format using the website and a quick viewer so that doctors can validate implant customization in 3D on the website.

In addition, a significant effort was made to ensure the mechanical properties of the implants after they had been customized and manufactured into the service. For this, a series of analyses was conducted using the finite element method (FEM), which enabled the mechanical properties of any adjustments made to the implants to be studied. The results of these analyses were then validated using mechanical tests, including testing the fatigue behavior of a femoral stem made by EBM that had undergone all post-processes, including sterilization.

Femoral stem for modular hip prosthesis manufactured with a medical-grade titanium alloy (Ti4Al4V ELI) as a finished product, packaged in a double blister pack and sterilized.

Service provided by:

MIPESA SURGICAL MACHINING is a contract machining company, working under UNE EN ISO13485 Standard and under LEAN Manufacturing Directives, in order to provide you the best quality at a reasonable cost.

We are focused in instruments and prosthesis mechanisation for othopaedic and traumatology surgery.

Furthermore, we offer individual collaboration, just to become the partner you need.High performance machines as Multitasking Turning Centers and 5 Axis Machining Centers allow us to attend high complexity parts like prosthesis components and surgical instruments.

Phone: +34 962 540 404 / customer@surgicalmachining.eu

mipesa SURGICAL MACHINING

Technology Partner

Instituto de Biomecánica (IBV) is a Research and Technological Organization (RTO) that studies the behavior of the human body and its interaction with products, environments and services.

IBV combines knowledge related to anthropometry, interfaces design, biomechanical evaluation and promotion of health and it applies them to very diverse areas with the aim to improve the competitiveness of companies and industrial sectors by addressing people's quality of life.

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IBV INSTITUTO DE BIOMECÁNICA DE VALENCIA

Design and manufacturing service for custom implants based on additive manufacturing technologies

Introduction

Today, medical practice requires implants that are better customized to individual patients. As such, expectations of 3D printing are growing, and it is increasingly common to see news about important clinical advances made thanks to this new technology.

The production flexibility that additive manufacturing brings compared with traditional methods (such as machining parts from forging or casting) seems likely to lend itself to these technologies. In addition, customized implants allow clinics and hospitals to reduce the volume of products in storage and avoid having to keep all different sizes of implants on hand.

Service objetive

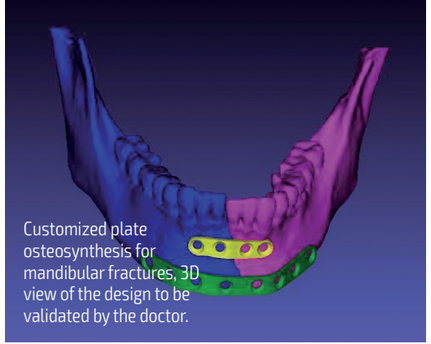
Design and manufacturing service for custom implants based on additive manufacturing technologies. The service has helped integrate and automate the processes that support the design and supply of custom implants produced by additive manufacturing technologies.

The service includes:

- The custom design of the implant or a short series.
- The subsequent rapid manufacturing through additive manufacturing technologies (EBM) in titanium alloy.
- Manufacturing specific instruments for surgery.
- The surgical intervention planning by manufacturing prototypes and bones in polymeric material.

These designs take advantage of additive manufacturing technologies, Selective Laser Sintering (SLS) or Electron Beam Melting (EBM).

SLS manufacturing machine of polymeric prototypes



Customized plate osteosynthesis for mandibular fractures, 3D view of the design to be validated by the doctor.

Service methodology

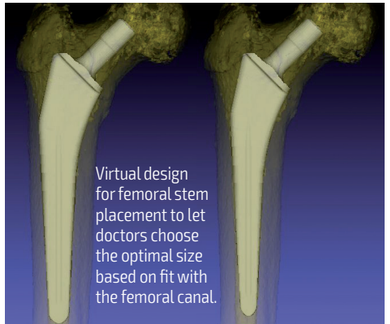
Customizing implants

The design will be made into a protocol to provide a quick response with an implant fully customized to the patient's body. Highly specialized tools such as Mimics® Innovation Suite by Materialise has been introduced for this purpose. This latest methodology has been used, for instance, to obtain customized plate osteosynthesis for mandibular fractures in the field of craniomaxillofacial surgery.

Manufacturing technology

Additive manufacturing by electron beam melting (EBM), the primary manufacturing technology for implants for trauma surgery, has become the best option. It allows custom manufacturing to be done profitably, with acceptable delivery deadlines and a quality equal to that of current implants. EBM also allows for using the same materials that are currently used for the vast majority of implants in the industry (medical-grade metals like titanium alloys and cobalt–chrome alloys).

In addition, to ensure a speedy response and the economic viability of EBM production, serial manufacture of certain volumes of implants using these technologies has been considered. The service allow companies to manufacture small series of **non usual sizes**.



Virtual design for femoral stem placement to let doctors choose the optimal size based on fit with the femoral canal.

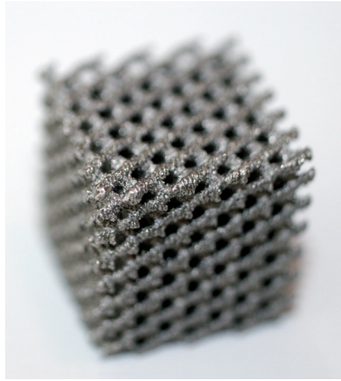
Supply chain

A significant effort has been made to detail the new supply chain that these custom implants will follow, thus completely defining the procedures and processes involved, including certification of additive manufacturing facilities. This supply chain comprises all the phases, from sending patients' medical imaging, measuring and model customization through to manufacture, sterile packaging and delivery of the finished product to specialists.

Here, manufacturers pinpointed a significant competitive advantage. The rapid supply, short production runs and one-off pieces offered by additive manufacturing represent major advantages compared with traditional processes such as forging, a process usually outsourced that requires ordering a large number of units with lengthy delivery periods. The company's production capacity can therefore be maintained, considerably reducing fixed costs and making supply planning much more flexible.

Online platform

The service has an online platform that encompasses and streamlines the processes for customizing and manufacturing the personalized implants in the project. To support these processes, which involve different organizations (hospitals, designers, additive manufacturing producers and manufacturers of the finished implants), a telematic platform has been created that lets all those involved in the supply chain communicate with one another.



The modules required for integrating the specialized tools used in customization were implemented in this platform: Solidworks®, Mimics® Innovation Suite and Ansys®. Of particular importance was the creation of a module that incorporates medical imaging in DICON