DESIGN AND MANUFACTURE OF CUSTOMIZED MEDICAL IMPLANTS

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Introduction

In the years 2006-2010 research on the subject of custom medical implants was carried out at the Department of Biophysics, Institute of Materials Science, Lodz University of Technology. The aim of this work was to assess the possible advantages of custom implants and whether their use was clinically justifiable. The study was carried out as a PhD programme and resulted in the clinical application of custom orbital implants. The results of this research were later commercialized in the form of a newly created Custom Medical Implants Unit that was established in 2011 at Bionanopark Ltd. To date, as a result of this research, over one hundred custom maxilla-facial and cranial implants have been designed, produced and clinically implemented (orbital wall reconstruction, cranioplasty, mandibular reconstruction). Each year, over 20,000 leg amputations are carried out in Poland as a consequence of different clinical conditions. These patients later require a limb prosthesis and physiotherapy in order to regain mobility. The standard prosthetic device that is commonly used to treat such patients, is the socket-suspension type prosthesis system, which unfortunately transfers loads through the soft tissues of the limb stump. However, there is an alternative method of treatment, which involves the use of osseointegrated implants that facilitate direct skeletal attachment of a prosthesis [1,2]. On the basis of the available data, we recognized a significant need for custom designed, osseointegrated percutaneous orthopaedic implants, which at present are not generally available. In our opinion the design and manufacture of such prostheses is worthwhile and should be developed into a clinically viable medical device.

Materials and Methods

The design stage must take into consideration such aspects as conforming these bespoke implants to individual and unique patient anatomy, implant mechanical strength analysis and its integration with bone tissue and selection of an appropriate biomaterial as well as a structural analysis of its surface. On the other hand, the manufacturing process must take into account additive techniques (3D printing), subtractive methods (CNC milling) and hybrid technologies, which can be used to make precise, controlled implant surface modifications. In addition to this, validation of different sterilization methods for such products as well as post-sterilization structural analysis, biocompatibility and thrombocompatiblity must be evaluated.

Results and Discussion

The above concept of designing and manufacturing osseointegrated percutaneous implants formed the basis of a project that was prepared by the authors and subsequently positively evaluated in the POIR programme 1/4.1.4/2017 and accepted for funding by the National Center for Research and Development.
The project consists of the following seven stages - implant design and biomaterial selection, implant mechanical strength assessment and integration with bone tissue (both theoretical and experimental approach), implant manufacture (including surface modification), validation of implant sterilization techniques and post sterilization biological evaluation (biocompatibility, thrombocompatibility and induction of neoplasia or tumor recurrence) and most importantly implant clinical application. The project will be implemented by four units within Lodz University of Technology (the project leader), Bionanopark Ltd, PAFANA SA and Medical University of Lodz and will last for 36 months starting from June 2018.

Conclusions

Finally, the developed methodology for designing and manufacturing such custom orthopaedic implants, will be implemented and commercialized by Bionanopark Ltd. In the initial phase implants will be available for clinical applications in Poland and later on foreign markets, also.
In the following years we will inform you about the progress of our work and implementation of the project.

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