CAGES BASED ON A CARBON-CARBON COMPOSITE

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Abstract: Osteosynthesis of adjacent lumbar vertebral bodies with the use of PLIF cages is a necessary procedure for degenerative spine disease. Intervertebral implants applied at degenerative spine disorders is to replace a resected damaged disc to preserve original space for transplanted bone tissue and thus enable osteosynthesis of neighboring vertebrae. This project is based on the development of implants made of biologically favorable materials, e.g., carbon-carbon composites, to be implanted in the lumbar spine region. Since the carbon-carbon composites exhibit good biocompatibility, stimulate ossification, are transparent for screening and can be made with mechanical properties approximating those of bone tissue, C-C components have been designed for application in the cage structure.

Introduction

Osteosynthesis of the lumbar spine is currently treated by implants of anterior and posterior types. A project developing intervertebral implants based on a carbon-carbon composite was initiated by some extraordinary characteristics of this material. The C/C-composite shows very good bio-tolerance, has a lower modulus of elasticity than titanium and its alloys, is X-ray transparent, and stimulates both tissue and bone to grow well into them. A disadvantage of the C/C-composite, i.e., loosening carbon particles into the neighboring tissue, can be eliminated by impregnating and covering the C/C-composite by a compatible material pHEMA (poly [2-hydroxyethyl methacrylate]). The project aims at applying the C/C-composite with a titanium mantle and without the mantle, to create T+C/C-, and C/C-cages, respectively.

Materials and Methods

The samples used in this study were 2-D C/C-composites based on a plain-woven cloth (Torayca carbon fibers, T 800H, Japan) and UMAFORM LE phenolic resin (SYNPO Ltd., Pardubice, CR) as a matrix precursor. Institute of Rock Structure and Mechanics prepared C-C composite samples in various modifications: a) carbonized; b) carbonized + 3x impregnated; c) carbonized + 1x impregnated + covered with PyC (pyrolytic carbon); carbonized + 1x impregnated + covered with PyC and pHEMA with biopolymer collagen (synthetic polymeric hydrogel utilized for biomedical applications). The cured samples were carbonized at 50°C/hr up to 1000°C in nitrogen. Three-step impregnation with a phenolic resin was used. Subsequently, HTT up to 2200°C in argon was applied. Pyrolytic carbon was deposited from propane in the tumbling bed reactor, at ambient pressure, at the reaction temperature of 850°C. Final values of the open porosity and apparent density of the samples were 6 % and 1.6 g/cm3, respectively. The samples were infiltrated and covered with pHEMA in the autoclave under pressure. Covering composite samples with pHEMA pursues two aims: i) to prevent loosening of the carbon parcels; ii) to stimulate the material growing in the bone tissue.

Prepared samples covered with PyC and pHEMA were tested by the microscopy and image analysis:

Figure 1: Micrograph of the sample surface, magnification 50x

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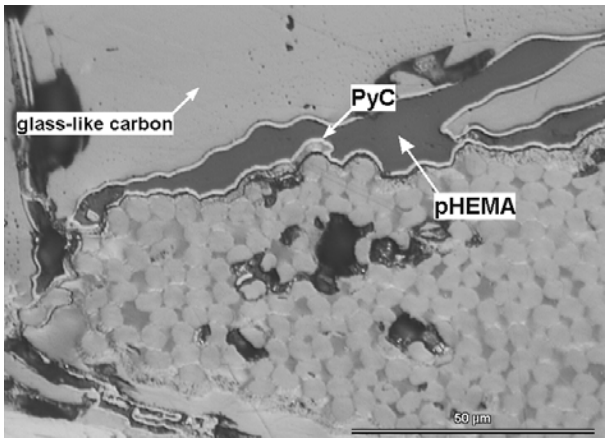

Figure 2: Micrograph to used for measurement of voids, 500x

Pores uninfiltrated with PyC were erased and the area fraction of open voids (pores and cracks) was measured. The same step was used to erase the pores not penetrated with pHEMA; the third area fraction measurement was the last step of image analysis.

Table 1: Image analysis results

	Volume fraction in all composite mass	Respective volume fraction between each measurement step
Voids (pores and cracks)	27.82%	27.82%
Voids infiltrated with PyC	16.28%	58.5%
Voids penetrated with pHEMA	9.28%	57%

Biological characteristics of the samples covered with PyC and pHEMA were tested in vitro and in vivo. In vitro tested biological characteristics – adherence, proliferation and metabolic activity of the cells growing on the samples and levels of inflammatory cytokines in a cell medium – are displayed in Fig.3:

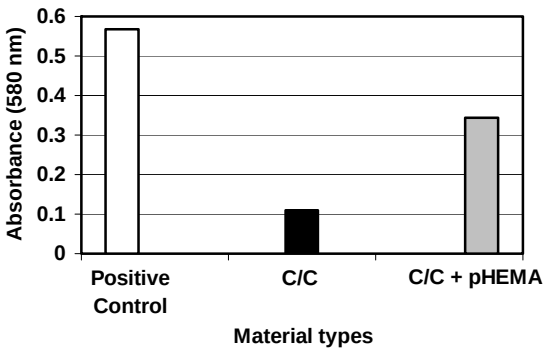

Figure 3: Assessment of the cell metabolic activity

In vivo a quality of the connective tissue in the vicinity of the implants were investigated by means of the histological evaluation. The C-C+PyC+pHEMA samples were implanted into the intercondylar region of the hind leg femur of pigs together with comparative samples of steel, titanium, and C-C composite without covering. After the implants removal, the bone tissue samples were fixed in the Baker solution, dehydrated by alcohol series, decalcified and were put into paraffin and acrylate resin. The acrylate blocks were cut to 0.7 µm thin pieces, colored with hematoxilin -eosin and mounted into Entellan. No inflammation was observed in the vicinity and carbon particles (probably loosened by the mechanical removal of the implant) were found only in traces.

Basic material characteristics of the C-C composite were determined by pressure tests of samples (10x10x1.5 –2 mm) on MTS 858.02 Mini Bionix Testing System. The samples were made by using the following technologies: a) carbonized; b) carbonized + 3x impregnated; c) carbonized + 1x impregnated + covered with PyC. The results are plotted in Fig.4. The b) sample technology could be an acceptable one for further application regarding the material characteristics determined by the tests executed so far. A complex set of the mechanical tests of the C-C composite samples has been carried out to determine elastic material characteristics and limit deformations in the principal directions of the composite structure.

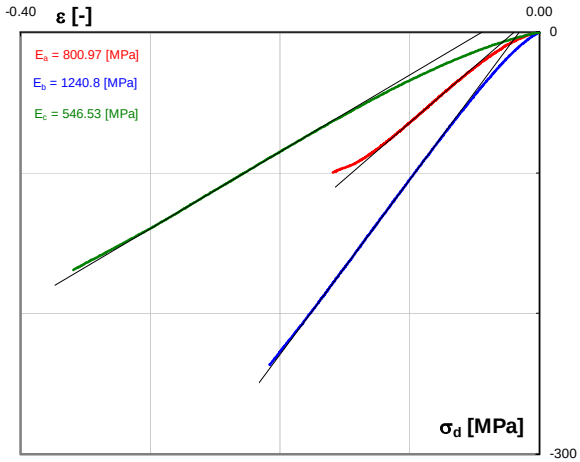

Figure 4: Elastic moduli and limit values of C-C composite samples

Great attention was paid to computer simulations of the stress states in the intervertebral implants and the adjacent vertebrae by means of the finite element method (FEM). In the course of the project a number of computational models were worked on, and these provided valuable information about the stress distribution in implants of various concepts. Gradually, a relatively complicated contact model has been developed, consisting of lumbar vertebrae L3 and L4, a pair of implants of the PLIF type, and a pair of internal

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fixations. This model aims at assessing the stresses not only in the implants themselves but also in the adjacent vertebrae. The problem was analyzed with the use of ABAQUS software, version 5.8-15. The structure of the vertebrae was modeled from C3D8 8-node linear brick elements. The vertebra material was chosen to characterize the bone tissue as well as possible. The thin external layer of the vertebra, made up predominantly of compacta, was treated as isotropic and linearly elastic. On the other hand, the spongy tissue inside the vertebra was modeled as anisotropic, and, besides, its elastic properties change in the direction from the vertebra center to its surface. This relatively complicated definition aims to respect the relation of the elastic modulus of the spongy bone to the trabecular density of the spongiosis. The posterior implants made of C/C-composite considered as orthotropic elastic were composed of C3D8 elements whose local coordinate systems were oriented to take into account the structure of the TORAYCA fabric. The whole model was stabilized by means of B31 structural beam elements of the BEAM type, which model the internal fixations applied in these types of operations. The internal fixations are screwed to the vertebrae by means of pedicle screws which were also modeled by B31 structural elements, but with a different definition of the cross-sectional characteristics. The material of the internal fixations and the pedicle screws was chosen isotropic and linearly elastic in order to correspond to the Ti6Al4V alloy. The whole FEM model comprises 72408 elements, including the contact elements which serve to define the contact surfaces.

Results

A microscopic examination showed that the pHEMA was present not only on the surface of the composite but also in its pores and cracks. The C/C-composite has been tested: i) in vitro (cell proliferation); ii) in vivo (by implanting into the femurs of pigs and by subcutaneous implantation into rats). In vitro tests (for the C-C+PyC+pHEMA samples comparing to uncovered C-C composite) proved the cells grow as a 3D - polymer mesh, which corresponds more to their own in vivo environment, while obtaining more space for proliferation. The cell density is influenced by the quality of a material uniform covering with the pHEMA, and the metabolic activity of the fibroblasts show multiple increase and contain of inflammatory cytokines decreases in the medium. In vivo tests (consisting in implanting samples in the pig hind femur) proved that in the vicinity of C-C composite samples a haematogenous bone tissue occurs in contrast to the titanium. Compared with the uncovered C-C composite, the bone tissue in the vicinity of the C-C+PyC+pHEMA samples contains almost no carbon and the trabecular bone appears to enclose the implant.

The computational FE-models of the implants themselves provided a relatively good idea about the stress distribution and the sites of the maximum stress values in the implant and contact pressures on implant-vertebra interface. The stress distribution obtained by one of the contact models is shown in Fig. 5

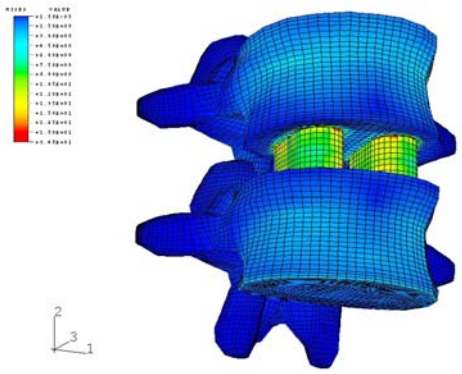

Figure 5: Von Misses stress distribution of a contact model of vertebrae L3-L4 with a pair of C/C-composite implants being vertically loaded.

Discussion

Testing C-C composite to be used in spine surgery consisted in: i) the microscopy and image analysis; ii) bio-tests - in vitro and in vivo; iii) mechanical tests; iv) FEM simulation of the implant stress distribution. In vitro tests (for the pHEMA covered samples comparing to uncovered C-C composite) proved: i) the cells grow as a 3D polymer mesh, which corresponds more to their own in vivo environment, while obtaining more space for proliferation; ii) the cell density is influenced by the quality of a material uniform covering with the pHEMA, and the metabolic activity of the fibroblasts show multiple increase and the contain of inflammatory cytokines decreases in the medium. In vivo tests (consisting in implanting samples in the pig hind femur) proved that in the vicinity of C-C composite samples a haematogenous bone tissue occurs in contrast to the titanium. Compared with the uncovered C-C composite, the bone tissue in the vicinity of the pHEMA covered samples contains almost no carbon and the trabecular bone appears to enclose the implant.

Conclusions

The titanium material shows a worse integration to the tissue than the C-C composite and markedly worse than the pHEMA covered samples. Mechanical compression tests of C-C composite samples, made by various technologies, served for choosing an optimal procedure yielding suitable mechanical characteristics which resulted in the carbonized and 3 times impregnated C-C composite. A decisive conclusion for the C-C composite cage application in the human surgery will be based on a computational simulation of the cages stress distribution when implanted in the human spine. The simulation is based on the FEM models profiting from the correctly determined material characteristics.

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