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CF/PA12 composite femoral stems: Manufacturing and properties

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Abstract

The fabrication process for a novel carbon fiber-reinforced polymer (polyamide 12) composite femoral stem using inflatable bladder molding was studied. Effect of processing temperature, holding time and applied internal pressure on the consolidation quality of the composite was investigated. Consolidation quality was evaluated by density and void content measurements and scanning electron microscope analysis. As expected, void content (porosities) and presence of large resin pockets were found to increase for lower processing temperature, holding time and applied pressure. Crystallinity as well as melting temperatures measured using differential scanning calorimetry could be related to molding conditions. A progressive reduction of the previous thermal history (crystalline peak of neat composite) and an increase in crystallinity were obtained for higher molding temperature. Static compression testing with void content analysis of molded specimens was used to determine optimal molding conditions. The composite structure molded showed compressive modulus close to cortical bone's. Compression load at failure of composites molded in optimal conditions were found to be three times higher than those of femoral bone for jumping on one leg or 10 times those for normal gait. The molded composite structure appears to be an excellent candidate for femoral stems used in total hip arthroplasty.

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Keywords: A. Carbon fibers; A. Polymer matrix composites; B. Mechanical properties; E. Consolidation; Total hip prosthesis

1. Introduction

1.1. Composite for hip prosthesis

In the last decade fiber-reinforced composites have gained importance in many new areas of application because of their high rigidity and high strength to weight ratio in comparison to metals, their mechanical reliability and the ease with which complex 3D shapes can be fabricated [1–4]. In this study, engineered composite materials based on a thermoplastic polymer matrix and continuous carbon fibers are used to fabricate femoral stems of total hip prostheses (THP) [4–6] used in total hip arthroplasty (THA), one of the most performed and successful surger-

ies; over one million hip replacements are annually carried out worldwide. Despite its success, THA still is associated with different problems related to the life span of the implants used [7,8]. Among these problems, aseptic loosening, the degradation of the bone-implant interface leading to discomfort, chronic pain and implant retrieval, is the predominant cause of failure in total hip replacement. Aseptic loosening can be mainly related to two phenomena: production of wear debris and micromotions. Micromotions are due to a lack of fixation stability at the bone-implant interface [9–12], while wear debris are generally produced at the artificial articular joint (polyethylene–metal, metal–metal or ceramic–ceramic) and lead to osteolysis [13,14].

Another important problem associated with THA is stress shielding, a bone resorption phenomenon occurring when the implanted bone is submitted to mechanical loads lower than normal bone loading, and recently related to

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large micromotions at the bone-implant interface [15]. The vast majority of THA stems are made of metallic alloys, namely Ti-based, Co–Cr or stainless steel, that present physical properties (e.g., rigidity and density) very different from those of bone. Despite their high strength and fracture toughness, these metallic alloys present considerably higher elastic modulus (ranging from 110 to 240 GPa) than bone (ranging from 10 to 20 GPa). In this situation, the implant assumes an important portion of the load usually carried by the bone. The bone then adapts by reducing its mass to become more porous (internal remodeling) or thinner (external remodeling) [16–18], which corresponds to stress shielding. It is the premise of this work that, when it comes to designing an ideal THP, its properties, whether physical, mechanical or chemical, all have to be biocompatible and should match perfectly those of the host tissue.

1.2. Previous attempts to solve stress shielding

In trying to solve the problem of bone resorption, different stems made from so-called “isoelastic” materials have been designed [19,20]. At the time, these stems seemed to be a compromise between both challenges; having a flexible stem that diminishes stress shielding and a stiff stem that maintains interface micromotions relatively low. Some studies have shown evidence of reduced bone resorption with flexible stems [21,22]. However, mid-term results for THA using such femoral stems have not been satisfactory [19,23,24]. Follow-up period of 5–9 years supported the fact that these stems were disadvantageous in clinical practice; concerns for long-term survival were raised from lack of fixation and too high a level of micromotions at the bone-implant interface, which were believed to be the main reason for the high failure rate [24,25].

Hip stems from polymer composite materials have also been used to address stress shielding. One of these attempts consisted in a thermosetting polymer-based composite hip prosthesis made by resin transfer molding (RTM) with stiffness similar to that of the surrounding bone [26]. However, unavoidable residual monomers present in the final product make the use of thermosetting polymers required for RTM undesirable. A composite femoral prosthesis with an internal Co–Cr core and a flexible composite outer layer manufactured by compression molding was also proposed [27–29]. In this case, the prosthesis still presented stiffness far from that of cortical bone to which it is fixed and a soft outer layer prone to shear deformation. Other attempts were based on different types of composites with a smooth surface such as pre-impregnated graphite/epoxy composites [30], polyetherimide with carbon and glass fiber reinforcement [31] and short carbon fiber-reinforced polyetheretherketone (PEEK) [32]. However they did not succeed at the clinical level. In fact, a human clinical study of a press-fit carbon fiber hip prosthesis with a smooth surface [33] concluded that insufficient bone fixation of the prosthesis caused early loosening of the implant, although

the composite stem had the mechanical properties to resist the physiological stress of a hip joint.

1.3. Objectives of the work

The overall goal of this work is to fabricate a femoral hip stem based on a continuous carbon fiber polymer composite presenting mechanical and physical properties similar to those of the femur, as well as good bone-implant fixation in a press-fit configuration. The present study describes the factors that affect the fabrication of the composite femoral stems using the inflatable bladder molding process and the determination of the process window for this process. In a second communication [34], the mechanical strength and fatigue performance of the stems are evaluated to validate this novel THP design. *In vitro* biocompatibility and *in vivo* osteointegration work is reported elsewhere [35].

2. Materials and methods

2.1. Material preparation

The materials used in this study were braids composed of commingled carbon and polyamide 12 (PA12) fibers obtained from Schappe Techniques (Charnoz, France). Composition and morphological details are provided in Table 1. This particular braiding architecture combines filament winding and weaving. Tubular braid features seamless fiber continuity from one end of the part to the other and like woven materials, the braided fibers are interlocked with one another, enabling the braids to evenly distribute load throughout the structure. The fiber orientation or the helix angle varied between 20° and 50° as a result of stretching occurring during the preparation of the multi-braids structures. Processing included 40 spindles of thread mounted on the carriers in order to obtain the two types of braided sleeves used: a thread-to-thread weave and a 2:2 twill weave.

Inflatable bladder molding [2] was used to fabricate the stems. Six overlaid braided sleeves of CF/PA12 yarns were placed around a silicone bladder mandrel. Two different sizes of sleeves were used to build the femoral stem structure. The flat sleeve width (measured when compressing the cylindrical sleeves into a flat configuration) in the first four layers was 18 mm and in the last two layers 35 mm. All specifications concerning each layer are detailed in

Table 1
CF/PA12 composite material characteristics

Volume fraction of CF	0.55
Weight fraction of CF	0.683
Density of CF (g/cm ³)	1.78
Density of PA12 (g/cm ³)	1.03
Diameter of CF (μm)	10
Diameter of PA12 fibers ^a (μm)	26

^a Prior to consolidation.

Table 2
Specifications of the femoral stem

Nth layer	Initial flat sleeve width (mm)	Final flat sleeve width (mm)	Length (mm)	Fiber orientation (°)
Bladder	7.5 (internal)	10.5 (outer)	270	–
1	18	18	230	50
2	18	19	250	40
3	18	20	270	35
4	18	22	290	30
5	35	35	230	50
6	35	35	240	50

Fig. 1. Mold used in inflatable bladder molding and resulting composite femoral stem.

Table 2. The assembly was then placed in a steel mold and inserted into a press equipped with heated/cooled platens as illustrated in Fig. 1. Once the desired molding temperature (above the melting point of the thermoplastic matrix of the composite) was reached upon heating, the bladder was inflated at a given pressure using nitrogen gas and the pressure was maintained for a given period of time, forcing the fabric against the steel mold cavity, which depending on the molding conditions squeezed out the excess resin between the two parts of the mold through the parting line. The mold was then cooled to room temperature. The approximate cooling rate was $-17\text{ }^{\circ}\text{C}/\text{min}$ as measured using a thermocouple inserted into the composite specimens. Internal bladder pressure was released only after crystallization was completed ($<110\text{ }^{\circ}\text{C}$). The nominal wall thickness of the composite structure was 3 mm. A picture of the composite femoral stem is shown in Fig. 1.

2.2. Molding process optimization method

The range used to determine the processing window of the inflatable bladder molding process used in this study was dictated by the materials properties or operating conditions. The criteria used to determine optimal molding was void content (see following section), as it was shown to affect structural characteristics of continuous fiber composites such as modulus of elasticity, strength and fatigue

resistance [36]. Three predominant parameters affect the inflatable bladder molding process: the maximum molding temperature, the effective pressure applied by the bladder and the duration of the application of this pressure at maximum molding temperature before cooling (designated herein as holding time). The upper and lower limit for the temperature was set by the thermal degradation temperature of PA12 and its thermodynamic melting temperature (T_m), respectively of 250 and $178\text{ }^{\circ}\text{C}$ [37]. The latter thermodynamic melting temperature is not affected by the size of the specimen analyzed, the heating rate, etc., and was preferred to the melting temperature measured using a thermal analyzer. Temperature during molding was monitored using a thermocouple inserted into the specimen. The upper and lower limit for the effective applied pressure was set by the burst pressure of the bladder system and the minimum pressure of the manometer used, respectively of 480 and 70 kPa. The effective applied pressure, P_{eff} , is the pressure in the bladder, P_a , minus the pressure required to inflate the bladder itself, P_{bladder} , before any pressure is transferred to the material. The holding time was more pragmatically varied within a realistic range of process cycles of 1–10 min, since longer holding times make the process unappealing from a manufacturing point of view.

Molding temperatures of 175, 200, 225, 240 and $250\text{ }^{\circ}\text{C}$ were used in a first round of molding cycle optimization with effective pressure set to its maximum employed value of 480 kPa and holding time to mid-range value of 5 min. Holding times of 1, 2, 5, 7 and 10 min were then used at the molding temperature determined in the first round with pressure maintained at maximum value of 480 kPa. Finally bladder pressure was varied from 70, 140, 275, 410 and 480 kPa, while holding time and temperature previously determined were used.

2.3. Microstructural characterization methods

To evaluate the consolidation quality of the composites molded in the three rounds of process optimization, microstructural characterization was done by microscopy, void content assessment and density measurements using Archimedes' method (water-immersion). According to Archimedes' principle, a body immersed in a fluid is buoyed up by a force equal to the weight of the displaced fluid. The required density can be calculated using this principle. The following equation was used to calculate the sample density ρ_2 :

$$\rho_2 = \frac{A}{A - B} \cdot \rho_o \quad (1)$$

where, A and B are the sample weights in air and water, respectively and ρ_o is the density of water at measuring temperature. To calculate the void content in the samples, the following equation was used:

$$\text{Void (\%)} = \frac{\rho_t - \rho_i}{\rho_t} \times 100 \quad (2)$$

where ρ_t represents the theoretical density of CF/PA12 composite (1.443 g/cm^3) and ρ_i is the actual density after processing. In this case, ρ_t was calculated from a simple rule of mixtures using the theoretical density of PA12 and CF and the volume fractions of PA12 and CF provided by the manufacturer (Table 1). To visualize voids or porosities, cross-sections were obtained from the molded composites, polished and observed with an optical microscope.

In order to determine the processing window of the composites, the thermal characteristics of the polymer matrix were obtained using a Perkin–Elmer differential scanning calorimeter (DSC-7). Thermograms were recorded from 30 to 250°C at a heating rate of 10°C/min . This rate was based on the recorded molding temperature cycle. Care was taken to collect the DSC samples from the middle section of the molded cylinders so that the samples were representative of the different molding conditions. Sample weight varied between 3 and 9 mg. Duplicate of each tested condition were obtained. From the DSC thermograms, the crystalline index X_c can be derived from the following equation:

$$X_c = (\Delta H_f / \Delta H_f^0) \cdot 100 \quad (3)$$

where ΔH_f is the measured heat of melting of the sample corrected for matrix content and ΔH_f^0 is the heat of melting of pure, fully crystalline PA12; a value of 95 J/g was used for ΔH_f^0 of crystalline PA12 [37]. Matrix content was obtained by pyrolysis of CF/PA12 specimens at 400°C for 3 h (estimated precision of $\pm 5\%$). Standard deviation for crystalline index X_c is estimated to be 10%.

2.4. Compression test methods

To evaluate the mechanical properties of the molded composites, uniaxial compression testing was done using an Instron electromechanical testing machine with computer data acquisition using a 100 kN load cell with parallel plates. The crosshead speed was 5 mm/min and cylindrical hollow tubes (length of 44 mm and wall thickness of 3 mm) with parallel flat faces were tested. Compressive strength and strain were calculated from the maximum load value on recorded load–displacement curves divided by the specimen cross-section. Deformation ratio reported was calculated as the reduced length during compression to initial length ratio. Compressive modulus was obtained from the slope of the initial linear region of the load–displacement curve. By optical microscope observation, the cross-section area of the molded cylindrical specimens typically varied by approximately 10% for any given molding conditions.

3. Results and discussion

3.1. Optimization of the consolidation process

To evaluate the realistic processing window from the inflatable bladder molding of CF/PA12 composites, the

void content as a function of maximum molding temperature, effective applied pressure and pressure/heat holding time prior to cooling was evaluated and is reported in Fig. 2. Void content decreased as molding temperature (Fig. 2a) and effective pressure (Fig. 2b) increased within the range studied. However, void content rapidly decreased to a minimum for a holding time of 5 min (Fig. 2c), and longer holding times did not lead to further reduction of void content within the range studied. Fig. 2 generally illustrates the well-known tendency of consolidation quality for a given thermoplastic composite to be improved at higher molding temperature, pressure and time [36].

Optical microscope observations of polished sections of the composites molded in different conditions showed that when a low molding temperature was used, several voids and poor fiber wetting was generally observed, in agreement with high void contents (Fig. 2a). Low pressures and/or too low holding times generally resulted in large pockets of air and poor fiber dispersion, also in agreement with high void contents observed in these conditions (Fig. 2b and c). When higher pressures, higher temperatures and holding times of 5 min and longer were used, the composites showed good dispersion and impregnation of the carbon fibers and low void content, as shown in Fig. 3. Apparently, adequate matrix viscosity and flow was only obtained in these conditions. It is concluded that molding the composite specimen at a temperature of 250°C maintained for 5 min under an applied pressure of 480 kPa led to best consolidation quality within the realistic range of molding conditions used.

3.2. Thermal characteristics

DSC thermograms were obtained from samples of pristine and CF/PA12 composite molded at 175, 200, 225 and 250°C for 5 min and also at 250°C for 1 and 10 min. These thermograms, shown in Fig. 4, were analyzed to obtain ΔH_f corrected for matrix content and, using Eq. (3), the crystalline index X_c . These results are reported in Table 3. The thermograms at lower molding temperatures (175 and 200°C) show the presence of two major endothermic peaks, the first very close to the reported melting point of PA12 (178°C) and the second above T_m , preceded by a minor endothermic peak around 160°C . The second major peak almost completely disappeared at 225°C and was not noted at 250°C . The minor peak progressively disappeared as the molding temperature increased from 175 to 250°C . The DSC thermograms of the pristine composites showed a different crystalline structure, with two major endothermic peaks: the first, less important, around 170°C and the second around 178°C (T_m).

These DSC thermograms indicate that molding temperatures of 200°C and below were not high enough in the 5 min allowed to completely melt the crystalline structure of the neat braids of composite and erase previous thermal history. These conditions led to partial melting of the composites and further crystallization of the non-molten

Fig. 2. Evolution of void content as a function of (a) maximum molding temperature ($P_{\text{eff}} = 480$ kPa, $t = 5$ min), (b) effective applied pressure ($T = 250$ °C, $t = 5$ min) and (c) pressure/heating holding time prior to cooling ($T = 250$ °C, $P_{\text{eff}} = 480$ kPa) for CF/PA12 braids consolidated by inflatable bladder molding (interpolation curve and standard deviation are shown).

matrix, as illustrated by peak presence at 179–183 °C (Table 3). Partial melting is evidenced by the minor peak around 160 °C and the major peak around T_m , while the further crystallization of the original crystalline structure is shown by the second major peaks above. As a result, crystalline index of neat fabric of approximately 57% further increased to 66% when molded at 175 °C since re-crystallization occurred while melting did not. When molded at 200 °C, the relative intensity of the peak around T_m reduced in comparison with the following peak associated with further crystallization of the original structure, showing that original crystalline structure did not disappear completely. Overall, the crystalline index for this molding condition decreased to 42%. When molding at 225 °C, melting was almost complete, with only a small shoulder left on the high temperature side of the major T_m peak.

In this case, the presence of the minor peak around 160 °C indicates that crystallization was still imperfect and that re-crystallization still occurred. Crystalline index for molding at 225 °C thus increased to 47% in comparison with molding at 200 °C. At molding temperature of 250 °C and/or longer holding time, crystalline index increased to 58% (250 °C/1 min) and 64% (250 °C/5 and 10 min). Crystalline index thus leveled off at 64% for holding times of 5 min and above. Optimal void content were obtained for holding times of 5 min and above also (Fig. 2c).

Very little information on the crystalline structure of PA12 is available in the literature, besides the melting temperature and glass transition. However, the melting behavior of PA12 indicates that it is thermally stable and that it usually crystallizes into the monoclinic α form [37].

Fig. 3. Optical micrographs of polished cross-section of CF/PA12 composites at a molding temperature of 250 °C, effective applied pressure of 480 kPa and holding time of 5 min.

Fig. 4. DSC thermograms (10 °C/min) of the molded specimens at different temperatures and holding times (indicated) and of neat composite (vertical line indicates thermodynamic temperature of melting of 178 °C).

Table 3
Crystalline index and heat of fusion of molded composites (P_1 and P_2 refer to first and second peak of melting when present)

Specimen	Melting peak (°C)	ΔH_f corrected for matrix content (J/g)	X_c (%)
Neat fabric	$P_1 = 171.1$ $P_2 = 177.8$	54.1	57
Molded at 175 °C (5 min)	$P_1 = 176$ $P_2 = 182$	62.6	66
Molded at 200 °C (5 min)	$P_1 = 176$ $P_2 = 183$	40.1	42
Molded at 225 °C (5 min)	$P_1 = 177$ $P_2 = 179$	44.3	47
Molded at 250 °C (1 min)	176	55.3	58
Molded at 250 °C (5 min)	178	60.4	64
Molded at 250 °C (10 min)	177	61.0	64

3.3. Mechanical properties

Engineering stress–deformation ratio curves are shown in Fig. 5 for different molding conditions. The compression test results of CF/PA12 composites are reported in Table 4, in terms of void content, compressive modulus and maximum load and corresponding ultimate strength in compression. These curves show that the molded composites undergo a first linear stress–strain behavior when subjected to compression, followed by yielding and abrupt softening until a plateau is reached. It was also observed that yielding occurred by shear deformation at $\pm 45^\circ$ planes with respect to loading axis (along the orientation of carbon fibers) in the cylindrical specimens, as shown in Fig. 5a. The following plateau observed corresponds to the extension of the sheared region to adjacent non-sheared regions. More importantly, these curves confirm that molding conditions have a significant effect on the mechanical properties of the molded composites. From Fig. 5, it is observed that the modulus, strength and shear plateau of the composites generally increased as a function of molding temperature, holding time and effective pressure applied.

Since all three molding parameters were shown to be related to void content in Fig. 2, the effect of these three molding parameters on the mechanical properties are reported using void content (Fig. 6). From the results in Fig. 6, it appears that the effect of temperature on the mechanical properties is very important, with values of both modulus and strength reducing by more than 50% at lower temperatures. At optimal molding temperature, the effect of holding time and pressure on the modulus and strength is less marked, with reduction of 30–40% at lower holding time or pressure. However, the non-negligible variation in initial cross-section area of the molded specimens as well as the fact that the effective cross-section increases upon compressive deformation resulted in non-negligible standard deviations in mechanical properties shown in Fig. 6. The latter effects of temperature, holding time and pressure on the modulus and strength of the composite molded should be considered as general tendencies for process improvement.

In optimal molding conditions (250 °C, 5 min and 480 kPa, see Section 3.1), the cylindrical specimens with a nominal wall thickness of 3 mm and external diameter of 22 mm (recommended for CF/PA12 composite stems in the loaded proximal region [15]) present modulus of 10–11 GPa and compressive strength of 155 MPa, which corresponds to loads of 28–32 kN for the present geometry. The modulus obtained is thus in the same order of magnitude and only slightly lower than the reported modulus of cortical bone of approximately 15 GPa [38]. The maximum load obtained is roughly 10 times larger than normal physiological loads experienced during gate (3 kN [39,40]) or three times larger than highest loads experienced while jumping on one leg (10 kN [39]). These results indicate that the composite structures fabricated have the potential to be

Fig. 5. Engineering stress–deformation ratio curves for different molding conditions: (a) variable temperatures with constant pressure (480 kPa) and time (5 min) with example of shear fracture at $\pm 45^\circ$ planes, (b) variable pressures with constant temperatures (250 °C) and time (5 min), (c) variable holding times with constant temperature (250 °C) and constant pressures (480 kPa).

Table 4
Void content, mechanical properties and molding conditions of the composite molded

Temperature (°C)	Time (min)	Pressure (kPa)	Void content (%)	Maximum load (N)	Ultimate strength (MPa)	Compressive modulus (GPa)
175	5	480	5.6	12,700	78	4.5
200	5	480	5.1	17,650	115	7.5
225	5	480	4.6	23,500	143	8.1
250	5	480	3.1	32,075	171	10.7
250	1	480	5.3	18,675	120	6.9
250	2	480	4.9	19,375	127	7.2
250	7	480	2.9	29,975	171	10.5
250	10	480	2.8	31,050	169	10.9
250	5	70	8.2	21,850	117	6.8
250	5	140	5.9	24,375	141	6.9
250	5	275	5.0	28,025	148	7.5
250	5	480	3.1	32,075	171	10.7

used to substitute or replace bones. Specifically in the case of this application, where a high rigidity control and high mechanical reliability are required in order to imitate the properties of cortical bone, the consolidation quality must be taken into account.

4. Summary and conclusions

The main goals of this study were to evaluate the effect of processing parameters on the consolidation quality of CF/PA12 composite obtained from inflatable bladder

Fig. 6. Compressive modulus (■) and ultimate compressive strength (□) of CF/PA12 composite samples for variable: (a) molding temperatures, (b) effective pressures, and (c) holding times, as a function of void content (interpolation curve and standard deviation are shown).

molding and assess their impact on the mechanical properties of the material. Observations showed that void content varied considerably upon molding the CF/PA12 composites depending on the conditions used, which reveals the influence of matrix viscosity and associated matrix flow on the consolidation process. A low molding temperature limited polymer flow and led to high void content, poor fiber wet-out and poor fiber dispersion. A higher temperature favored impregnation and led to lower void contents. However, molding temperatures were limited to 250 °C in order to avoid thermal degradation of the polymer matrix. Holding times shorter than 5 min led to insufficient consolidation and high void content. Finally, the applied pressure was an essential factor in the consolidation process. Experimental data showed that impregnation pressures greatly affect the final outcome of the molding. The optimal processing window was found to be a temperature of 250 °C, an applied pressure of 480 kPa, both maintained for a period of 5 min.

As expected, mechanical properties were affected by consolidation quality and the microstructure of the CF/PA12 composite. A high void content with large air pockets or porosities renders poor consolidation quality and consequently a reduced stiffness and rigidity. A thermal analysis of the composite by DSC revealed the presence of a melting temperature near 180 °C. It was found that the processing conditions studied greatly affect the crystalline structure of PA12 and its thermal behavior, and that a molding temperature of 250 °C was necessary to remove all traces of previous thermal history on the DSC thermograms.

This study demonstrates the feasibility of fabricating tubular structures from CF/PA12 composite braids using inflatable bladder molding, an inexpensive method that leads to reproducible stem performance based on mechanical properties and void content. Further issues concerning the biomechanical performance of the femoral stem in short and long-term are addressed elsewhere.

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