Biocompatibility of the Intellirod System in an Ovine Posterior Lumbar Fusion Model

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Statement of Purpose: Spinal fusions are an important treatment for number clinical spinal issues. While plain film radiography and computed tomography provide important qualitative information concerning the progression of healing, they fail to provide direct biomechanical data. Breakthrough technology that can allow in vivo monitoring of the mechanical strain environment of a fusion has enormous clinical and economic implications.

The Intellirod ACCUVISTA™ sensor (Intellirod Spine, Akron, OH) is an implantable strain-sensing device designed to measure changes in spinal rod strain over time which may be an adjunctive method to assess fusion in vivo. The device consists of a titanium clamp and housing unit: hermetically sealed zirconia ceramic and titanium enclosures containing microelectronics and a battery-less, wireless sensor capable of measuring static and dynamic strain that can be recorded telemetrically using a hand-held reader unit. The transponder attaches to commercially available posterior pedicle screw systems using 5.5 mm titanium rods in non-cervical fusion (Figure 1, A). This study evaluated the safety, biocompatibility and in vivo response of the Intellirod™ system following implantation for a large animal adult lumbar posterolateral spinal arthrodesis.

Methods: Seven skeletally mature (3-4years) cross-bred ewes underwent a two level non-consecutive instrumented lumbar fusion at L2-3 and L4-5. The two levels were instrumented bilaterally with polyaxial pedicle screws (4.75mm x 30mm) and solid titanium alloy rods (Ø5.5mm) using standard technique for pedicle preparation and screw placement (Fortex® Pedicle Screw System, X-Spine Systems, Inc., Dayton, OH). The Intellirod ACCUVISTA sensor was attached to one rod at each operative motion segment, centered between the pedicle screws with the device “cap” oriented at approximately 15-20° to the sagittal plane of the spine. The contralateral rod served as an operative control. Morselized corticocancellous autograft harvested bilaterally from the iliac crests (20cc total) and placed in equal amounts into the right and left posterolateral gutters, spanning the intertransverse space. Two animals were allocated to an 8 week pilot trial and subsequently, 5 animals to 16 weeks thereafter. Blood work was performed pre-operatively, 4 weeks post-operatively and the allocated time points.

Wound healing over the implanted sensors was carefully monitored throughout the study. The ACCUVISTA sensor was confirmed to be operational throughout the study by weekly non-invasive measurements as well as at time of harvest. A complete necropsy was performed at the allocated time points. Plain film radiography and micro computed tomography studies were conducted to assess the progression of fusion. The tissue overlying the sensor at each operative level and the contralateral rod was inspected, photographed and harvested (Figure 1, B). Tissues were fixed in formalin and processed for routine H&E paraffin histology was evaluated for local tissue reactions following ISO 10993-6 in a blinded fashion.

The sensors and rods were inspected prior to surgery for any evidence of damage, wear or corrosion using macroscopic images. Following harvest and retrieval, the surfaces of the sensors and rods were re-examined for comparison.

Results: All animals recovered uneventfully following surgery. No evidence of wound breakdown or adverse events related to the surgery or ACCUVISTA sensor was noted. All blood work was normal. Fusions were progressing radiographically in a normal manner as expected. Necrospy revealed normal healing at all surgical sites and normal pathology of the distant organs. The pedicle screws, rods and ACCUVISTA sensor were covered with a thin band of loose adhesions that was easily dissected free.

Comparison of the pre-surgery and harvest images of the sensors and rods showed that all components were intact and free from wear and corrosion.

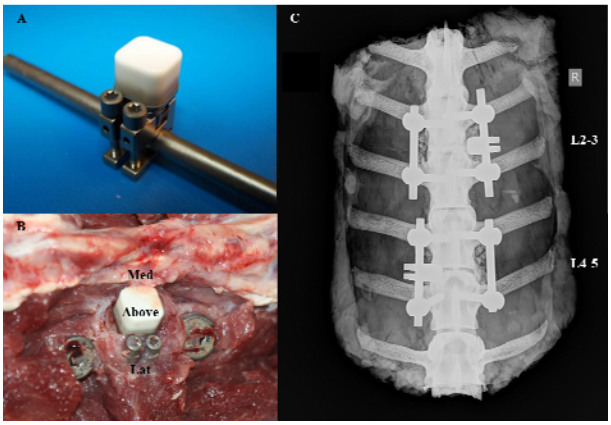

Figure 1:A) ACCUVISTA Sensor; B) In situ at 8 weeks; C) Faxitron X-ray at 8 weeks.

Histological review was uneventful at 8 weeks. The tissue overlying the titanium rods, screws and ACCUVISTA sensor components was similar in all animals at 8 weeks with a fibrous encapsulation. No adverse reactions were noted.

Conclusions: During the term of the 8-week and 16 week trials, we were able to successfully monitor prospective rod strain in vivo without adverse effects to the animals. Upon necropsy at 8 weeks we found loose fibrous encapsulations surrounding the sensor, screws and rods similar to the control levels and without adverse cell propagation. In conclusion we report the successful in vivo use of the Intellirod ACCUVISTA sensor regarding safety, biocompatibility and in vivo response following implantation for a large animal adult lumbar posterolateral spinal arthrodesis.