DESIGN AND MANUFACTURE OF CUSTOMIZED MEDICAL IMPLANTS - FINAL REPORT

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[Engineering of Biomaterials 163 (2021) 24]

Introduction
In recent years, we reported herein about the progress of our project Program POIR 1/4.1.4/2017 financed by the National Center for Research and Development in Poland (NCBiR). The project concerned the design and manufacture of patient specific osseointegrated transcutaneous orthopaedic implants, intended for patients who have undergone an above the knee amputation. Such implants are implanted into the medullary cavity of a long bone and connected directly to an external prosthesis. As a result, loads can be transferred directly from the femoral stump to knee prosthesis and not through the soft tissues of the amputated limb, which is the case when using a socket-suspension type prosthesis system. A significant part of the planned research was carried out in line with the project schedule. However due to various reasons, at the end of 2020 the consortium was forced to make the decision to prematurely terminate the project. As a result of this the project did not enter the clinical stage. It is currently being evaluated by the NCBiR.

Materials and Methods
Implants were designed using reverse engineering, biomodelling and CAD software described in previous reports. Finite element analyses were performed for all of the implant prototypes and its connector. Prototypes were then 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. The sterilization technique used was the hot dry air method. Implant sterility was evaluated using microbiological tests. Thrombocompatibility was assessed using scanning electron microscopy and flow cytometry tests. Cytotoxicity was assessed by XTT test and genotoxicity by micronucleus test. The carcinogenic potential of the materials intended for the manufacture of the implants were also evaluated. For this purpose, qRT-PCR technology was used to analyse the expression of selected genes known to be involved in neoplastic processes. Additionally, cells were tested for proliferation potential, level of apoptosis and intensity of the DNA damage/repair process. The cells examined were primary and tumour osteoblast and chondrocyte lines.

Results and Discussion
Last year, we reported that the initial implant prototypes failed fatigue testing. The results of these tests were taken into account and several design changes to the implants were made. These new protypes were also manufactured from titanium alloy and consequently underwent fatigue testing. This time the protypes completed the entire fatigue testing procedure successfully.
The results of the work carried out, including sterilization validation, biological studies, implant design and in particular fatigue testing made it possible to initiate the final, clinical stage of the project. Although the clinical team prepared procedures for the surgical implantation process and had started recruiting patients to participate in the study, as mentioned above the project had to be terminated before any surgical procedures were performed.

Conclusions
A significant proportion of the project has been successfully completed with implant prototypes designed, tested and validated to the point where they could be applied clinically. Unfortunately, due to various factors including the ongoing COVID-19 pandemic and its significant impact on the health care system as well as the economy, the project had to be terminated before the clinical stage could be completed.

Acknowledgments
The project is financed by the National Center for Research and Development in accordance with the contract POIR.04.01.04-00-0058/17-00.