



Composite based on polyetheretherketone reinforced with carbon fibres, an alternative to conventional materials for femoral implant: Manufacturing process and resulting structural behaviour

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ABSTRACT

Composite stems obtained by injection moulding of polyetheretherketone reinforced with carbon fibres (CF/PEEK) can concurrence metallic ones in total hip replacement. By the combination of process simulations and structural analysis, different compositions of CF/PEEK and injection conditions are explored. The resulting implants are compared to the bone alone and the bone-implant system based on conventional metallic materials, under walking load. Comparisons are done through four objective criteria: stress shielding, stress deficiency, debonding and global deformation. CF/PEEK injected implant presents very good results.

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1. Introduction

Total hip replacement (THR) is a surgical operation where a damaged hip joint is replaced with prosthesis. The number of THRs increases constantly: in the 1980s the annual number of total hip arthroplasty was estimated to 170,000 in the USA and 300,000 worldwide [1].

Conventional materials used for the femoral shaft and neck in THRs are Stainless Steel (316L), Co–Cr and Ti alloys. But these materials present an important difference of stiffness with the femur bone that can induce stress shielding effect in the bone. As a result the bone remodelling process can be affected leading to bone resorption and eventually aseptic loosening of the prosthesis [2–4].

Implant loosening can be reduced through improvements in the prosthesis design [5] but also through the use of new materials with mechanical properties close to the ones of bone. Biocompatible polymer matrix composites are then interesting candidates for THR [2,6–11].

Stress shielding is generally in competition with micro-motions between the bone and the stem. Too low stiffness for the implant can increase these micro-motions, not to mention pains cause to the patient. Composite implants based on PEEK polymer matrix reinforced with carbon fibres have been designed and realised by

injection moulding. The first clinical tests on animals have shown a good mechanical stability of such prosthesis [2]. A clinical test on a 55-year-old man is reported in [13]; unfortunately, a car accident 21 months after the operation stopped the experiment.

In the present paper, numerical investigations on CF/PEEK artificial hip joint realised by injection moulding are proposed. Particularly the influence of the manufacturing process on the structural behaviour of the implant is studied. Furthermore comparisons with conventional metallic prosthesis are proposed.

Section 2 presents the environment of the work. The material and the CAD model for the implant are specified. Simulations of injection moulding and structural analysis of the prosthesis are described. A method for linking the two finite element programmes, in order to take into account the potential influence of the process on the functional behaviour, is proposed. The approach is checked on a standard test where numerical predictions and experimental measures are compared.

In Section 3, the procedure is applied to the final stance of horizontal walking loading conditions where the different (CF/PEEK, 316L, Ti and Cr–Co alloys-made) implants are evaluated.

2. Material and material models

2.1. Material and CAD model for implant

The selected material for the implant is a CF/PEEK composite. It has been chosen for its mechanical properties close to bone, its

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Table 1
The three CF/PEEK composites used in the study.

Name	Volume fraction in carbon fibres (%)
Composite 1	15
Composite 2	20
Composite 3	30

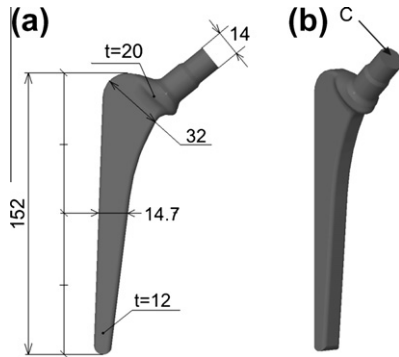


Fig. 1. The Echelon model proposed by Smith & Nephew for the hip implant (a) geometry and dimensions and (b) 3D CAD model.

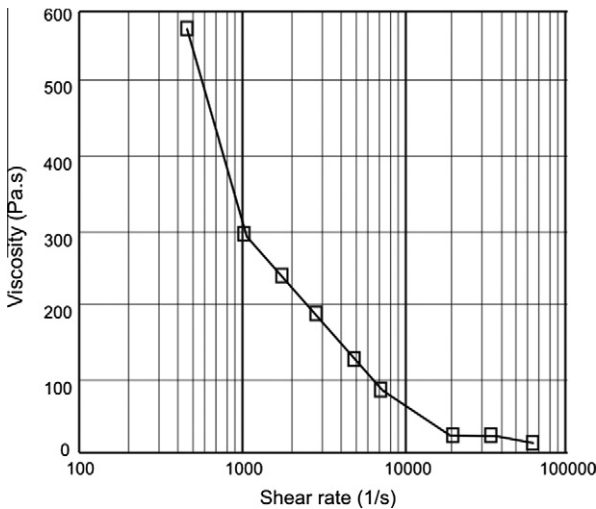


Fig. 2. Experimental viscosity-shear rate curve for a CF/PEEK 30 wt.% obtained for an injection temperature of 400 °C and a nozzle temperature of 180 °C.

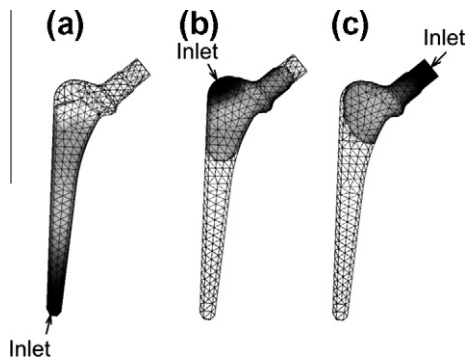


Fig. 3. The three inlet locations investigated for injection moulding simulations.

biocompatibility, its environmental stability, its excellent chemical resistance, its wear performances and its resistance to repeated sterilization by gamma radiations and steam [12,14].

This composite can be formed by injection moulding which is an interesting production process for mass production. Injection moulding is a repeatable process and a low cost process for a thousand batch production. Furthermore it is already largely used for producing numerous components for medical devices.

Composites prosthesis present the advantage to be tailored in such a manner that it is possible to optimise stress distribution in the bone when implanted. With CF/PEEK material, one can question about the possibility to find the right fibre volume fraction and the best fibres orientations and repartitions leading to an interesting compromise between stress shielding and micromotion for femoral implant application [12,15].

Then three types of CF/PEEK composites with different weight fractions of carbon fibres, named Composite 1, 2 and 3, are considered (Table 1). The variation in fibre orientation will be obtained with different conditions of injection moulding that is described later.

For the present investigation the chosen implant geometry is based on the Echelon model proposed by Smith & Nephew [16]. The simplified 3D CAD model for the implant used in the following is illustrated in Fig. 1.

2.2. Injection moulding simulation

Simulations of implant injection moulding are carried out using Moldflow Plastic Insight© (MPI©) software. The main results are the fibres orientation and distribution in the prosthesis that will be used for evaluating its anisotropic elastic properties for later use in structural analysis.

Table 2
Parameters used in injection moulding simulations.

Mesh characteristics	22,051 2D elements (tetrahedral 4-nodes element) 3832 nodes
Mould temperature	170 °C
Injection temperature	395 °C
Injection time	1 s
Mould material	TOOL STEEL P-20
Injected material	Poly-ether-ether-ketone (PEEK) with 30 wt.% high-modulus carbon fibres (from LNP Plastics)
Viscosity law	See Fig. 2

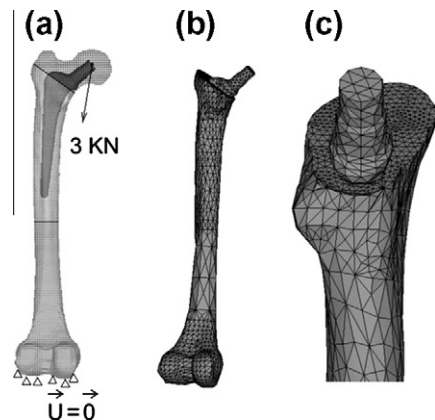


Fig. 4. The FE model for the structural analysis with ANSYS©: (a) boundary conditions in effort and displacement, (b) the 3D solid model, and (c) detail of the 3D solid model.

Table 3
Specifications of the FE model for structural analysis.

Element type	3D tetrahedral solid element N92
Number of nodes per element	10
Degrees of freedom (dofs)	Displacements in the three directions (UX,UY,UZ)
Number of elements in the implant model	35,004
Total number of elements in the bone-implant model	22,051
Total number of nodes in the bone-implant model	78,811
Number of active dofs in the bone-implant model	149,214
Maximum wavefront	4876

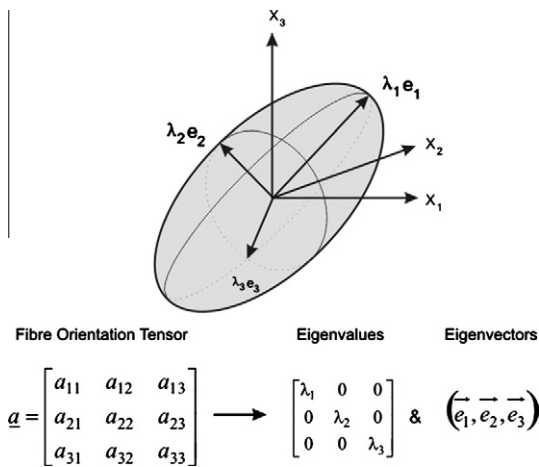


Fig. 5. Relation between the Fibre Orientation Tensor (FOT) and the anisotropy directions.

Actually, CF/PEEK composite is anisotropic; its elastic properties and strength are higher along the fibre direction [12] that results from the configuration of the injection process. Fibres alignment

is generally not uniform that implies heterogeneities [17,18] and then gradient of mechanical properties in the injected component. These factors may have a significant influence on the resulting mechanical properties of the prosthesis and need to be studied and taken into account for an optimal use of CF/PEEK composite for hip implant.

For injection simulations, the viscosity used for the flow simulation is given in Fig. 2 and the other parameters are listed in Table 2. As already said, final quality of components obtained by injection moulding depends on process parameters. In case of injection of composite the location of the injection point presents a relative importance. It can influence the fibres orientation and distribution in the implant and consequently its elastic properties. For these reasons, injection moulding of the hip implant has been simulated by considering three different locations for the inlet as it can be observed in (Fig. 3). From these simulations it is possible to evaluate the fibres orientation and distribution in the implant volume as a function of the inlet location by using the Tandon–Weng micromechanical model [19] available in MPI© software. The results file contains, for each element, five independent values corresponding to a transverse isotropic material: two Young’s moduli, two Poisson’s coefficients and one shear modulus. The accuracy of the elastic modulus predictions with MPI© has been verified by experimental measurements based on vibrations characterisation for Composite 1 [20]. For Composite 2 and Composite 3, approximations have been done assuming a linear dependence on fibres proportion.

2.3. Structural analysis of the implant-bone system

The simulation of the mechanical behaviour of the hip prosthesis implanted in the femur bone is conducted by using the ANSYS© software.

A FE model of femur bone available from VAKHUM project website [21] has been rebuilt into a solid model in order to allow further remeshing.

The hip implant obtained by simulation of the injection moulding with MPI© is imported into ANSYS and combined with the femur bone model. Chopped fibres have been used. Repeatability data concerning elastic properties are not directly available.

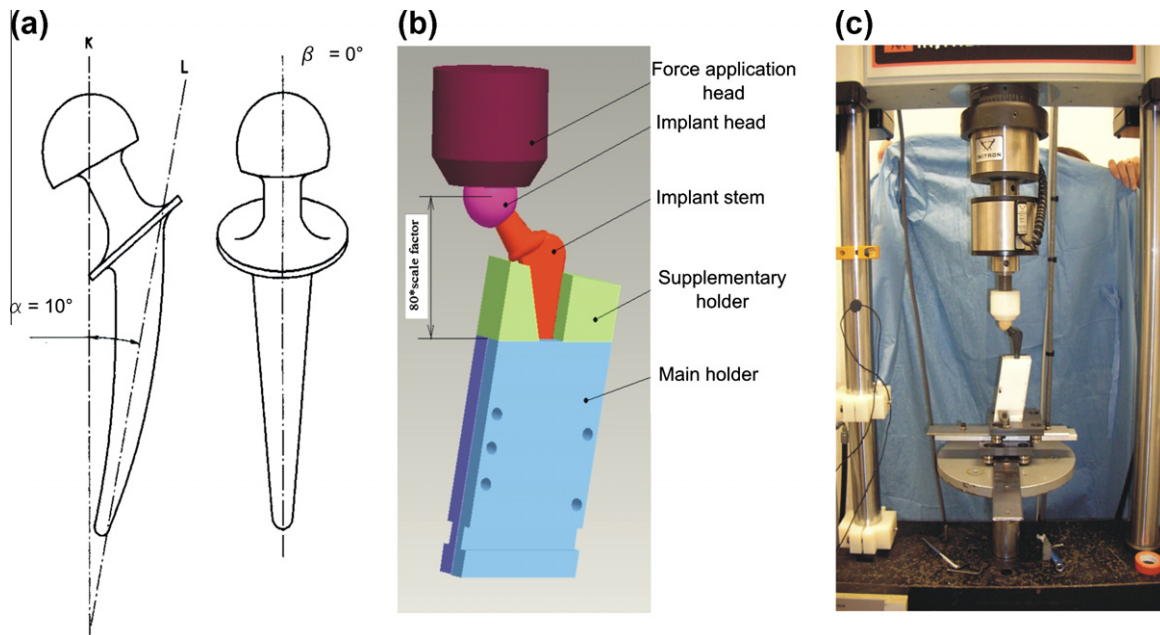


Fig. 6. Specification of the standard NF S90-448: (a) orientation of the stem, (b) CAD model, and (c) experimental set-up.

Table 4

Elastic data based on flow simulations with Moldflow® (except for bone) used for structural analysis with ANSYS® and information on anisotropy and heterogeneity taken into account in the simulations.

Materials	Anisotropy	Heterogeneity	Young's modulus	Poisson's coefficient
Bone	No	Yes	2.2–23.4 GPa	0.3
CF/PEEK 15 wt.%	Yes	Yes	5–12 GPa	0.33–0.47
CF/PEEK 20 wt.%	Yes	Yes	5–15 GPa	0.31–0.49
CF/PEEK 30 wt.%	Yes	Yes	6–21 GPa	0.26–0.54
Stainless Steel	No	No	193 GPa	0.3
Co–Cr alloy	No	No	193 GPa	0.3
Ti alloy	No	No	114 GPa	0.316

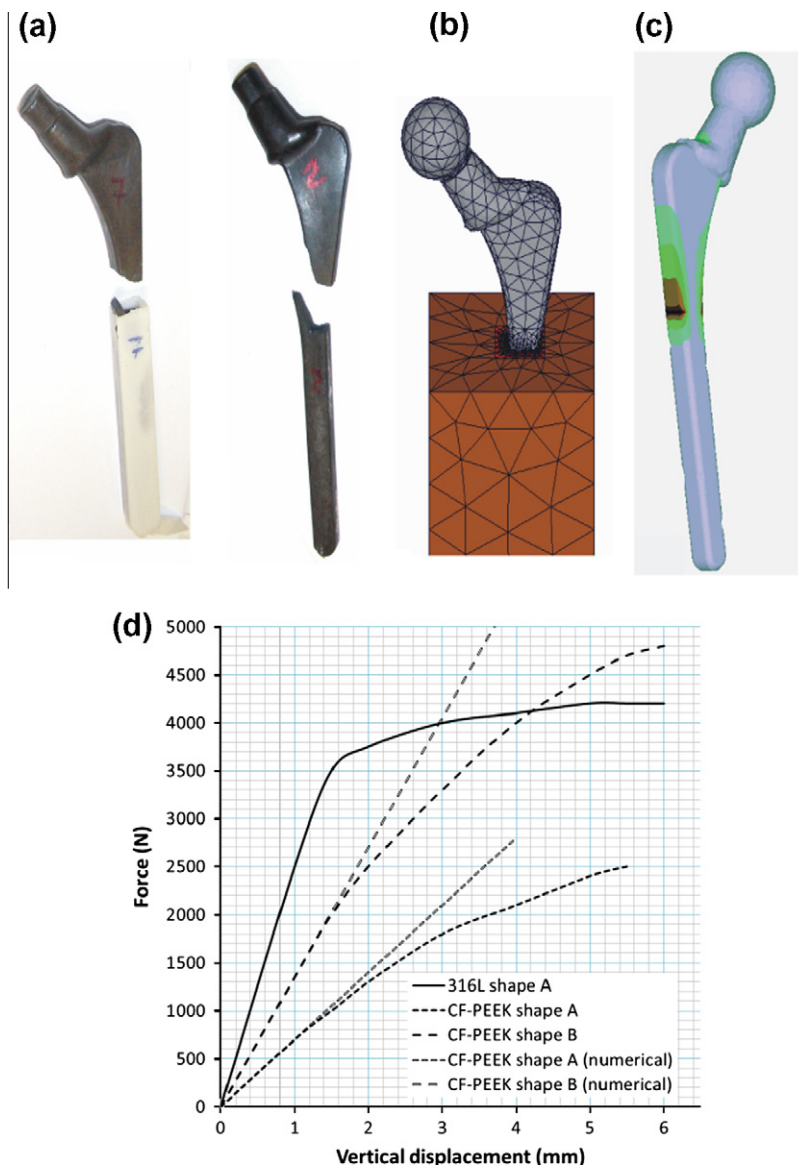


Fig. 7. (a) Typical experimental failure, (b) FE model, (c) FE results of the NF S90-448 standard for CF/PEEK stems, and (d) experimental and numerical force–displacement curves.

Indirectly, cycling test results of different samples indicate low to moderate dispersion of mechanical properties.

Two types of FE simulations are carried out: the natural bone alone and the implant–bone system. The same mesh is used for the simulations to simplify the comparisons. In the first case the bone properties are attributed to all the elements. In the second case the elements corresponding to the implant are assigned to the composite mechanical properties.

Boundary conditions correspond to the terminal stance of horizontal walking. They correspond to the most critical loading case concerning the muscles effect on the femoral bone [22]. In reference to [10,12] muscles action is modelled by a force of 3 kN applied to the head of the implant. The force is oriented towards the centre of the knee joint. For the nodes at the distal end of the model, all the degrees of freedom are constrained to zero as in [10,12]. The FE model is presented in Fig. 4 and specifications are

given in Table 3. As 3D tetrahedral solid elements usually provide stiffer response, preliminary simulations have been performed to evaluate the number/size of elements required for adequate accuracy.

2.3.1. Specifications of the FE model for the bone alone

Isotropic heterogeneous properties are assumed for the bone tissue according to the original VAKHUM project estimation [21]. The elastic properties of the bone are taken from the original FE model on the basis of element-by-element. The variation of elastic modulus inside the bone is respected and modelled in ANSYS© corresponding to 173 values of the Young's modulus between 2.33 and 23.4 GPa (Table 4).

2.3.2. Specifications of the FE model for the bone-implant system

The elastic properties of the implant are obtained from the injection moulding simulations with MPI©. For that a C/C++ program, described in next section, has been developed to realise an interface between the two codes ANSYS© and MPI© (Section 2.4). So it is possible to assign to each element the material properties corresponding to those of the implant obtained by injection moulding. The implant material is considered as a heterogeneous

anisotropic elastic material and a transversely-orthotropic material model is used.

To complete the model, a perfect contact between the bone and the implant, corresponding to a cementless prosthesis, is assumed. This assumption is justified as we study the normal physiological state after the surgical operation fully completed. In this case the relative micro-motions between implant and intramedullary canal surfaces can be avoided. An aseptic loosening which is one of the major problems of hip joint failures is a result of a long-time process caused by the stress shielding studied in this paper. However the stress shielding is a mechanical phenomenon that arises before loosening in a normal situation of perfect bounding between implant and bone.

2.4. Interface between MPI and ANSYS© programmes

Because of the incompatibility between the MPI© and ANSYS© programmes, it is not possible to have a direct access to the elastic properties contours in CF/PEEK implants obtained by injection moulding simulation for further structural analysis with ANSYS©.

A procedure and a C/C++ interface programme have been developed for this purpose.

The procedure is the following:

- (1) With MPI© code, results file containing Fibre Orientation Tensor (FOT) and elastic moduli for each element of the model is exported in PATRAN© format.
- (2) A C/C++ programme converts the data in PATRAN© format to an ANSYS© batch file format that defines materials data and attributes them to the corresponding elements. The transversely-orthotropic material model from ANSYS© is used.
- (3) Another C/C++ programme calculates the eigenvectors of the FOT (Fig. 5) and writes them in an ANSYS© batch file; these vectors correspond to the anisotropy directions and define a local coordinate system for each finite element.

With the previously described procedure, the heterogeneity and the anisotropy of the elastic properties of the composite material constituting the CF/PEEK implant are evaluated (Table 4).

2.5. Validation of the approach

For the validation of the approach an experimental set-up of the French standard NF S90-448 has been developed (Fig. 6). This standard is a destructive testing of femoral implant under compressive force. According to this standard, the stem, after preliminary immersion in physiological liquid, is cemented in a holder in a specific manner so that:

- (1) The distance between the implant head centre and the cement level equals 80 ± 2 mm.

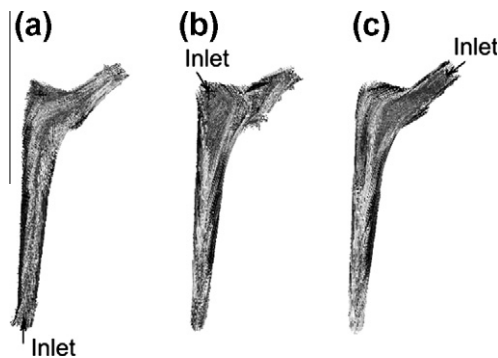


Fig. 8. Final fibres orientation after injection moulding of the hip implant for three different inlet locations: (a) bottom, (b) middle, and (c) top.

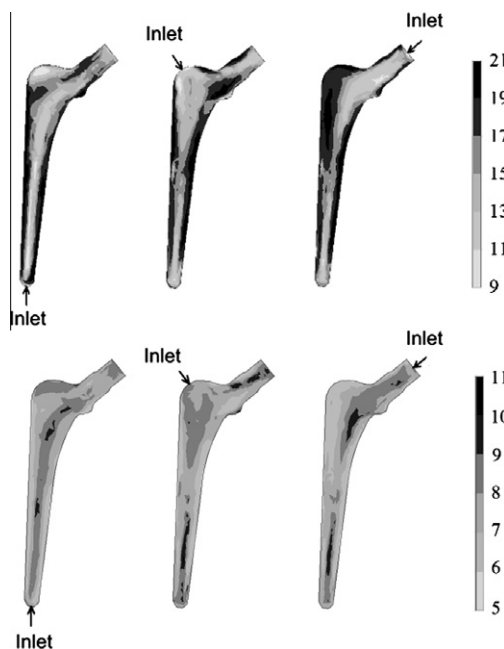


Fig. 9. Resulting heterogeneous elastic anisotropy for the three inlet locations. Representation of the contours for the longitudinal Young's modulus (top) and the transversal Young's modulus (bottom).

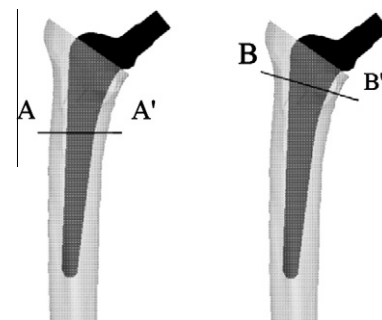


Fig. 10. Localisation of the two critical zones of the bone (sections AA' and BB') where stress contours comparison is done.

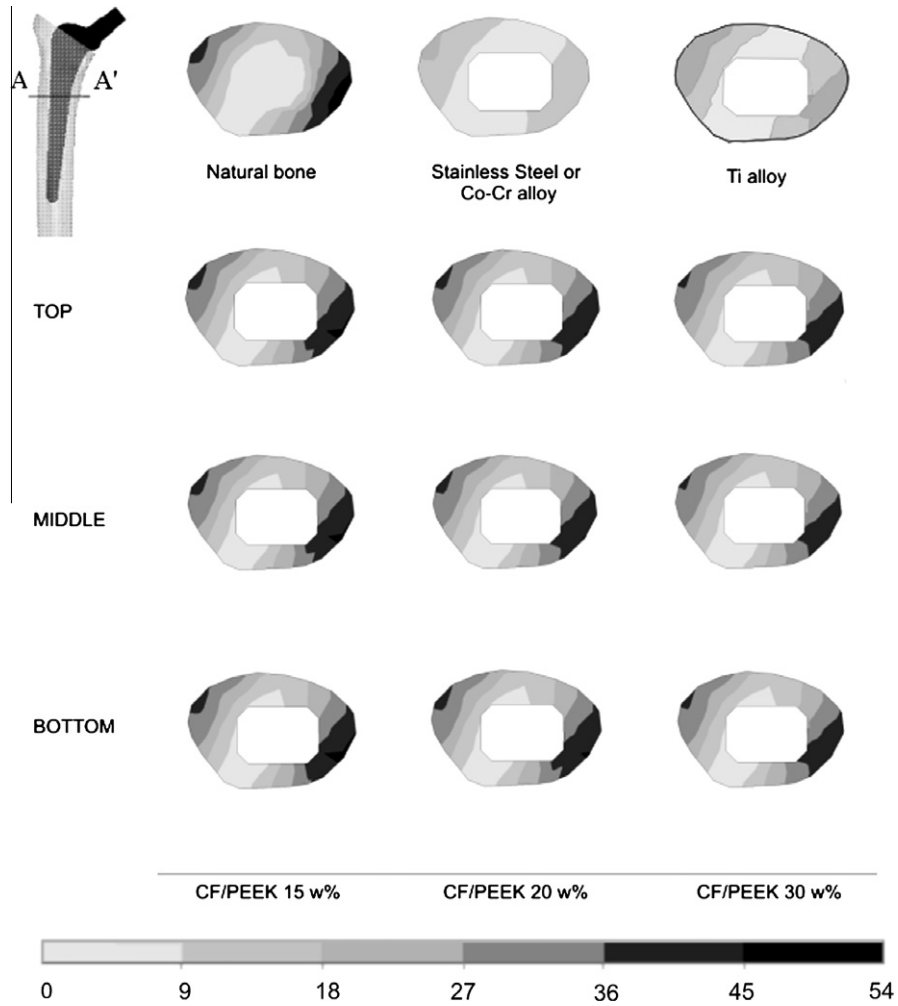


Fig. 11. Comparison of the von Mises's stress (in MPa) contours in section AA' for natural bone and bone-implant system with different materials.

Table 5
Comparison of relative deflection obtained by structural analysis for the different tested materials in comparison with the natural bone.

Materials	Inlet location	Offset from the same point in natural bone (mm)
Natural bone	/	0
CF/PEEK 15 wt.%	Bottom	1.123
	Middle	1.323
	Top	1.199
CF/PEEK 20 wt.%	Bottom	0.872
	Middle	1.067
	Top	0.946
CF/PEEK 30 wt.%	Bottom	0.53
	Middle	0.709
	Top	0.597
Stainless Steel	/	1.577
Co–Cr alloy	/	1.577
Ti alloy	/	1.181

(2) The implant longitudinal axis is oriented with ($\alpha = 10^\circ \pm 30'$; $\beta = 0^\circ$) so that there is no torsion effect.

The holder with the implant is placed on a compression test machine and an increasing vertical compressive force is applied. The test assembly should allow free displacement of one of the two parts in the plane orthogonal to the force direction. As the force grows, the force–displacement curve is recorded until the implant

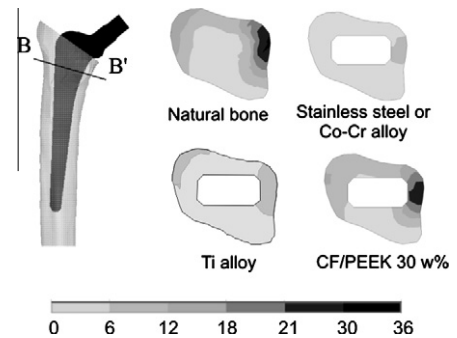


Fig. 12. Comparison of von Mises's stress (in MPa) contours in section BB' for natural bone and bone-implant system with different materials.

fails. This test allows the simulation of the implant loosening when only the bottom part of the stem remains fixed in the bone. FE simulations following the procedure described in Section 2.4 have been carried out and the numerical results are compared to experiments (Fig. 7). Numerical curves are a line, as a linear model has been used for the simulations. It is found that the experimental maximal force for the CF/PEEK stems is equal to 2464 ± 20 N that is in good agreement with the value of 2300 N reported in [23].

The experimental value is slightly higher than those predicted by the simulations (2212 N). It can be explained by the following observations:

- (1) The von Mises's criterion has been developed for linear and homogeneous isotropic materials and may be not adapted for heterogeneous anisotropic composite material; moreover fracture mechanisms in fibres-reinforced composite materials are complex, and different types of failure may occur under different conditions [24,25].
- (2) As the material is heterogeneous, its tensile and bending strength limits vary also in space.
- (3) Fibres orientation is taken into account in a simplified way in numerical modelling.

Considering the above remarks, the simulation results may be judged as adequate and the proposed approach is then validated.

3. Results and discussion

3.1. Injection moulding simulations

The aim of these simulations is to determine a realistic anisotropic elastic behaviour for the composite composing the implant by taking into account the manufacturing process.

From injection moulding simulations the visualisation of the fibres orientation in the stem is possible as illustrated in Fig. 8. The flow simulations indicate that fibres are parallel to the flow lines in surface and perpendicular to them in volume. These observations are in agreement with the flow theory and other results published in the literature [23]. As a result the hip implant presents a heterogeneous elastic anisotropy as illustrated in Fig. 9 that represents the contours for the longitudinal and transversal Young's moduli in the injected stem for the three inlet locations using the procedure described in Section 2.4.

3.2. Structural analysis

The anisotropic elastic coefficients obtained from flow simulations are given in Table 4 for CF/PEEK 15, 20 and 30 wt.%. These data are completed with data for natural femur bone and more conventional materials for stem such Stainless Steel, Co–Cr and Ti alloys. These last ones are considered isotropic and homogeneous which is close to truth because such implants are obtained by machining.

Finite element simulations are conducted with the model presented in Section 2.3 and the different material data of Table 4 for the stem implanted in the bone.

The analysis is focused on the study of the stress contour in the bone with the loads of Fig. 4 in two critical zones of the bone where the risk of bone resorption is the highest: section AA' near the middle and section BB' in the proximal region (Fig. 10).

The stress contours obtained for the different materials constituting the hip implant are compared to the bone alone submitted to the same loading conditions. The comparisons can be observed in Figs. 11 and 12.

The results show that a composite stem generates in the bone a stress field very close to the one existing in the natural condition (bone alone) and much better in comparison with metallic prostheses. These observations are valid for all the considered fibres proportions and inlet locations. Therefore stress shielding effect and then the risk of bone resorption with a CF/PEEK implant would be very weak even inexistent. The influence of fibres proportion and of injection point location is not significant. Another view of the stress contours, in a longitudinal section, leads to the same conclusions (Fig. 13). In Fig. 13 it can be observed that metallic stems transfer the high stress zone in a more distal (lower) region. It is important to precise that the typical stresses obtained with the proposed FE models are in the same order in magnitude than those found in the literature [10].

It is also interesting to compare the displacements between the bone alone and the bone-implant systems under the current

loading conditions because they are responsible of possible micro-motion. Fig. 14 gives an idea of the deformed shape of the bone applied to the terminal stance of horizontal walking and Table 5 reports the results obtained for the different bone-implant systems compared to the bone alone in the same loading conditions. It is evident from these comparisons that an implant obtained by injection moulding of a CF/PEEK 30 wt.% with a bottom inlet location reveals a mechanical behaviour the closest to the bone alone.

The results show clearly that CF/PEEK moulded stems present the best properties for bone replacement. It has also been observed that process conditions have not so much influence on stress distribution in the bone contrary to the displacement. For stress analysis it is necessary to have a more objective analysis as done in next section.

3.3. Criteria for choosing the best material and the best process conditions for hip implant

In previous sections, the injection moulding process with different conditions (inlet locations, percentage of carbon fibres) of a carbon fibres reinforced PEEK polymer has been simulated in order to take into account fibres orientation and distribution in the

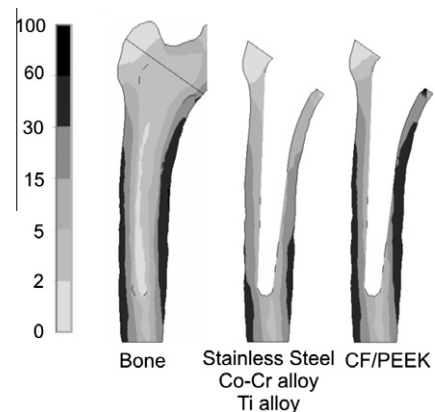


Fig. 13. Comparison of the von Mises's stress (in MPa) contours in a vertical section for natural bone and bone-implant system with different materials.

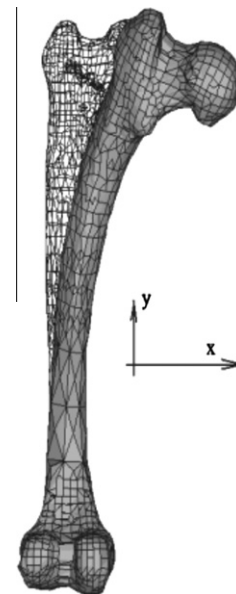


Fig. 14. Deformed shape of the bone under loading conditions corresponding to the terminal stance of horizontal walking.

implant. Thus existing elastic anisotropy and heterogeneity have been taking into account for structural analysis of the bone-implant system. These results have been compared to cases where the implant is done in a homogeneous isotropic machined material such as Stainless Steel and Ti or Co–Cr alloys.

In order to optimise the constitutive material for stems it is essential to have an objective evaluation. This can be achieved by defining objective functions.

3.3.1. Definition of the objective functions

Stress-shielding is considered as the major problem in bone replacement. Consequently the main objective of the present problem will be to minimise the risk of stress shielding.

Stress-shielding is essentially due to the resulting stress contours in the bone in the case of bone-implant system. So the objective function(s) will consider the stress state in the bone.

- (1) In the literature, Katoozian et al [12] proposed the following criterion to evaluate the stress-shielding risk in an implant-bone system:

$$F = \sum_{i=1}^N \left(\frac{\sigma_{rep}(i)}{\sigma_{nat}(i)} - 1 \right)^2$$

where N corresponds to the total number of finite element defining natural bone and σ_{nat} , σ_{rep} the von Mises' stress in the natural and in the repaired bones respectively.

The value of F-criterion characterises then the relative difference between stress levels in the natural bone and in the bone-implant system with integration all over the corresponding bone volume between the two cases. Because the element volume is not the same for each element of the FE model, a modified criterion is proposed:

$$F_1 = \frac{1}{V_{nat}} \sum_{i=1}^N \left(\frac{\sigma_{rep}(i)}{\sigma_{nat}(i)} - 1 \right)^2 \times V(i)$$

with $V_{nat} = \sum_{i=1}^N V(i)$ (1)

$F_1 = 1$ corresponds to a total stress-shielding case (bad) and $F_1 = 0$ to the ideal case.

- (1) But bone resorption is not just the result of a moderate stress excess [3]. It is caused essentially by stress deficiency. To take into account this fact, another criterion is proposed:

$$F_2 = \frac{1}{V_{nat}} \sum_{i=1}^N f \left(1 - \frac{\sigma_{rep}(i)}{\sigma_{bone}(i)} \right) \times V(i) \quad \text{with } f(x) = \begin{cases} 0 & \text{if } x \leq 0 \\ x^2 & \text{if } x > 0 \end{cases}$$
 (2)

F_2 -criterion is non symmetric. It takes into account the stress deficiency in exactly the same manner as the F_1 -criterion. But stress excess created by the implant is not taken into account in this last criterion.

- (1) Another important criterion has to be considered: the risk of failure. Implant failure may be caused by interface debonding and micromotions at the bone interface. So to evaluate the risks of mechanical failure and interface debonding, a third criterion is defined:

$$F_3 = \sqrt{\frac{1}{V_{int}} \cdot \left[\sum_{i=1}^{N_{int}} \sigma_{rep}^2(i) \times V(i) \right]}$$
 (3)

where N_{int} and V_{int} are the number and the volume of the finite element of the bone at the bone-implant interface.

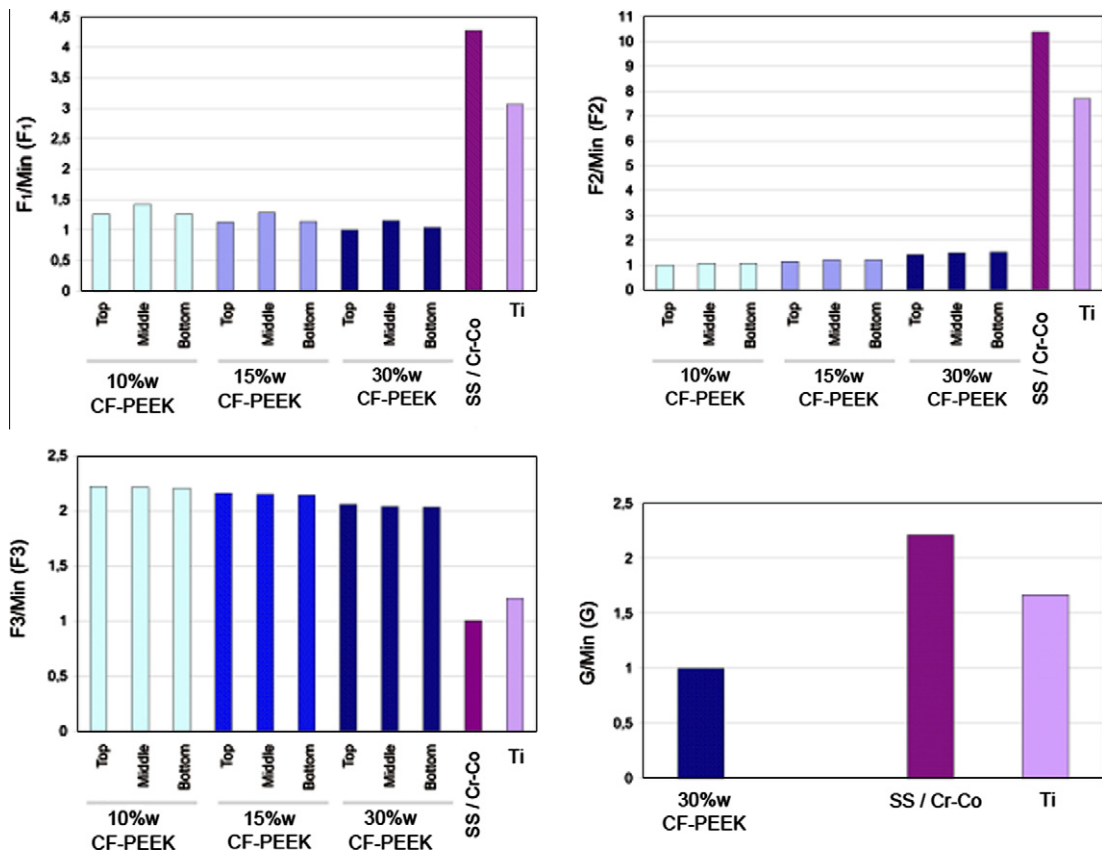


Fig. 15. Comparison of the four criteria for the three composites, 316L Stainless Steel, Co–Cr, and Titanium alloys.

This last criterion corresponds in fact to the root square average of the von Mises' stresses in the bone elements near the bone-implant interface.

- (1) The previous objective functions can be completed by consideration on the displacement of point C of Fig. 1:

$$G = \|\vec{U} - \vec{U}_{bone}\| / \|\vec{U}_{bone}\| \quad (4)$$

3.3.2. Application and results

The four criteria defined previously are used to propose the best material-process couple for efficient implant. The mathematical problem to solve is then:

$$\begin{cases} F_1 = \text{Minimum} \\ F_2 = \text{Minimum} \\ F_3 = \text{Minimum} \\ G = \text{Minimum} \end{cases} \quad (5)$$

The results for these four criteria are summarised in Fig. 15.

Concerning stress-shielding effects (F_1 criterion) and stress deficiencies (F_2 criterion), the use of injected CF/PEEK leads to a manifest improvement of bone resorption in comparison to metallic implants. With 30% fibres proportion, stress shielding is close to that found in natural bone but stress deficiency is slightly higher. With 15% in fibres, stress deficiency is the lowest due to its lowest elastic modulus. Anyway, the differences between the different fibres proportions and injection point locations are not large. A filling from the bottom seems to present a slight advantage.

For interface stress (F_3 criterion), classical materials such as Stainless Steel or Co–Cr present a better behaviour but the relative difference with CF/PEEK stays small compared to those obtained for F_1 and F_2 criteria. Moreover, with surface coating it could be possible to solve these interface problems [24].

For G criterion corresponding to the deviation at point C of the bone-implant system under the studied loading, bones repaired with CF/PEEK implants present closer deviation to natural bone than those repaired with Stainless Steel or Co–Cr implants.

4. Conclusion

Based on a basic geometry for femoral implant, its realisation by injection moulding of CF/PEEK is investigated. Injection moulding has been modelled using MPI© software and several injection conditions (inlet locations, fibre proportions) have been tested resulting in different fibre orientations and density.

These fibres orientations lead to an anisotropic elastic behaviour. A program has been developed to transform the Fibre Orientation Matrix resulting from MPI© simulations into anisotropic elastic data for structural analysis to be carried out with ANSYS©.

The structural analysis has explored boundary and loading conditions corresponding to the terminal stance of horizontal walking.

Comparison between numerical results obtained for the different injection conditions to product the CF/PEEK implants and those obtained for machined Stainless Steel or Co–Cr implants is done by using four objective criteria to be minimised: stress shielding, stress deficiency, risk of interface failure and deviation under studied load.

The injected composite implant permits to minimise three of the criteria. The interface stress is not satisfying but with progress in surface coating, this problem could be solved without changing fundamentally the global behaviour for the bone-implant system. Moreover, the presence of carbon fibres at the interface bone-implant could present health problem for the patient with the creation of fragments due to friction and wear between implant and bone. Adequate surface coating could insure the integrity of such a CF/PEEK implant and the respect of the patient [25].

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