Introduction to a new motorized growing rod:
Animal study and preliminary clinical results

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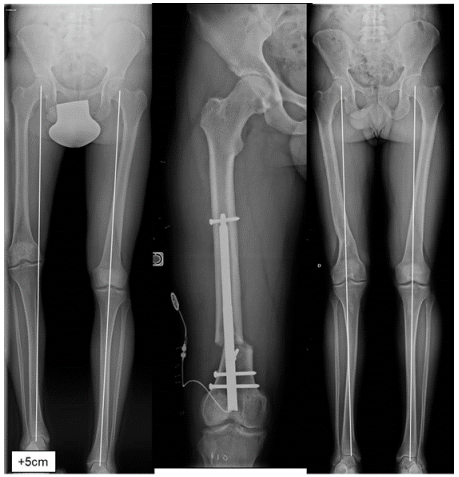
Background

- EOS treatment often remains a challenge
- MCGRs have allowed improvement of care

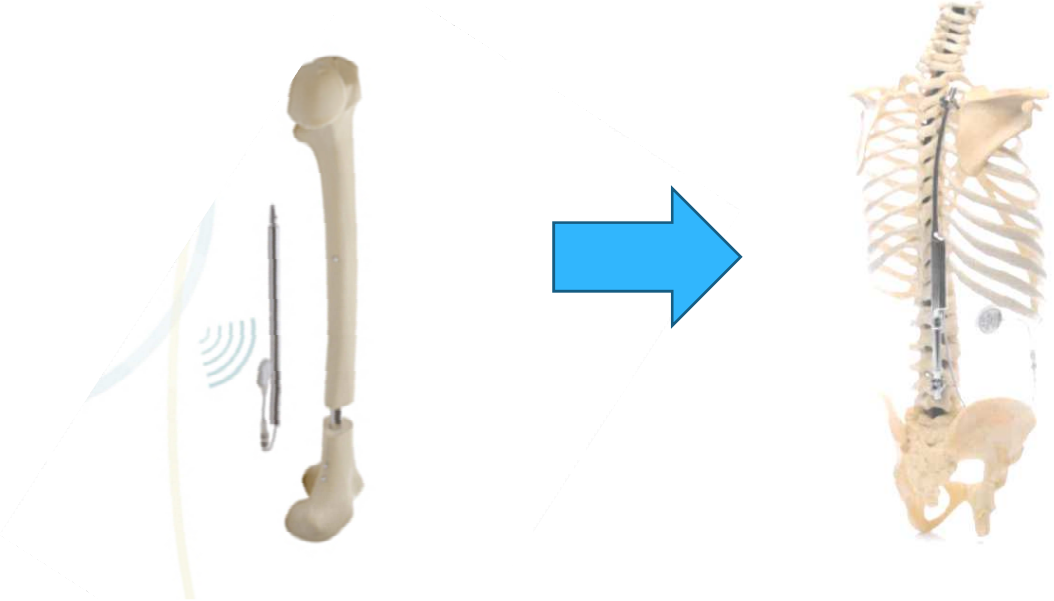
  Implant breakage, reliability issues, 'diminishing returns' *Lebon et al. Eur Spine J 2017*
- Fitbone motorized IM nail safe and reliable

  for bone lengthening *Accadbled et al. OTSR 2016*

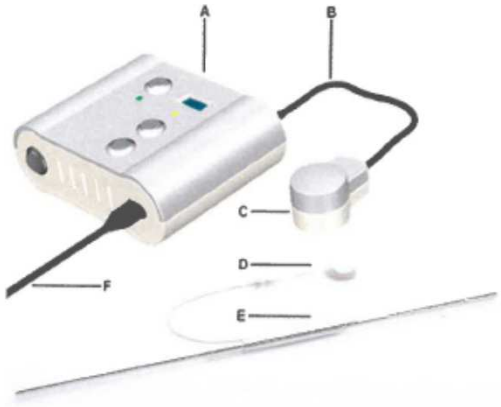


Objective

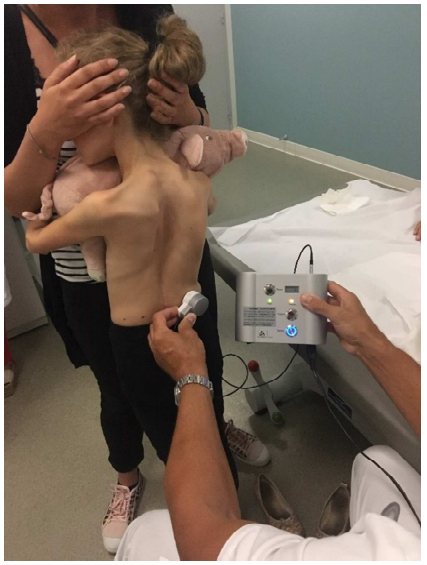
To adapt Fitbone technology to design a new spinal growing rod



Design

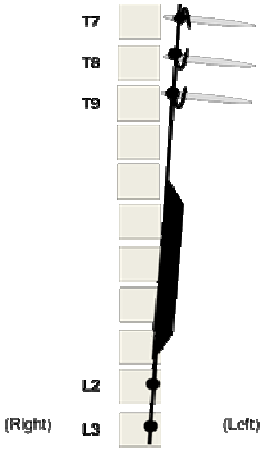


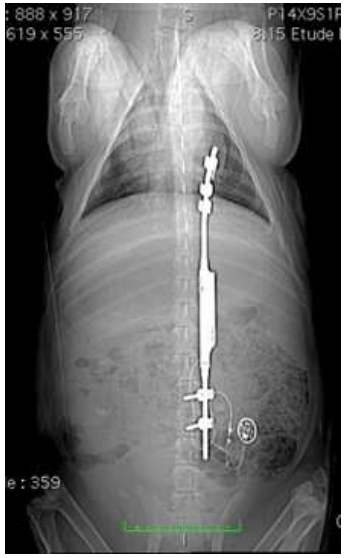
- 5.5mm diameter stainless steel
- Subcutaneous receiver
- Activation via external control unit and transmitter
- 50mm distraction reserve
- Visual & acoustic feedback during distraction



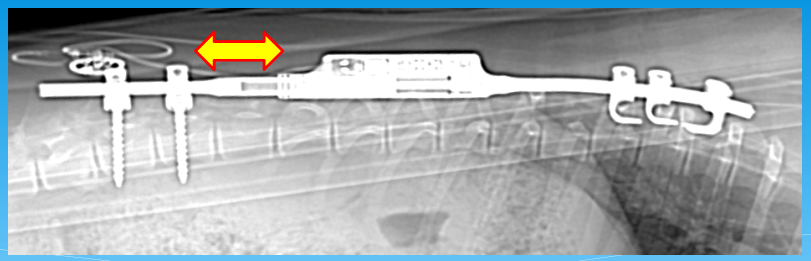
Animal Study. *Method*

- 3 10-month-old Göttingen pigs
- T7-L3 Single rod construct
- 2mm distraction procedure every second day
- Immediate post op CT scan then scout view weekly
- MRI scan & histology

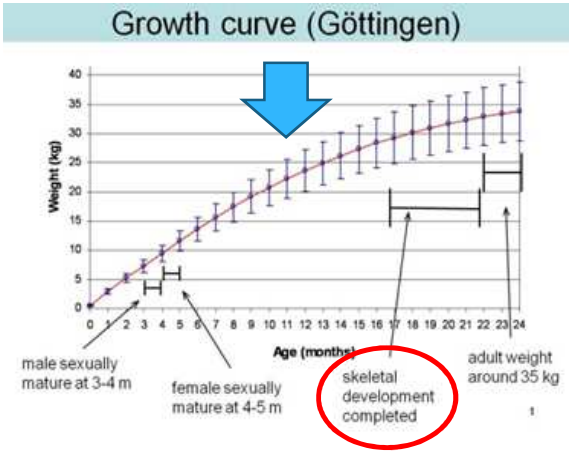




Animal Study. *Results*

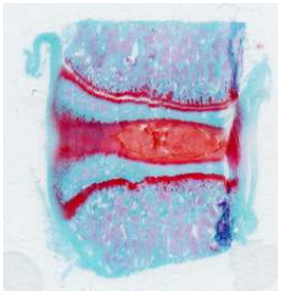


- Expected length gain reached in all cases as per by CT scan then explants measurements
- Distraction interrupted after 4 weeks as pigs reached skeletal maturity. Length gain =27mm
- Necropsy: No adverse reaction. MRI: No IVD damage



Coronal view

Caudal side (arrows: instrumented vertebrae

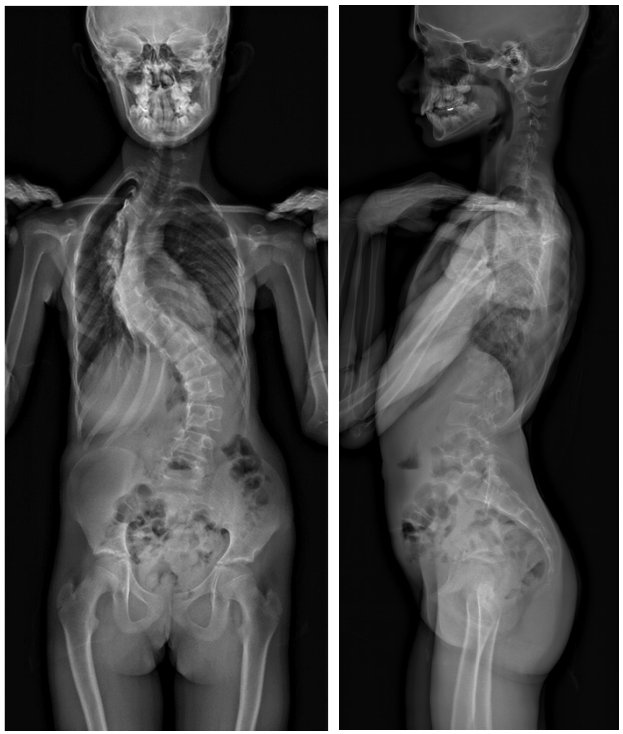


Clinical trial. *Method*

- Prospective single center study for safety in France
- 5 patients 4 to 10yo with severe EOS (>40°) included over 12-month period
- Single or dual rod constructs
- Growth compensation: 3mm every 3months
- Data recorded (complications, length gain, Cobb angle, PROMs…)

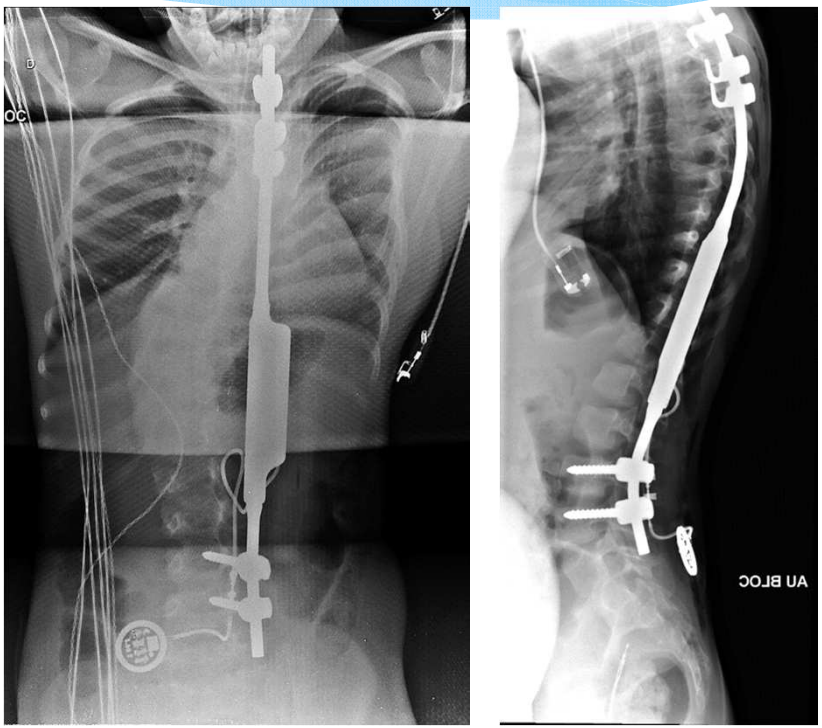
Clinical trial. *Results* #1

- 9yo girl
- Idiopathic
- Cobb angle 86° →61°



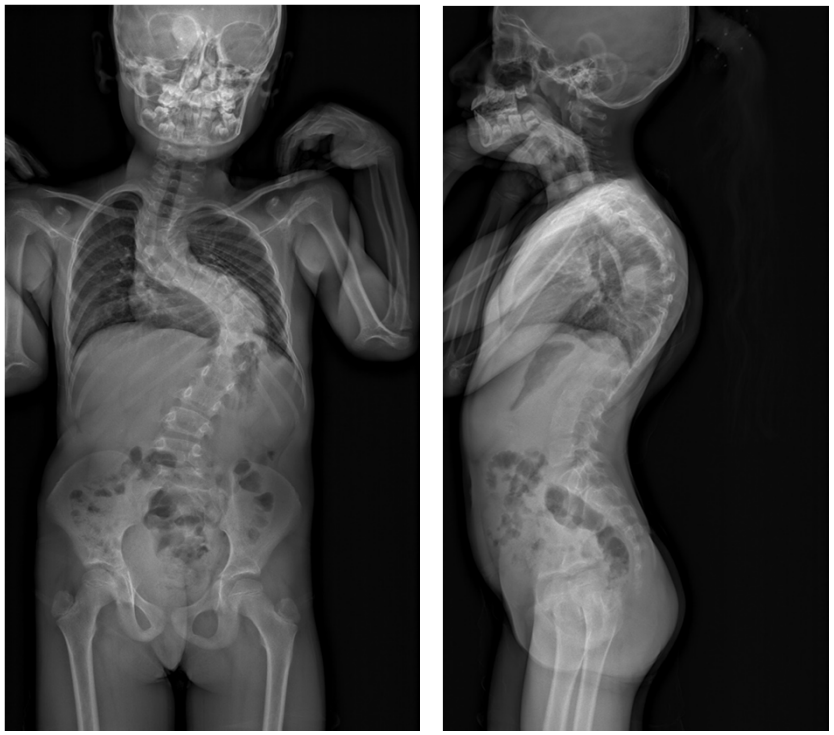
Clinical trial. *Results* #2

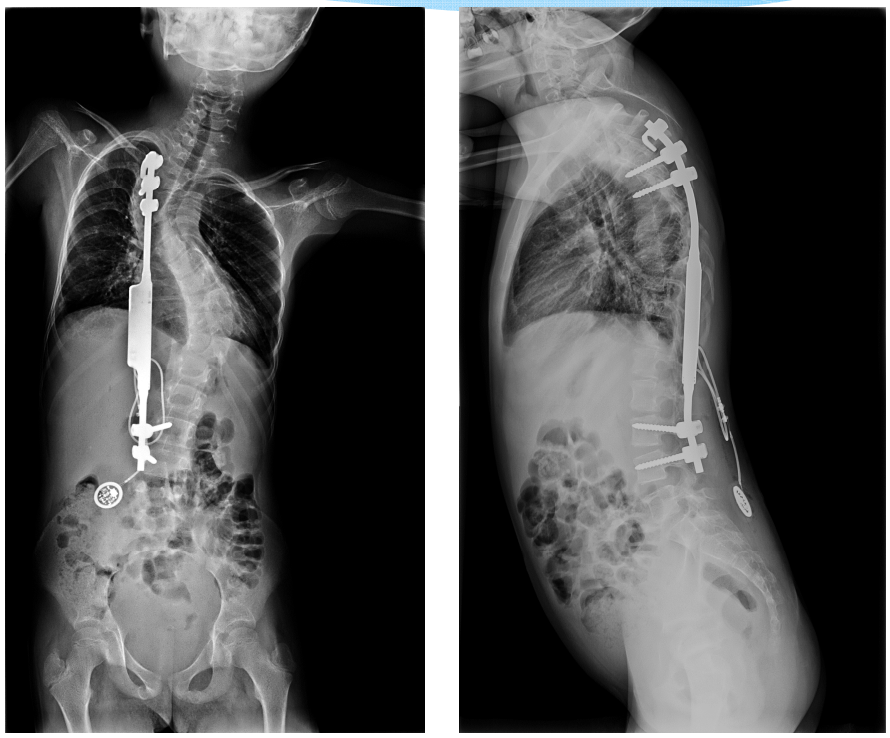
- 9yo girl
- Congenital (abdominal muscles agenesia)
- Cobb angle 87° → 41°



Clinical trial. *Results #3*

- 9yo girl
- Idiopathic
- 4/52 halo traction
- Cobb angle 96°→63°





Conclusion

- Promising preliminary results regarding safety, efficiency, and functional reliability
- Further investigation needed / multicenter study

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EPOS

European Paediatric Orthopaedic Society

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