

Design of a polymeric composite material femoral stem for hip joint implant

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Abstract

Hip joint prosthesis are structural components that still have some challenging problems such as the interaction of physical and biological properties between the stem and the human femur. Composite materials allow to obtain high strength structures with a large variety of modulus of elasticity and favorable characteristics in the context of orthopedic implants. Therefore, the objective of this work was the development of a prosthesis model with biopolymeric matrix, namely the polyurethane (PU) derived from castor oil, reinforced with fiberglass. The implants were made of pure PU, PU with fiberglass, and PU with glass fiber and calcium carbonate. The reinforcement was constructed in the form of a core to be inserted into the hip prosthesis. The core and stem prototypes were produced using three-dimensional printing techniques, and subsequently used in the manufacture of flexible silicone molds. The results showed good mechanical potentialities of this material for orthopedics applications.

Keywords: *calcium carbonate, composite, femoral stem, fiberglass, polyurethane.*

How to cite: Costa, R. R. C., Almeida, F. R. B., Silva, A. A. X., Domiciano, S. M., & Vieira, A. F. C. (2019). Design of a polymeric composite material femoral stem for hip joint implant. *Polímeros: Ciência e Tecnologia*, 29(4), e2019057. <https://doi.org/10.1590/0104-1428.02119>

1. Introduction

Fiber reinforced composites have been used in many industrial applications such as, aerospace, automotive, and military, due to advantageous mechanical properties when compared to metallic materials, namely specific strength and stiffness^[1,2]. Associated to this, excellent ratio between fatigue resistance and weight, as well as fatigue resistance and wear ratio^[3]. One of the segments that are considering the advantages of composite materials is the bioengineering, more specifically in the development of joint prosthesis. The composite materials allow the achievement of high strength structures with a wide range of elasticity modulus, which seems benefit from the standpoint of an orthopedic implant^[4].

Prostheses made of metallic materials presents some disadvantages regarding biocompatibility issues and discrepancy of stiffness compared to the human bone. The Young modulus of human cortical bone varies from 12 to 20 GPa. On the other hand, the Young modulus of some special titanium alloys used in orthopedics components vary between 60 and 80 GPa^[5].

A femoral stem for hip joint implants is a structural component that still presents challenging problems with no solutions in the field of orthopedic surgery. Among the complications of this process, stands out the inadequate combination amid the femoral stem and the cortical bone of the human femur. The application of materials that present

the Young's modulus and strength close to that of the cortical bone is the goal to be achieved^[6].

The optimization of femoral prostheses involves, essentially, the determination of the geometry and the elasticity's module of materials that attenuate the stress shielding effect to acceptable levels of interface micro movements. Stress shielding is a process that occurs because the stresses sensed by bone are lower than those sensed by the healthy joint without a prostheses, which leads to bone resorption in a given region^[4].

The mechanical properties is the principal determinant of functional compatibility of polymeric structures. The adequate interface between the artificial structure and the host tissue is only ensured if mechanical properties of this structure are similar to those of the tissue that is desired to recover or to replace^[7].

The biopolymer used at this research is a PU, which is presented in the form bicomponent, being constituted of polyol and prepolymer. The polyol is synthesized from castor oil and the prepolymer is synthesized from the diphenylmethane diisocyanate. Since 1996 the PU have been used as bone cement for prosthetic implants and reparative substance in bone loss^[8]. Currently, PU's is the class of polymers most consumed in the world, being applied as, for example, paint components, coatings, foams, domestic,

and industrial components, as well as construction and biocomponents sectors^[9-13].

Biocompatibility^[14] studies using PU have been developed, as well as implant procedures for filling bone defects^[15]. Souza^[15] presents the application of PU derived from castor oil as filler to bone failures in legs affected by cancer. In almost all cases studied, the most important aspect to be satisfied was the perfect adaptation of bloody bone surface with the polymer surface, followed by a rigid stabilization, to allow the bone-polymer osseointegration.

Dontos^[16] evaluated the biocompatibility of a wire knurled of castor oil PU (Biologic Lifting Wire) applied at the facial rejuvenation. Through his study, it was revealed an excellent Biologic Lifting Wire biocompatibility when implanted in subdermal tissue of mice, with the presence of small inflammatory reaction and quick collagen synthesis.

This work aims to present the design and the fabrication methodology of a femoral stem built in polymeric composite material reinforced with fiberglass and calcium carbonate, also to get the approximated value of the theoretical elasticity's module of the stem's core calculated according to the rule of mixture. And, to experimentally verify the properties of the fabricated stems, there were static tests made according to the standards of ABNT NBR ISO 7206-04^[17] e ABNT NBR ISO 7206-06^[18].

2. Manufacturing Process of Femoral Stem

The composite material used to produce the femoral stem consists of a PU matrix, which is obtained by mixing prepolymer (synthesized from diphenylmethane diisocyanate) [329 L (60% m/m)] and polyol (derived from castor oil) [471 (40% m/m)] supplied by Poliqual Araraquara Polímeros Químicos Ltda., in conjunction with glass fiber roving type E (TEX 2400) supplied by TEXIGLASS Ind. and Com. Têxtil Ltda., and Calcium Carbonate P.A. supplied by Synth. These last are used as reinforcement, in order to improve the mechanical strength and rigidity of the stem.

The femoral stem drawing was developed in SolidWorks, based on references^[6,19-22]. In this production process, the dimensional parameters and shape that would satisfy the bio-mechanical requirements in relation to the request of the weight and the rigidity of the remaining bone.

After obtaining the drawing of the femoral stem, which consists of core made of a fiber glass and PU composite, the plastic model and the centering jigs (Figure 1) were printed on a 3D printer (Stratasys Objet 24). The plastic model was then used to produce a silicon mold (the negative of the model) to produce the stem. The centering jigs were used to center the core during the PU resin injection into the mold.

These printed parts were then used to make silicone molds. Figure 2 shows the three silicone molds made by pour casting, for the different parts of the stem, namely:

- (a) Stem mold with channels to vent and PU injection. It opens in two parts to extract the stem after curing and also to allow the introduction of the core and its centering before the injection process;

- (b) Core mold (core on PU reinforced fiberglass used to improve mechanical properties of the stem). It opens in two parts to extract the core after curing. It has two holes at the tips to remove resin excess;
- (c) Centering jigs open mold.

The first step in obtaining the stem is the manufacturing of the PU composite core reinforced with fiberglass (Figure 3a) to give the necessary shape and the fibers alignment (Figure 3b). Eight (8) and sixteen (16) fiberglass



Figure 1. Plastic models of stem and necessary parts for stem manufacturing process obtained by 3D printing.

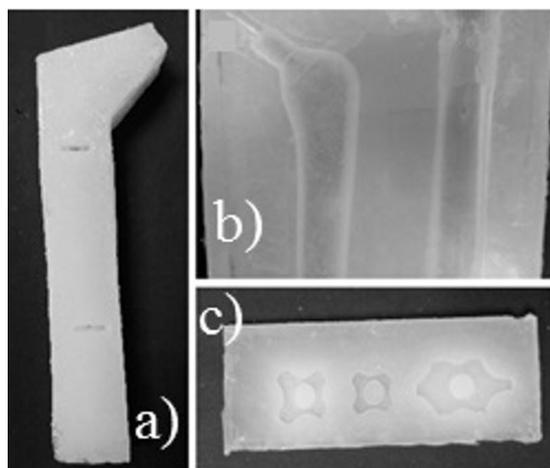


Figure 2. Silicone molds obtained using the printed models for manufacturing of: (a) the core, (b) the femoral stem and (c) the jibs for positioning of the core.

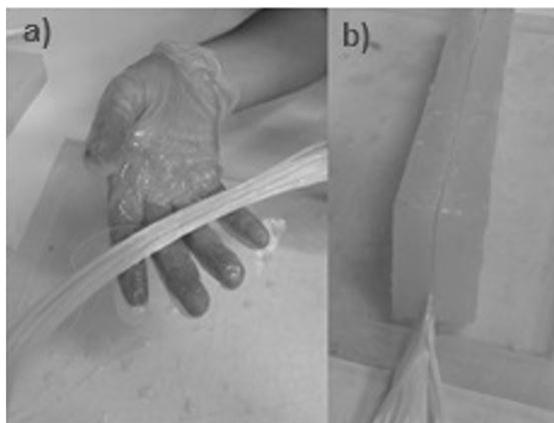


Figure 3. Fabrication process of the core: (a) Fiber impregnation with PU, (b) Placement of the impregnated fiber into the mold.

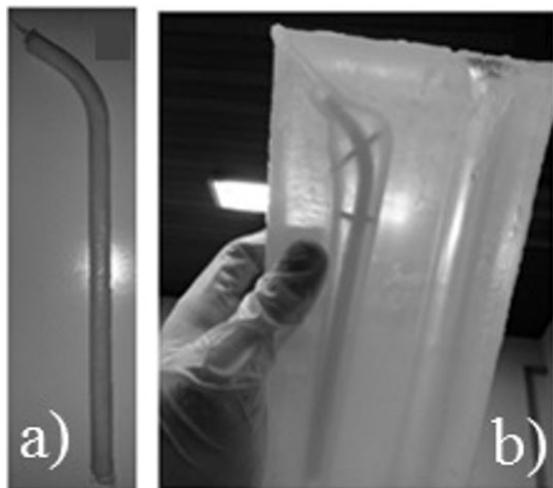


Figure 4. (a) Composite core composed of glass fiber and PU matrix; (b) core positioned in the silicon mold for the manufacturing of the stem.

bundles were placed along the length of the core, thereby obtaining, for each configuration, different mass fractions of fiber, matrix and void. Mechanical properties depend on these fractions. These were calculated by measuring samples mass before and after the complete degradation of the PU in an oven at the temperature of 600°C, since the melting temperature of fiberglass is higher than that.

According to Costa^[23], the elastic modulus for PU is 1.43 GPa. This was verified in experimental tensile tests. The elastic modulus is a key parameter for the success of femoral stems design for hip joint implant. Since glass fibers have an elastic modulus of about 70 GPa, the idea of combining it with PU to produce a composite material, is to achieve an elastic modulus close to that of human femur bone, which has a value of 17.3 GPa^[6].

According to the rule of mixtures, considering iso deformation hypothesis, it was possible to calculate the theoretical elastic modulus of the composite material following Equation 1:

$$E_c = E_f V_f + E_m V_m \quad (1)$$

where E_c , E_f and E_m are the composite, fiberglass, and matrix elastic modulus, respectively. V_f and V_m are the fiber and matrix volume fractions, respectively, that can be calculated using the Equations 2 and 3:

$$V_f = \frac{v_f}{v_c} \quad (2)$$

$$V_m = \frac{v_m}{v_c} \quad (3)$$

where v_f , v_m , v_c are, the fiberglass, matrix and composite respectively volumes. Remembering that the total composite volume v_c is the sum of the fiber glass volume, v_f , the matrix volume, v_m , and the voids volume v_v , according to Equation 4:

$$v_c = v_m + v_f + v_v \quad (4)$$

To proceed with the proper fixation of the core (Figure 4a) in the stem mold, centering jigs were placed in a 90 degrees angle with the core axis, as shown in Figure 4b.

The base mixture to obtain the matrix (prepolymer and polyol) was placed in a vacuum chamber to remove bubbles, therefore reducing voids volume. Those stems manufactured with calcium carbonate (30% in mass), this component was previously mixed in to the polyol before the addition of the prepolymer. The purpose of using calcium carbonate was to improve osseointegration at stem surface. Furthermore, Taguti has shown that PU reinforced with calcium carbonate presents increased elastic modulus and strength when compared to pure PU^[24].

With the core properly aligned in the mold, it was sealed with tape to prevent leakage during injection of the mixture. Then the mixture was injected into the mold, with the aid of an embolus, until the total filling of the mold. During the curing process, the mold was kept inside a pressure chamber at 0.8 MPa for 8 hours.

The stems were divided into four different types, stems without a center (PU), stems reinforced with 8 strands of fiberglass (PU8G), stems reinforced with 16 strands (PU16G) of fiberglass and stems with 30% of CaCo3 (calcium carbonate) e reinforced with 16 strands of fiberglass.

2.1 Quasi-static tests

Quasi-static tests were made in accordance to the standards of ABNT NBR ISO 7206-04 e ABNT NBR ISO 7206-6, which give the specifications concerning the positioning of the stems for the tests. These specifications say how far the stem needs to be inserted into the setting, both to the respect of the depth and the angle, to represent how it would be placed in the human femur. According to the standard ABNT NBR ISO 7206-04, the angles must be from, $\alpha = 10^\circ$ degrees and $\beta = 9^\circ$ degrees, with 1° (one degree) of tolerance in both cases, and the insertion of the stem, that is the distance between the center of the sphere to the surface where the setting is, there must be $D=80$ mm. For the tests in accordance with the standard ABNT NBR ISO 7206-6, the angles must be $\alpha=10^\circ$ and $\beta=9^\circ$, com 0.30° (zero point thirty degrees) and 1° (one degree) of tolerance respectively, and the level of insertion of the

stem into the femur coinciding with the real case of a total or partial substitution of the pelvic joint.

To assure that the stem would be positioned correctly, there were two templates of the position, made with a 3D printer. In the Figure 5a and 5b, the templates are according to the standards ASTM 7206-04 AND ASTM 7206-06, respectively. The femoral stem is placed into the template and them placed into the interior of a tube filled with concrete (Figure 5c). After the positioning of the stems, the verification of the height and angles was made with a digital microscope, model Dino-Lite Digital Microscope Pro. To make the measurement, the software DinoCapture 2.0 was used.

The tests were conducted with an advanced velocity of 2mm/mm utilizing a device developed by Almeida^[25], that guarantees the fixation of the concrete base and the free movement of the “head” of the prosthesis, by way of bearings and a smooth upper base. The device for the test can be seen in Figure 6. The tests were made in a machine of universal tests model WDW-100E, made by Time Group Inc.

3. Results and Discussions

Figure 7a shows the central nucleus (core) of the stems that was manufactured in two configurations: reinforced with 8 or 16 fiber bundles. Moreover, Figure 7b shows the

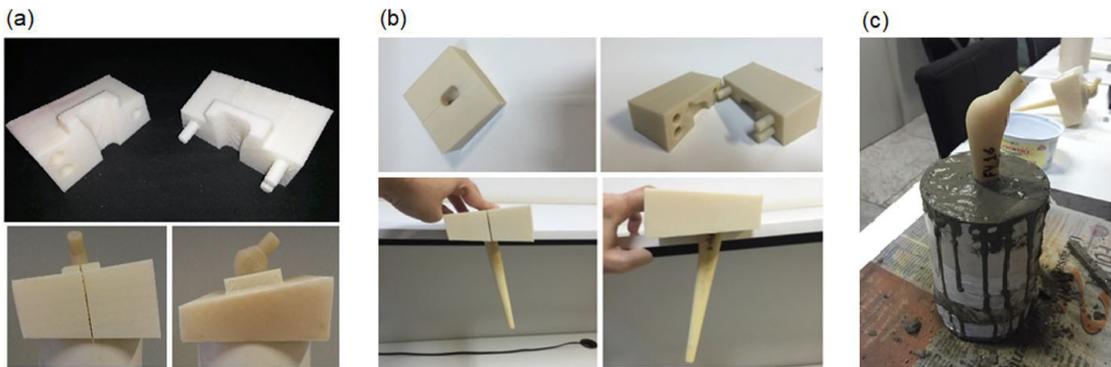


Figure 5. Template for the positioning of the stems (a) ASTM 7206-04; (b) ASTM 7206-06; (c) stem placed in concrete^[25].

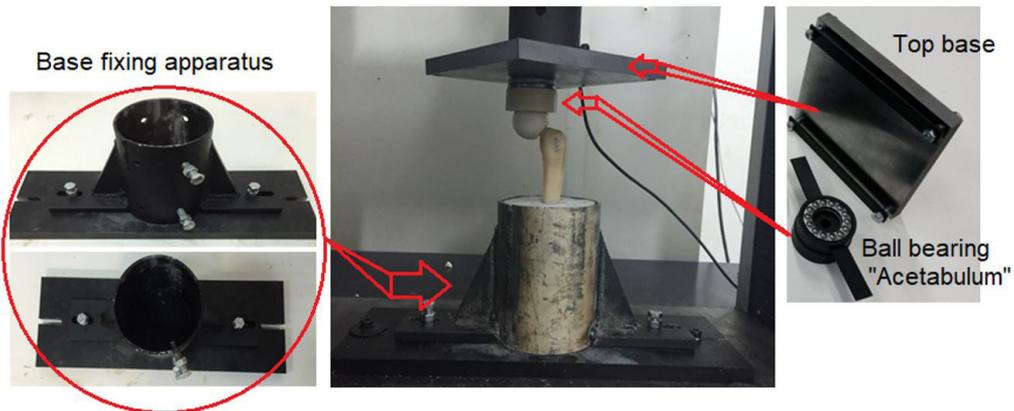


Figure 6. The device used in the tests of flex-torsion.

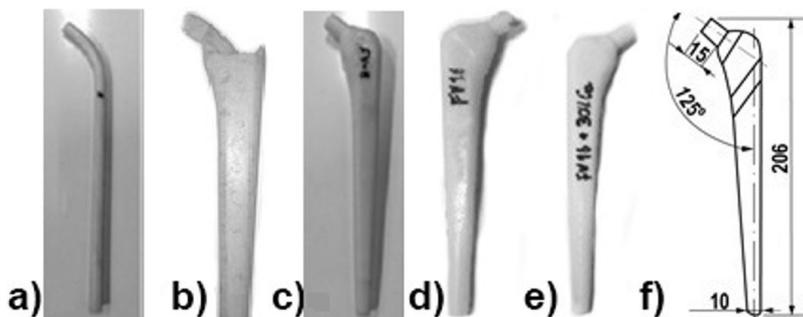


Figure 7. (a) composite core PU reinforced with fiberglass, (b) positioning of the core on the stem, (c to e) stems using different portions of fiber and (f) draw view of stem.

positioning of the core on the stem, Figure 7(c to e) shows the core with 8 fiber bundles coated with PU, 16 fiber bundles coated with PU, and 16 fiber bundles coated with PU plus calcium carbonate (30% in mass), respectively. Finally, Figure 7f shows the basic dimensions of the stem design, in millimeters.

The average values found for fiber volumetric fractions, matrix and voids and the elastic modulus for the fiberglass E-type, and polyurethane derived from castor oil are shown in Table 1. With those values was possible, through the rule of the mixture, the calculation of the composite theoretical elastic modulus of with distinct volumetric fractions of fiber and matrix, according to the different cores using 8 and 16 fiber bundles. As mentioned, the appropriate value for the elastic modulus of the material that composes the stem should be similar to that of the bone, specifically the femur, according to the literature, is 17.3 GPa^[4]. The value of 24.03 GPa, which was obtained with 16 fiber bundles, fits perfectly to the necessary mechanical requirements. It has a slightly higher value than the human bone.

3.1 Tests quasi-static of the stems

After the template of the stems according to the standard ABNT NBR ISO 7206-4:2011, there was a verification of their height and the angles. The measurements were analyzed with *software* DinoCapture 2.0. Figure 8 shows the image of the microscope on a screen indicating the

height of the center of the sphere in relation to the surface of the concrete used in the the stem template. In Figure 8, the measurements of the height of the center of the sphere in relation to the surface of the concrete can be seen (L) and the angles α and β , showing the real fixation of the stem, the closest required by the standard used.

There were three hip implant stems tested of the four different types for the analysis of mechanical behavior: PU, PU8G, PU16G and PUCa16G. The medium load and medium maximum displacement of each type of stem is seen in Table 2

It is evident that the increase of the maximum load supported by the stems conforms to the increase of the applied reinforcement. However, the values obtained appear to be promising, considering the values required for surgery of a femoral stem, according to literature. Because the tests made in this work were quase-static, thus, when a dynamic load is applied to test of the fatigue, the material will respond more intensely, being able to reach a level of force much higher than that obtained by the type of test used in the present work. In accordance with Bergmann et al.^[26] and Ramakrishna et al.^[27], the medium force applied in hip joint is around 238% of the body weight, being able to reach peaks up to ten times the weight the body weight during intense activities such as jumping and running

Silvestre^[6], in his work, also did quasi-static tests with a femoral stem made in polyurethane without reinforcement of

Table1. Fractions of mass and elastic modulus of the core calculated by the rule of mixture.

Portions of glass fiber	Em [GPa]	Ef [GPa]	Vf [%]	Vm [%]	Vv [%]	Ec [GPa]
8	1.43	72	0.14	0.8	0.06	11.23
16	1.43	72	0.32	0.69	0.02	24.03

Em -Elasticity Modulus of the Matrix; Ef - Elasticity Modulus of the Fiberglass; Vf – fiberglass volumetric fraction; Vm – matrix volumetric fraction; Vv – volumetric void fraction; Ec - Elasticity Modulus of the composite.

Table 2. Values obtained in the tests of femoral stems – ISO 7206-4.

Relation Load-Displacement	Results	
	Test according to ISO 7206-4	
	Maximum Load [N]	Displacement until the Maximum Load [mm]
PU	615.03±71.02	10.86±1.63
PU8G	767.18±104.62	14.34±1.02
PU16G	871.46±79.43	7.72±1.44
PUCa16G	922.54±42.26	9.42±2.09

Stems without a center (PU); Stems reinforced with 8 strands of fiberglass (PU8G); Stems reinforced with 16 strands (PU16G) of fiberglass and stems with 30% of CaCo3 (calcium carbonate) and reinforced with 16 strands of fiberglass (PUCa16G).

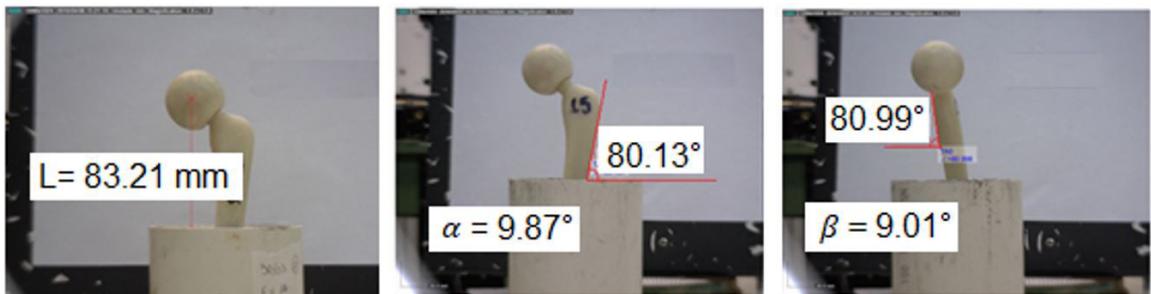


Figure 8. Measurement of the height of the template of the stem in relation to the center of the sphere and the angles of positioning.

the center, with a positioning of the stem calculated according to the standard ABNT NBR ISO 7206-4. During the test, he saw in his results that the maximum load supported by this stem without a center was approximately 750 N and a displacement equal to 7.5, mm. In this present work, for the same composition of the stem, the values found for the maximum load and the maximum displacement were, respectively, around 615 N and 10,86 mm. These discrepancies can be justified, for example, by the differences of geometry between the proposed stems, variations in the angles α and β and by small weaknesses in the securing elements during the tests, to analyze the mechanical behavior of the stems, they presented a supple behavior, without apparent fracture.

Following the same procedure during the tests of the stems in accordance with the standard ABNT NBR 7206-4, new stems with identical composition to those already cited were submitted to tests in accordance with the standard ABNT NBR ISO 7206-6.

Thus, three hip transplant stems of the four different types were tested to analyze the mechanical behavior: PU, PU16G and PUCa16G. The Information of the medium load and medium displacement of each type of stem are seen in Table 3.

At the end of the test, stem number 7 of pure PU was the only one in which a total fracture of the neck of the prosthesis (Figure 9). However, as was expected with this form of fixation (ISO 7206-6), it resulted in a load resistance of approximately 48% greater than the form of fixation of the ISO 7206-4 and the displacement reached approximately 43% of this.

In these tests, all of the stems were submitted to the maximum displacement possible until there was no limitation of contact, therefore, the obtained data is referring to the beginning of the test until the point in which there would be the contact of the sphere with the concrete (Figure 10).

Observing the results obtained, it can be assumed that a possible cause of the low values of the maximum load was the lack of rigidity of the joint of the fixing device, that is, the load applying device, the axial socket and the acetabulum, Figure 6. Table 3 presents the data referring to these tests.

The stems of PU 16G demonstrated an increased load capacity of approximately 20%, in a comparison with a stem of the same composition testes according to the standard ABNT NBR ISO 7206-4. On the other hand, the displacement according to ISO 7206-6 went beyond the other standard at 8.03%.

The stems of PUCa16G presented the best results in the analysis according to the standard ABNT NBR ISO 7206-6.

The value of the maximum load went above 88% of that which was obtained according to the first standard of the stem of the same composition, reaching a value of 1739.73 N.

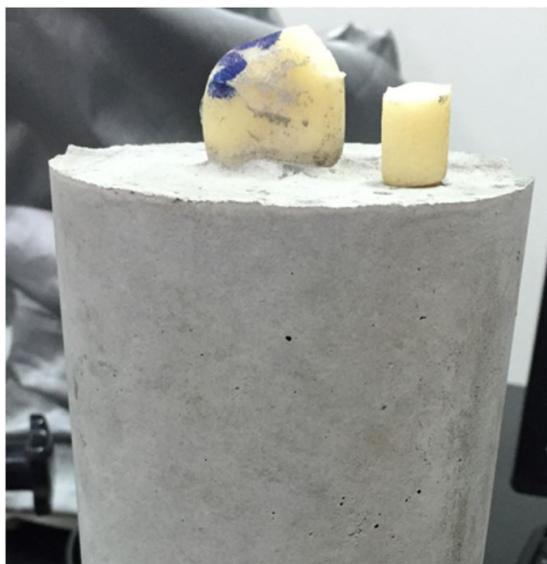


Figure 9. Fracture of the neck of the femoral stem without a center.

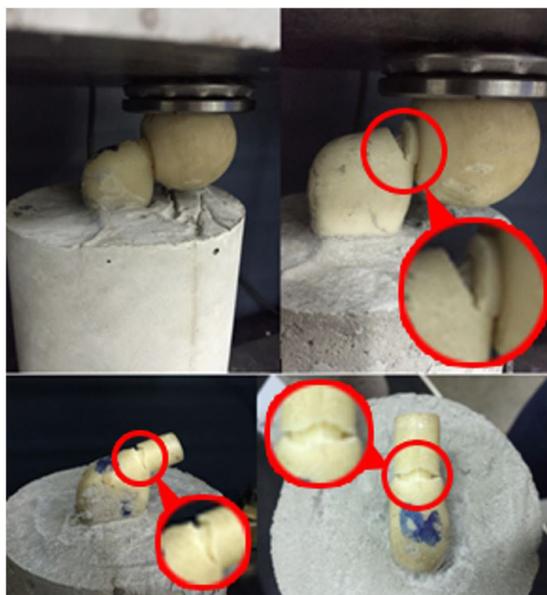


Figure 10. Aspect of the behavior of the stem during the tests.

Table 3. Values found in the tests of the femoral stems – ISO 7206-6.

Relation Load-Displacement	Results	
	Test according to ISO 7206-6	
	Maximum Load [N]	Displacement until the Maximum Load [mm]
PU	911.90±82.01	4.67±0.71
PU16G	1043.84±132.57	8.34±1.56
PUCa16G	1739.73±79.68	5.07±1.12

Stems without a center (PU); Stems reinforced with 16 strands (PU16G) of fiberglass and stems with 30% of CaCo3 (calcium carbonate) and reinforced with 16 strands of fiberglass (PUCa16G).

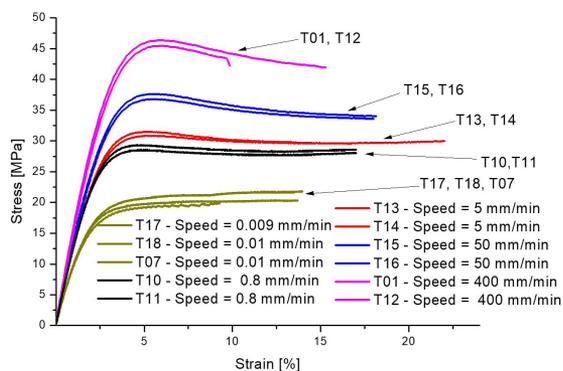


Figure 11. Stress-strain curve of monotonic tensile test at different strain rates.

The displacement was 5.07 mm until the maximum load, that is, it moved 53.8% of the earlier displacement.

All the tests made according to the standard ABNT NBR ISO 7206-6 were made until a complete or partial fracture of the necks of the femoral stems, Figure 10. As stated, the stem of pure PU was the one to have a complete fracture of the neck. The fractures of the reinforced stems show that the centers are more resistant when compared to the external form of the stem and that there is a problem in the interface of the center with the covering that it involves, which is the form of the stem. Thus, the composition between the center and this form resulted in the stem being more rigid, in a way that total fracture of the neck was avoided. For all the stems that have a center, this remained true after the tests, only the displacement of the outer form occurred. Figure 10 shows the aspect of the stems after the test, as well as the breaking of the interface between the center and the outer form.

The results obtained were promising and show that the process of production needs adaptations and improvements of the experimental volumetric portion between the fiber and the matrix for all of the body of the stem. So, there should be encouraged an increase in the resistance of the material^[28], principally the polymeric material, especially paying attention to the adhesive behavior, Figure 11. Thus, when the stem is submitted to a load with higher speed or fatigue, it should be expected that the limit of resistance similarly increases to that which occurs to polyurethane without reinforcement.

4. Conclusions

This work discusses production of a composite stem made of a biocompatible PU derived from castor oil, glass fibers and calcium carbonate. Special attention in this discussion was the structural stiff composite core, using different fiber volume fractions, corresponding to either 8 or 16 fiber bundles. These stem prototypes were produced with and without addition of calcium carbonate exhibiting, in both cases, good homogeneity of the polymer, which resulted in no apparent bubbles.

With the values of the volumetric fraction of the fiber and the matrix was possible to determine the theoretical elastic modulus of the composite material used in the cores. Considering that the core is the main structural part, responsible to support the majority of the loads developed during gait and transfer them to the femur, the whole stem (core and PU casing) will possibly be able to resist them. The theoretical value of 24.03 GPa (presented by the core with 16 fiber bundles), calculated using the rule of mixture, is higher than the elastic modulus of human bone (femur), which is 17.3 GPa^[4].

In future works, proposed to validate the functional compatibility validation, using numerical methods for the simulation of the mechanical behavior and mechanical tests based on appropriate standards^[29,30] to analyze the fatigue strength of the stem. Further simulations are also needed to analyze the influence of the stem in the stress field around the stem, and the consequent stress shielding effect due to the presence of this stem. This analysis will be made by comparing the designed stem presented here with another stem with the same geometry made of titanium alloys. Since this stem solution is to be assemble into the bone by press fit, and later to be progressively fixed by the osseointegration process, relative micromovements between stem and bone should be limited to allow new bone to grow over the stem surface. According to literature, these relative micromovements should be below 150 μm ^[31]. These micromovements depend on the stem stiffness, and therefore on its geometry and material properties. Hence, in future design iterations, the stem and core geometries will probably be changed to this future analyses. However, the present work shows very promising results aiming the improve the stress shielding effect of current gold standard solutions in titanium alloys.

5. Acknowledgements

Poliquil Araraquara Polímeros Químicos Ltda. CAPES – Coordenação de Aperfeiçoamento de Pessoal de Nível Superior.

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Received: Mar. 18, 2019
 Revised: Nov. 26, 2019
 Accepted: Dec. 05, 2019