DESIGN AND MANUFACTURE OF CUSTOMIZED MEDICAL IMPLANTS - CONTINUED

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Introduction

Last year, we reported the commencement of work under the POIR programme 1/4.1.4/2017 financed by the Polish National Center for Research and Development. The project concerns design and manufacture of customized, osseointegrated percutaneous orthopaedic implants, intended for people after amputation of the leg above the knee. Such an implant allows the load to be transferred directly from the femur to the prosthesis omitting soft tissues usually involved in this process when using a socket-suspension type prosthesis system. In the area of design work, our project is currently advanced in about 70%.

Materials and Methods

Implants were design 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) one of the leading software applications used for mechanical design; 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 project of prototype implant was analyzed from a manufacturing perspective using CAM software (Hypermill, OPEN MIND Technologies AG, Germany) and CNC milling was performed with the use of hybrid milling system (Laser 1300, C.B. Ferrari, Italy). Implant prototypes were sterilized with hot dry air. 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.

Results and Discussion

Using commercially available engineering programs, we made 19 subsequent versions of the implant prototype fitted to the anatomical structures of the patient's amputated bone. Subsequent versions took into account both orthopaedic remarks and the results of numerical analysis by the finite element method. The last version of the prototype, made in a series of 10 copies, after evaluation of microbial pollution and sterilization, is currently undergoing strength and fatigue tests.

At the same time, tests of thrombo-compatibility as well as cytotoxicity and genotoxicity of materials planned for use in the manufacture of the final medical devices are carried out, taking into account their surface modification made in order to achieve effective integration with bone tissue and limiting the development of microorganisms in the place of contact and penetration of soft tissues.

Conclusions

To date, we have not encountered insurmountable difficulties and we are approaching the moment when we prepare implants for patients currently selected for clinical procedures.

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