

The Effect of a New Bi-planar Hinge Construct on a Normal Animal Spine: Scoliosis Creation with Retention of Flexibility.



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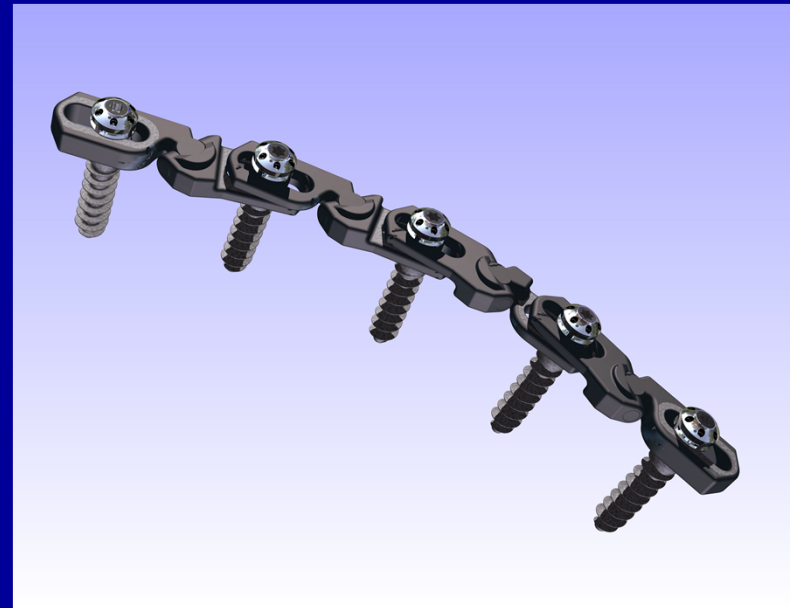
Medical Research Council Marshall Building, Roslin and The Royal Dick School of Veterinary Studies, The University of Edinburgh, UK

Introduction

- Early Onset Scoliosis is a challenging area of spinal practice in which treatment methods are evolving continuously
- A variety of growth modulating implants and instrumentation techniques are available/in development
 - Growing rod (multiple lengthening)
 - Shilla Growth Guidance technique
 - VEPTR
 - Hybrid techniques
 - Use of anterior tether

Introduction: New Growth Modulation Device

- Flexible anterior tether consisting of four sloppy angled hinges linked together and attached to the spine via 5 vertebral body screws
- The device allows a near physiological defined range of motion

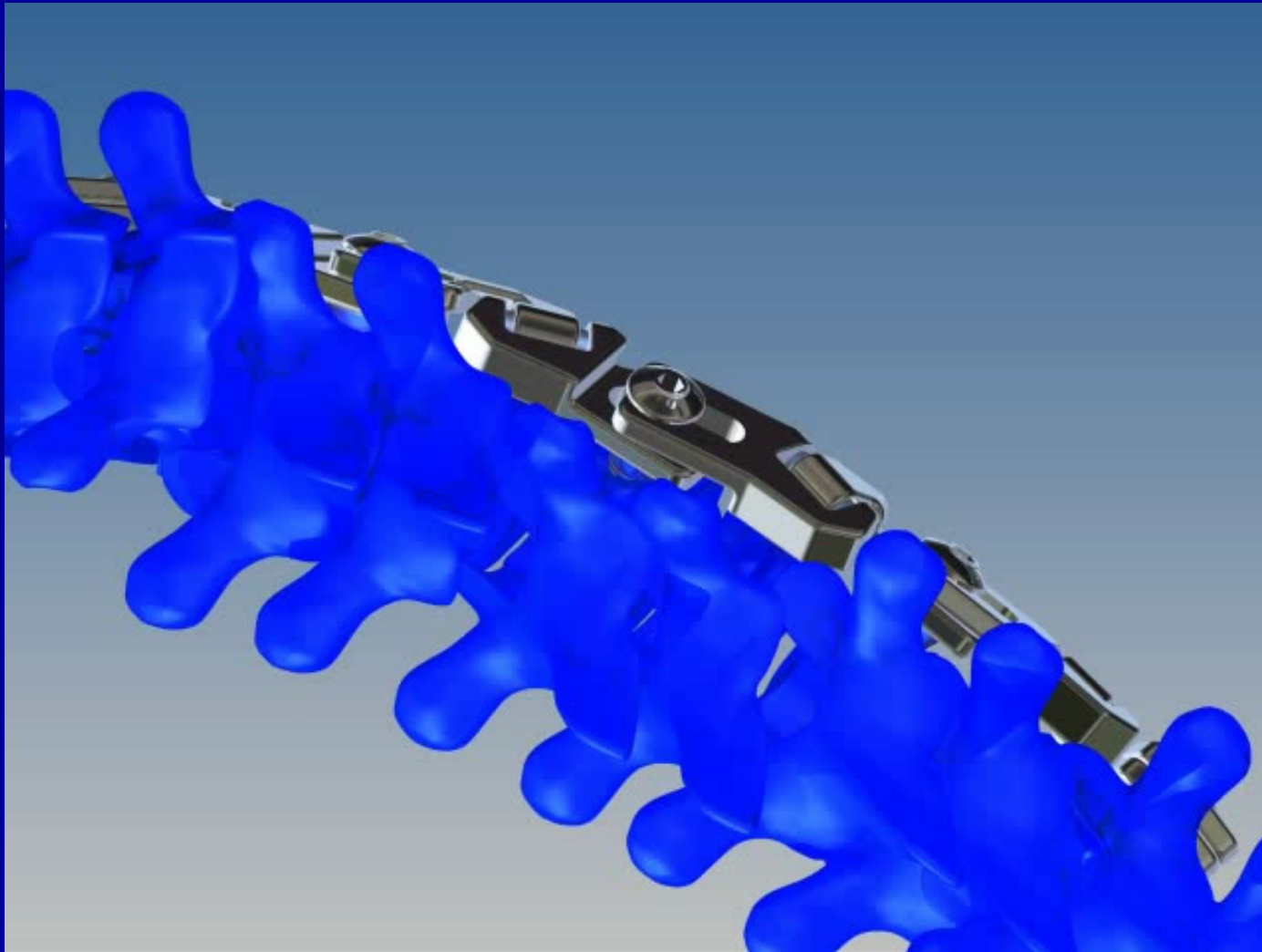


Introduction: New Growth Modulation Device

- Flexible rod is composed of sloppy hinges orientated at an angle
- Individual hinges are joined together via a variable angle system to make the construct (this angle defines the sagittal contour)
- Flexible rod/tether changes 3D shape after implantation driven by the patients own growth



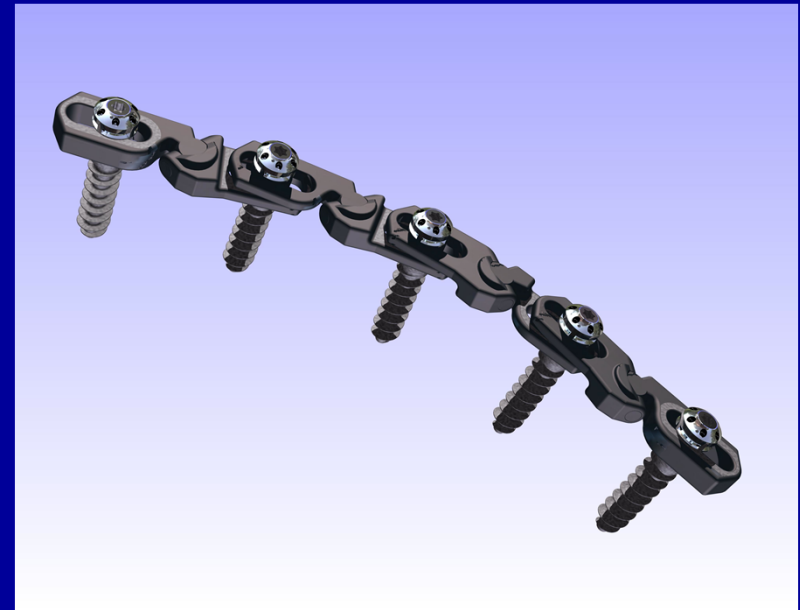
Introduction: New Growth Modulation Device



Aim

The aim of this study was to test this novel spinal device in vivo in a large animal model

- 1) To evaluate the effects of the device on spinal growth and motion
- 2) To evaluate the safety of the device



Materials and Methods

Ethics Committee Approval and the necessary Home Office Licences were obtained

Medical Research Council Grant

Marshall MRC and University of Edinburgh Sheep Facility, Roslin



Materials and Methods

11 female Blackface lambs aged 10 weeks were entered into the study

5 lambs were used as controls and had no surgical intervention

6 lambs underwent a double right thoracotomy and instrumentation with the device from T4 to T12

The lambs were recovered and returned to their mothers



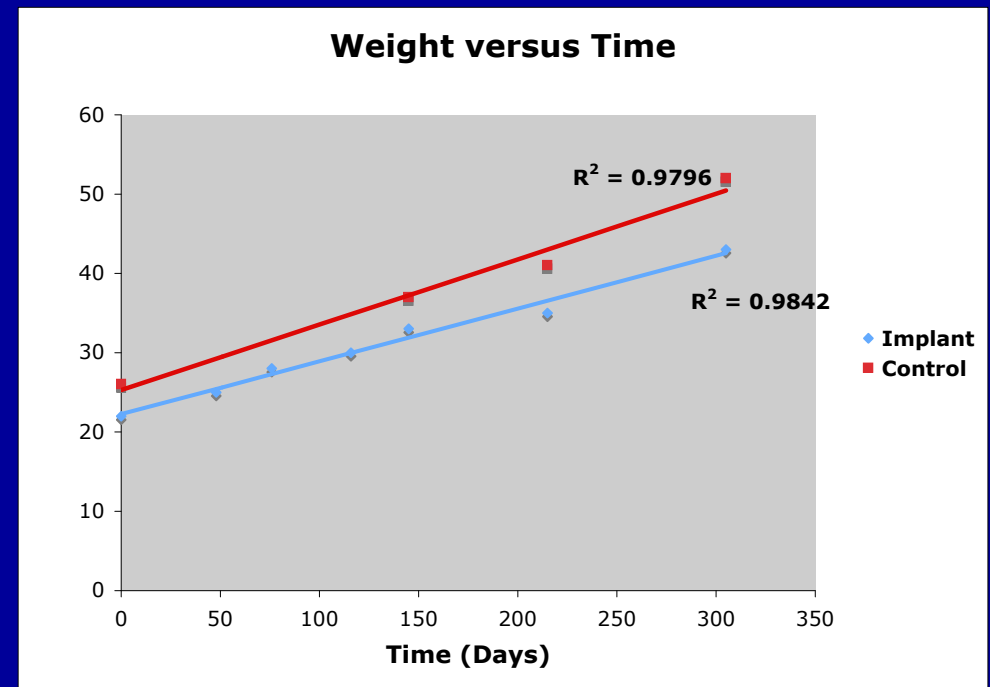
Materials and Methods

- Assessment of impact on Health
 - Weight gain at 6, 10, 16, 20, 30, 44 weeks
- Assessment of Deformity Generation
 - AP/lateral thoracic spine X rays at intervals (6, 10, 16, 20, 30, 44 weeks)
- Assessment of Spine Mobility
 - Stress Right and left Lateral Bending films and Stress Flexion/Extension films (20 and 30 weeks post op)

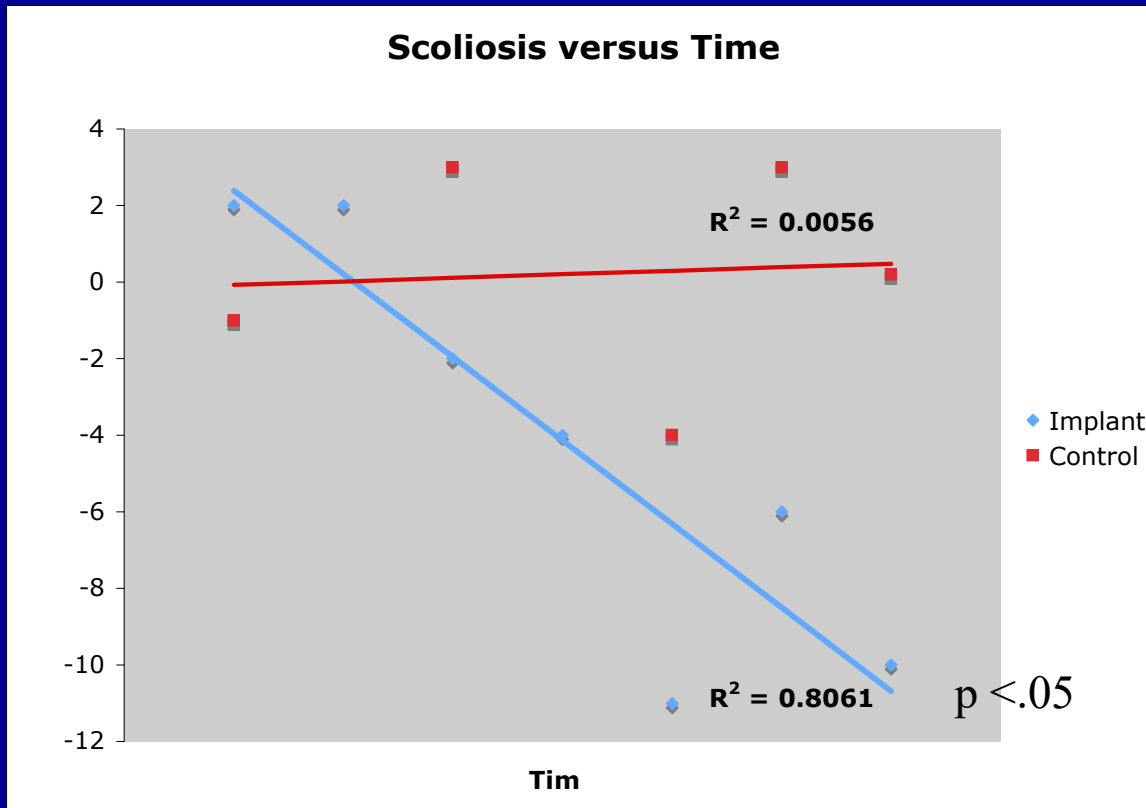


Results

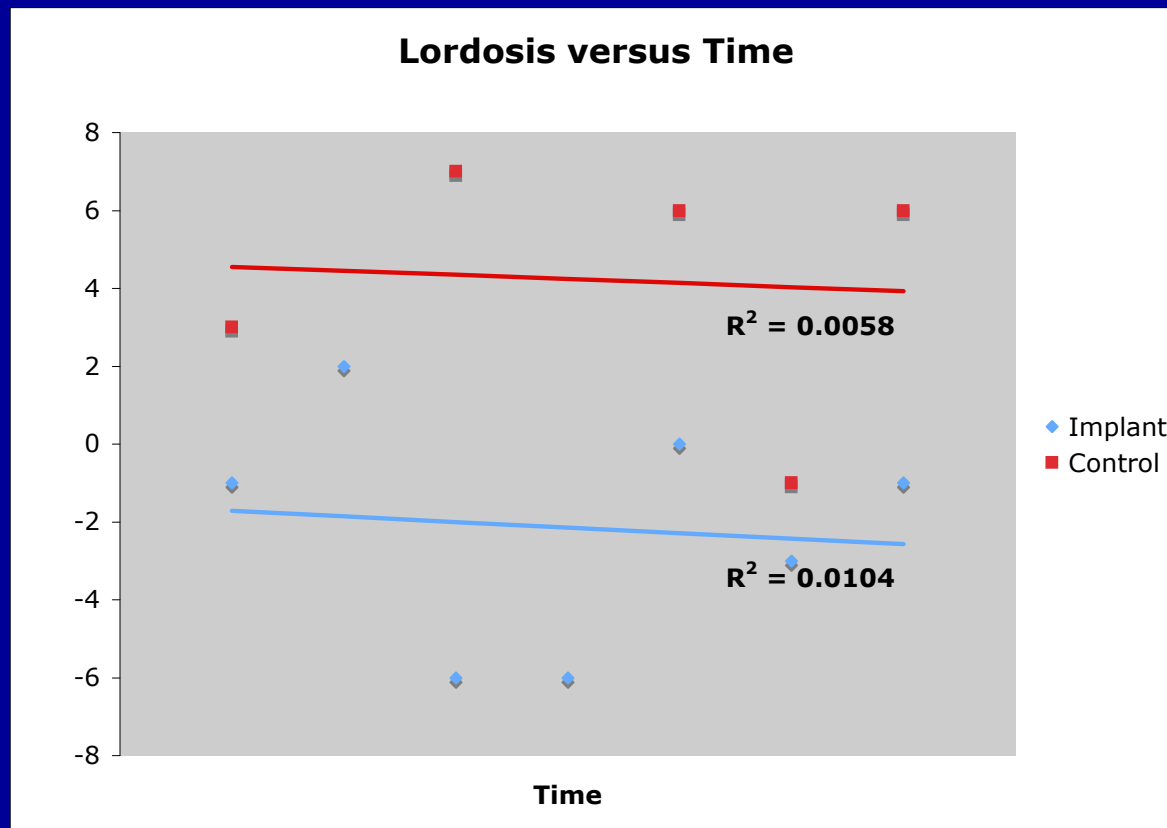
- All animals recovered satisfactorily following surgery
- There were no cases of implant breakage or migration
- The control and operated animals gained weight satisfactorily and no differences in behaviour were discernable between the groups (once recovery from surgery had occurred)



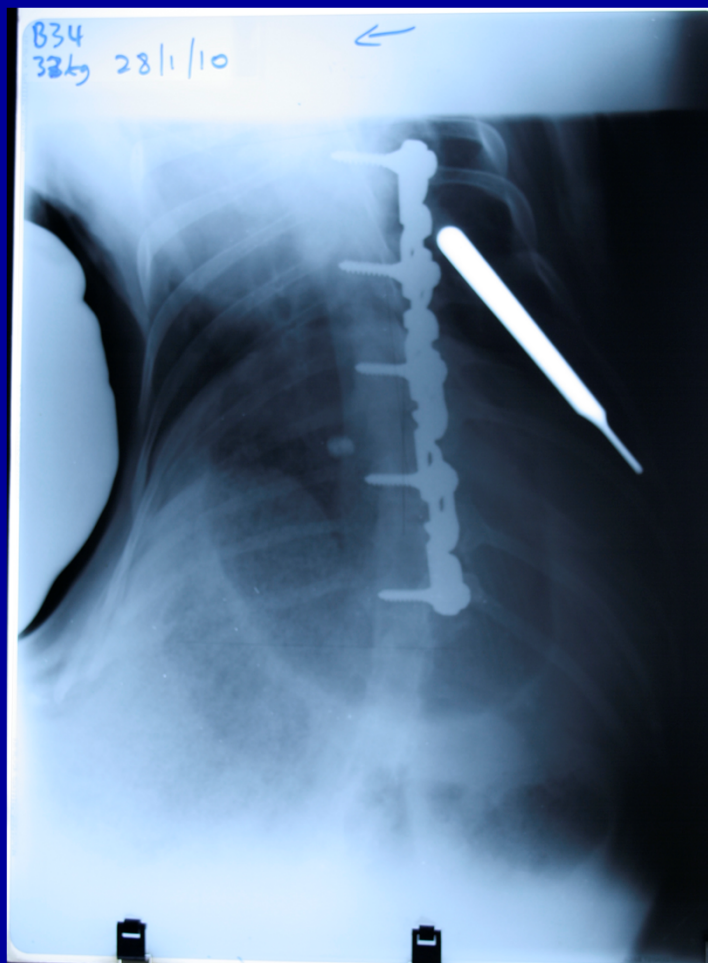
Results: Induction of Scoliosis



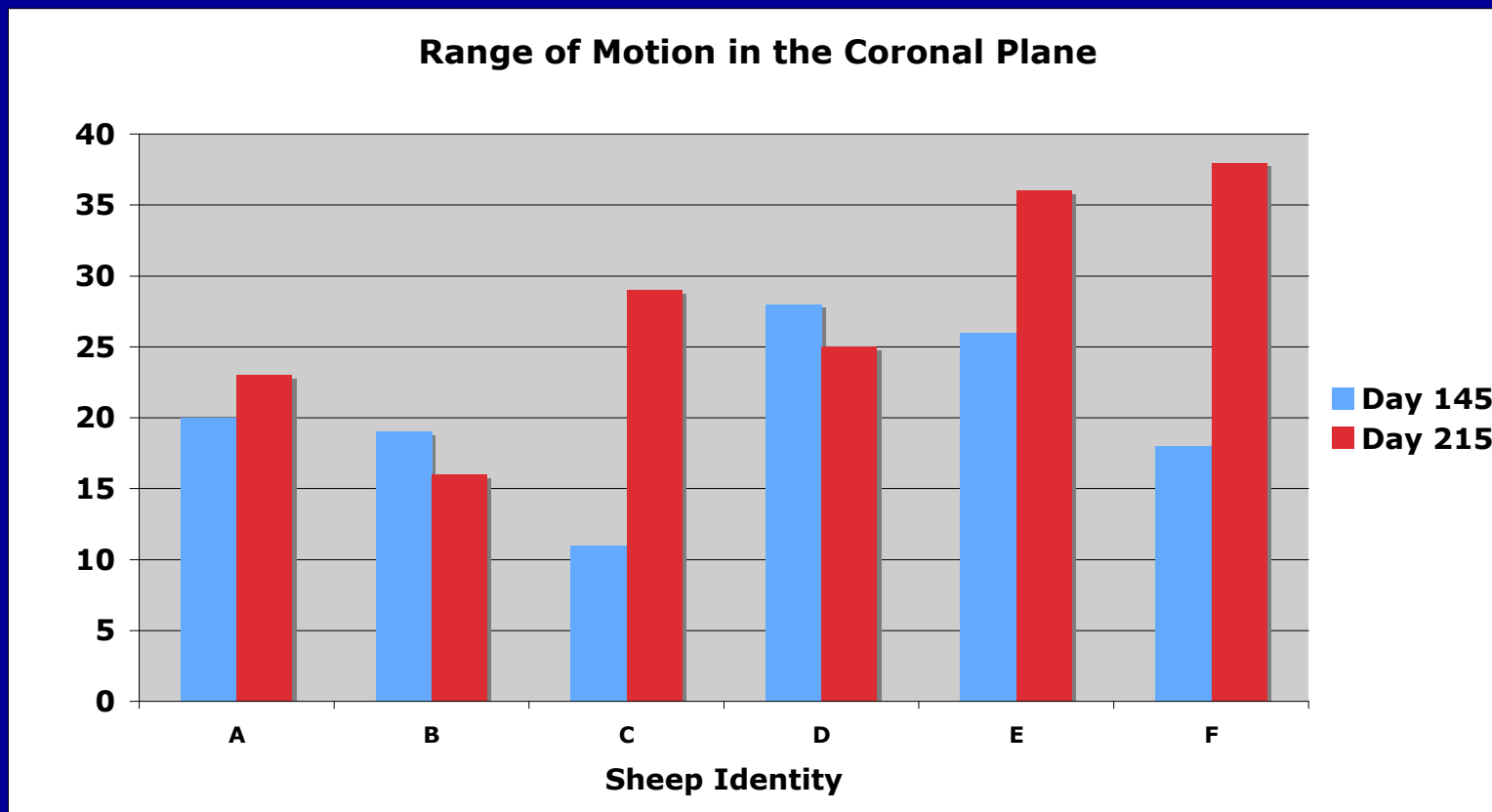
Results: Sagittal plane



Range of Motion: Coronal Plane



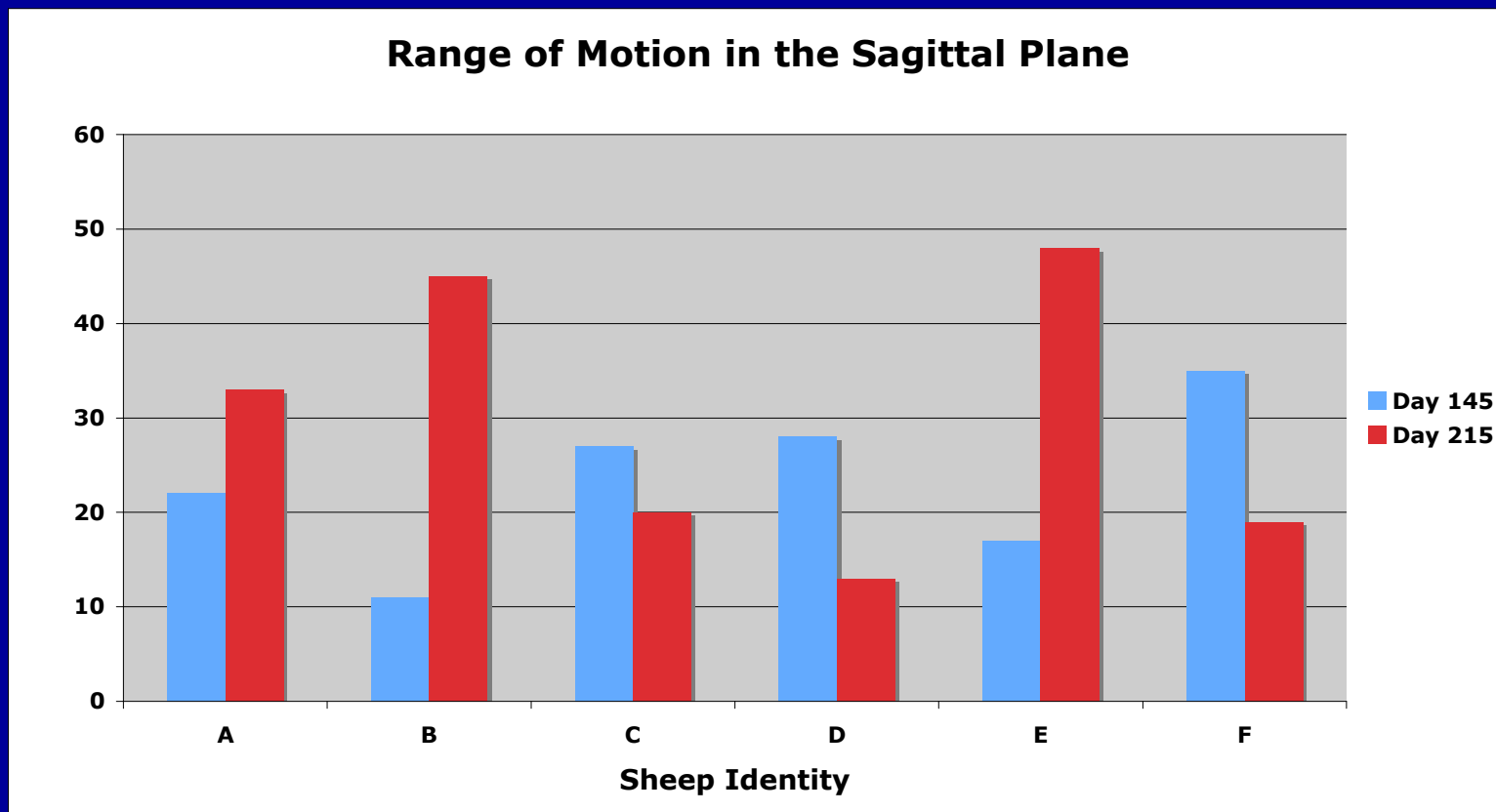
Range of Motion: Coronal Plane



Range of Motion: Sagittal Plane



Range of Motion: Sagittal Plane



Summary

- There were no implant related adverse events and there was no impairment of general health of the animals.
- The implant induced a scoliosis but maintained the sagittal profile as it was designed to do.
- The implant allowed a significant amount of spinal movement as evidenced by stress radiographs in two planes on 2 occasions.

Discussion

- The **Key concept** is the flexible rod which changes shape as growth occurs
- The **Hinge orientation** determines the direction of future growth
- The hinge **sloppiness and orientation** determines the potential range of motion



Thank You



Medical Research Council