



HemiBridge Update

Eric Wall, MD

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Disclosure



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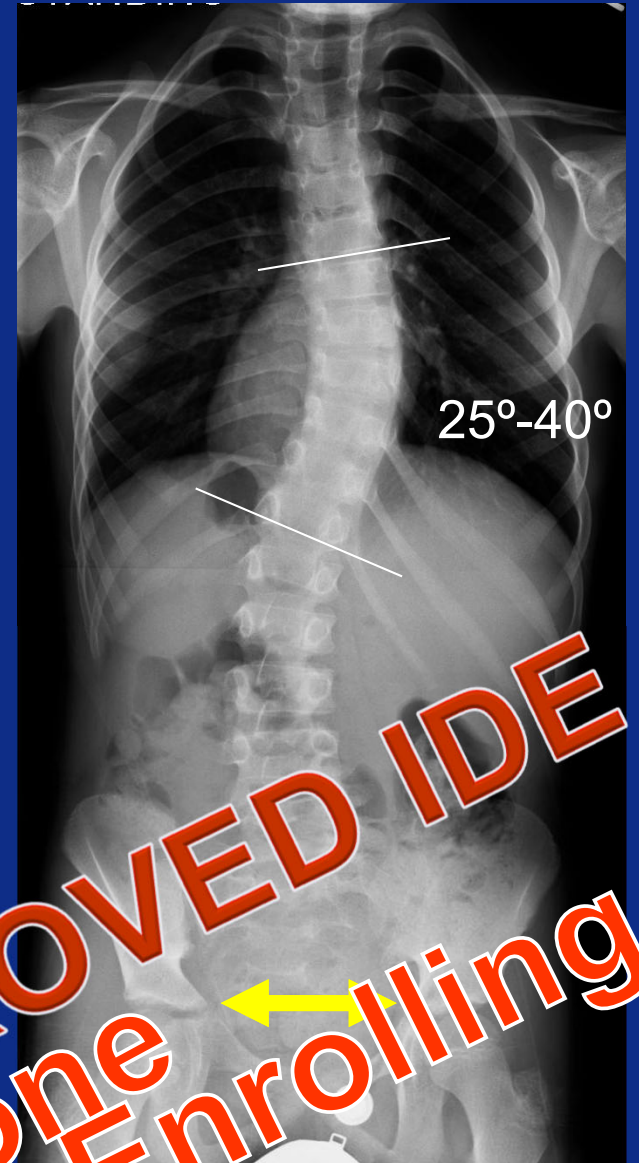
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Human Study

- 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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Initial FDA Study Results

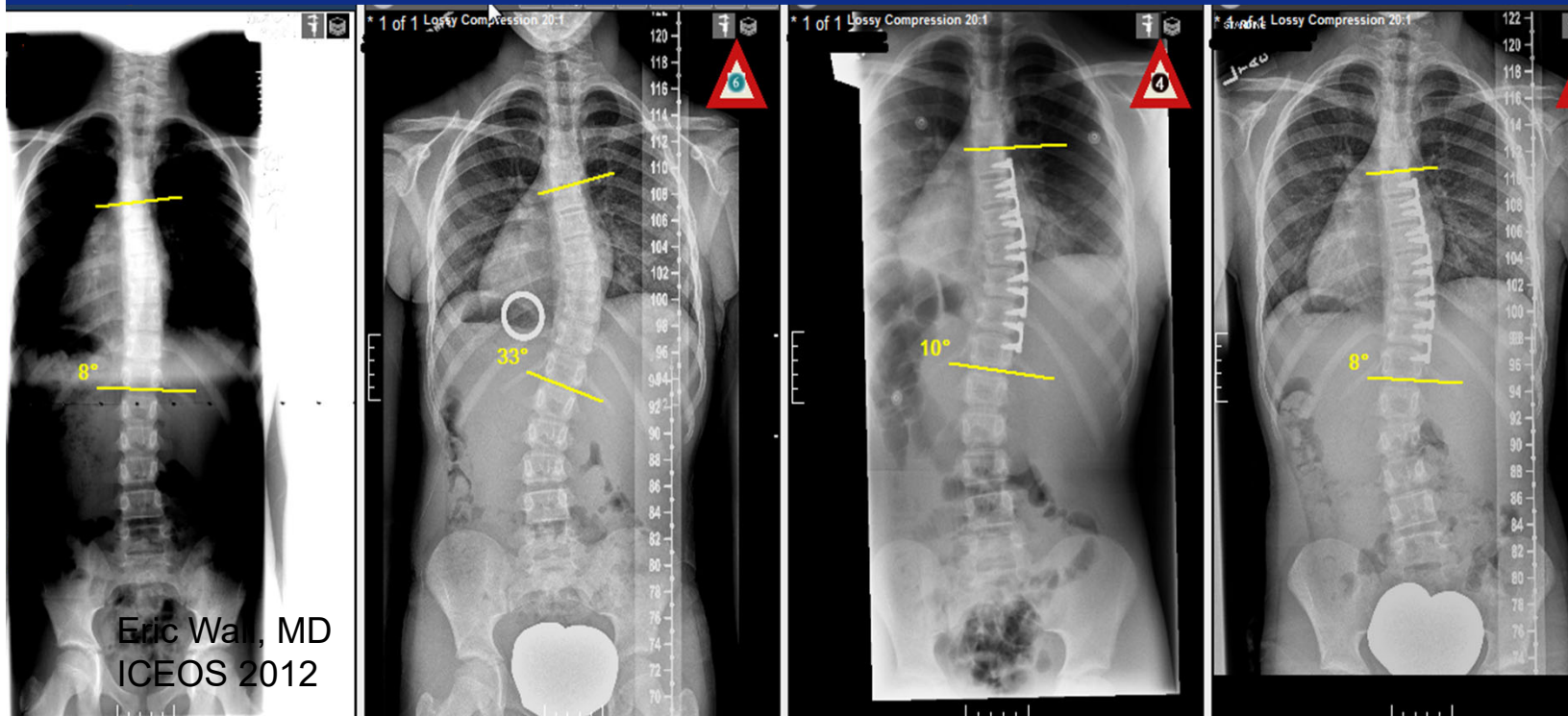
- No Device Related SAEs
- Procedure related AEs, Mostly Pulmonary
- Efficacy unknown

2 years preop

Pre-op 33°

1 month

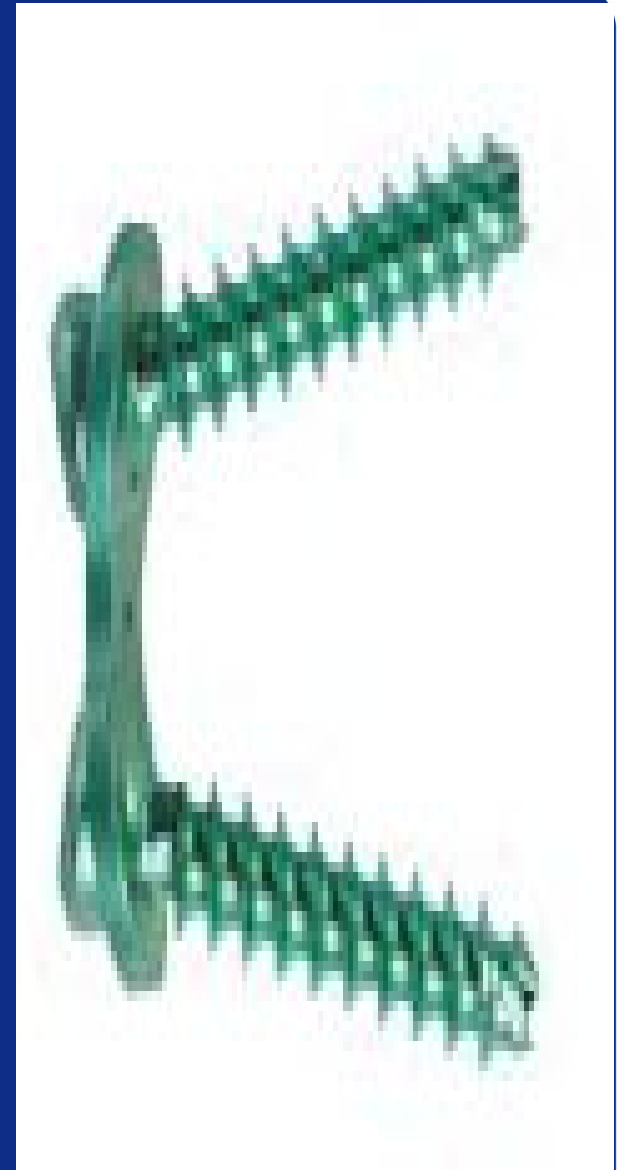
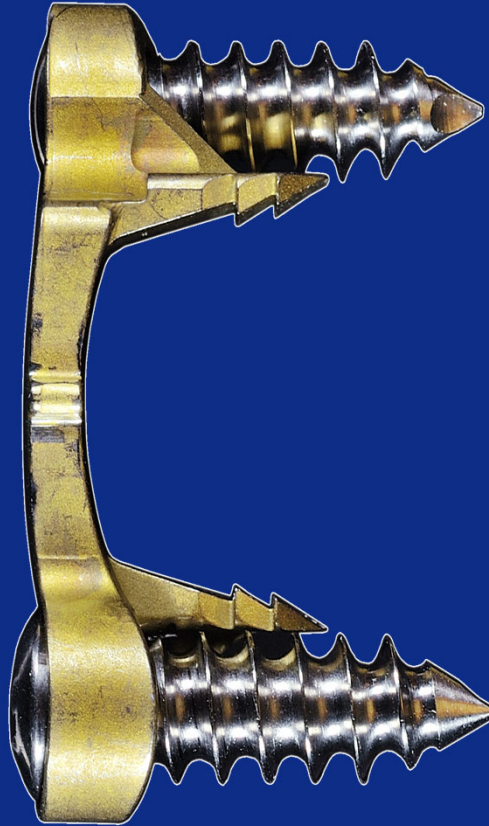
3 months 16°



Parents want to avoid spine fusion

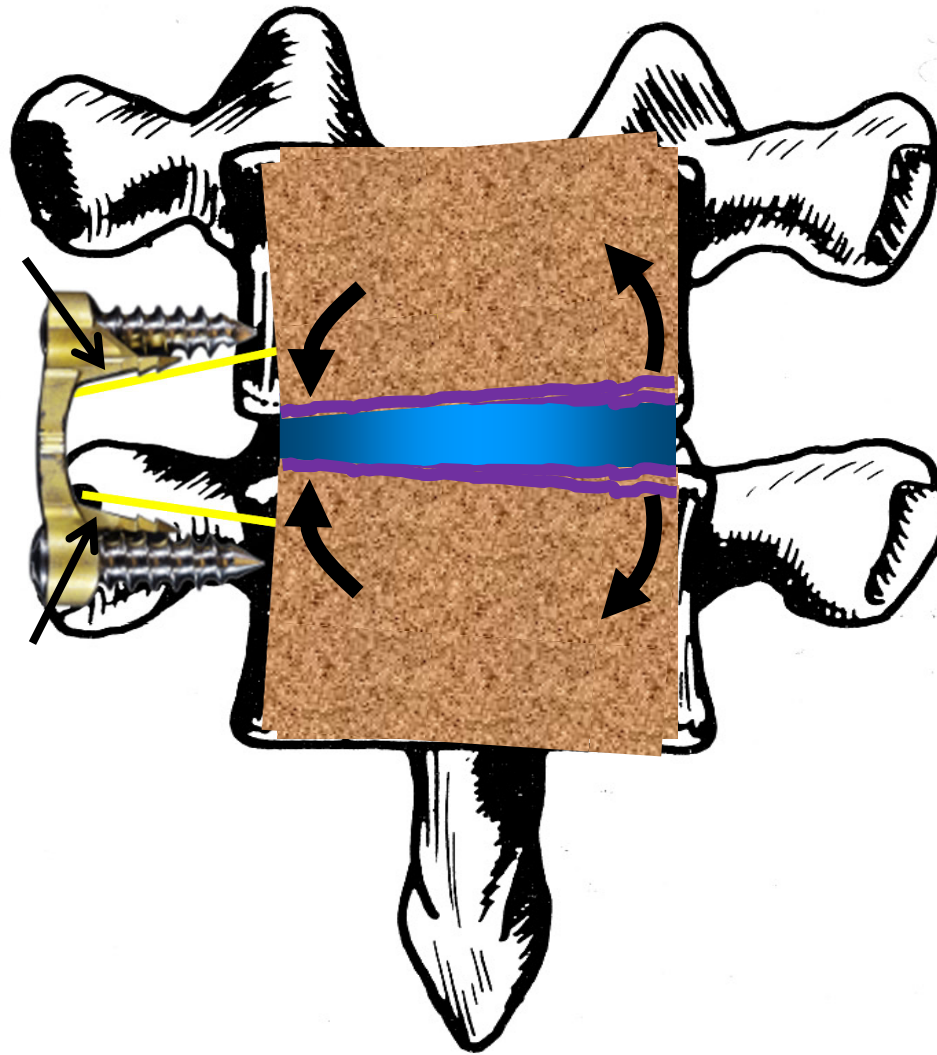
- 100% study enrollment

HemiBridge



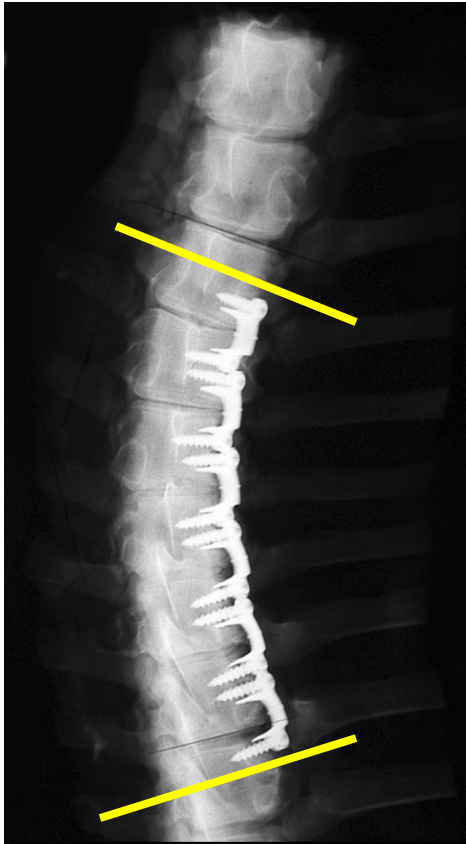
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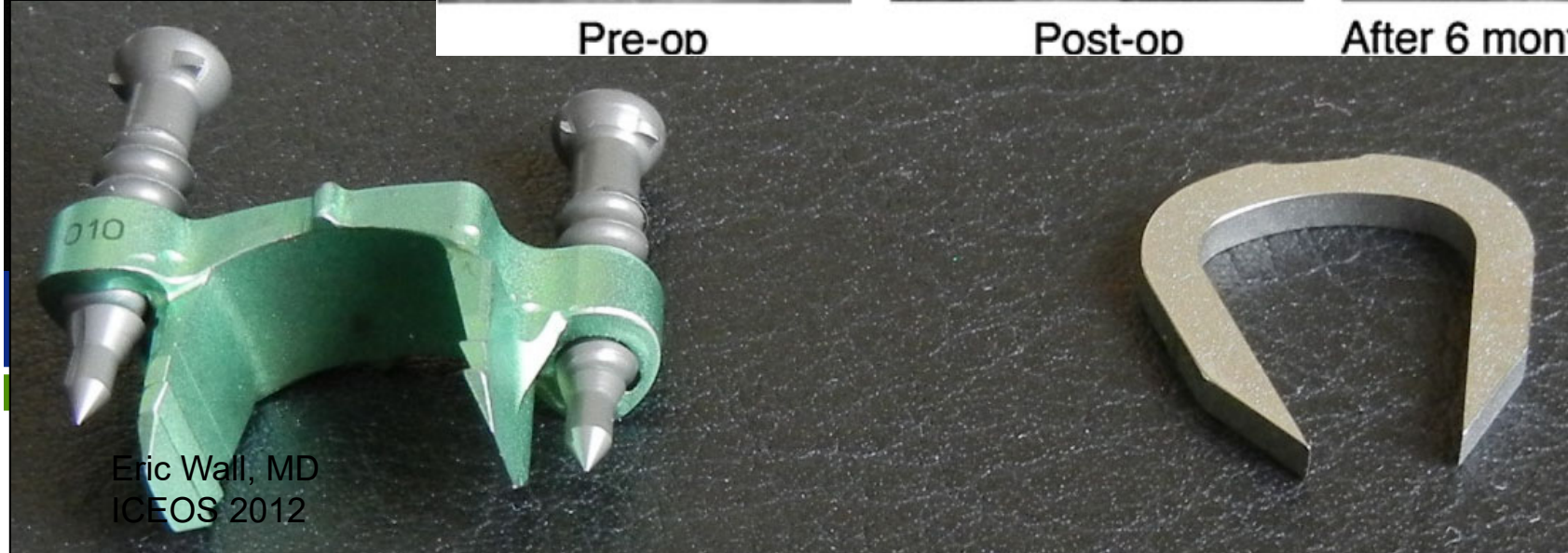
Pre-op



Post-op

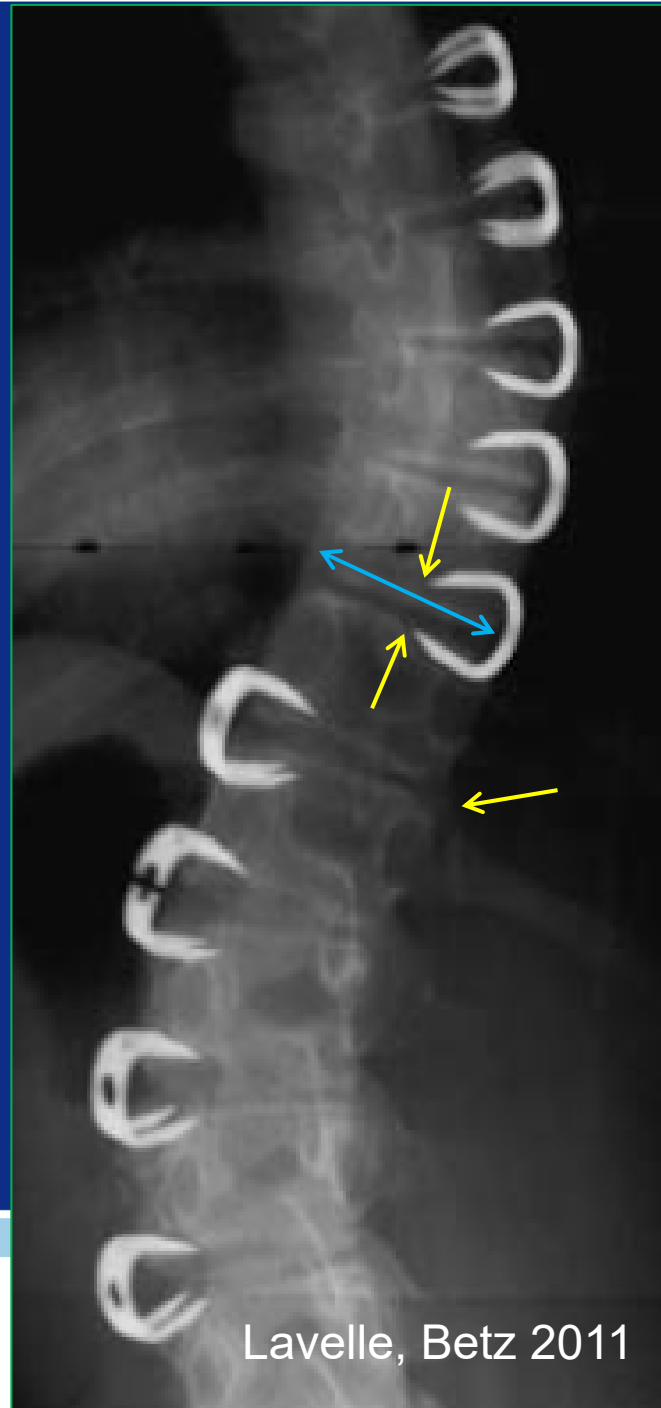


After 6 months growth



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Cincinnati
Children's



Lavelle, Betz 2011

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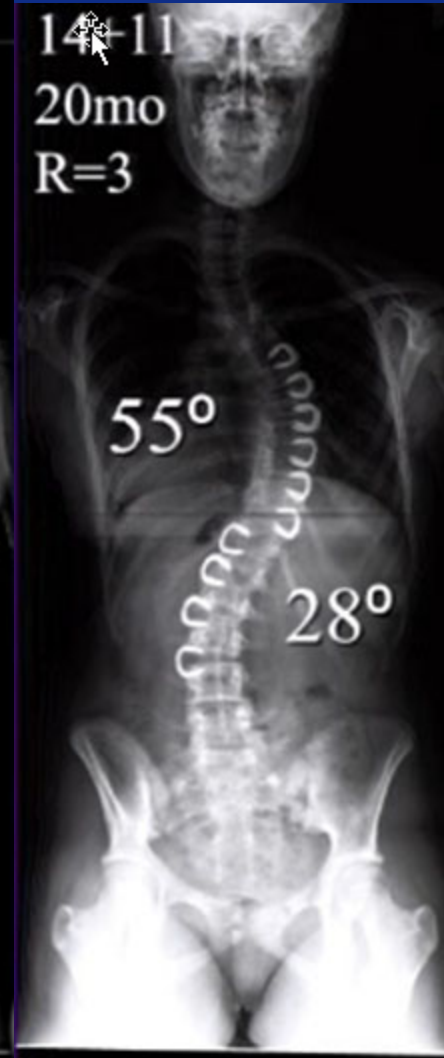
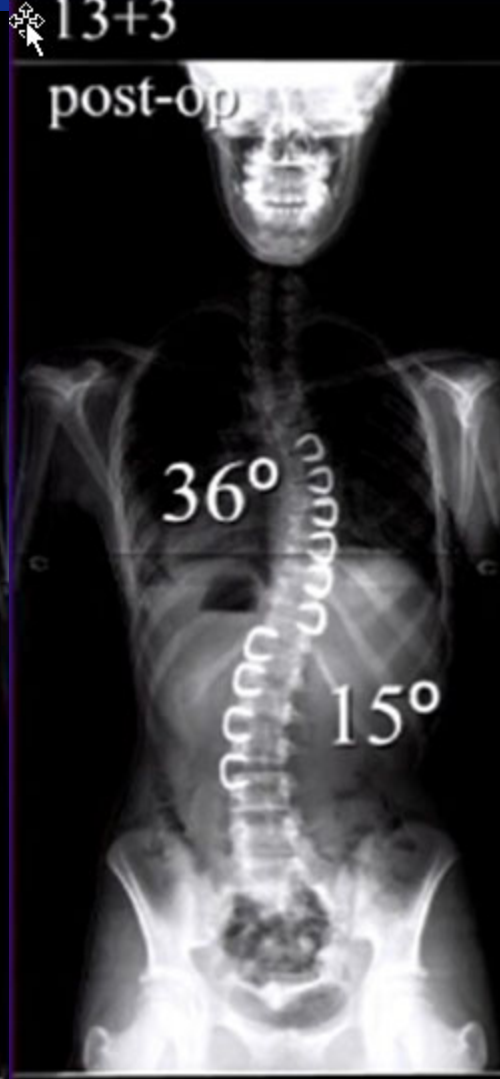
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Braun SRS Abstract 2012^{37°}

- 9 AIS patients (Risser 0-1)

- 4 Nitinol Staples: $34.5^{\circ} \Rightarrow 31.3^{\circ} \Rightarrow \Rightarrow 44.5^{\circ}$
→ Don't Work
- 5 Dynesys Tethers: $36.6^{\circ} \Rightarrow 21.4^{\circ} \Rightarrow \Rightarrow 18^{\circ}$
→ Works, 40% screw migration



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Braun SRS Abst 2012



Ohlin SRS Abstract 2012

- 9 AIS patients, Risser 0
- Nitinol staples $38^{\circ} \Rightarrow 34^{\circ} \Rightarrow \Rightarrow 48^{\circ}$

Conclusion: Nitinol staples don't work



< 35° Success

> 35° Failure

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Ohlin, SRS Abstract 2012

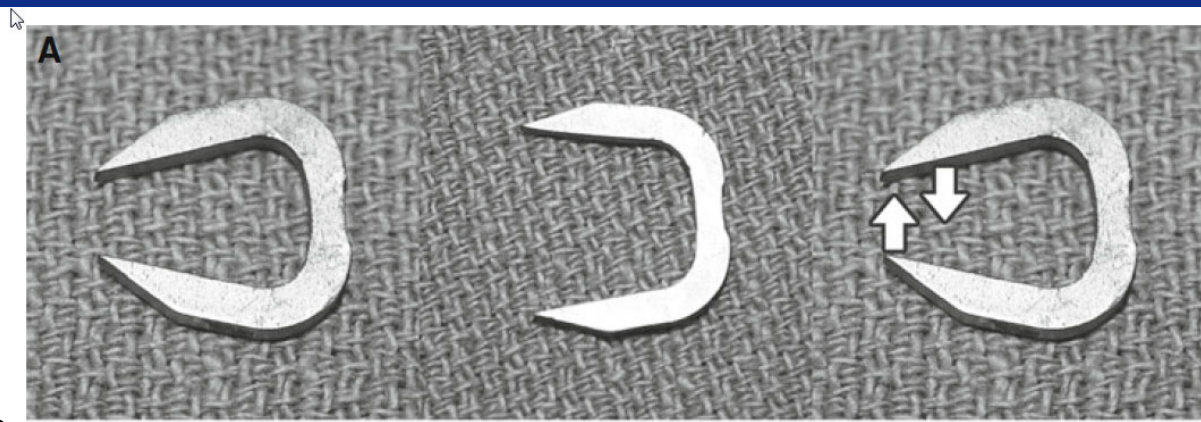


Betz et al

- Thoracic Curves
 - $> 35^{\circ}$ 75% Failure
 - $< 35^{\circ}$ 80% Success

Carreau & Newton 2012

- Nitinol staples in Mini-Pig
 - 7.7° scoliosis created p 6 months
 - ↑ vertebral wedging, ↓ disc height
 - 26% growth plate closure
 - No effect in hypertrophic zone



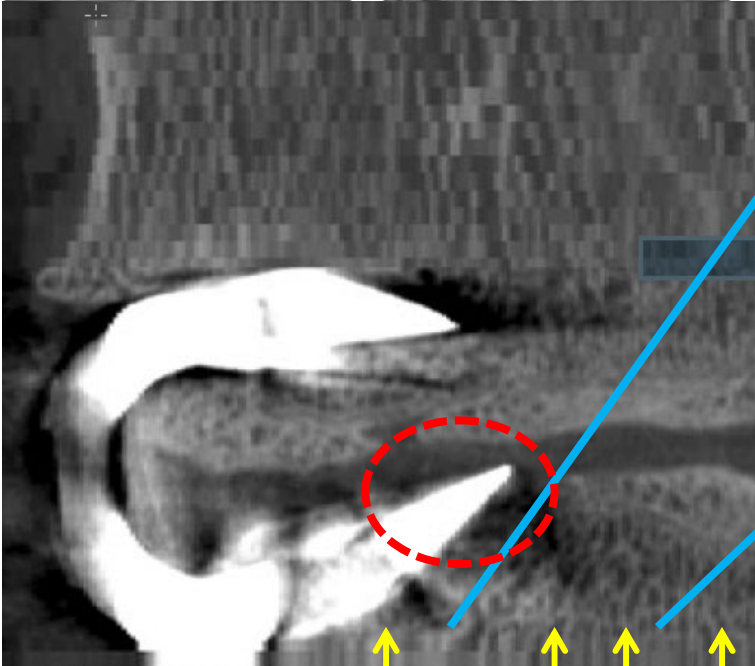
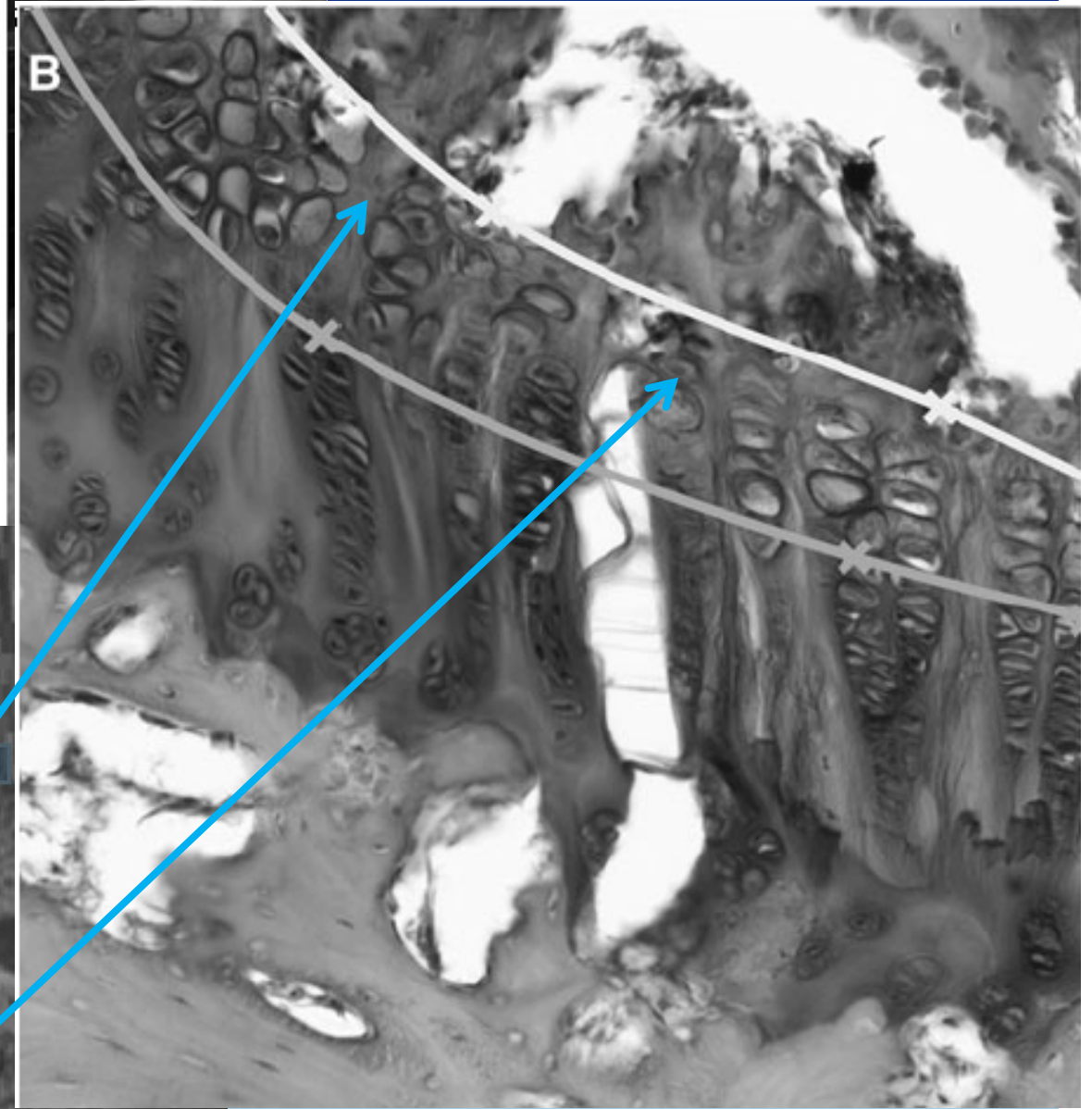
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*Preshaped rigid
staple*

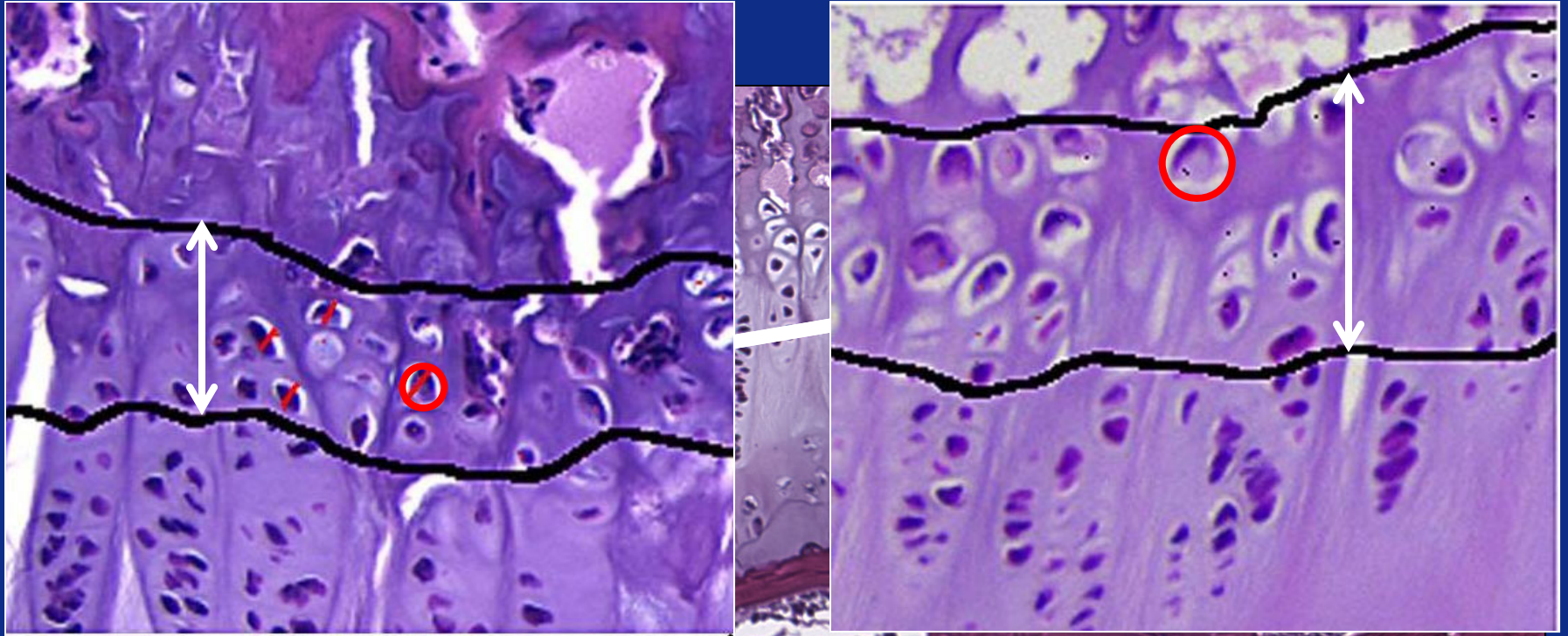
*Flexible when
cooled to (-)20°*

*Warmed staple,
regains shape*



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Staple Heuter-Volkman?



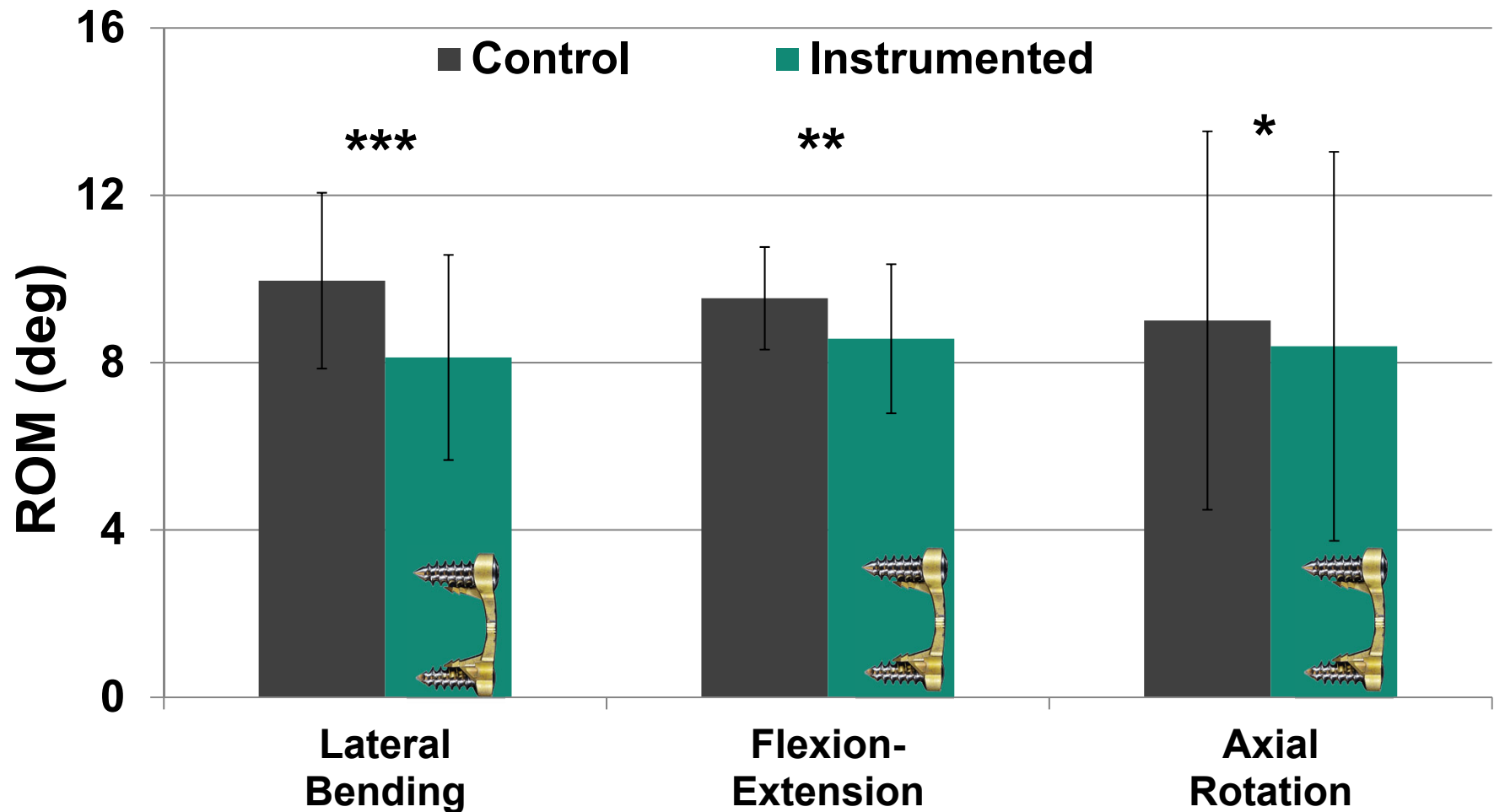
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Bylski-Austrow, JBJS 2008



Minimally Restricts ROM



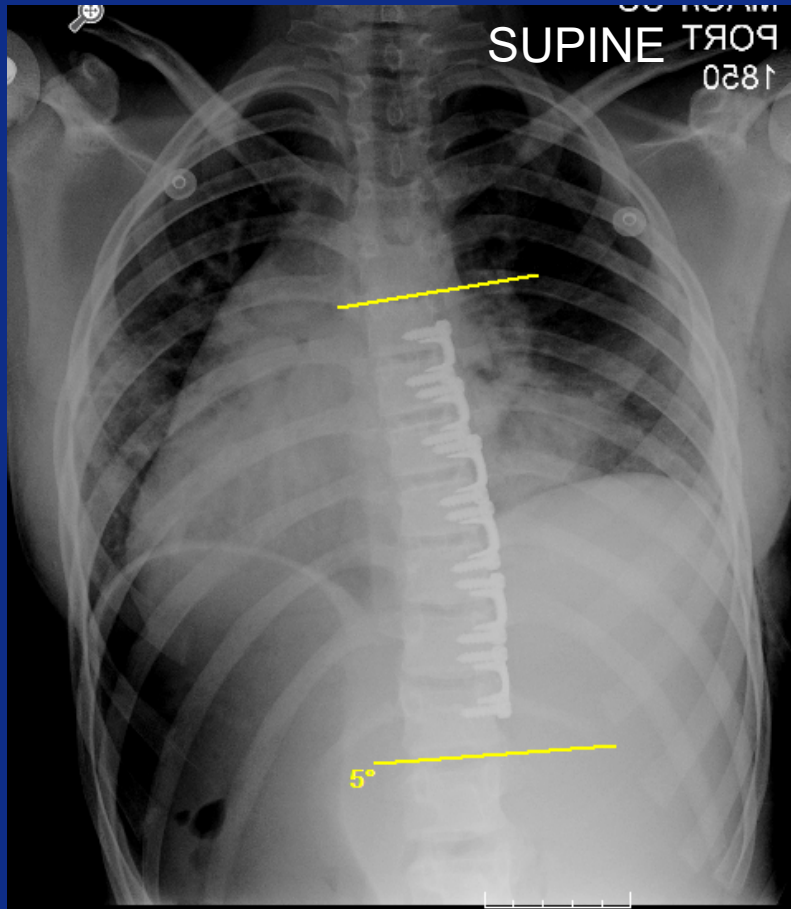
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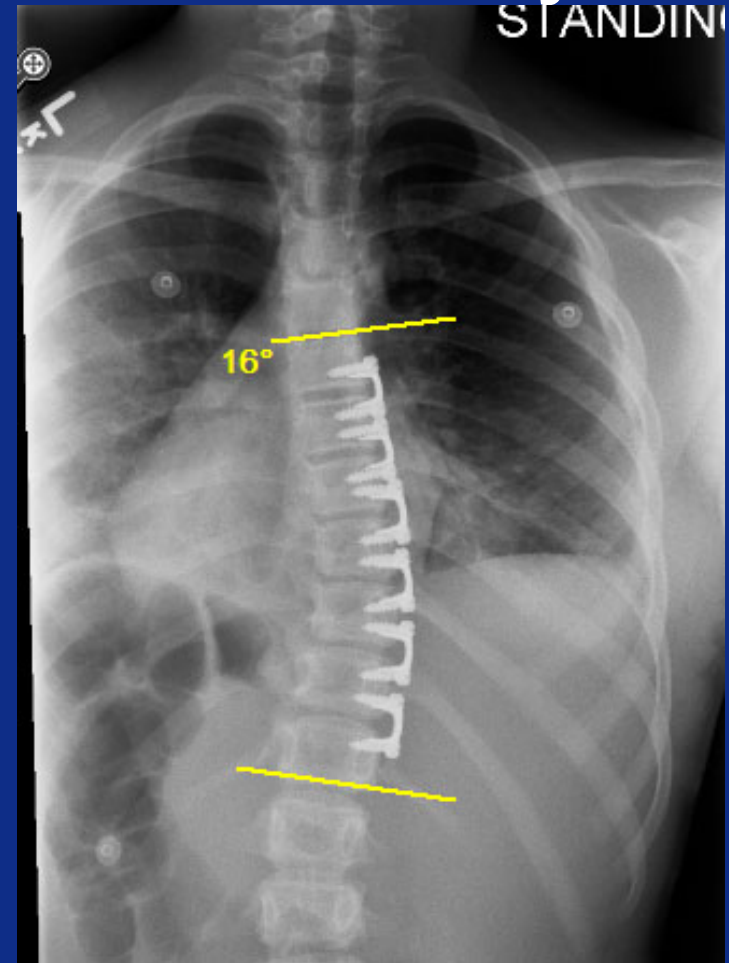
Bylski-Austrow ICEOS 2012



Titanium Staple Flexibility



SUPINE ANEST

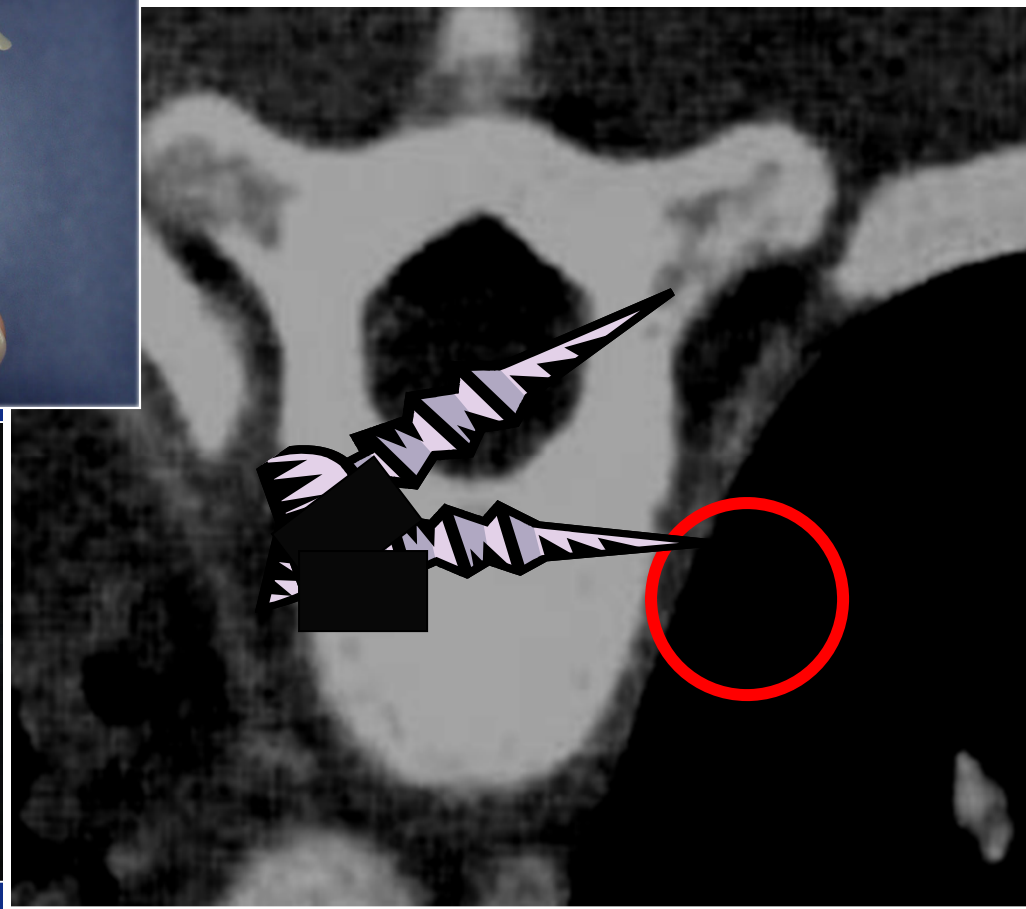
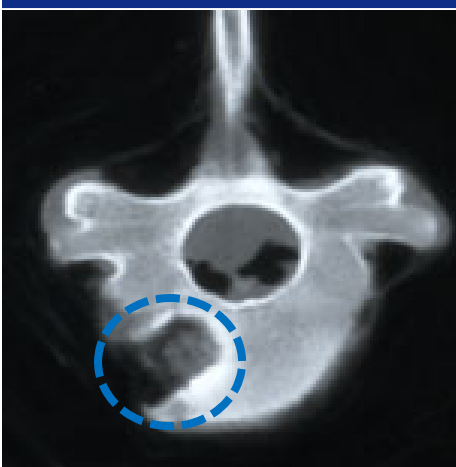
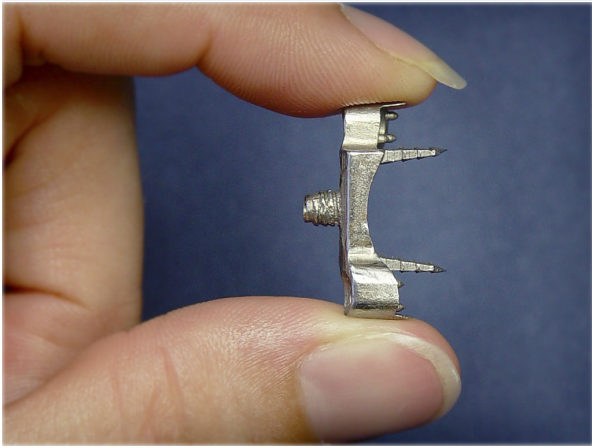


1st STANDING

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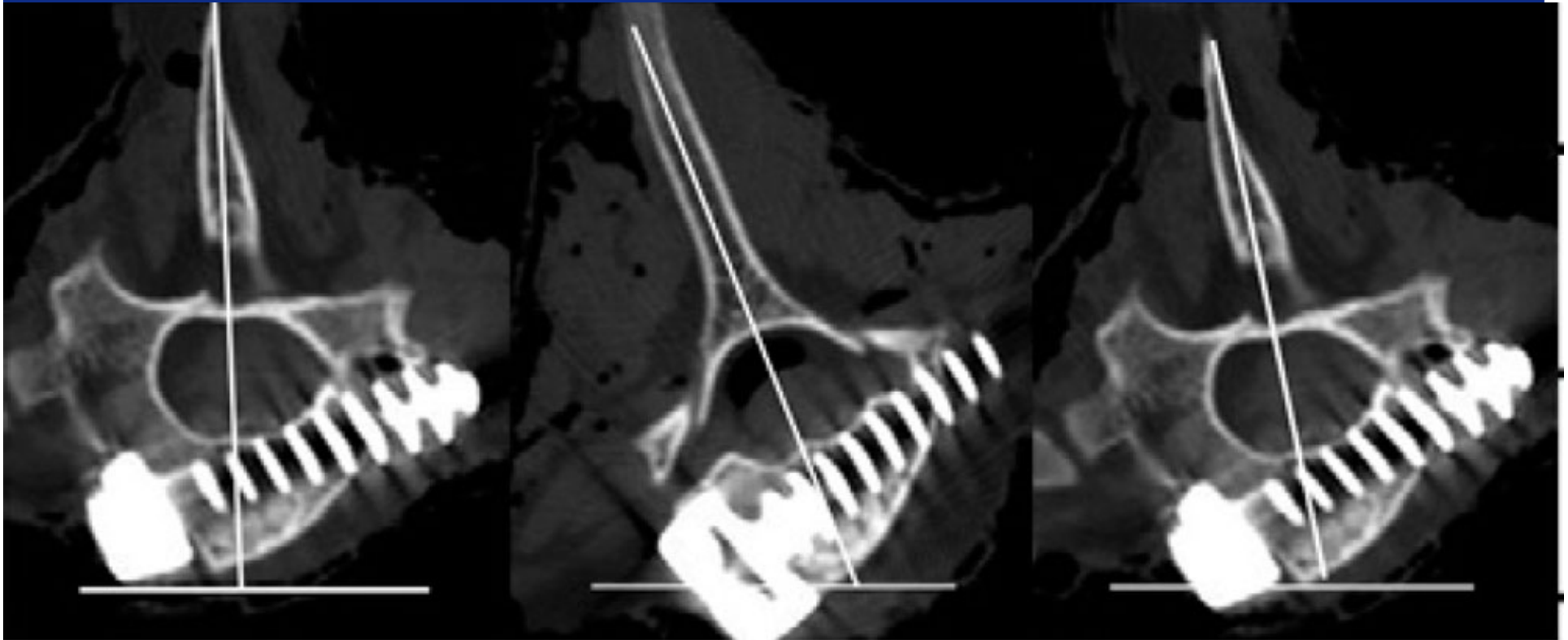
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Safety First !



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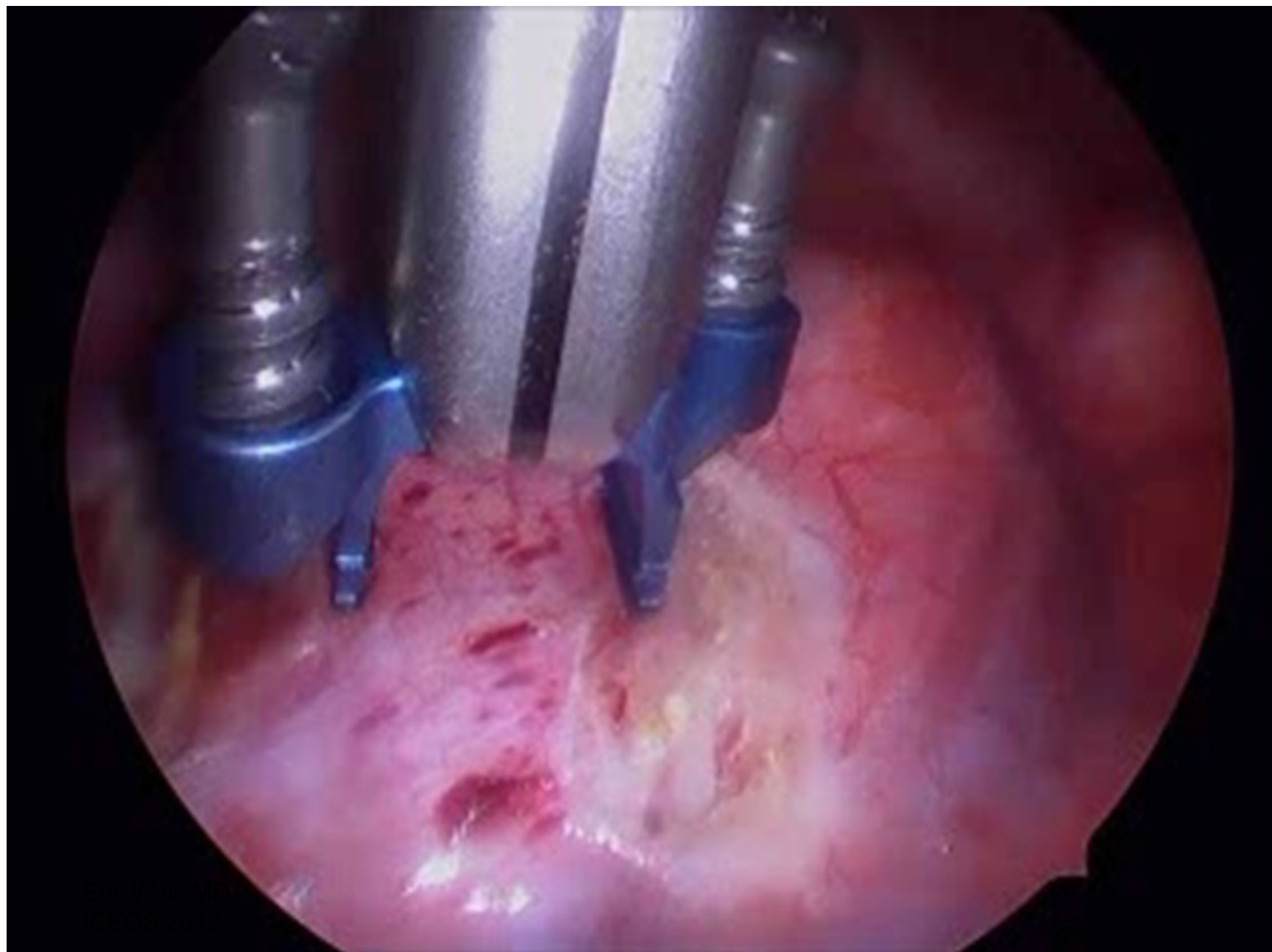


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Upasani & Newton 2011





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Thank You

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

Rolf Stuecker

Randall Betz



Atraumatic Removal
Titanium (biocompatible)
Single implantation
No clock tick

Irreversible compression
50% Nickel (allergy?)
Chisel + Implant
Rapid phase change