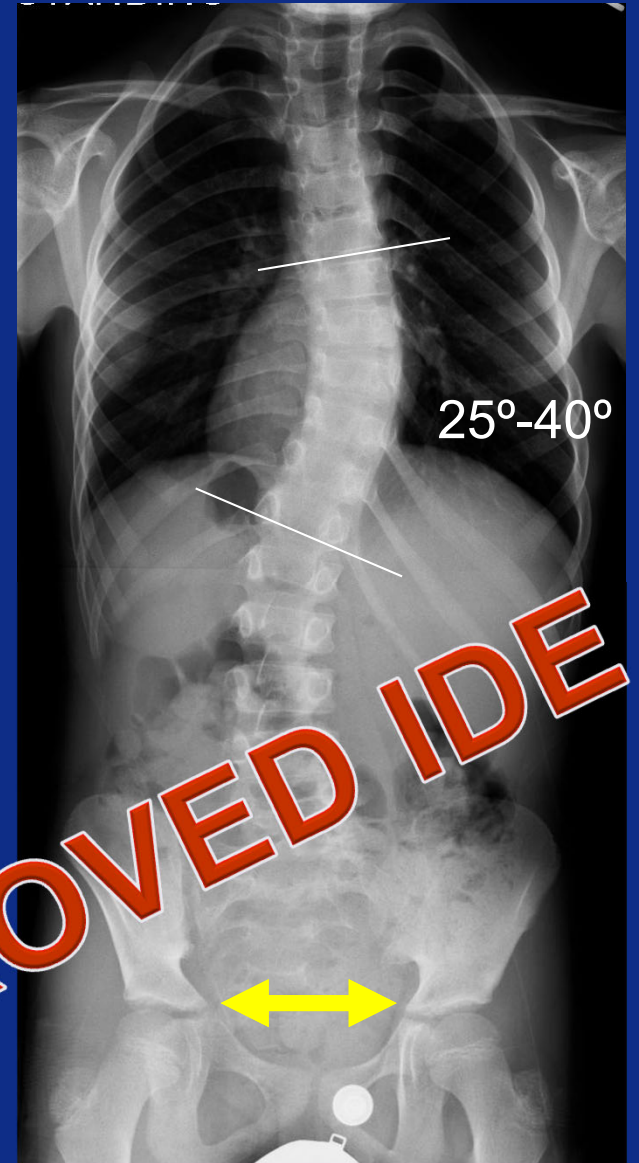
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Human Study

- Lenke 1A, 1B Thoracic
- T3-L1
- Ages 10+
- Risser 0, **Open Tri-radiate**
- Cobb 25°-40°

Near 100% predicted fusion

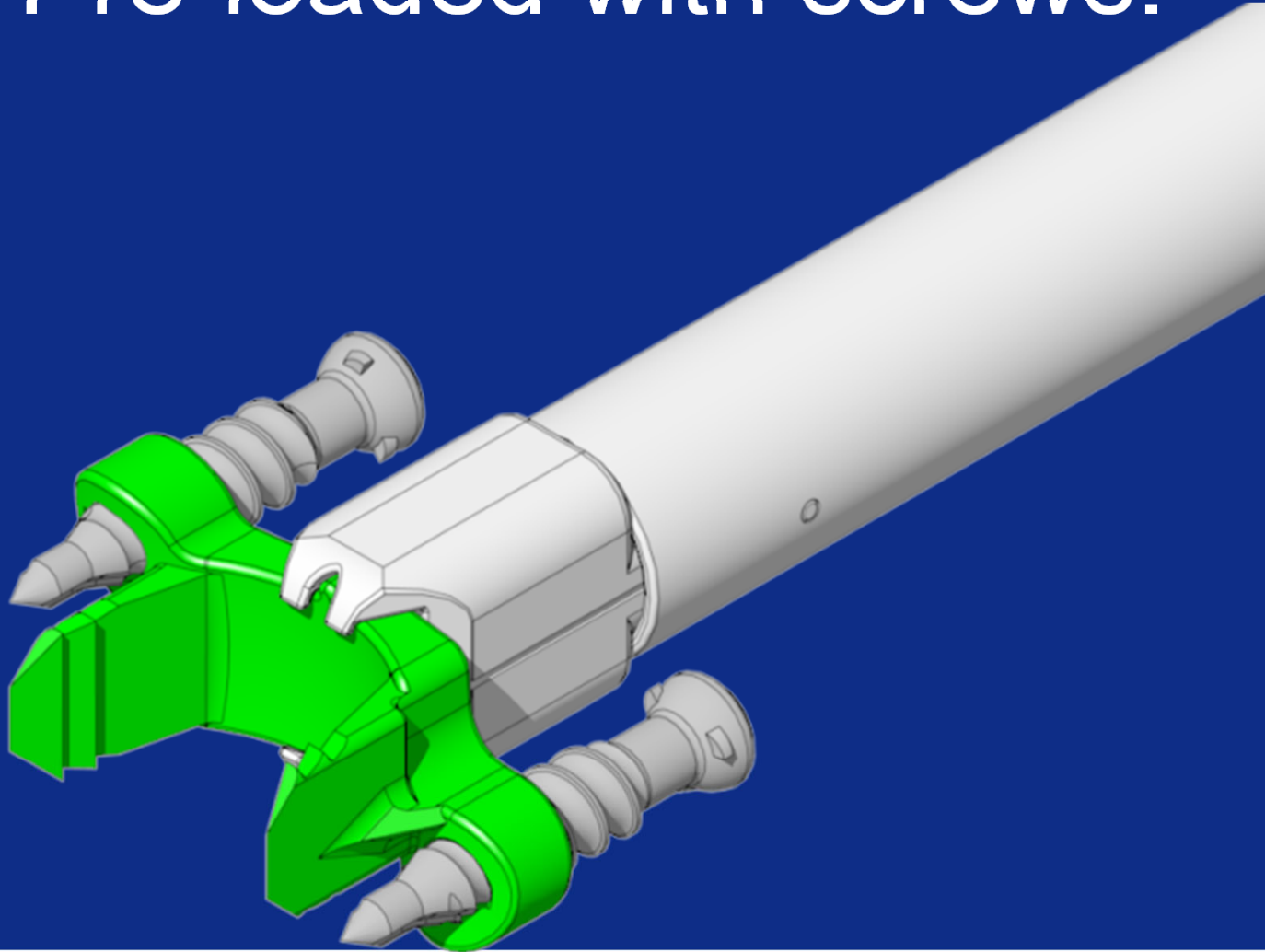


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 Cincinnati
Children's®

Pre-loaded with screws!



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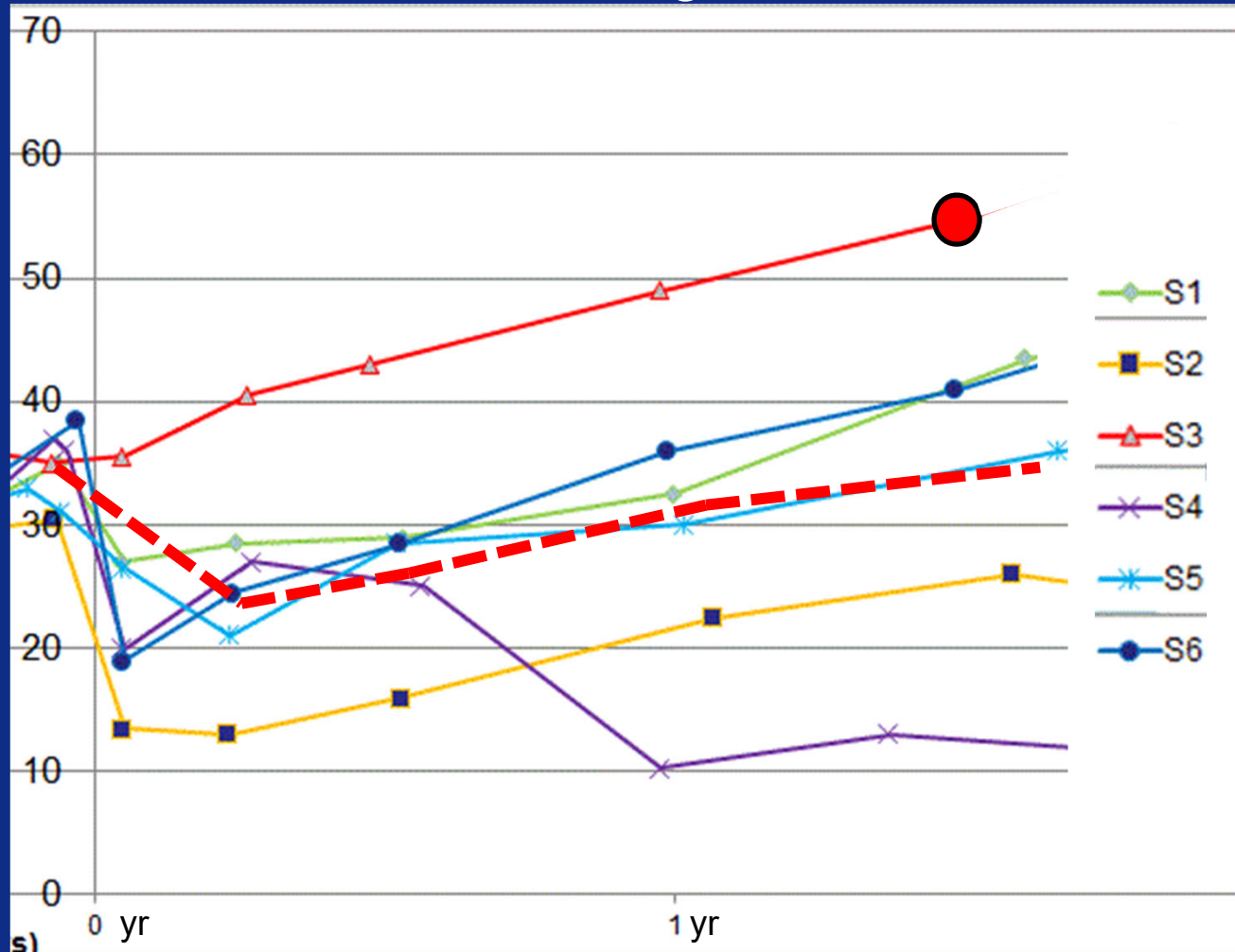


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18 Month Results Cobb Angle Coronal

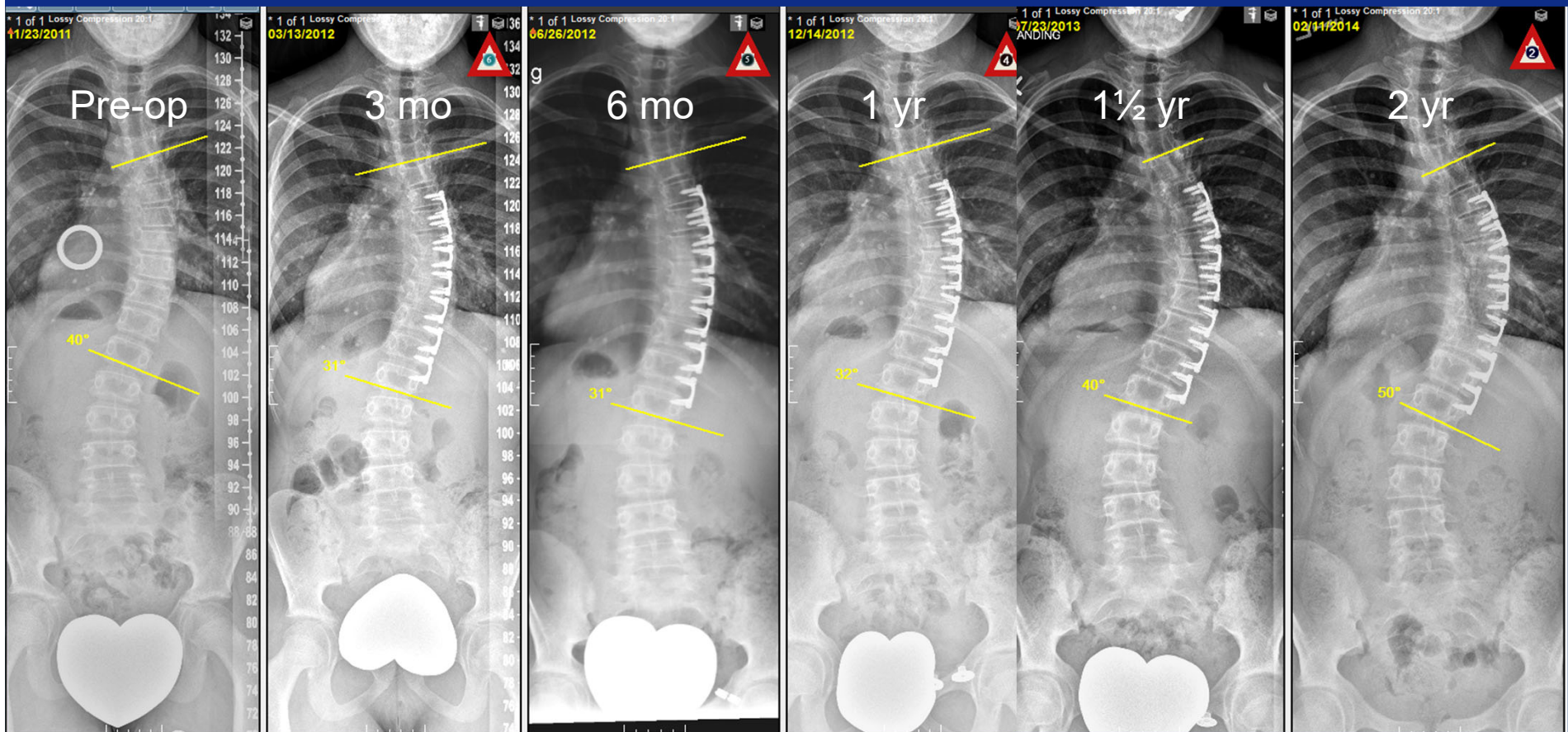


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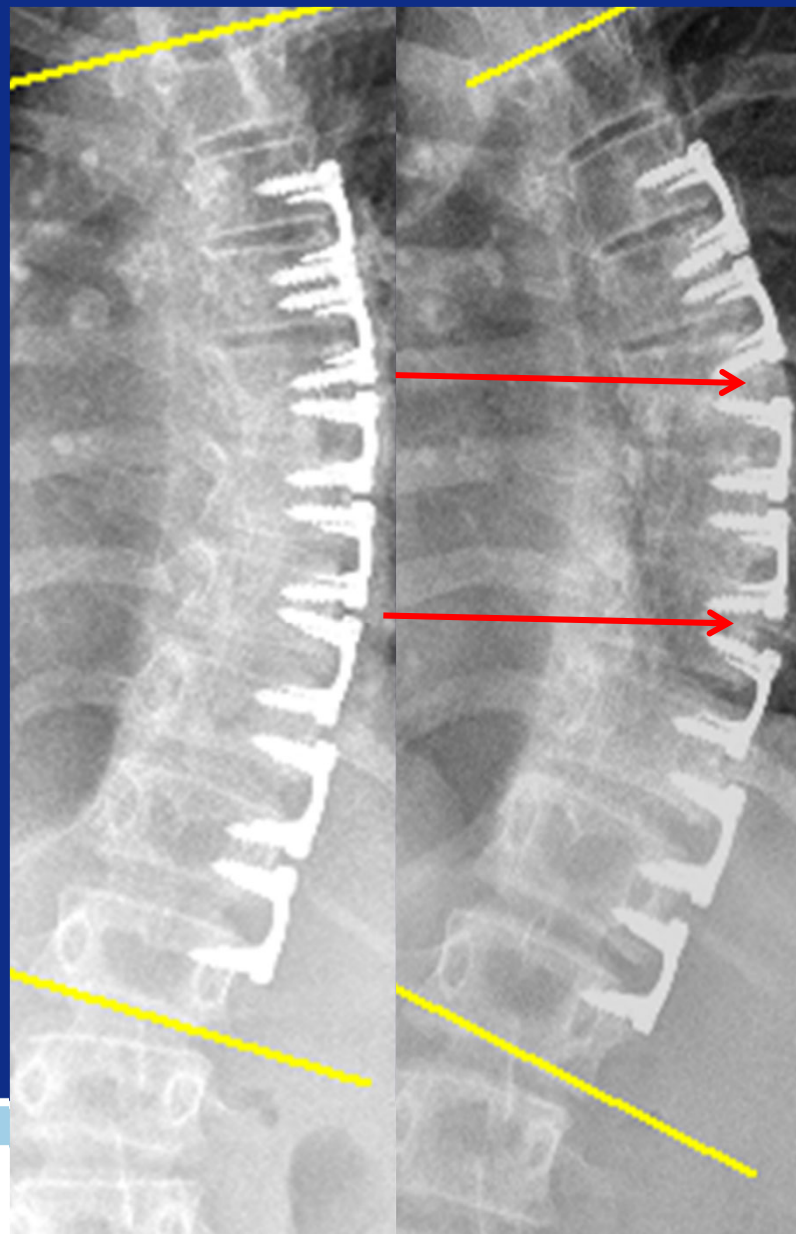


HB 1



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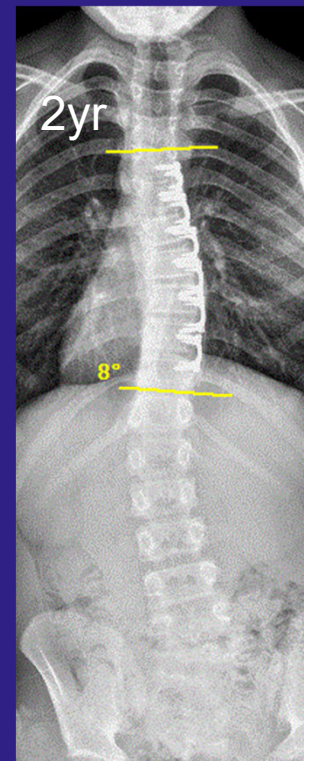
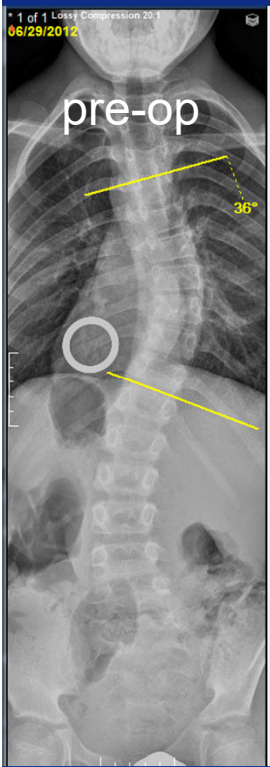
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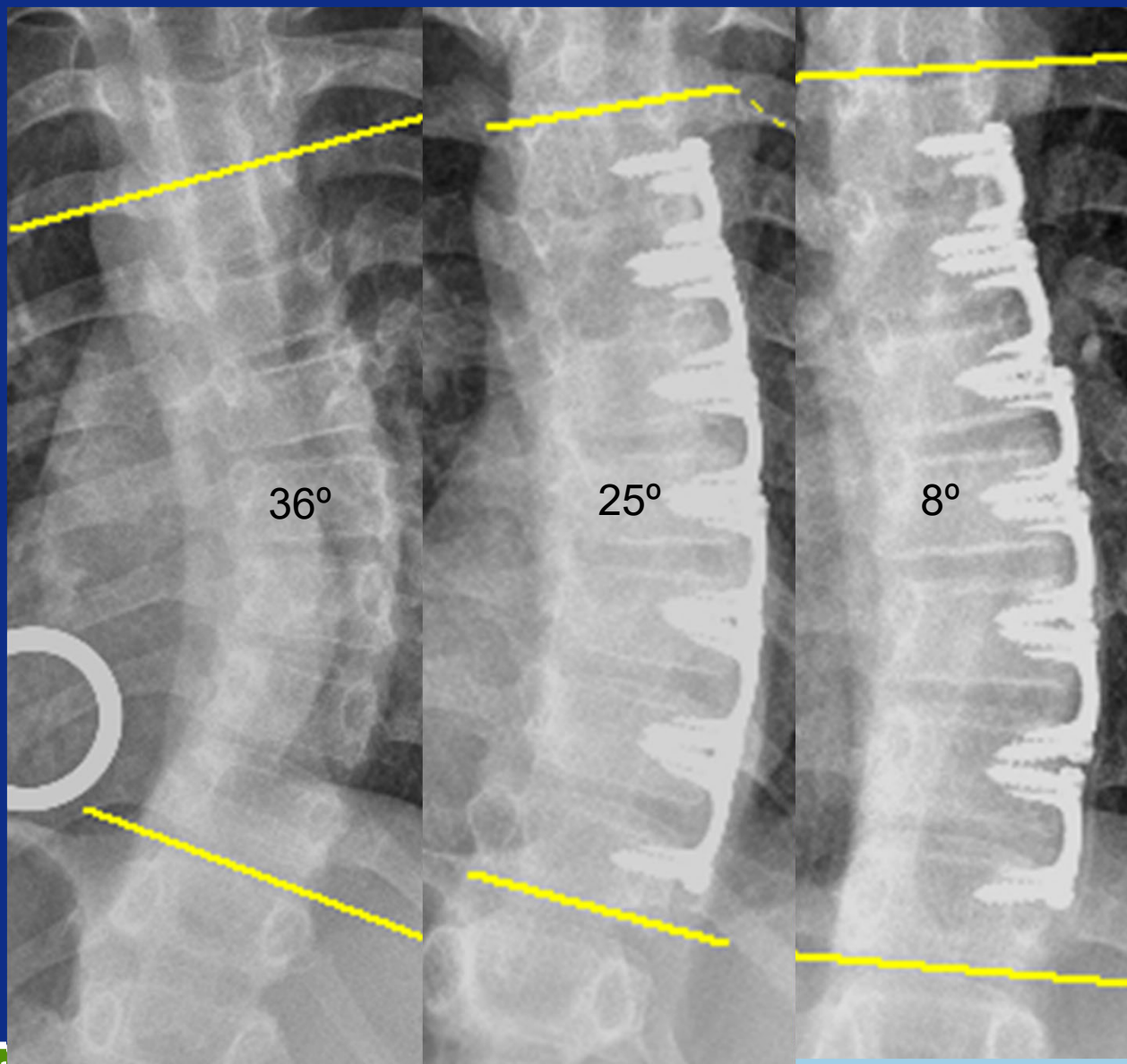
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HB 4 Sequence



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Initial FDA Study Results

- No Device-Related Complications (no gross migration, loosening, plow)
- Few procedure related AEs, Mostly Pulmonary
- Final Efficacy pending, one revised to fusion

Other Data

- Surgical Time 2½ hrs
- Implant time 84 min
- EBL < 50ml-100ml
- SRS scores stable
- Cobb 34°⇒36°
- SRS-22 4.36⇒4.31



Future Design HB 2

- More flexible bridge
- Locking screws
- Larger size tines
- Ingrowth coating

Volunteerism

George Thompson

Alain Dimeglio

Greg Redding

Jose Herra-Soto

Viral Jain

Tim Hresko

Peter Sturm

Alvin Crawford

Mark Ericson

Bob Campbell

Courtney Brown

Rick McCarthy

Muharrem Yazici

Jo-Chen Son Hing

Behrooz Akbarnia

Laural Blakemore

Ralf Stüecker

Randall Betz

Thank you from Cincinnati

