

Bioresorbable fibre reinforced composites for spinal fusion application: *In vitro* analysis

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INTRODUCTION: Poly(α -hydroxyl acids) have been studied as a material for bioabsorbable spinal fusion devices¹. Their composites with osteoconductive component, hydroxyapatite, have also been studied for the same application². In the current study a novel bioabsorbable composite composed of poly-L/DL-lactide 70/30 (PLA70) matrix containing osteoconductive component β -TCP, with or without poly-L/D-lactide 96/4 (PLA96) fibre reinforcement was studied.

METHODS: Laminar composites composed of 50 wt-% of PLA70 and 50 wt-% of β -TCP (50/50) with or without PLA96 fibre reinforcement were subjected to *in vitro* follow up in phosphate buffer saline (PBS) at 37°C. Compression strength was measured according to standard ISO 604:1993(E). Measurements were made in two directions, parallel and perpendicular to the laminar sheet structures to analyze the anisotropy of the material. Dimensions of test specimens were 10*10*4 mm. PBS was changed fortnightly and pH was checked shortly before change of PBS. Test specimens were gamma sterilized using 25kGy irradiation. Molecular weights were monitored by means of gel permeation chromatography.

RESULTS: Composites of this study demonstrated initial compression strength of 98-125 MPa after gamma-sterilization, depending on composition and direction of sample loading. When measured parallel to laminar structure, the composites retained ca. 50% of their initial compression strength for ca. 20 weeks, whereas in perpendicular direction composites retained ca. 50% of their initial compression strength after 40 weeks incubation in PBS (Fig. 1). No great differences on compression strengths between the fibre reinforced and non reinforced specimens could be measured in both directions analyzed. 38 week incubation decreased molecular weight (Mw) ca. 70% when compared to initial value of gamma-sterilized specimens which was ca. 49000 Da (Fig. 1). pH of the buffer saline remained near 7.4 during the whole follow-up

and there were no great differences between specimens and control solutions (Fig.2).

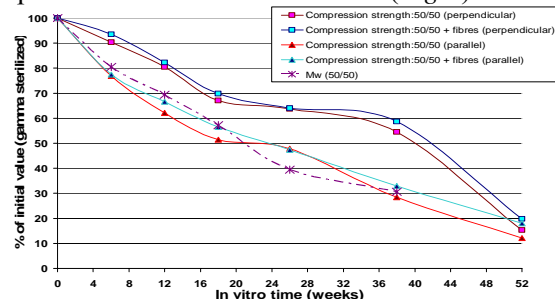


Fig. 1: Percentual compression strength retention and decrease of weight average molecular weight (Mw) *in vitro* (PBS).

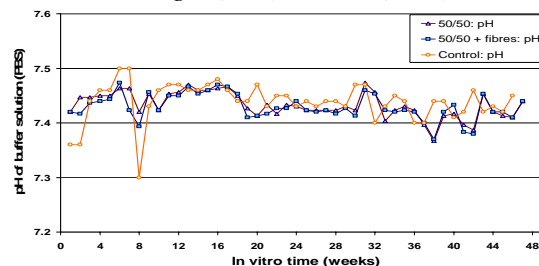


Fig. 1: The pH of the *in vitro* specimens and the control (PBS).

DISCUSSION & CONCLUSIONS:

Compression strength retention *in vitro* followed the decrease of molecular weight and the pH of incubation media remained near 7.4 during the follow-up. Composites demonstrated anisotropic behaviour and they could retain ca. 50% of their initial compression strength for 20-40 weeks. Even after 52 week hydrolysis the weakest composites had compression strength of ca. 12 MPa which is comparable to that of cancellous bone (2-12 MPa³) and healthy intervertebral discs (11 MPa⁴). Therefore the studied composites may have applications as a material of spinal fusion devices.

REFERENCES: ¹A.R. Vaccaro *et al* (2003), *Spine J* 3(3):227-37. ²Y. Shikinami, M. Okuno (2003), *Biomaterials* 24(18):3161-70. ³L.L. Hench and J. Wilson (1993), *An Introduction to Bioceramics*, World Scientific Publishing co. ⁴M. Mathey *et al* (1993), *Biomed Eng-Appl, Basis&Communications* 5(3):18-23

ACKNOWLEDGEMENTS: Research funds from the European Commission (EXPERTISSUES Project NMP3-CT-2004-500283), Technology Development Center in Finland (TEKES) and the Academy of Finland (Center of Excellence 40056/04) are greatly appreciated.