COATINGS OSTEOINDUCTIVE EFFECT CALIBRATION IN ASEPTIC LOOSENING SIMULATION OF ANIMAL OSTEOINTEGRATION EXPERIMENT

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Introduction

Cementless stems are becoming more frequent in total hip arthroplasty surgeries. Despite recent progress, aseptic loosening due to incorrect osteointegration is still one of the main causes of failure [1]. With inadequate primary stability, physiological loading induces relative micromotion, and the bone tissue at the interface differentiates into fibrous, causing pain and the need for revision surgery. Long-term implant stability can be improved using an osteoinductive stem coating. The effect of induced micromotion on long-term osteointegration has been investigated in animal models [2]; nevertheless, these tests are invasive and painful and no longer approved by ethics committees. This study aims to develop a Finite Element (FE) model to predict implant osteointegration and partially replace animal experiments. To achieve this, a previous interface remodelling simulation [3] was extended and calibrated using data from animal tests without induced micromotion.

Materials and Methods

Cylindrical titanium alloy implants were inserted in four rabbits' tibiae, which were sacrificed 12 weeks after surgery. Bone-to-implant contact (BIC) percentages at the initial and final time were measured as well as the distances between bone and implant along the pin surface that was not in contact with bone (gap) at time zero. From micro-CT and Rx images, a FE model of the rabbit tibia (E=11 GPa, v=0.3) implanted with titanium pins (E=96 GPa, v=0.36) was generated (Figure 1A). The contact surface was modelled by assigning a different state to each contact element according to the initial configuration obtained from the animal experiment. Boundary conditions were applied to replicate physiological loads during rabbits' running. Based on the results of the simulations, contact elements changed their states according to the finite state machine proposed in the previous study [3], updated with the introduction of a gap threshold value (Figure 1B) to consider that bone has a limited ability to bridge the distance from the implant. Simulations were run until convergence. *In vivo* data (final BIC=53% at 12 weeks) was used to calibrate the model and identify this threshold value. Following the calibration, the model was used to simulate a push-out test and predict the axial load that caused the macroscopic mobilisation of the pin.

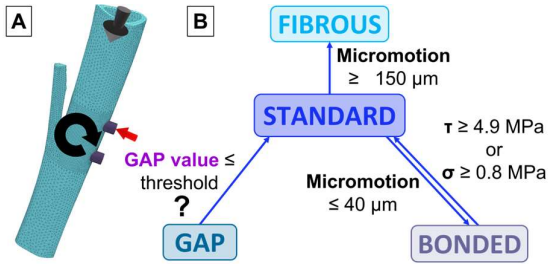

Figure 1: A) Rabbit tibia implanted with titanium pins B) Finite state machine: Standard state represents contact elements not yet osseointegrated. Gap elements have no initial bone-implant contact. Gaps are filled over time unless the gap is larger than a threshold (defined with calibration). With micromotion below a limit [3], standard elements osseointegrate (Bonded). Bone bridges fail if tensions exceed specific values [3]. Tissue differentiates into Fibrous with micro-motion above a limit [3].

Results

The maximum bone-implant gap the bone could bridge in 12 weeks was 80 µm, which reproduced the final experimentally measured BIC (53%). From the push-out test simulation, it was found that a force of 19 N (4.56 MPa) was needed for the macroscopic mobilisation of the pin.

Discussion

The push-out strength predicted was comparable to the one measured in a previous animal study (4 ± 1 MPa), performed with the same pin material coated or uncoated [4]. This modelling framework can be applied to predict improved long-term stability with osteoinductive coatings. Future work will apply this method for predicting the long-term stability of cementless hip stems, where data from animal models inform the human (femur-stem) model. This would represent an important tool for new stem design.

References

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