THE PREVENTION OF LOOSENING IN TOTAL HIP REPLACEMENT USING GUIDED BONE REGENERATION

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INTRODUCTION

The main problem facing the long-term survivorship of total joint replacements is wear particle mediated osteolysis. Friction at the articulating surfaces produces wear particles that migrate to the implant bone interfaces, causing osteolysis with subsequent implant loosening. Preventing the path of the particulate debris to the interfaces would be a method to avoid this bone loss. We propose the use of a semi-occlusive, osteopromotive, prototype expanded polytetrafluoroethylene (e-PTFE) membrane for this purpose. Our aim was to place the membrane to form a physical seal for the interfaces from the joint space. Maxillofacial and periodontal experience demonstrates that membrane placement, with the exclusion of fibrous ingrowth, enhances osteogenesis. In our application this will form a secondary biological seal. We hypothesized that, by the use of this membrane, wear particles generated at the acetabular cup-femoral head articulation, could be prevented from migrating along the implant interface, and hence prevent wear-particle induced osteolysis. This hypothesis was tested in an animal-loosening model.

MATERIALS AND METHODS

Unilateral total hip replacements were performed on twelve female adult goats in accordance with the laws and regulations for scientific procedures in the United Kingdom. All goats were implanted with roughened CoCr modular heads to produce wear particles at an accelerated rate. The goats were randomly divided into test and control groups. Gamma-irradiated UHMWPE acetabular cups and Ti6Al4V femoral stems were cemented into place in both groups. The test group had the e-PTFE membrane occluding the bone-implant interfaces (Figure 1). The control groups did not have the membrane applied.

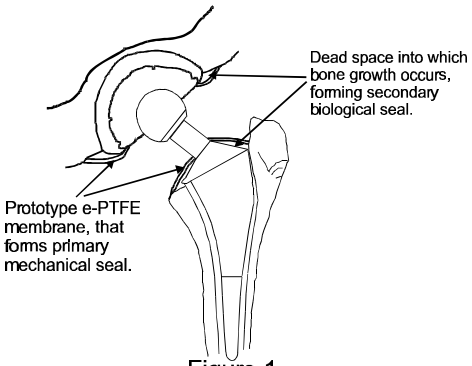

Figure 1

The e-PTFE was attached to the bone surface with the butyl-cyanoacrylate, Histoacryl®. Radiographs were taken at 4, 8 and 12months post-operatively. At 12months post-op, the hip joint, superficial inguinal lymph nodes and a spleen biopsy were retrieved. A sample of the synovial fluid was taken for culture and microscopic examination. Penetration rates of the femoral heads into the acetabular cups were measured with shadowgraphic techniques. The surface parameters were taken across four planes of the retrieved femoral heads. Circular capsule biopsies were taken, incorporating the pseudo-capsule directly around the neck of the prostheses, sectioned and stained with H&E, Oil Red O and Trichrome stains. Polyethylene particles were isolated by acid digestion of separate 20μm thick capsule sections. The particles obtained were characterized by scanning electron microscopy. The proximal femur and acetabulum were then processed by undecalcified histology and impregnated with methacrylate resin. Before grinding the samples, serial radiographs were taken of the sections. Transverse samples from the diaphyseal femur, along the stem, were decalcified and sectioned in paraffin wax. Loosening of the acetabulum was quantified by measuring the thickness of the radiolucent line of the cement-bone interface.

RESULTS

During the 12 month *in situ* period, osteolytic lesions within the acetabulum, first noticeable at 4 months, became larger in the control groups. Osteolytic areas were not observed in the test groups. Radiographs of the thin sections were taken for quantification of acetabular loosening.

Every 5° around the cup the cement/bone distance was measured. This proved to be parametric and was tested with the student's t-test. A significantly larger cement-bone gap was seen in the control group ($p=0.04$). In addition control animals exhibited a scalloped edge to the bone, whereas smoother bone surface was apparent in the test group.

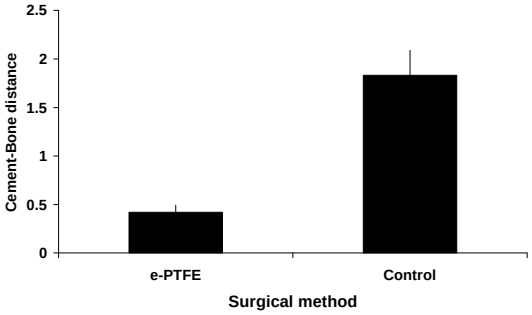

Figure 2

The interfacial tissue in the controls contained particulate debris, whereas the test groups did not. Moreover histology of the capsule demonstrated many swollen macrophages, laden with intracellular polyethylene particles, in both the control and test groups. These particles were similar in size and morphology to those seen in human retrievals, with the characteristic "head and tail" appearance. The femoral head penetration was 0.6mm±0.1 for both groups.

The e-PTFE membranes were well incorporated into the bone surface. New mineralised bone had formed in the dead space between the membrane and bone surfaces. There was also reactive bone formation around the end of the e-PTFE, reinforcing the biological seal. The glue used to attach the membrane had been completely resorbed such that the membrane and bone were in direct contact, as shown below.

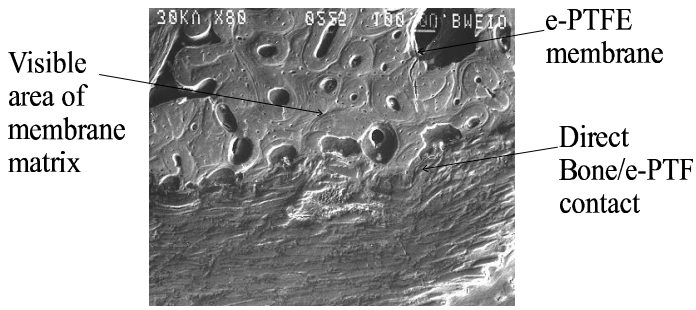

Figure 3

DISCUSSION

The results indicate that in a loosening model we have prevented osteolysis of the cemented acetabular component. The membrane formed a primary mechanical seal. A secondary biological seal, of bone, formed adjacent to the membrane.

Wear particles were excluded from the interface, and osteolysis was prevented.

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