DESIGN AND MANUFACTURE OF CUSTOMIZED MEDICAL IMPLANTS - THIRD REPORT

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Introduction

Last year, we informed about the progress of our project POIR program 1 / 4.1.4 / 2017 financed by the National Center for Research and Development in Poland. The project concerns the design and manufacture of customized, osseointegrated percutaneous orthopaedic implants, intended for patients who have undergone an above the knee amputation. Such an implant allows load to be transferred directly from the femur to the prosthesis omitting soft tissues, that are usually involved in this process, when using a socket-suspension type prosthesis system. All planned work, both design and research, are currently advanced at around 80%. We plan to complete the project within the next year (2021).

Materials and Methods

Implants were designed using reverse engineering, biomodelling, and CAD software: Geomagic Design X (3D Systems, USA) industry standard reverse engineering software with advanced mesh editing tools; Solidworks (Dessault Systems Solidworks Corporation, USA); Geomagic Freeform (3D Systems,USA) a voxel based biomodelling software package that converts models into virtual clay that can be manipulated much like physical clay. All finite element analyses were performed using ANSYS R19.1 (ANSYS, Inc. Canonsburg PA, USA). The 3D implant project was analyzed from a manufacturing perspective using CAM software (Hypermill, OPEN MIND Technologies AG, Germany) and prototypes were manufactured form titanium alloy using a hybrid CNC milling system (Laser 1300, C.B. Ferrari, Italy). Sterilized implant prototypes were subjected to strength and fatigue tests in order to assess their suitability for long-term use. Microbiological environmental testing was carried out at the site where the implant prototypes were produced, so as to prepare and later implement procedures that would lead to a reduction of microbiological contamination. Implant prototypes were sterilized with using hot dry air method. Sterility of implant prototypes was checked by microbiological tests.

Thrombo-compatibility was assessed using scanning electron microscopy and flow cytometry tests, cytotoxicity was assessed by XTT test, and genotoxicity was assessed by micronucleus test. The carcinogenic potential of the materials intended for the manufacture of the implants was also evaluated. For this purpose, qRT-PCR technology was used to analyse the expression of selected genes involved in cancer processes. Primary and tumour lines of osteoblasts and chondrocytes were examined.

Results and Discussion

The production site where the implant prototypes were manufactured was subjected to microbiological control and the presence of a significant number of microorganisms was shown, both in the air and on work surfaces. Furthermore, particularly high concentrations of microorganisms were found in the cooling lubricants used in the CNC milling systems. Washing of the CNC machinery, coolant replacement and an improvement of sanitary procedures carried out by personnel resulted in a reduction of the number of microorganisms to an acceptable level. Using commercially available engineering programs, we successively designed 19 different versions of the implant prototype, that was fitted to the anatomical structures of an amputated femur. Subsequent versions took into account both feedback form the orthopaedic surgeons as well as the results of numerical analysis by the finite element method. The latest version of the prototype, following evaluation of microbial pollution and sterilization, was subjected to strength and fatigue testing. The fatigue testing results obtained to date have not been satisfactory, therefore several necessary changes will have to be introduced into the implant design. The hot dry air sterilization procedure proved to be efficient and very effective. We are currently awaiting the sterility results of the product after a shelf life of 3 and 6 months. Tests for thrombo-compatibility as well as cyto and genotoxicity evaluation of the materials, that will be used in the manufacture of the final medical devices, have been completed. None of the materials, nor any of the surface-modified samples, showed any adverse effects due to cyto and genotoxicity or due to thrombogenicity. The results of qRT-PCR analysis of the expression of selected genes involved in cancer processes are currently under analysis.
The clinical team has prepared a detailed surgical procedure that will be used to implant the devices. Whilst, the patient recruitment process to find suitable candidates for this procedure has commenced.

Conclusions

Despite numerous difficulties encountered during the implementation of the project the level of progress has been satisfactory and it will be possible to start work, in the nearest future, on personalized implants for specific patients. Next year, we should have the initial results of the first implemented procedures.

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