Introduction: Intramedullary (IM) nailing is the standard method of internally stabilizing closed diaphyseal long-bone fractures. Whilst immobilisation and surgery facilitate bone healing, continuous monitoring of changes in the load distribution between the implant and surrounding bone could improve patient outcome. This may be achieved with a strain gauge and a telemetry system. With progression of fracture healing, the load shared between the implant and the bone changes, which can be tracked using a strain gauge positioned within the nail[1]. To test this hypothesis, a telemetric IM nail was developed to measure implant load in an ovine femoral fracture model. The objective of the study was to determine whether the lower plateau of the strain curve predicts fracture healing. A successful outcome of the study would enable us to develop a commercially viable telemetric IM nail to monitor and record fracture healing in human patients.

Materials and Methods: An ovine Ti64 femoral IM nail, 13mmx13cm (ODxL) was instrumented with multiple turns of enamelled copper wire, PCB, and a s/c strain gauge to enable implant strains to be acquired wirelessly using a customised reader system. The sensor was embedded in the mid-shaft section on the anterior surface. Components were embedded in machined pockets on the outer surface of the implant and protected with potting material. The nail was powered and read using wireless technology. The circuitry operates continuously modulating the load and modulation frequency is related to the resistance of the strain gauge. Nails were calibrated between 0 and 200N, a loading regime representative of an intact hind ovine leg. Implant design and surgical technique were based on the S&N Inc. TriGen® nail. Sheep selected were skeletally mature 2-3yrs old with a mean weight of 88Kg. Animal experiments were carried out in accordance with the Animal Scientific Procedures Act. Two pilot studies (n=3) determined the effect of IM nailing on animal welfare. The pivotal study comprised of 8 sheep. 8/8 successful outcomes “lower plateau=healed” would mean that the lower 95% one-sided confidence interval for the proportion will lie at 0.75(p<0.05). A 12wk healing period was chosen since it has been shown that osseous bridging is achieved 8-9 wks[2]. Left hind limbs were treated with standard reamed femoral nails in the lateral recumbency position. The insertion point was the piriformis fossa. The diaphysis was osteotomized using a 1mm oscillating saw, through a lateral skin incision. The osteotomy was positioned using a customised jig attached to a trial implant. After insertion, nails were locked with 2 proximal and 2 distal screws. The second shorter proximal screw was designed to create purchase on the lateral cortex to minimise rotation about the osteotomy. To aid targeting of the distal locking screws, a custom-made distal targeting device was developed. Wounds were closed in layers and covered with spray dressing. A/P and M/L radiographs were acquired postoperatively.

Sheep were trained preoperatively to walk over a pressure mat to assess weight bearing capacity. Weekly vertical GRF measurements were recorded when the sheep placed all feet on the platform. Weekly implant strain measurements were acquired during stance phase. Fluoroscopic images were acquired bi-weekly. The operated femur from each animal was excised at sacrifice and submitted for microCT and histomorphometric analysis.

Results: The initial pilot study data indicated that the vertical GRF measured from the operated limb increased towards the baseline value for the intact femur suggesting that load bearing capacity of the operated limb recovered during the study.

Discussion: The results described above provide evidence to support our hypothesis that implant strain can serve as a predictor of fracture healing following IM nailing. These experimental findings demonstrate the potential of integrating smart technology into trauma fixation devices providing a clinical diagnostic tool for monitoring and diagnosing fracture healing. We envisage that this technology could enable the early detection of delayed/nonunion facilitating more effective care to the patient.


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