A Novel Osteostimulatory Resorbable Composite for Orthopaedic Fixation Applications

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Statement of Purpose: Metallic implants for orthopaedic fixation applications are being replaced by absorbable polymers for certain indications to overcome limitations including distortion of MRI and permanence. Polymers also have limitations. They are not osteoconductive and do not integrate with surrounding bone. Furthermore they elicit a foreign-body reaction that manifests as fibrous encapsulation of the implant[1]. As a consequence of this they may have little potential to be replaced by bone following absorption[2]. A significant complication associated in particular with rapidly degrading PGA and its copolymers is autocatalytic degradation. This leads to a localized build up of acid that can result in acidosis, weeping sinus and sterile abscess at the clinical site[3,4].

Composites of bioactive fillers and absorbable polymers have been developed to provide absorbable implants with an improved hard-tissue response and the potential to be replaced by new bone when fully resorbed. Hydroxyapatite (HA) and beta tricalcium phosphate (TCP) are slowly resorbing while calcium sulphate (CS) is rapidly resorbing. It is proposed that incorporation of CS in a bioabsorbable polymer, poly L Lactic Acid (PLLA), will give an 'osteostimulatory' material by virtue of controlled dissolution and release of the bioactive CS component following moisture ingress.

Methods: A composite of PLLA and anhydrous CS was compounded and a range of test samples were injection molded. All samples were sterilized by gamma radiation. A rabbit trans-cortical femoral implantation study was undertaken. Pins, 2mm in diameter, were implanted for a period of 28 days. Fluorochrome labels were administered at 1 and 2 weeks post implantation. Following sacrifice undecalcified sections were prepared for histological examination using fluorescent microscopy.
Test specimens for mechanical characterization were aged in a phosphate buffered saline (PBS) solution at pH=7.4 and 37°C for times up to 12 weeks. Flexural, tensile and compressive strength were measured at up to 12 weeks, which is the time at which significant healing in a bony site would be expected. SEM observations were made of both the surface and the internal microstructure of the specimens at 0 weeks (un-aged), 6 and 12 weeks.

Results: *In vivo:* Figure 1 shows new bone growth at 1 (yellow) and 2 (red) weeks post-implantation, periosteally, endosteally and at the implant/cortical bone interface. This has not been observed in studies where both metallic and polymer pins have been implanted. *In vitro:* SEM images of the outer surface of the screws show a layer of hydroxyapatite, confirmed by FTIR analysis. SEM images of the fracture surface of molded interference screws following 12 weeks of ageing in PBS at 37°C show the retained presence of the CS filler in the bulk of the composite. Following 12 weeks of *in vitro* ageing, there was 34% and 23% loss in flexural and tensile strength respectively and no significant change in compressive strength as shown in the Table below.

Strength MPa	0 wk	6 wk	12 wk
Flexural	98	80	65
Tensile	47	37	36
Compression	65	64	66

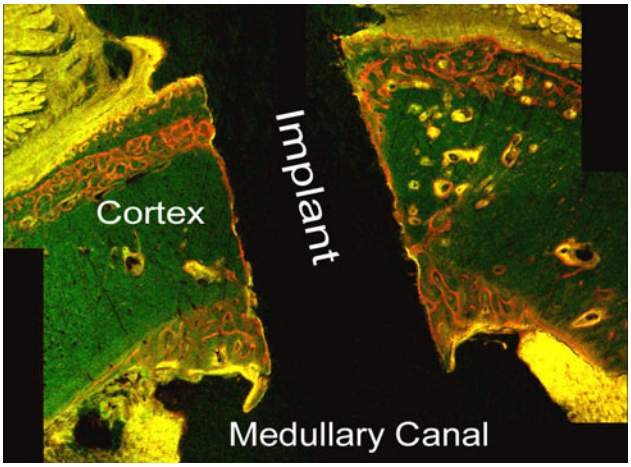

Figure 1. Fluorescent microscopy

Conclusions: New bone stimulation has been shown in a rabbit trans-cortical femoral defect model at early time periods up to 4 weeks implantation. *In vitro* ageing tests have shown good strength retention out to 12 weeks post-implantation. A new bioabsorbable composite has been developed with potential for use in bone and ligament-to-bone fixation devices that may provide early biological fixation.
Future work will assess the long-term degradation characteristics and tissue response of this new composite biomaterial.

References:

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