Experimental Study On The Safety And Efficacy Of A Novel Growth Guidance Rod System For Early-onset Scoliosis In A Sheep Model

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The disadvantages for current growing rod techniques:

- Lengthening procedure twice a year for several years.
- High complication rate related to repeated operation
- Growing rod only partially correct the spinal curve by distraction
- Little control to the apex of the curve
- The rigidity of the spine after a growing rod procedure interfere with the final correction. [Cahill PJ, 2010; Acaroglu E, *2002*]

Ideal instrument

- three-dimensionally (3D) correct the curve from the first procedure
- permit the instrumented spine grown under the 3D guidance of the system without operative lengthening instruments
- no final spinal correction fusion procedure needed

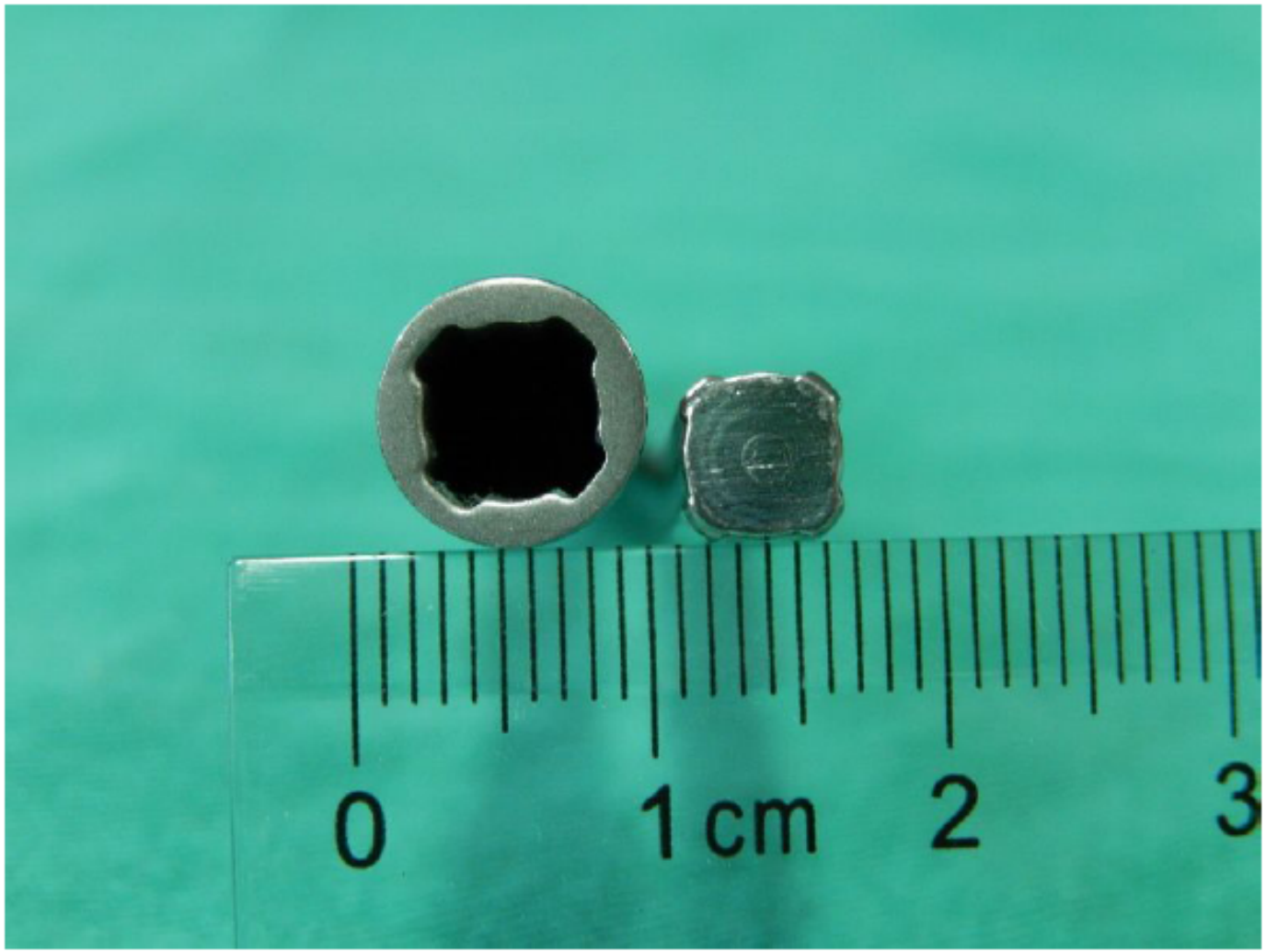
Our innovative instrument (US patent pending): Multi-Segment Growth Guidance Rod (MSGGR)

- The MSGGR is a rod consisting of segments.
- Spinal deformation in scoliosis is corrected and maintained by the rods without fusion.
- The system allows the growth of the fixed spinal segments.
- It is stable when twisted and bent but extendable when stretched.
- Rod extension occurs through sliding between the segments along the sockets in accordance to the growth of spine.

Detoured MSSGR

Assembled MSSGR (up) and disassembled MSSGR(down)

Detail of the socket structure of the rod.



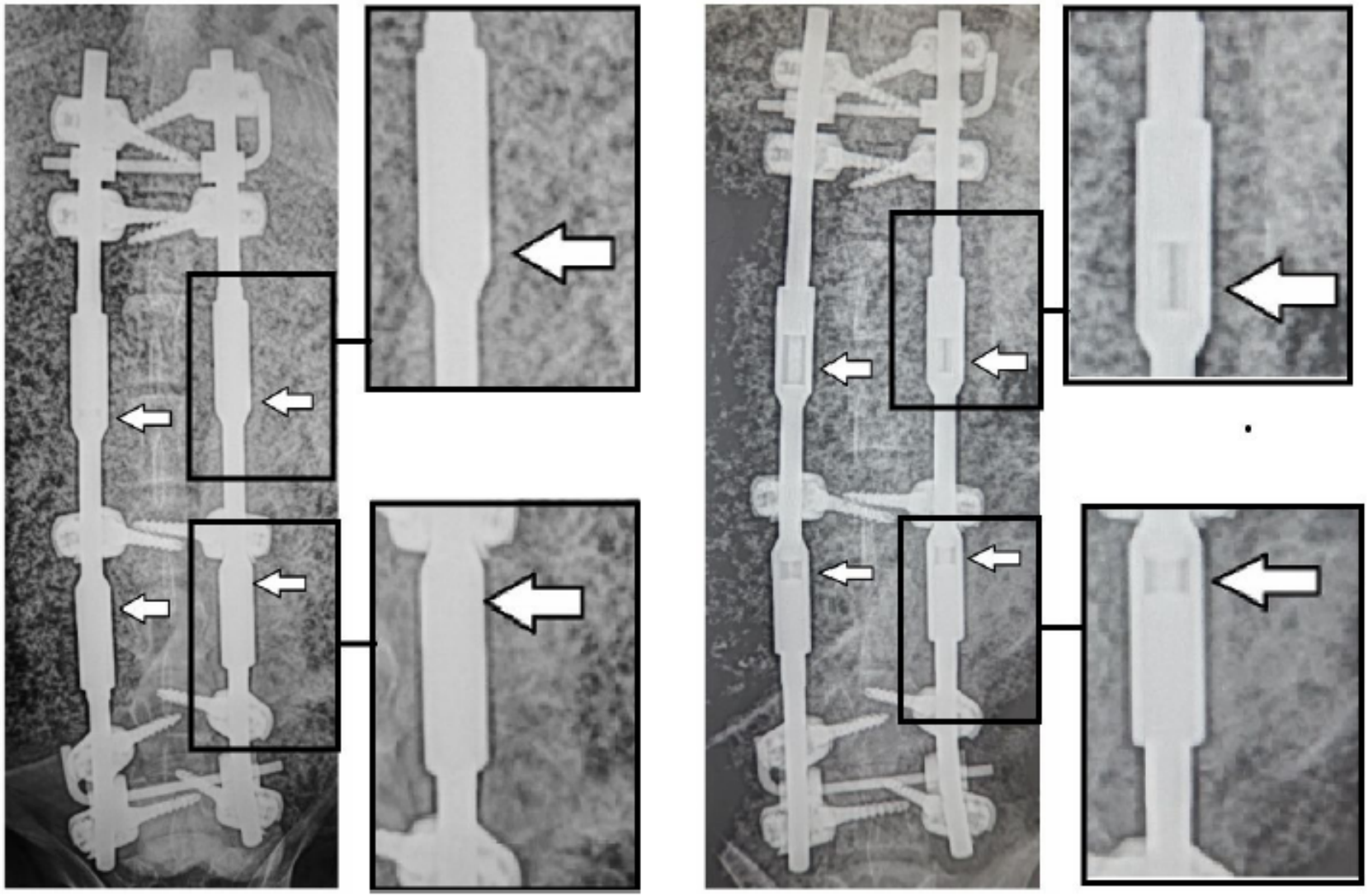
Methods:

- Ten 3-month old immature sheep were used in this study.
- Dual MSGGRs were implanted to fix the lumber and low thoracic spine.
- Radiographs, magnetic resonance image (MRI) and CT scan of the spine.
- Rigidity of the spine column was assessed manually after implant remove.

Results

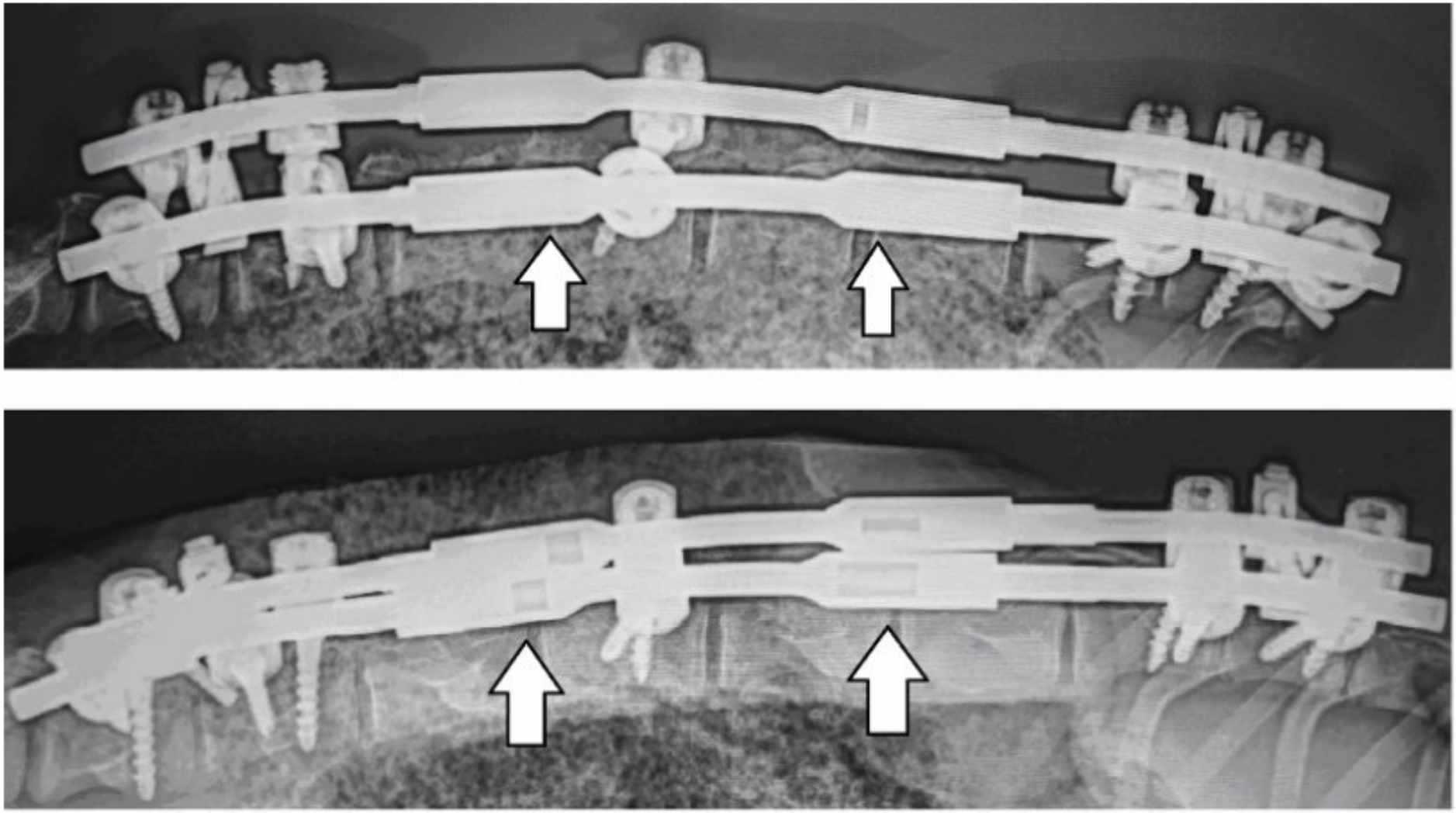
- The spine segments within the instruments were 12.5±0.8 cm and grew by 10.9% (range 6%-18.4%) from its original length in 4 months.
- None of the implants failed. No MSGGR-related complications were observed.
- MRI showed normal disc within the instrumented segments.
- CT showed no auto-fusion
- Motion of the instrumented spinal segments was preserved but had less range of motion than those non-operated

AP view of the sheep spine after MSSGR procedure.



Immediately after operation (left) and 4 months post-operative radiographs (right).
Lengthening of the device occurs through the socket portion of the device (white arrow)

Lateral view of the sheep spine after MSSGR procedure.



Immediately after operation (upper) and 4 months post-operative radiographs (lower)

Conclusion

- Growth guidance with this novel MSGGR allowed for continued growth in this sheep model and repeated lengthening of the system is not needed.

Reference

- Acaroglu E, Yazici M, Alanay A, Surat A. Three-dimensional evolution of scoliotic curve during instrumentation without fusion in young children. *J Pediatr Orthop 2002;22-4:492-6.*
- Cahill PJ, Marvil S, Cuddihy L, Schutt C, Idema J, Clements DH, Antonacci MD, Asghar J, Samdani AF, Betz RR. Autofusion in the immature spine treated with growing rods. *Spine (Phila Pa 1976);35-22:E1199-203.*

Co-operation in development and commercialization are welcome.

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