
Innovation in Growing Rod Technique; Study of Safety and Efficacy of *Remotely* Expandable Rod in Animal Model

Behrooz A. Akbarnia, M.D.

Gregory M. Mundis Jr., M.D.

Pooria Salari, M.D.

Burt Yaszay, M.D.

University of San Diego, California, San Diego, USA

San Diego Center for Spinal Disorders, La Jolla, California , USA

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DISCLOSURE

Author

Relationships Disclosed

Behrooz A. Akbarnia Allez Spine (c)	DePuy (d,e), K2M (b,d,e), Ellipse (b), Nuvasive (b,d,e)
Gregory Mundis	DePuy (a), Nuvasive (a,b)
Pooria Salari	No Relationships
Burt Yaszay	Depuy (a,e), Ellipse (a,b), KCI (a)



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(a) Grants/Research Support
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INTRODUCTION

- Treatment of early onset scoliosis is a challenge
- Growing Rods are commonly used but require multiple surgeries for lengthening
- Improved technology may allow remote lengthening without surgery
- We aimed to evaluate the safety and efficacy of a remotely expandable rod



Material & Methods

- ETID (Ellipse Technologies, Inc. Device) is a newly developed spinal distraction system
- Using ETID, non-invasive lengthening/shortening of an implanted rod can be performed
- ETID comprises two major elements
 - Implantable distraction rod (IDR)
 - External adjustment device (EAD)



Material & Methods

Implantable Distraction Rod (IDR):

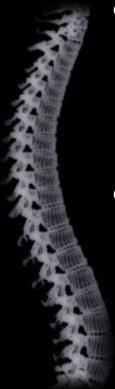
- A non-shapeable actuator, 9.0mm diameter
- The shapeable rod comes in 4.5, 5.5, or 6.35mm diameters
- A fully rigid construct may be chosen(a) or a freely-swiveling joint to lower stress on the construct and bone(b)
- Requires standard hooks and screws to be implanted



Material & Methods

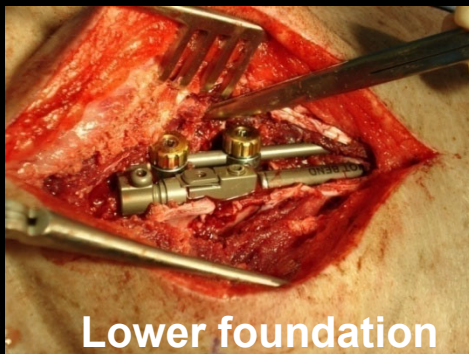
External Adjustment Device:

- A portable, hand held unit that uses a pair of permanent magnets to automatically modify the length of the implant through touch of a switch
- The amount of applied lengthening/shortening is shown on a built in display
- Lengthening/shortening sensitivity is 0.32mm
- Lengthening occurs at 1mm/ 7 sec.

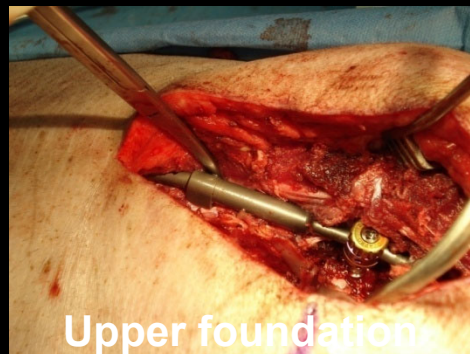


Material & Methods

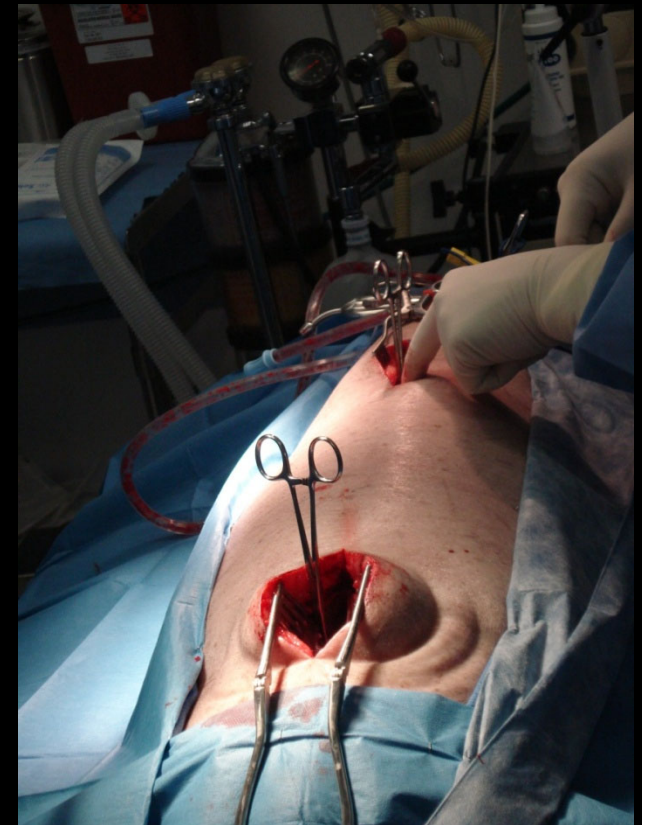
- 9 immature male Yucatan mini pigs
 - Experimental group (EG): 6 pigs
 - Sham group (SG): 3 pigs
- Both groups had 3-level cephalad and 2-level caudal foundations
- EG instrumented with unilateral rod



Lower foundation



Upper foundation



Material & Methods

- 7-9 levels were un-instrumented between cephalad and caudal foundations
- 7 mm of remote distraction was performed weekly for 7 weeks in EG under sedation
- Implants removed at 7th week
- Animals sacrificed 3 weeks after implant removal



Material & Methods

- AP and Lateral X-rays
 - weekly for 10 weeks (fluoro)
- CT Scan & plain xrays-
 - after index surgery, before implant removal & before sacrifice
- Spinal growth recorded throughout the study
 - Vertebral body height inc. disc
 - on weekly X-rays
- Spines harvested for further study after sacrifice



RESULTS

- Mean age in EG and SG was 7.1 and 7.3 months
- No difference in weight between EG & SG at initial surgery(IS) or throughout the study
- 1 EG pig died after IS; neurologic complication caused by screw malposition
- Mean distraction achieved in EG was 39mm (32-46)
 - Planned distraction was 48mm
 - We feel that increased thickness of fatty tissue may affect distractions forces resulting in this difference



RESULTS

- No complication resulted from distractions
- No implant failure
- Histopathology
 - Internal organs no significant changes in EG
 - Para-aortic lymph nodes no significant changes in EG
- Magnetic field from the magnets (implant and external device)
 - falls within international nonionizing radiation guidelines
 - for patient and user exposure



RESULTS

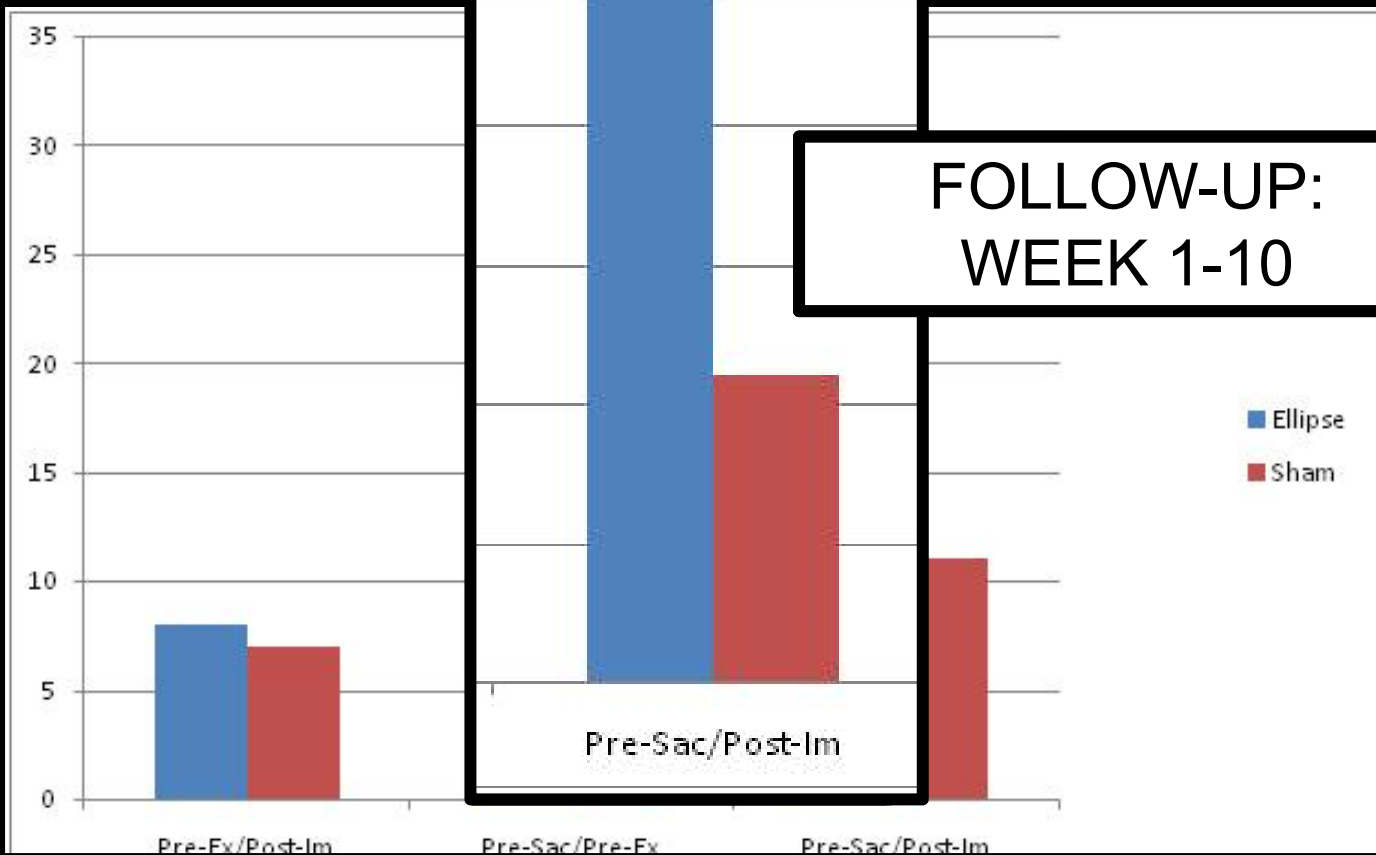
- 1 pig had a sterile fluid collection at lower foundation, treated with drainage and prophylactic antibiotics
- A retained sponge was found after sacrifice

**Surgeons have no business doing the final count!!*



RESULTS

RESULTS



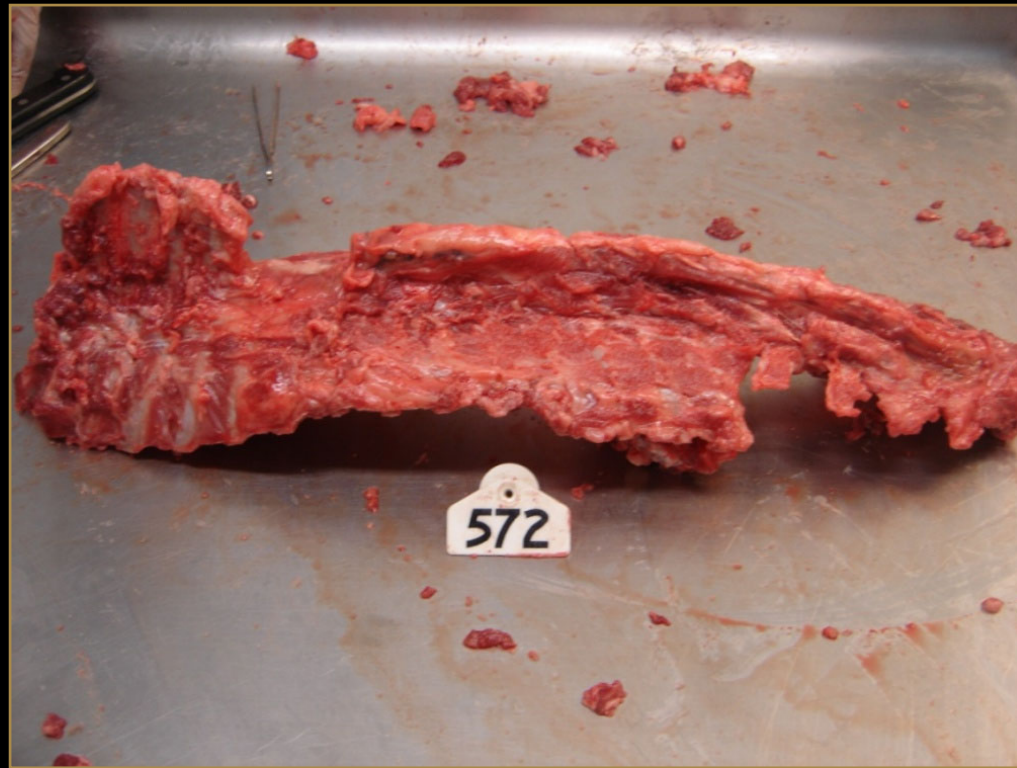
- After implant removal spine growth increased significantly in EG between preoperative and postoperative (12 weeks) was greater in EG and EG

CONCLUSION

- **ETID was shown to be safe and effective**
- **No complication resulted directly from distraction**
- **ETID distinguishes itself by:**
 - **Distraction accuracy/precision**
 - **Shortening ability**
- **ETID shows promises as the next generation of distraction based treatment for EOS**



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