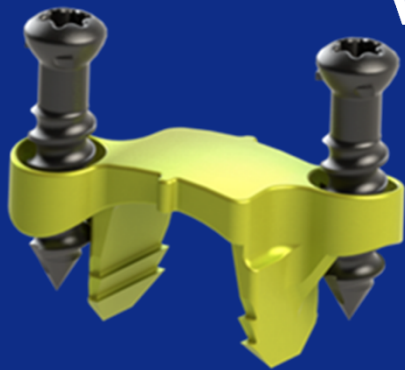


FDA Prospective Clinical Trial on a Scoliosis Growth Modulation Clip/Screw Device: One-Year Results

Wall E, Thompson G, Reynolds J, Jain
V, Bylski-Austrow D, Samuels P,
Barnett S, Crawford A



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Approved IDE Study

- Prospective Initial Safety Trial
- Non-fusion Growth Modulation
- Adolescent Idiopathic Scoliosis
- 6 Patients

www.clinicaltrials.gov NCT01465295

FDA R01 Grant

Ohio 3rd Frontier Grant



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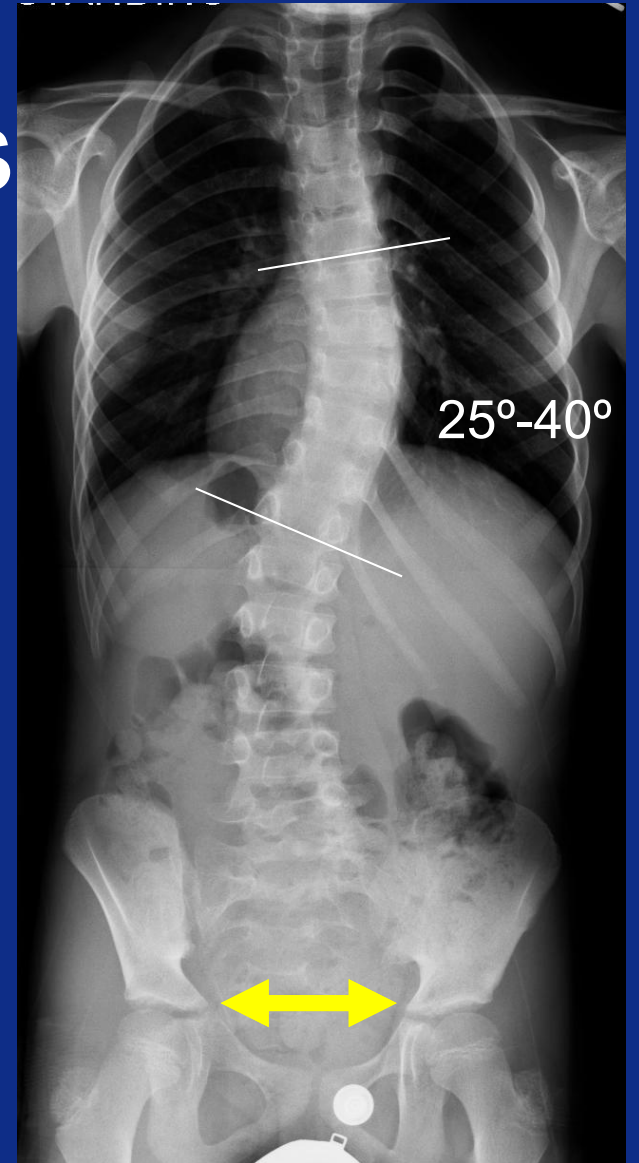
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FDA Study Indications

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

Near 100% predicted fusion

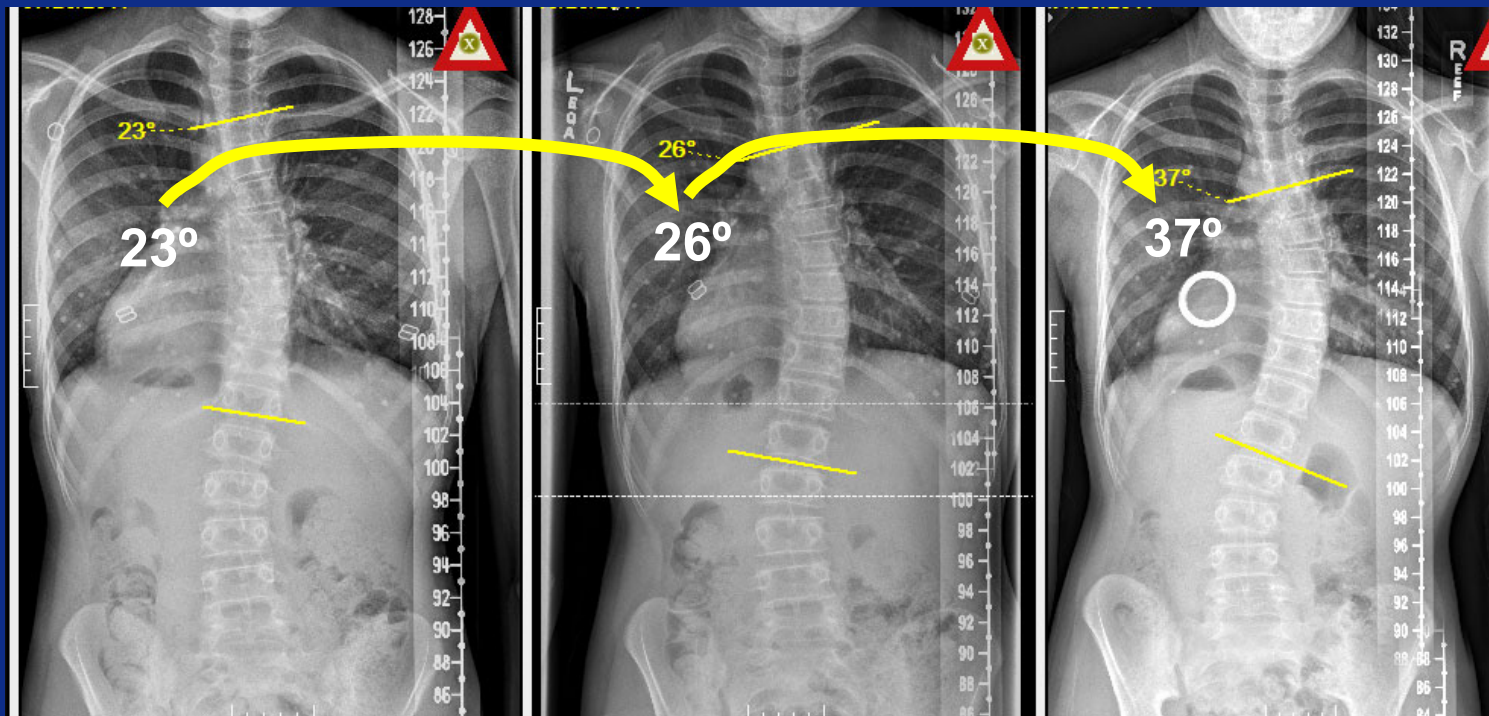


Very Rapid Progression

4 mo pre-op

1 mo pre-op

T = 0

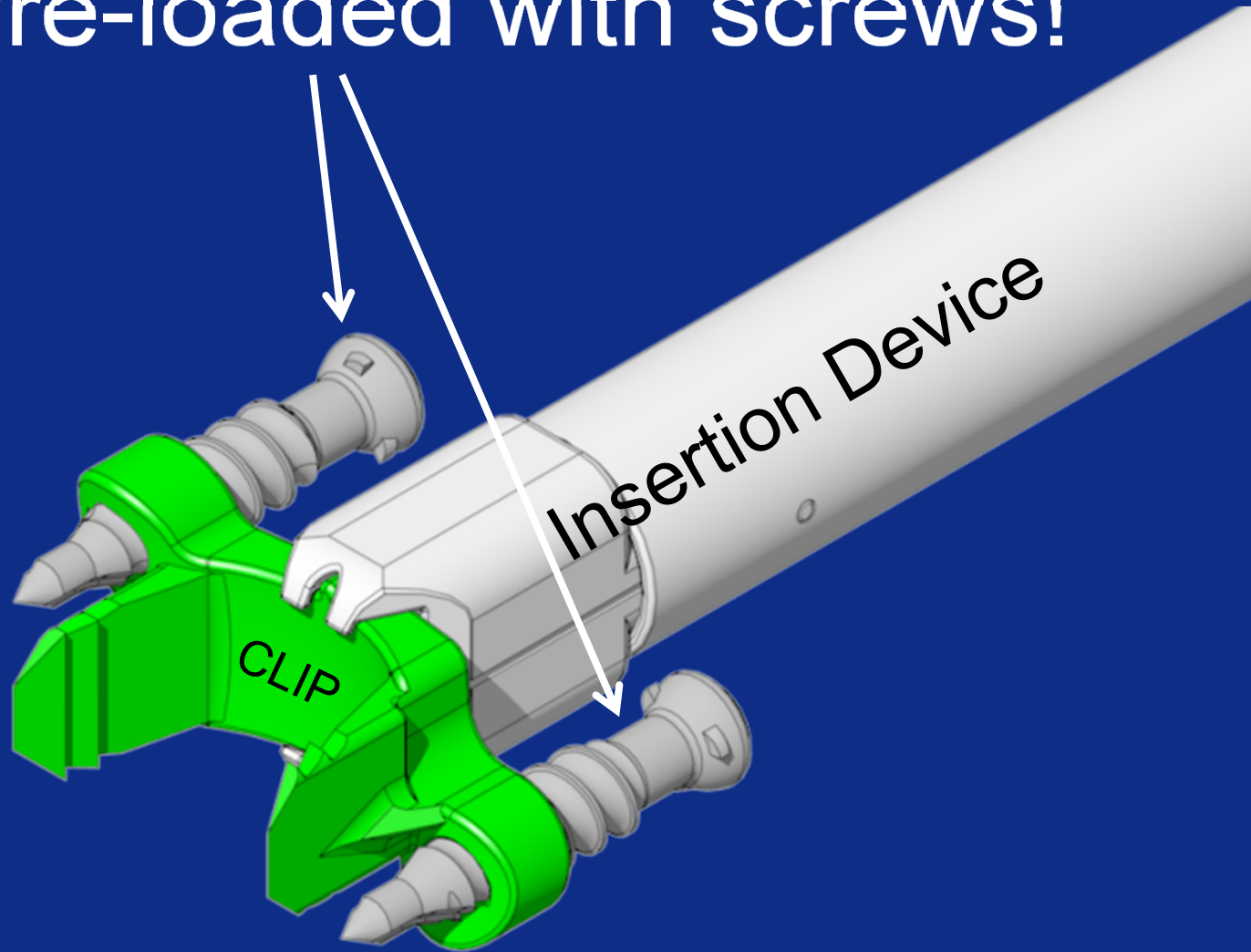


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Pre-loaded with screws!



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- Endoscopic anterior approach
- Two insertion portals
- Lateral position
- One clip at each level
- Clip entire Cobb angle



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Safety Results:

- No Device Related Adverse Events:
 - No device misplacement, loosening, breakage, migration, auto-fusion
 - No disc contact
 - No spinal canal intrusion/neuromonitoring Δ
 - No return to OR

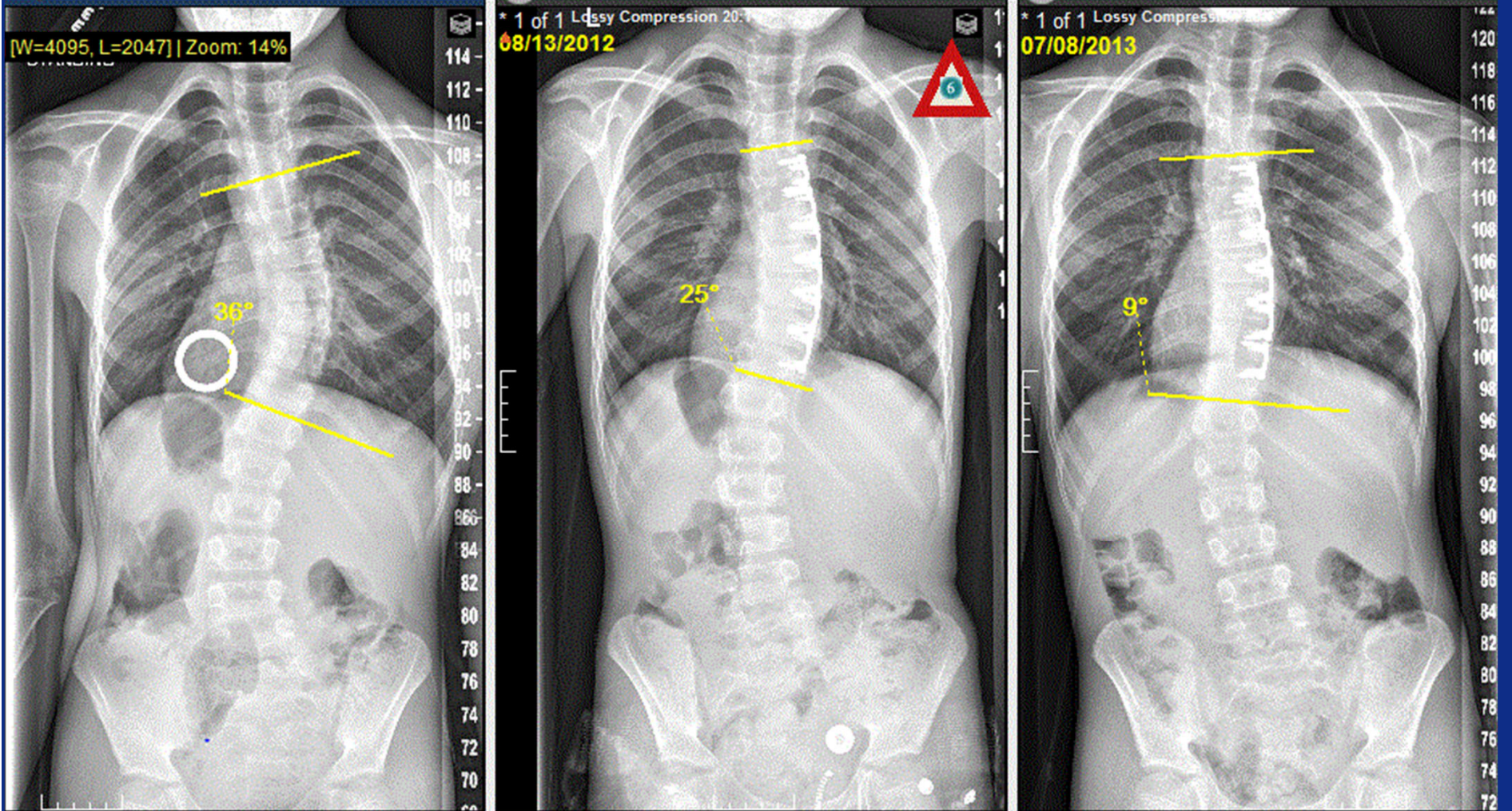
Procedure Related AEs

- 1 Post-op Mucous Plug
- 1 Chylous Effusion tx with diet (NPO) and pigtail catheter
- Minor AEs of nausea, dizziness, pain, atelectasis, slight pneumothorax/effusion

Results

- Hospital Stay <4 days
- EBL 75ml
- Surgical time 90 min (57-124 min)
- Cobb 35° preop, 27° @ 1yr

Example Correction @ 1yr



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ICEOS 2013

Conclusion

- Enrollment completed on FDA IDE study
- No serious device-related AEs
- Efficacy pending
- FDA approved for 30 pt expanded IDE study

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!

