Machining of a Novel Bioactive Fixation Device

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Statement of Purpose: Despite the great advances in the field of orthopedic fixation devices, repair of tissues in load bearing areas without stress shielding and fibrous encapsulation is limited by available materials with proper mechanical properties and biocompatibility. Silica Calcium Phosphate nano-Composite (SCPC) is a bioactive ceramic with engineered resorbability that has been shown to have comparable mechanical properties to human cortical bone[1]. Therefore, it would seem that SCPC is an attractive material for use in orthopedic fixation devices. Unfortunately, ceramics by nature are difficult to process into complex geometries without applying expensive techniques. The objectives of this study were to vary the processing conditions and investigate the machinability of SCPC into screw-type fixation device. Bone cell response to SCPC was compared to medical grade (Ti-6Al-4V) orthopedic implant material.

Methods: SCPC of chemical composition in mol percent 20.3 P_2O_5, 19.5 SiO_2, 40.7 CaO and 19.5 Na_2O was prepared as previously reported[1]. Particle size analysis was performed using the Saturn Digisizer 5200. SCPC cylinders (10mm dia. x 40mm) were prepared using powder metallurgy techniques. Optimization of the processing parameters included: varying pressure application conditions (one vs. two die plungers), compact pressure (30-300MPa), pressure hold time (0-3hrs), die lubrication, sintering temperature (600-900˚C or green) and sintering duration (1-2hrs). Cylinder mechanical properties were evaluated by compression testing using an Instron 3010 at a rate of 2 mm/min. Fracture surface was analyzed by scanning electron microscopy (SEM). Cylinders were machined by manual lathe using high speed steel (HSS) tooling (Fig. 1a) and rated for machinability on a custom scale (1 to 5), with 1 being failure of sample during initial machining and 5 being a sample machined without the presence of surface flaws as seen by profile projection and SEM. SCPC screws were subjected to an additional sintering treatment at 900˚C/1hr following machining. Dimensional shrinkage was measured using a Model TC-14 Optical Comparator and Measuring Machine. To evaluate cellular response, SCPC and Ti-6Al-4V disks were sterilized in 100% ethanol and seeded with $2x10^5$ rat bone marrow stem cells and incubated in tissue culture medium containing 3mM β-Glycerophosphate, 50μg/mL Ascorbic acid and 10^{-8} M Dexamethasone, at 37˚C and 5% CO_2. Cellular response was determined by assessment of alkaline phosphatase (AP) activity after 4 days in culture and mineralization at 4 and 8 days. Statistical analysis was performed using a student's t-test ($p < 0.05$).

Results: Particle size analysis showed a multi-modal distribution of particles with average particle size of 14μm. Cylinders pressed using: two die plungers and stearic acid lubrication at 30MPa, held at pressure for 3 hours, and then sintered at 700˚C/2hrs resulted in a machinability rating of 5 (Fig. 1b and 1c).

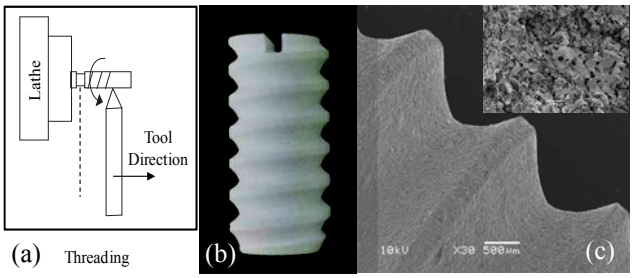

Figure 1. (a) Schematic showing the threading of the SCPC cylinder using manual lath. (b) Digital image of the SCPC screw, (c) SEM analyses of surface of SCPC screw.

SEM analysis of cylinders with a low machinability rating (< 4) showed the presence of an amorphous phase at the grain boundaries while an amorphous phase was not observed for cylinders receiving machinability ratings of 4 and 5. The ultimate strength and modulus of elasticity of SCPC cylinders prepared at (30MPa/3hrs, 700˚C/2hrs) were comparable to human cortical bone[1]. Fracture surface analyses (Fig.1b insert) showed smaller particles filling voids between larger particles enhancing inter particle fracture and machinability. Comparable AP activity of stem cells attached to Ti-6Al-4V and SCPC disks was observed. However, SEM-EDX analysis demonstrated that a mineralized cell matrix was present on SCPC after 8 days in culture. On the other hand, a fibrous (unmineralized) layer was observed on the surface Ti-6Al-4V after the same time period.

Conclusions: SCPC screw-type fixation devices were machined by manual lathe. Presence of an amorphous phase at grain boundaries was found to impede machinability. Modulus and ultimate strength of cylinders indicated no stress shielding effects would be observed when implanted *in vivo*. Moreover, *in vitro* studies showed that the bone cells attached to the SCPC produced mineralized bone-like matrix while those attached to Ti-6Al-4V produced unmineralized fibrous tissue. Results of the study suggest that machinable SCPC has the potential to serve as an attractive new material for orthopedic fixation devices. Future studies include biomechanical and *in vivo* models to determine the overall success of an SCPC fixation device.

References:

[1] Gupta G. J Biomed Mater Res Part B: Appl Biomater. 2007:81B:387-396.