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

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
FDA Study Indications

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

Near 100% predicted fusion

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Very Rapid Progression

4 mo pre-op  1 mo pre-op  T = 0

23°  26°  37°
Pre-loaded with screws!

Insertion Device

CLIP
• Endoscopic anterior approach
• Two insertion portals
• Lateral position
• One clip at each level
• Clip entire Cobb angle
Safety Results:

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

- 1 Post-op Mucous Plug
- 1 Chylosus 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

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Thank you from Cincinnati!