IMPROVEMENT OF A TRAPEZO-METCARPAL PROSTHESIS BY USING ELECTRON BEAM MELTING

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SUMMARY

Currently, most bone implants are made out of Titanium alloys coated with Hydroxyapatite. This choice is essentially due to the excellent biocompatibility properties of Titanium alloys. However, the Young modulus of these alloys is largely higher than the bony one, and this difference in stiffness is the major cause of the bone tissue degradation.
By simulating the behavior of the bone-prosthesis set of a trapezo-metacarpal implant, we have demonstrated a significant improvement of the implant's lifespan in the case of a prosthesis made, along its length, of an hypothetical Titanium material with decreasing Young modulus.

INTRODUCTION

Total arthroplasty of the trapezium-metacarpal articulation is a surgical intervention that has the need to place an implant instead of the normal articulation between the metacarpal bone and the trapezium bone. This operation is quite common and remedies to traumatisms or sharp and painful arthritic situations. Different types of prosthesis exist but we will focus our attention on Dr. Ledoux's prosthesis.
Dr. Ledoux's prosthesis has an anatomical design which precisely fills the previously prepared central channel in the metacarpal bone and provides maximal surface contact between the implant and the bone (Figure 1).
It is composed of three different parts. The first part is a non-axisymmetric cementless stem made of embossed Titanium (Ti6Al4V) implanted in the metacarpal bone. The second part is a Titanium axisymmetric cementless socket with a winged Polyethylene nucleus, which is set up in the trapezium bone. The last one is a Titanium ball, linked by a neck to the stem, which moves freely inside the polyethylene nucleus.

Acquired experience with this implant shows the development of new progressive pathologies (osteolysis) which can lead to the loosening of the implant in a short time. The aim of this paper is to describe this damage and emphasize on the technological possibilities to improve the implant regarding the osteolysis problem (Figure 2) and to study its manufacturing possibilities by using Electron Beam Melting (EBM) technology.

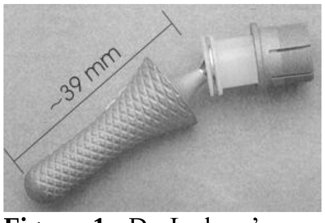

Figure 1: Dr. Ledoux's prosthesis.

Figure 2: Bone lysis shown in a X-ray photography.

METHODS

The mismatch between the Young modulus of the Titanium prosthesis and that one of the bone causes the "stress-shielding effect" where the applied load to the bone is insufficient and therefore leads to local bone resorption after a certain period of time. This bone resorption causes a slight loosening of the implant. The normal constraint distribution without the prosthesis is determined by the "reference configuration (refc)" in [1]. The constraint distribution with the prosthesis is determined by the "prosthesis configuration (pc)" [1]. In places where stress is high, bone specific mass and stiffness increase whereas in places presenting low stress, bone specific mass and stiffness decrease.

The following hypotheses have been put forward:
Firstly, realistic loading and boundary conditions were applied to a 3D finite element model (FEM) with and without the inserted implant [1].
Secondly, perfect fit between the bone-implant interface without any gap and relative displacement.
Thirdly, under loading conditions (Table 1), isotropic elastic laws were used to model the behavior of the bone in which the inhomogeneity in initial and subsequent (after remodeling) states is only represented by an evolutionary distribution in space and time of elastic modulus **E** and poisson's ratio $\boldsymbol{\upsilon}$ (Table 2). The last hypothesis was to establish a link between the mechanical stimulus **S** and the derivative of the specific mass $\boldsymbol{\rho}$ versus time **t** according to Wolf's law [8] to govern the remodeling process. The stimulus **S** is defined as $(\mathbf{E_{pc} - E_{refc}})$, E being identified in (pc) and (refc) configurations as the energy of distortion per unit of bone mass. A given step of time $(\boldsymbol{\Delta_t = t_{i+1} - t_i})$ allows to calculate a new local bone modulus as: $\mathbf{E_{i+1} = C\ (\rho_i + \Delta_t\ (d\rho/dt))^3}$ where **C** is a constant equal to $3790 \mathrm{MPa.cm^6/gr^3}$ (international unit system).

RESULTS AND DISCUSSION

The distribution of local specific mass in the bone, as a consequence of the remodeling process is presented at different time periods, $T_j = j\boldsymbol{\Delta_t}$ (j=0, n). T_0 being the time immediately after the surgical intervention. Figure 3 predicts a progressive destruction of the metacarpal bone which is confirmed by the X-Ray postoperative photography (Figure2).

To improve this pathological distribution, we intuitively developed a virtual functionally graded Young's modulus implant in Titanium. Figure 4, compared to Figure 3 shows an improvement for a given time with a significant extension of the lifespan of the implant. More details are available in [4].

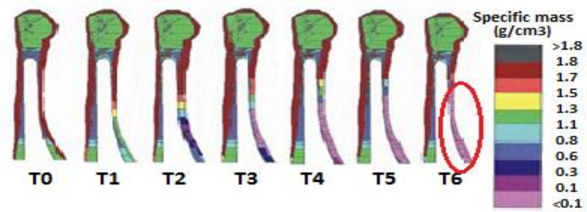

Figure 3: Sagital view: Time depending bone specific mass evolution (Dr. Ledoux's prosthesis).

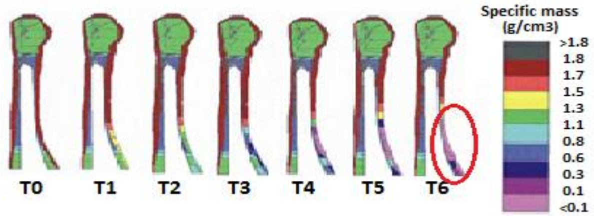

Figure 4: Sagittal view: Time depending bone specific mass evolution of an intuitively optimised prosthesis.

In conclusion, the presented results define the principle guidelines which we shall follow in order to optimize our implant:

1) To maintain the external geometry (anatomical design and maximal area for the bone-implant contact).
2) To optimize the Young's modulus distribution to match with the initial elasticity of the cortical and trabecular bone.
3) To present an adequate external surface which can be porous, with a specific pore size promoting the bone ingrowth, or a continuous surface with a certain roughness facilitating the coating deposit. This second option facilitates a surgical revision if necessary.
4) To examine the contact stresses applied on the interface between the bone and the prosthesis in order to evaluate the implant's anchorage. This aspect was completely disregarded in this paper but it may be approached in future studies with the same FEM model.

The EBM process of Arcam (Sweden), available in Belgium at SIRRIS allows the realization of all the mentioned constraints presented in this paper. EBM is an Additive Manufacturing process in which fully dense solid parts as well as porous ones are fabricated by melting a Ti6Al4V powder layer by layer with an electron beam. The process uses a powder particle size from 10-80µm, with a thickness layer of 70µm in a vacuum chamber. The machine focuses the electron beam on the powder bed in order to melt the powder in accordance to the CAD driving file.

The process is suitable for the fabrication of solid parts with mechanical strength superior to those built by using conventional manufacturing processes.

Some examples of cubic parts (15x15x15/23 mm^3) can be found in [5, 6, 7] with their Young's modulus varying from 0.57 to 3.9 GPa. Figure 5 shows some prototypes designed by Sirris with interconnected macro porosity.

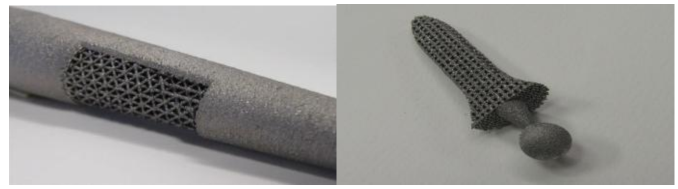

Figure 5: Samples produced by SIRRIS (A2 machine).

CONCLUSIONS

The pathologies affecting an implant are now relatively well known and the FEM models enable us to simulate them.

The EBM process has proven its capabilities to produce the adequate material for implant manufacturing. We hope that the collaboration between engineers and surgeons may allow significant advances in a very short period of time in order to improve the implant's lifespan.

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Table 1: Loading on Metacarpal bone

Lateral pinch (50N)	Value(N)
Normal Force in Metacarpal Bone	250
Shear Force in Metacarpal Bone	10
Normal Loads in Pulleys	20

Table 2: Initial Mechanical properties

	E(GPa)	υ
Titanium	110	0.3
Cortical bone	18	0.2
Trabecular bone	1.3 - 6.55	0.2