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# FABIO PROJECT: DEVELOPMENT OF INNOVATIVE CUSTOMIZED MEDICAL DEVICES THROUGH NEW BIOMATERIALS AND ADDITIVE MANUFACTURING TECHNOLOGIES

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***Abstract:*** *A goal in clinical practice is the total adaptation and personalization of medical devices to the special needs of the patient. Customization will be the best way to satisfy higher levels of quality, functionality, safety and biocompatibility during surgical treatment. Additive manufacturing technologies become the best alternative to produce customized medical devices. The FABIO project was proposed to develop new biomaterials and to adapt additive manufacturing technologies to obtain a new generation of customized medical devices. Four customized prototypes were designed, additively manufactured and validated within the project. Results have enabled the marketing of customized medical devices with high added value, great competitiveness and good levels of quality, functionality, safety and biocompatibility, in order to increase the satisfaction of the patient.*
***Key words:*** *Biocompatibility, Additive Manufacturing, Prosthesis, Customized medical devices*

## 1. INTRODUCTION

In the short term, current clinical vision involves a progressive incorporation, in the surgical and rehabilitation treatments, of medical devices adapted and customized to the patients. Nowadays patients demand higher levels of quality, functionality and safety in the treatments. These targets must be achieved without biocompatibility problems. The best way to successfully reach these requirements is by means of the complete personalization of medical devices. However, a medical tailor-made device manufactured by means traditional techniques can imply economic and time costs that are impossible to assume by industry. For that reason the new additive manufacturing technologies constitute the best alternative for obtaining this class of products.

Additive Manufacturing is the name given to all technologies which can provide the direct production of pieces or final products. A whole 3D part is obtained by means of the addition of material layer by layer, from 3D CAD files. The main advantage of this kind of technologies is the freedom to design and build in one stage and without tools (molds, etc.) pieces or end items with complex designs. In many cases, they are unique manufacture solutions (lattice structures). In addition, they constitute an economic alternative against other manufacturing techniques, like injection molding or CNC milling, for manufacturing small series of products with complex geometry, as is the case with customized products.

Additive Manufacturing Technologies have enabled the development of successful totally-functional customized products with applications in many industrial sectors. Nevertheless, the materials' biocompatible properties are a must in the biomedical sector, specially with implants. Therefore, it limits the medical applications scope of the present Additive Manufacturing Technologies.

Currently, few compatible biomaterials – processed by additive manufacturing technologies – are allowed for the development of customized medical devices for patients, that also satisfy the quality, functionality, safety and biocompatibility requirements.

Additionally, in those cases in which the material can be processed, the cost of product certification – a required step before putting it in the market – always force us to think about large series of products to compensate this cost.

In this context, the FABIO project was proposed with the goal to demonstrate the capacity to develop and to apply new biomaterials and additive manufacturing technologies for obtaining an innovating customized medical devices generation. For this reason, three broad, differentiated and interrelated lines of research were undertaken: (i) identification and generation of metallic and polymeric biomaterials that could be processed by means of additive technologies; (ii) adaptation of the present additive technologies to process the generated biomaterials; and, (iii) development of the design methodology for a new customized medical devices generation.

## 2. DEVELOPMENT

The work-plan of the FABIO project was structured in the following phases, with interdependence relations as shown in Figure 1.

Four customized medical devices were selected and developed to show that the target was reached. Such examples consisted of (see Figure 2) socket for transtibial amputee, ankle-foot orthesis for correction of articular rigidity, bony substitute for mandibular defect of critical size and femoral stem for hip prosthesis.

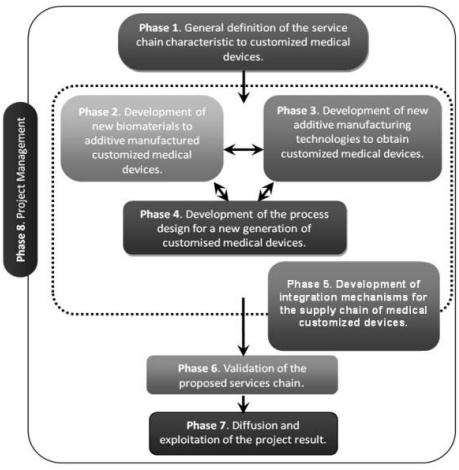

Fig. 1. The work-plan of the FABIO project

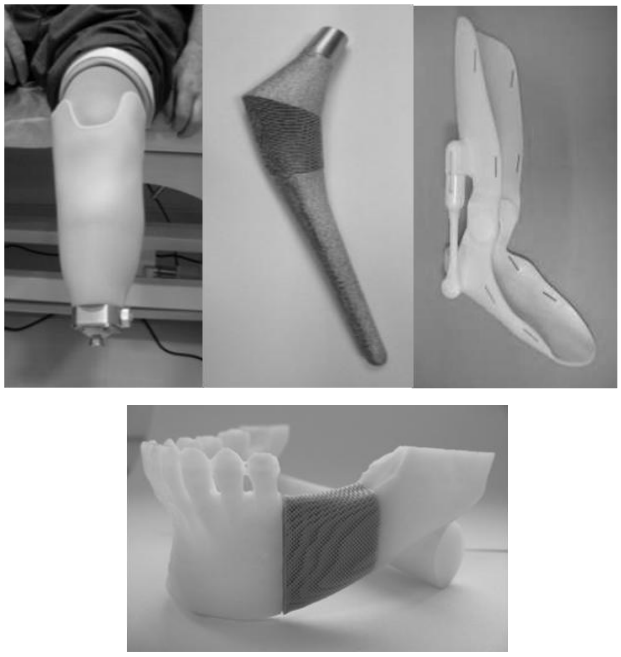

Fig. 2. Protoptypes developed in the FABIO project. From left to right: transtibial socket, femoral stem of a hip prosthesis and Anckel-Foot Orthesis. Mandibular bone substitute

The development processes of the transtibial socket (external medical device of polymeric material) and of the femoral stem of a hip (implantable medical device of metallic material) are described in the following paragraph.

The transtibial socket is the fundamental part of the prosthesis for an amputee of the inferior member at the transtibial level. It has to provide the faying surface and transfers the corporal weight from the stump to the prosthesis. The development processes of the customized socket for a transtibial amputee (Figure 2) began with the data acquisition by means of the manual three-dimensional optical scanning of the patient. Computer Assisted Design Software (3D CAD) was employed for the digitization of the patient's stump geometry. The design of the socket was defined by optimal fitting of load transmission between the socket and the stump. Analytic evaluation of the design was performed at a later stage with finite element models. The transtibial socket CAD design file was used to directly build a part with polymeric resin at the stereolithography (SLA) facilities at AIMME. The product was put under static mechanical tests and under cyclic loading according to Spanish Standard UNE-EN ISO 10328:2007, and passed the test successfully. The product was evaluated by medical personnel and by the final patient to check for correct adjustment and function during its use.

The femoral stem is the hip prosthesis element that replaces the head of the femur. Customized development of a femoral stem for a hip prosthesis (Figure 2) was carried out from a CAT-scan (Computed Axial Tomography) of the patient's leg. Specific image treatment software was used to segment the femur. Once segmented, the data were imported to a CAD software in order to carry out the design of the hip prosthesis. The femoral stem geometry was made to agree, as far as possible, with the femoral channel of the patient. An interconnected porous region was designed with the aid of the computer to enable the proper growth of bone towards the interior region of the femoral stem in order to hold the implant in its place and increase its stability. As with the transtibial socket, analytic evaluation of the design was performed before the product was manufactured with finite element models. The femoral piston rod CAD design file was used to directly build a part with implantable titanium alloy at the Electron Beam Melting (EBM) facilities at AIMME. The femoral stem was put under mechanical tests according to International Standard ISO 7206-4: 2002 with satisfactory results, allowing the product to withstand normal mechanical operation once it is implanted.

## 3. CONCLUSION

The goal of the FABIO project was to obtain a new customized medical devices generation that can be made with economic and time costs that can be assumed by industry. These products will allow an improvement in welfare, fewer annoyances, a reduction in rehabilitation duration, lower probability of the need for a second surgical intervention and an increase in the patient's quality of life.

The four prototypes developed within the framework of the project fulfill the requirements of quality, safety, functionality and biocompatibility for customized medical devices which is a required step before putting it in the market. Additionally, it has been able to increase the supply of biomaterials, manufacturing technologies and highly competitive customized medical devices by his high added value. Everything is put at the disposal of industry through an integrated service and support chain by means of a collaborative platform. The services generated in the FABIO project could also be used in the future by other industrial sectors that require product personalization.

## 4. ACKNOWLEDGEMENTS

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