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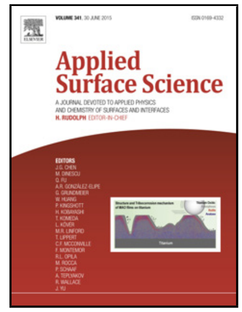

Title: Personalized Hip Implants Manufacturing and Testing

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<AT>Personalized Hip Implants Manufacturing and Testing

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<ABS-HEAD>Highlights► Personalized implants with fenestrated design were made for mechanical testing. ► Fenestrations reproduce trabecular structure of natural bone structure. ► Static tests revealed an elastic behavior compared to a commercial implant. ► Endurance limit was determined by realization of dynamic tests. ► Both fenestrated models can be safely used in the medical practice.

<ABS-HEAD>Abstract

<ABS-P>Two models of Ti6Al4V personalized femoral stems for hip replacement have been designed and laser sintered with different sizes of fenestrated architecture that mimics the natural structure of bone, ensuring postoperative bone ingrowth and increasing the elasticity of the entire structure. They were tested statically and dynamically versus a commercial femoral stem. Mechanical tests were performed in order to determine the fatigue limit using the Locati method. The tests were conducted in a thermostatic bath (37°±1°) with the implants immersed in distilled water salted solution 0.91%. For probe embedment poly-methyl methacrylate (PMMA) was used.

<ABS-P>The characteristic curves of the two personalized fenestrated implants reveal an elastic behaviour by their nonlinear appearance. After dynamic tests an inverse relationship between displacements obtained in the static tests and the fatigue limit was observed. Large fenestrations conferred the desired elasticity to the implant, but contributed to a life service reduction.

<ABS-P>The fatigue limit for both implants was much above the minimum value specified by ISO 7602: 2010, so both models can be safely used in the medical practice, leading to increased life service of implants.

<KWD>Keywords: 3D laser sintering; personalized implant; mechanical rigidity; fatigue limit.

<H1>1. Introduction

Experimental studies [1,2], have shown that in total hip arthroplasty, adaptation of geometric shape of the uncemented implant stem to the inner contour of the cortical bone of the proximal femur is essential for optimizing load takeover and for a better mechanical stability. Taking into account these studies and also the characteristic trabecular structure of the proximal end of the femur and using the idea to reproduce (at a macroscopic scale) this natural bone structure [3], two models of customized femoral stems for hip replacements were designed. These models had a fenestrated architecture that mimics the natural bone structure, providing postoperative bone ingrowth and final implant fixation, enhancing the elasticity of the entire structure, thus approaching much more to the natural elasticity of the healthy bone. During the daily human activities in the femoral joint are induced forces that exceed three times the body weight of the patient. Due to these forces, the internal architecture of the upper end of the femur has a trabecular structure which can be easily seen on a section in the frontal plane. Forces acting at this level are distributed along three main trabecular patterns which follow the direction of principal stresses, ensuring maximal strength for minimum mass of the bone as a whole.

The two models of implants were provided with two different sizes of fenestrations, the mechanical tests that followed aiming to determine which one of the two models withstands better the loading occurring during normal use. The personalized design was based on the CT images from a patient requiring a surgery for hip arthroplasty, their manufacture was made using biocompatible titanium alloy powder (Ti6Al4V) by 3D additive manufacturing (laser sintering). Implants made using additive manufacturing are presently used in some cases for patient specific anatomy to reduce stiffness and stress-shielding effects, to obtain enhanced mechanical performances and also for new functionalities like drug controlled delivery after implantation [4,5,6]. Additive manufacturing has opened new possibilities so complex theoretical designs can now become reality, ensuring flexibility in manufacturing parts due to their capability to manufacture several parts with different geometries using a single setup and with minimum material consumption.

The research is also important because although the realization of personalized implants is already known, accepted and applied in orthopaedics, study of their mechanical strength was poor, almost not studied. However, a study regarding