ABSTRACT INTRODUCTION:
Delayed and nonunion are a prevalent problem in tibial fractures but early diagnosis is difficult, however, treatment options are available if applied in a timely fashion. Internal joint forces and moments have been approximated, however, direct correlation between implant forces and healing status is difficult during stance phase loading due to the uncontrollable forces imposed by the soft tissues. Our research group has investigated the load sharing between a femoral nail and bone in a sheep subjected to off-axial compression (stance phase) loading using a strain gauge positioned close to the fracture site, which produced mixed results [1]. In the current study, a tibial nail has been over-gauged enabling strain measurements to be made during torque and 3 pt bending loadings where patient posture can be more easily controlled. Consequently, the objective of the study was to correlate nail strains with healing status assessed by digital radiography to determine whether smart technology can either replace or augment existing methods for assessment of fracture healing. A successful outcome to the study would enable us to commercially develop human telemetric IM nails which allow fracture healing to be monitored and to identify delayed or non-union patients at an earlier stage.

MATERIALS AND METHODS:
A standard TRIGEN META-NAIL™ 10 mm x 18 cm (ODxL) was instrumented with 6 thin film strain gauges (SMD, UK) enabling 6 degrees of freedom strain measurements to be achieved wirelessly using a customised reader/energizer system. The instrumentation components were embedded in a machined pocket on the outer surface of the implant on the anterior face and protected with a biocompatible grade silicone elastomer encapsulant reinforced with an abrasive resistant over-mould of silicone-polyurethane copolymer. The nail was designed such that it obtained power inductively from a dual coil reader at a frequency of 1.216 MHz. The sheep selected for the study were skeletally mature cross Suffolk approximately 2-3 years old with an average weight of approximately 90 Kg. All animal experiments were carried out according to the policies and principles established by the Animal Scientific Procedures Act, UK. A pilot study, using three sheep aimed at investigating animal welfare with a standard non-instrumented nail, was followed by laboratory testing of the instrumented implant during simulated healing followed by a preliminary study comprised of 12 sheep (6 instrumented and 6 standard nails). A twenty-four week live phase period was chosen for this study enabling healing status and electronics survivorship to be investigated using a novel encapsulation method. During the pilot study, left hind limbs were treated with a reamed tibial nail under general anaesthesia in the dorsal recumbency position using the TRIGEN META-NAIL™ surgical technique. The entry point for all nails was the proximal tibia approximately 1 cm medial to the patellar ligament and lateral eminence. The diaphysis was osteotomized using a 1 mm thick oscillating saw, through a lateral skin incision at a defined distance from the medial malleolus. After conventional insertion, all nails were locked with mediolateral screws, two proximal and two distal, using standard and customized aiming devices respectively. Careful attention was paid to the preservation of the soft tissues to exclude influences on the process of bone-healing and to establish standardized experimental conditions. All wounds were closed in layers using a standard surgical technique and were covered with spray dressing. Finally, anteroposterior and lateral radiographs were acquired immediately postoperatively. All sheep were trained preoperatively to walk over a pressure mat (Tekscan Walkway system, MA, US) to assess weight bearing capacity. Bi-weekly vertical GRF measurements were recorded at a frequency of 46Hz when the sheep placed all four feet entirely on the platform. These measurements were synchronized to the implant strain recording system during normal walking. Bi-weekly implant strain measurements were also acquired during torque and 3pt bending of the operated limb with the animal anaesthetized in the dorsal recumbency position. Digital x-ray images of the healing callus were acquired on a bi-weekly basis. The operated left femur from each animal was excised at the end of the study and submitted for both microCT analysis, mechanical torsion testing and histomorphometric analysis.

RESULTS SECTION:
The initial pilot study indicated that two out of three animals healed within the first 12 weeks with bridging occurring on the posterior an medial cortices, Figure 1. The other animal was diagnosed as delayed based on radiographic imaging. Full weight bearing (defined as comparable ground reaction forces to the pre-operative state) was achieved at week 7, 11 and 12 for animals W300, W301 and W299 respectively (Figure 2). This compared favorably to other researchers [2]. A correlation between implant strain and simulated fracture healing in the laboratory was established for all loading conditions. For example, torque gauges were able to show changes away from the fracture site but could not determine site location, whereas offset axial loading detected site location from multiple gauge sites, but could not detect changes at remote locations from the fracture site if far away from it.

DISCUSSION:
The objective of this study was to correlate nail strains with healing status determined from digital radiography to determine whether smart technology can either replace or augment existing methods of fracture assessment. The combined results of the pilot study and laboratory testing of the instrumented nail suggests that a telemetric strain-measuring nail opens exciting possibilities for monitoring and diagnosing fracture healing. This will investigated in the upcoming preliminary in- vivo study in a sheep.

REFERENCES: