CREEP PROPERTIES OF A BIORESORBABLE POLYMER FOR AN AXIALLY COMPRESSIBLE FRACTURE PLATE

ABSTRACT INTRODUCTION:
The objective of this research was to determine the mechanical and clinical effectiveness of a new internal fracture fixation plate system as compared to a standard dynamic compression (DC) plate. Clinical effectiveness in this case was defined as increased fracture healing during the union phase as well as a decrease in stress shielding during the remodeling phase. Earlier studies showed that a fracture plate design which allowed for increased movement in the axial direction, increased fracture healing significantly when compared to DC plates1. The plates used in this study were designed for canines and could not be used in humans. A university-industry grant from the Canadian Institute of Health Research (CIHR) enabled the development of a prototype fracture plate that incorporated the design features of the previous canine plate and that was suitable for use in humans. The in-vivo results while promising suggested that excess micromotion was occurring due to the premature breakdown of the insert polymer. Additional biomechanical testing was conducted to aid in understanding these results.

METHODS:
Plate Design:
The new Axially Compressible Plate (ACPTM)* has an outer shell fabricated from ProtosulTM 100 with dimensions similar to standard 6-hole DC plates. The ACP incorporates polylactide (PLA) inserts press-fit around the screw holes. These inserts are designed to allow for increased micromotion during the union phase and for gradual degradation over time. Ideally this will increase fracture healing during the union phase and decrease stress shielding during the remodeling phase. As well the design of the ACPTM limits contact between the plate and underlying bone.

In-vivo Pilot Study:
The protocol for these experiments was approved by the University of Ottawa Animal Care Committee. Four mongrel canines (mean weight, 25.4kg) were used in this pilot study. A unilateral osteotomy was performed with an oscillating saw on the mid-shaft of the femur. A 6-hole plate randomly assigned from either the experimental group (n=2) with the ACPTM or the control group (n=2) with standard LC-DCP was fixed on the lateral side of the femur. At 8 weeks, a biopsy was performed on all four pilot canines and tissue overlying the plate was preserved for analysis of foreign body reaction. The preserved tissue was stained with hematoxylin eosin and observed qualitatively under a microscope. At 16 weeks, the pilot canines were euthanized and the state of healing was observed radiologically.

Creep Test:
A custom designed creep fixture was built to allow for creep testing at body temperature with the implant immersed in a phosphate buffered saline solution (PBS). The creep fixture used a dead weight system to apply loads of up to 125N to the insert with displacements being measured with a high precision LVDT (Model 0350-0000 Intertechnology, Scarsdale ON) with a range of +/- 1.27 mm. Both experimental PLA and control polyethylene (PE) inserts were tested in order to measure the creep behavior over time.

Creep Test Results:
Creep test results were conducted on both PLA and PE versions of the ACP insert. The testing was stopped after 24 hours when it became clear that the PLA insert had progressed from primary to tertiary creep (0.20mm) in a 24 hour time period. In contrast, the control insert made from PE was still in the primary creep phase with only 0.01 mm of displacement.

DISCUSSION:
Although a reduction in stress shielding was seen in-vivo with the ACPTM, it was evident that some unknown factor was resulting in excessive motion during the early stages of fracture healing. A custom creep test fixture was designed to allow for the creep measurements to be made in a PBS solution at 37°C. The current PLA polymer exhibited approximately 0.20 mm of displacement after only 24 hours of loading. By comparison a PE insert in the same medium exhibited only 0.01 mm of loading during a comparable time period. Although the ACP is designed to allow an intermediate amount of micromotion, the PLA insert was displacing by 28% of the insert thickness after only 24 hours. This amount of movement could have a detrimental effect on fracture healing as seen in the study by Foux et al1. Further research will focus on selecting a more creep resistant polymer material. This will reduce the amount of micromotion during the union phase and hopefully reduce excessive callus formation. Some callus formation is desirable as bone bridging serves as a clinical assessment of the state of healing of the fracture.

REFERENCES:

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