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DEVELOPMENT AND NUMERICAL MODELLING OF A FEMURAL BIOCOMPOSITE IMPLANT

The general target of the work was the development of a computer model of femoral implant manufactured from biocompatible composite materials. The composite implant shape and architecture have to be adapted to the bone characteristics in order to optimize the answer of the bone/implant mechanical system. This answer, in term of stresses and strain energy density in the system, is due to ensure a durable bonding between the implant and the bone, as explained further. In addition, the implant must be in accordance with modern manufacturing processes, which allow rapid prototyping of composite parts and manufacturing of made-to-measure products, the final aim being to obtain the best adaptation of the implant to each patient bone.

One of the major problems is the mismatch of stiffness between the femur bone and the prosthesis. Nowadays conventional femoral implants use Ti or Co-Cr alloys, which are much stiffer than natural bone. Such stiff stems, when implanted in the bone, affect his mechanical environment. As a matter of fact, these prostheses assume an important part of the stresses during the patient activity, which implies stress decrease in the bone surrounding the stem. This decrease of bone stimulation leads to bone resorption and eventually to prosthesis debonding and loosening (stress shielding). In order to prevent this evolution, the use of composite materials has been considered. These materials allow tailoring mechanical properties for a perfect matching of stiffness.

On the other hand, a too low stiffness stem is unlike to provide a sufficient stability of the prosthesis. Implant deformation leads to small relative movements, called micromotions, which obstruct the strong bonding of the bone on the stem. That is why composite femoral implants should be designed by using an numerical analysis including both phenomena.

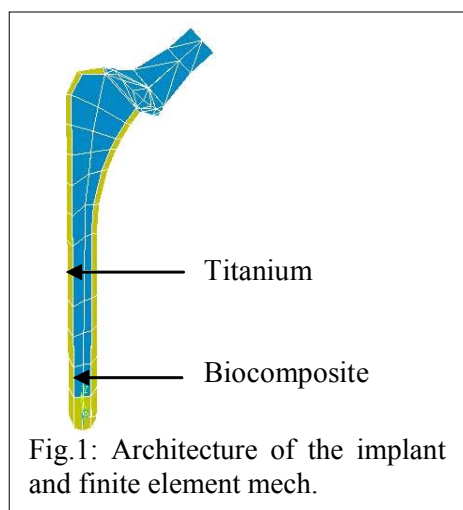
In order to develop a model available for a rapid prototyping process, the possibility of manufacturing composite implants by Sintering Laser System and Powder Injection Moulding has been studied. We have concluded on the large possibilities of manufacturing complex shapes.

We have chosen a simple architecture for the femoral implant: titanium core + biodegradable polymer composite shell (Fig.1). The outline of the developed implant has been inspired on an existing implant, with average dimensions. The final shape has been designed on Solid Works.

The implant developed has then been meshed, using ANSYS, in order to perform a finite element study. We have created several meshing with various numbers of elements, to verify the convergence of the model.

The modelled implant has also been tested according to the ISO standard, assuming firstly the material properties of a titanium alloy, and secondly the properties of titanium alloy for the core and starch-base polymer reinforced by 5% of hydroxiapatite for the shell. The results are consistent for the standard titanium prosthesis: maximum stress 500Mpa, tensile strength 2000Mpa. Concerning the composite structure, the calculation indicate the breaking of polymer shell, for the considered thickness of titanium core, arbitrary chosen.

The model of the bone has been positioned with the implant to ensure the full contact between the cortical bone and the stem at the distal extremity, along the medial side, and along the anterior



side; the centre of the spherical head of the prosthesis coincident with the approximate centre of the hip joint. This full model has been meshed, using six different material properties: titanium alloy and polymer composite for the implant, marrow, cancellous bone, metaphysis cortical bone and diaphysis cortical bone. The orthotropic properties of the cortical bone implied the definition of a cylindrical coordinate system. The loads have been defined on the basis of the comparison of several documents including values, positions, and directions of the forces, during the heel strike phase of the walk. We have now to determine a mathematical expression, using the mechanical results, which characterise both micro-motions and stress shielding phenomena, in order to perform an optimisation of the titanium core thickness.

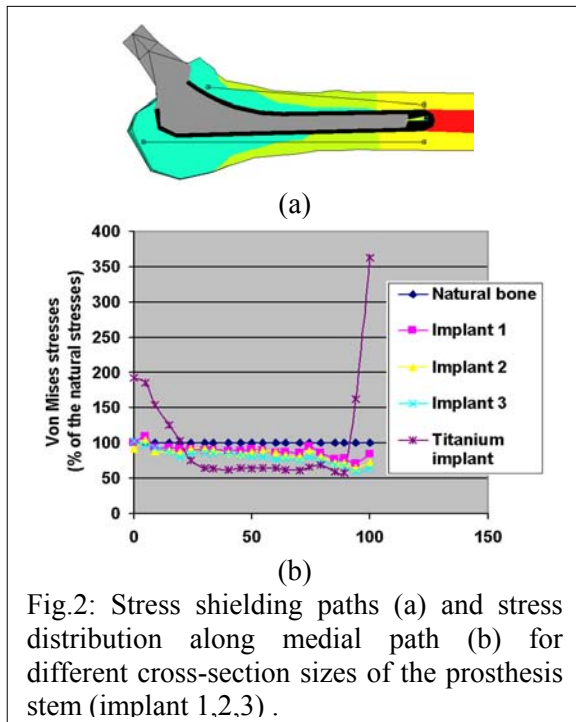


Fig.2: Stress shielding paths (a) and stress distribution along medial path (b) for different cross-section sizes of the prosthesis stem (implant 1,2,3) .

In order to assess the intensity of the stress shielding phenomenon, we have to compare the natural bone with the implanted one. The most representative criteria of stress shielding is the strain energy, but several references use Von Mises stresses, simpler to use. We have observed the evolution of Von Mises stresses along two paths crossing the areas of high risk of bone resorption (Fig.2a). To compare with natural bone, we have shown the evolution of the ratio Von Mises stresses after prosthesis / before prosthesis. This comparison is shown in the following graph (Fig.2b). This graph perfectly fits our expectations. For every implant, stresses are lower than in the natural bone almost everywhere along the path. The stiffest is the implant; the most important is the difference with natural stresses. In addition, at the distal extremity, we can see a peak of stresses for the titanium implant, which is consistent with clinical observations, i.e. proximal resorption and distal strengthening.

We have modelled the system according to the assumption of full bonding between the implant and the bone. We consider that it is the initial situation, just after a perfect implantation. Micromotions will then appear when a crack occurs and grows along the interface. The micromotions condition is then the occurring of micro-crack in one of the materials, near to the interface.

In addition, the comparison of ratios Young modulus/ tensile strength in the different materials points out that the breaking is more willing to occur in the bone, for an equal strain. We can then consider that the micro-crack will occur in the bone.

That is why we choose to observe Von Mises stresses along the most constrained edges of the implant, lateral-posterior and medial-anterior. We have defined paths going through the bone at 0.1 mm of the interface. We have focused on the maximum values of Von Mises stresses on these paths, which are thought to be representative of micromotions risk. Without consideration to the titanium implant results, the graphs obtained show consistent results; the less stiff is the implant, the more important are the micromotions risks.

Although, the problem of composite architecture optimisation has not been solved, the work has highlighted criteria of prosthesis viability, and compared several implants according to these criteria. The realisation of a real optimisation will only be possible when a threshold of micromotions occurring will be determined. However, we have already revealed the behaviour differences between several implants, in terms of stress shielding and micromotions. These results are consistent and globally agree with the expectations.