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Characterization of a peek composite segmental bone replacement implant

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A composite material of polyetheretherketone and short, chopped E-glass fibers was used to produce a segmental bone replacement implant. Problems with current metallic implants include stress-shielding of the surrounding bone and subsequent loosening of the implant. A better match between the bulk material properties of the implant and the bone it replaces can decrease the occurrence of these problems. Composite materials were chosen because their properties can be tailored to match the requirements. Material selection was accomplished with the aid of modeling software, which predicted the composite properties based on its composition and fiber directional parameters. Prototype parts were completed through a series of in-house molding and machining processes. Sections complete with an embedded metallic porous surface were tested to measure the strength of the attachment of the surface. The molded parts were characterized both destructively and nondestructively. The results of tensile tests performed on molded parts were comparable to those using commercially supplied samples. The fiber orientation was measured to verify the random positioning of fibers throughout the part, as assumed in the initial material selection. Ultrasonic C-scanned images confirmed that the molded parts had a very low density of air pockets or voids.

1. Introduction

Bone is a natural composite material with a matrix of organic and inorganic substances. A synthetic composite material is an obvious choice to use as an implant, such as a segmental bone replacement implant, to replace a missing or diseased segment of bone. Several conditions can lead to a permanent loss of bone, including irreparable damage due to trauma, arthritic diseases and musculoskeletal defects, the removal of malignant tumors, and the replacement of a failed implant.

Orthopedic implants used today are typically fabricated from metal, using pure or alloyed forms of titanium (Ti) or cobalt chrome (Co-Cr). Initial stabilization of the implant is achieved through the use of bone cement (polymethylmethacrylate, PMMA). The PMMA fills the interfacial space between the bone and the implant. Long-term stabilization of the implant in bone is achieved through the application of a porous coating on the surface of the implant [1, 2] (usually made of metal or a bioceramic [3–5]). The porosity must allow the passage of bone cells, which hold the implant in place by reconnecting with adjacent bone tissue throughout the porous mesh.

Problems with the current implant design arise from a difference in the mechanical properties of the materials interfacing with the implant [6–10]. The metallic implants are a minimum of 8 times stiffer than the surrounding cortical bone. This large gradient causes stress shielding, where the metal implant supports and absorbs most of the load and leaves the bone virtually inactive and unstressed. The shielded, unstressed bone around the implant begins to resorb [11], creating cavities between the implant and the bone and allowing micromotion of the implant. The continuous motion and wear of the implant produce microscopic foreign body wear debris that triggers the body's defense mechanism and causes infectious reactions in the surrounding tissue.

Loosening of the implant is irreversible without intervention and ultimately leads to a revision operation. After two or three revisions, the bone becomes too weak and osteoporotic to support another replacement and is considered non-functional. An isoelastic implant system (the use of an implant with a modulus close to that of bone) would minimize, if not eliminate, the stress shielding effect and lead to a longer implant lifetime in the body [12–17]. Research has shown that composites are an excellent choice of materials to use for implants, specifically when the tailoring of its material properties has a large impact on its success [10, 18–20].

The current study applied composite technology to the development of a bone replacement implant. The

implant is made of polyetheretherketone (PEEK), a high-temperature thermoplastic, and short, chopped E-glass fibers. This paper concentrates on characterization of the properties of the composite implant material. A laminate analysis program was used to predict the properties of short, chopped fiber composites with fiber orientations that varied from those that are aligned with the flow direction to those that are completely random in orientation. Included is sectioning of both purchased and in-house fabricated parts to microscopically observe the fiber orientation and to measure properties of the implant and compare them to those of bone. Also included are Ultrasonic C-scans of the implants to verify that the fabrication technique did not leave voids. Finally, push-out studies were performed to show that embedding titanium in the composite surface would produce a good interface for bone ingrowth.

2. Materials and fabrication

The first step in producing an isoelastic implant was to develop a material that has bulk mechanical properties similar to those of bone. A high-temperature thermoplastic polymer PEEK was chosen as the resin, or matrix material, for its low stiffness relative to bone, high toughness, strong chemical resistance and previously recorded biocompatibility with bone tissue cell [21–23]. PEEK is virtually immune to solvents and exhibits very little effect on material properties by the penetration of moisture and/or saline solution. Although graphite (carbon) fibers have been used as a reinforcement in a PEEK matrix [7, 21, 24–26], E-glass, or electrical glass, fibers were selected as the reinforcing material for this implant. Relative to other fiber materials, E-glass has a combined benefit of high stiffness and low cost. The processing of the preforms was easier with E-glass fibers, since they are less abrasive than graphite and flow more smoothly through the narrow channels of the injection molding system. Most importantly, the glass fibers are transparent to radiation therapy and would not create shadows in X-ray images or interfere with other post-operative treatment. The defining mechanical properties of the two constituent materials are listed in Table I. The combined material used for processing the implants was commercially supplied, and the sizing on the fibers was pre-optimized to the PEEK matrix.

A software package, called SMC Micromechanics Model for Composite Materials [27], was used to predict the thermoelastic properties of PEEK reinforced with E-glass fibers. Calculations were made based on the constituent properties of the resin and reinforcement phases, their composition, the fiber aspect ratio, and the degree of orientation of the reinforcement throughout the resin. Similar to the transverse isotropy of cortical bone [8, 19, 28], a random fiber composite material has a different modulus in its three material directions longitudinal, transverse, and perpendicular. The most critical direction of stress through the implant and the bone, when considering stress-shielding, is longitudinal. The longitudinal modulus for the implant substrate being created should be slightly lower than that of bone, in anticipation of additional stiffening from a metallic porous surface added later in the fabrication process. Although it is not critical for this design, both the cortical bone and the PEEK composite have a lower transverse modulus relative to their respective longitudinal moduli.

TABLE I Mechanical properties for the resin and fiber materials of the composite implant

Material	Elastic modulus, GPa (psi)	Poisson's ratio
PEEK resin	4.2 (0.6×10^6)	0.41
E-glass fibers	72.4 (1.1×10^7)	0.20

Commercial compounding services typically provide fiber volumes of 10, 20, and 30% for both glass and graphite fibers. These are the compositions used in SMC to determine material properties. Instead of relying solely on commercial data published for these materials, this program was used to predict the properties of the same compositions but with various fiber orientations. Two parameters are used to describe the fiber orientations (Fig. 1): f_p describes the planar fiber orientation in the 1-2 plane, and is defined by Φ; f_a describes the axial orientation relative to the 3 axis, and is defined by θ. The program calculated the moduli for different material compositions having a range of fiber orientations.

Prototypes of the composite implant were made using a pressure/injection molding system developed for this project (Fig. 2). The assembly consists of a reservoir, where the material sits and heats up to its molten state. The channel is opened and closed by a two-way valve connecting the reservoir to the tightly clamped mold. The injection speed was controlled by pressure applied via a piston to the material in the reservoir. The material was released when the valve was opened, and it was pushed into the end of the mold in the direction of the long axis of the part. Temperatures of the reservoir and the mold were controlled individually by a set of four heaters each.

Small pellets of 10% glass-filled PEEK, provided by RTP Co., were heated up to 377.8 °C (680 °F) to reach

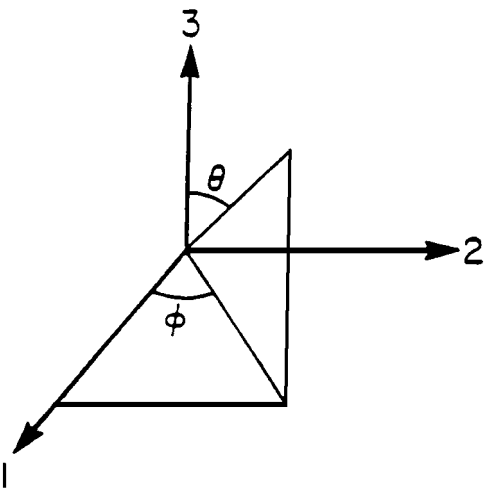


Figure 1 Reference definitions of orientation parameters f_p and f_a in the SMC program [27].

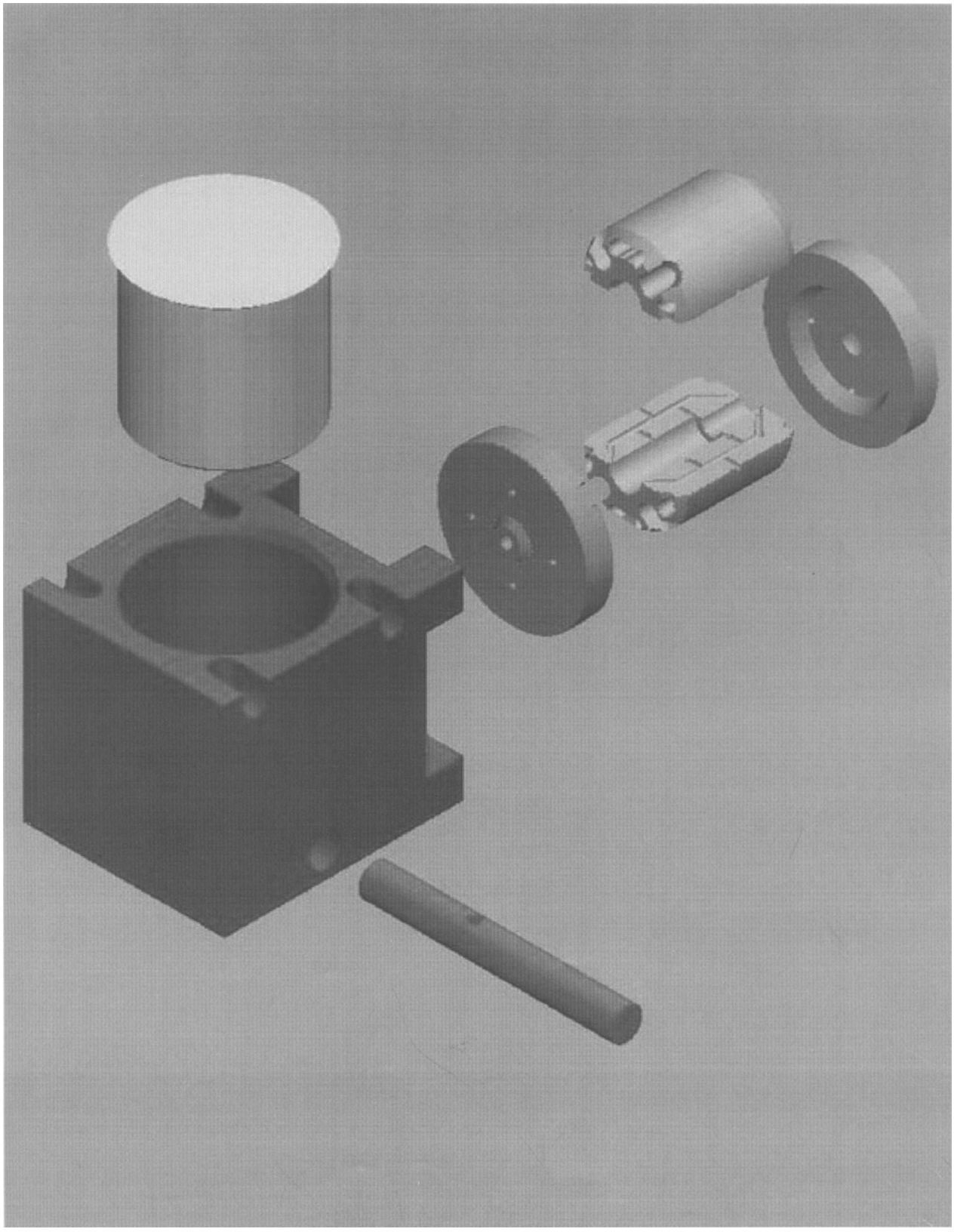


Figure 2 Schematic representation of the in-house injection molding assembly.

its molten state. Since PEEK is such a highly viscous material, even in its molten form, the injection pressure was increased to 517 MPa (75,000 psi). A 207 MPa (30,000 psi) back pressure was held while the part cooled from 250 °C (450 °F) to 152.8 °C (275 °F). The high injection pressure created the fastest injection speed within the constraints of the system, providing the best possible alignment of the fibers along the length of the part. The back pressure forced residual air pockets to escape. The molded parts were only preforms of the final implant. To reach the final shape, several additional machining and molding processes were required. In commercial use, these processes can efficiently be combined into one or two steps to reach completion.

A final implant includes two pieces, each with a tip that fits into the bone's medullary canal (Fig. 3). The

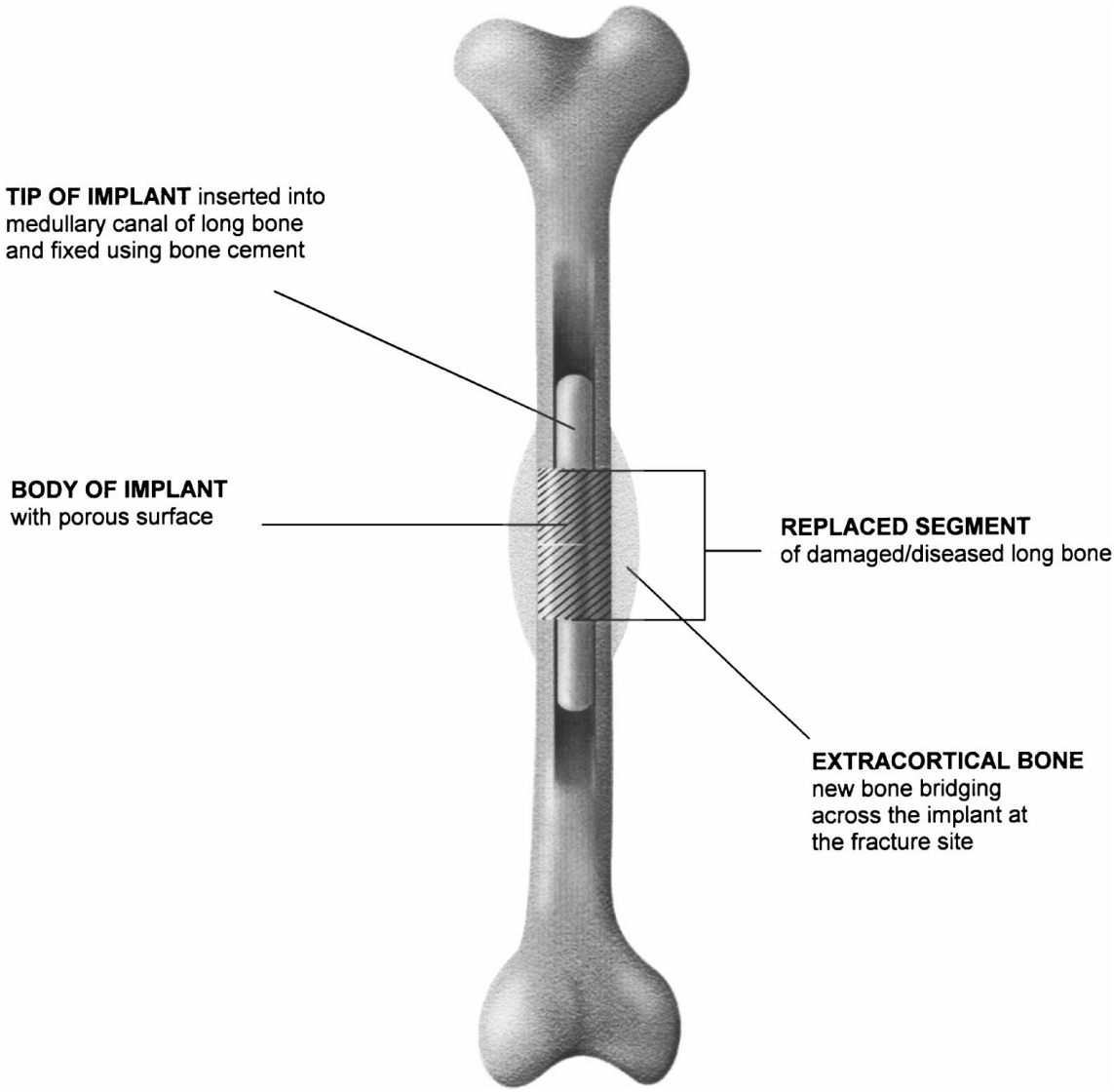


Figure 3 Artistic rendering (not necessarily to scale) of a segmental bone replacement implant replacing a section of damaged or diseased long bone.

wider body has a porous coating to support the growth of extracortical, or new, bone tissue. The tips are inserted into the exposed ends of the fractured bone at the diseased or damaged site. Bone cement is used to fix the tips in the bone, and grooves on the tips (Fig. 4 bottom) provide additional surface area for the cement to fill. The implant tip in the bone must be long enough to insure anchorage in healthy bone (i.e., the dimensions of bone replacement implants are custom designed to fit each individual patient). The implant halves are joined by connecting the mating flutes (Fig. 4), which closes the fracture site.

The final fabrication process is the creation of a porous surface on the body of the implant to facilitate the development of a strong, stable tissue-implant interface. This is accomplished by embedding a tight, Commercially Pure Titanium (C.P.Ti) wire coil into the surface of the implant (Fig. 5). The titanium is used for its proven biocompatibility [3, 5, 24, 29, 30]. Proprietary methods were used to create this surface.

To demonstrate that the coil was securely embedded into the surface while providing adequate porosity for bone tissue to connect to, push-out tests were performed. The body of the implant was set in an epoxy, using a 33 : 100 ratio of EPON Curing Agent V-40 to EPON Resin 826. The epoxy represents bone tissue surrounding the implant, interlocking throughout the pores of the embedded coil. The tests were performed on an Instron Machine running a general compression test.

3. Results

3.1. Material selection

The SMC program calculated the range of moduli for compositions of E-glass and graphite filled PEEK from a completely random distribution of fibers to a relatively aligned distribution (Table II). A composition of PEEK with 10% glass fibers had a predicted modulus range from 6.05 GPa (0.88×10^6 psi) to 10.54 GPa (1.53×10^6 psi) for completely random to completely aligned fiber orientations, respectively. The highest value is still less than the modulus of bone, 17.2 GPa (2.49×10^6 psi) [19, 31, 32], allowing for additional stiffening with the application of a metallic porous surface. The final implant, with the porous surface, will then have a modulus approximately equal to that of bone. The peak moduli of the 20% and 30%

TABLE II Longitudinal moduli predicted for composite materials having either completely random or perfectly aligned fiber orientations (from SMC program)

Composition (% fiber)	Longitudinal modulus, GPa (psi)	
	Completely random	Perfectly aligned
10% E-glass	6.05 (0.88×10^6)	10.54 (1.53×10^6)
20% E-glass	8.22 (1.19×10^6)	16.98 (2.46×10^6)
30% E-glass	10.65 (1.55×10^6)	23.15 (3.36×10^6)
10% Graphite	6.89 (0.99×10^6)	16.27 (2.36×10^6)

E-glass/PEEK and 10% graphite/PEEK compositions predict that final implants made with these materials would be stiffer than bone. Therefore, the composition of PEEK with 10% E-glass fibers was chosen to be the substrate material for the composite implant.

3.2. Characterization of fabricated parts

Tensile tests run on commercial and in-house fabricated samples verified the predicted mechanical properties of the composite material. The commercial tensile bars were run to failure to measure their elastic moduli and ultimate tensile strengths. The in-house samples failed in the threads (used to fit the sample to the machine), and the ultimate tensile strengths were never reached. The elastic moduli were comparable for all tests, confirming the predictions of the SMC program and verifying that the material integrity was conserved through the in-house molding process (Table III).

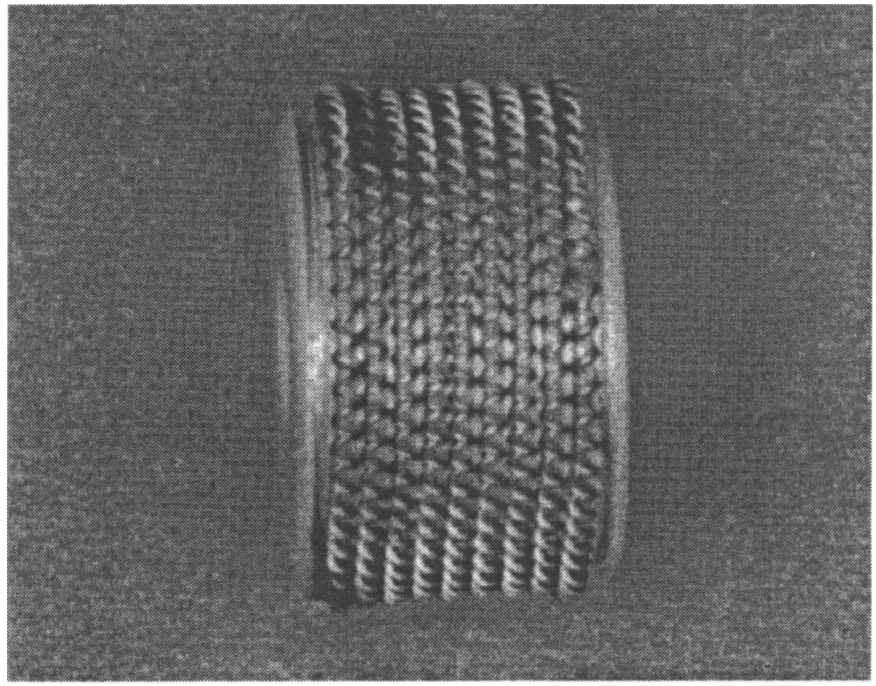
The orientation of the short E-glass fibers throughout the PEEK matrix, measured from a cross-sectioned preform part, had an average off-axis angle (with respect to the longitudinal axis) of 26.13°, with a range of 0° to 93.92°. The angle measured represents the position of the fiber in the 1-2 plane as described with the SMC program (Fig. 1). Only the fibers that were predominantly laying in that plane of each image were selected to be measured (Fig. 6). Assuming that the same results

TABLE III Tensile testing results confirming original material properties

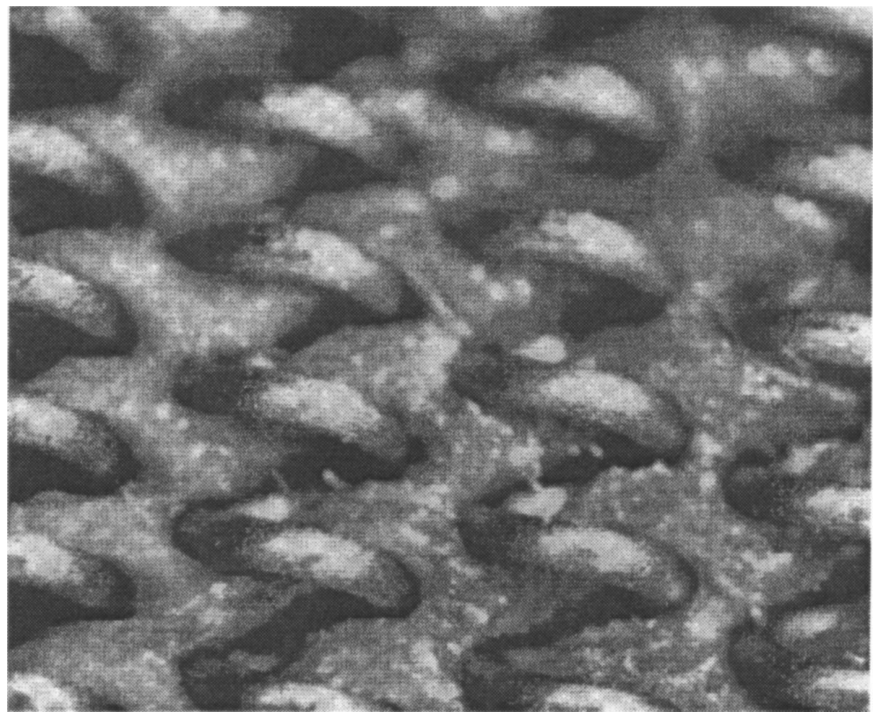
Material	Elastic modulus, GPa (psi)	Tensile strength, MPa (psi)
Neat PEEK (0% glass)	3.66 ± 0.13 ($0.53 \pm 0.02 \times 10^6$)	92.7 ± 1.05 ($13{,}450 \pm 151.7$)
Molded 10% glass/PEEK[a]	7.86 ± 2.17 ($1.14 \pm 0.32 \times 10^6$)	81.1 ± 13.56[b] ($11{,}765 \pm 1966.6$)[b]
Commercial 10% glass/PEEK[c]	6.62 ± 1.99 ($0.96 \pm 0.29 \times 10^6$)	110.72 ± 8.71 ($16{,}060 \pm 1262.7$)
Commercial 20% glass/PEEK[c]	8.96 ± 0.49 ($1.30 \pm 0.07 \times 10^6$)	149.33 ± 2.47 ($21{,}660 \pm 357.8$)
Commercial 30% glass/PEEK[c]	1.10 ± 0.79 ($1.60 \pm 0.12 \times 10^6$)	164.62 ± 1.42 ($23{,}877.5 \pm 206.6$)

[a]In-house molded preforms.
[b]Tensile strength measured when failed at threads.
[c]Commercially provided ASTM standard tensile test bars.

Figure 4 The two halves of the titanium implant (top) and the composite implant (bottom). The Ti implant has a wire mesh of Ti sintered on. The composite implant shows the mating flutes and the tip grooves.



(a)



(b)

Figure 5 A Ti coil wrapped around [a section of] the implant (a); a magnified picture of the embedded Ti in the surface of the PEEK (b).

would be seen in the plane going into the screen (Fig. 6), these images confirm that the fiber orientation may be classified as completely random.

The Sonix C-scan software's acoustic peak reflectance image (Peak) of the lower portion of a PEEK sample, recorded a very low void content (Fig. 7). The top image is for Gate 1, looking at the near surface, and shows typical signals from surface bubbles and the roughness found at the parting lines. The copper foil tape is visible as the front surface at 5°. The tape cannot be seen at the back of this sample due to the large return from the parting line at 180°. The line seen at about 33.02 mm (1.3 in.) from the bottom is the location of the change in diameter of the sample. The second data gate shows scattered small porosity located at approximately 19.05 mm (0.75 in.) from the bottom of the sample, while the third gate shows none, except at the top of the image where the diameter changes.

The time-of-flight data (TOF) gives information about changes in acoustic velocity through the thickness of the material, usually due to differences in material density. Gate 2 data shows a lot of variation (Fig. 7), indicating the presence of some sort of inclusion, possibly fibers, but not voids, since little was visible in the Peak image. The cross section of this sample, used to calibrate the images, confirms the

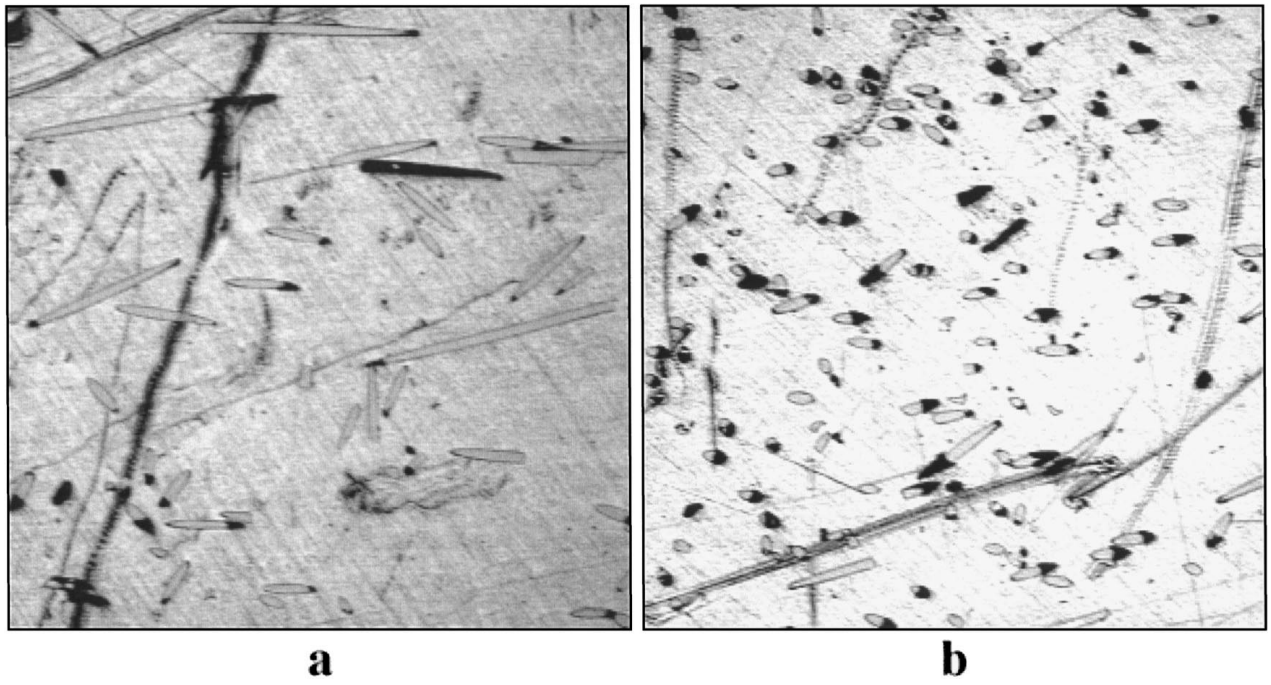
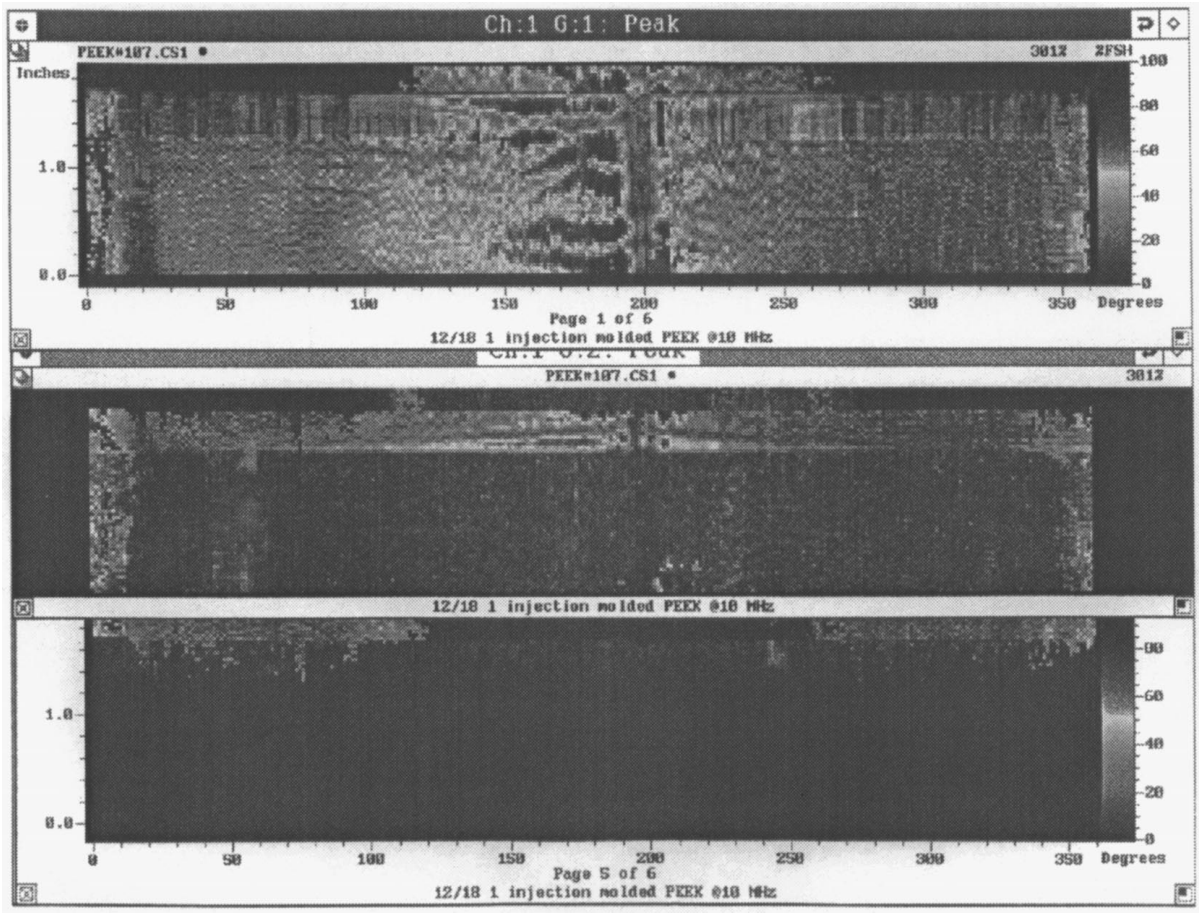


Figure 6 (a) An image showing relatively aligned fibers (darkened) lying predominantly in the 1-2 plane. (b) example of fibers pointed into the plane, and thus not chosen for measurement of orientation.

absence of obvious voids (Fig. 7). A closer look at the center of the part shows definite inclusions of dark material and regions of lighter material, with only two very small voids.

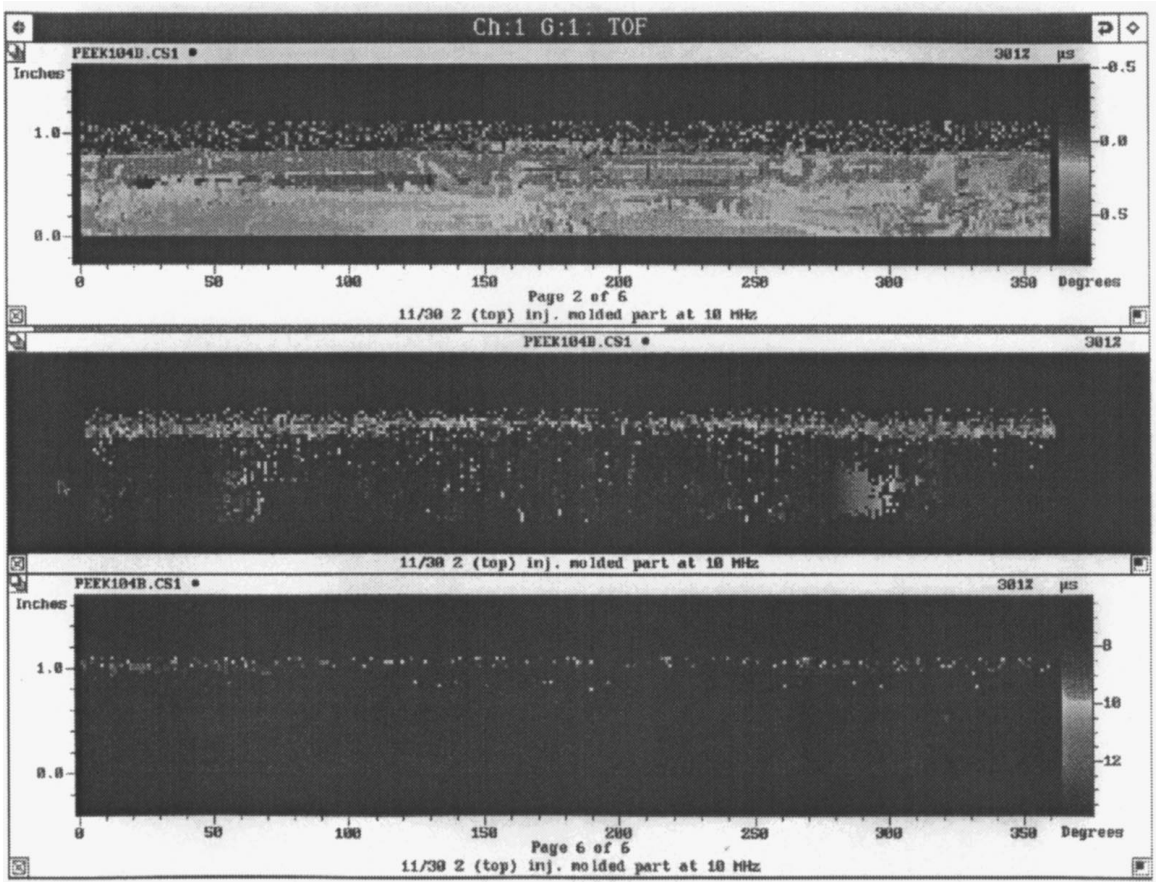
3.3. Push-out tests

To ascertain the effectiveness of embedding the C.P.Ti coil in the PEEK composite, push-out tests were performed. An initial test was done using a section of the



(a)

Figure 7 The acoustic peak reflectance, Peak (a), and time-of-flight, TOF (b), scanned images of a molded part. The images show an overall low void content, calibrated by sectioning a part after scanning (c). (*Continued*).



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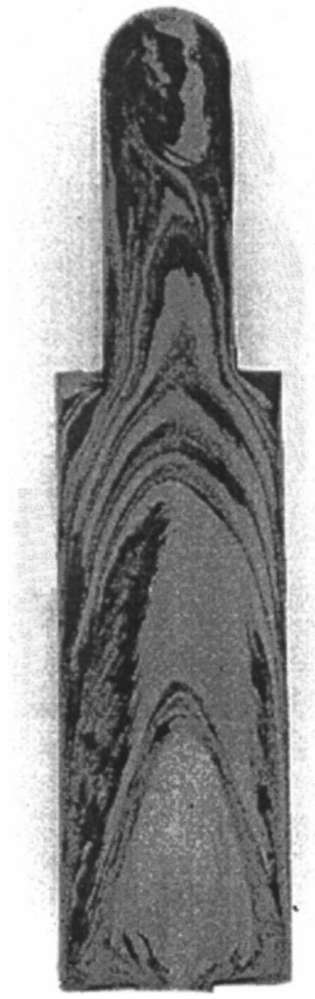


(c)

Figure 7 (*Continued*).

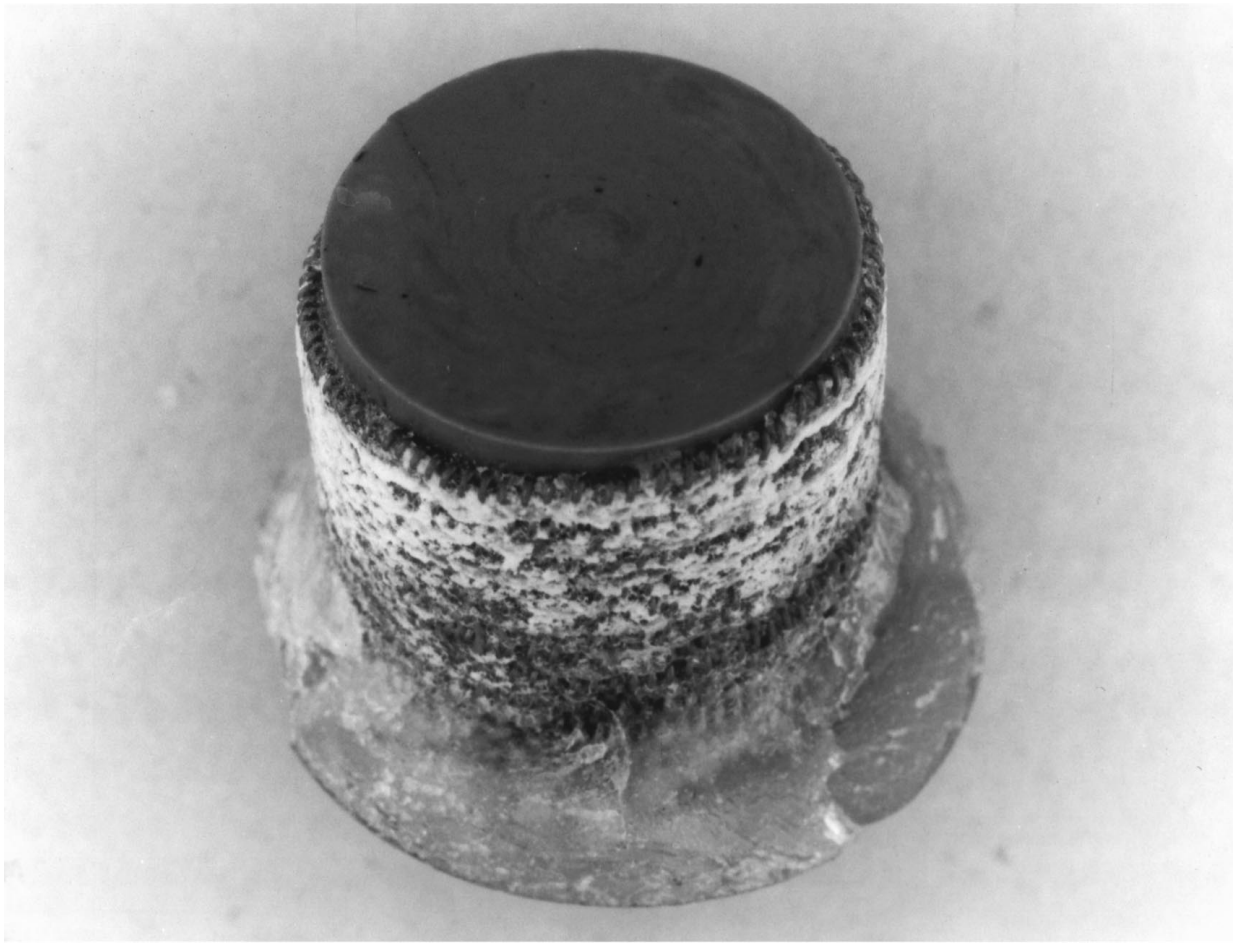
implant without any coil embedded in the surface. The result verified that there was no bonding of the epoxy to the PEEK. The implant was smoothly pushed out with a maximum load of 24.0 kN (540 lb), creating a shear stress of 2.9 MPa (419 psi). There was no shearing or failure of the epoxy, which would have resulted if it bonded with the PEEK.

Tests were then done using sections of the implant with the C.P.Ti coil embedded in the surface. Three tests were done with the Instron Machine compressing at a low, constant rate of displacement, 1.27 mm/mim (0.05 in./min). The maximum recorded push-out load was an average of 15.1 kN (3386 lb), with an average maximum shear stress of 15.6 MPa (2269 psi). The fourth test had a higher rate of displacement, 254 mm/min (10 in./min), simulating a worst-case scenario of the force the implant might experience with a major impact on the bone. The maximum force approximately doubled compared to the slower tests. The coil sheared out of the epoxy but remained completely anchored in the PEEK, fracturing only the epoxy (Fig. 8). The amount of epoxy that remained attached to the coil proves that the mechanical interlock of the material through the porous surface is extremely strong.

4. Discussion

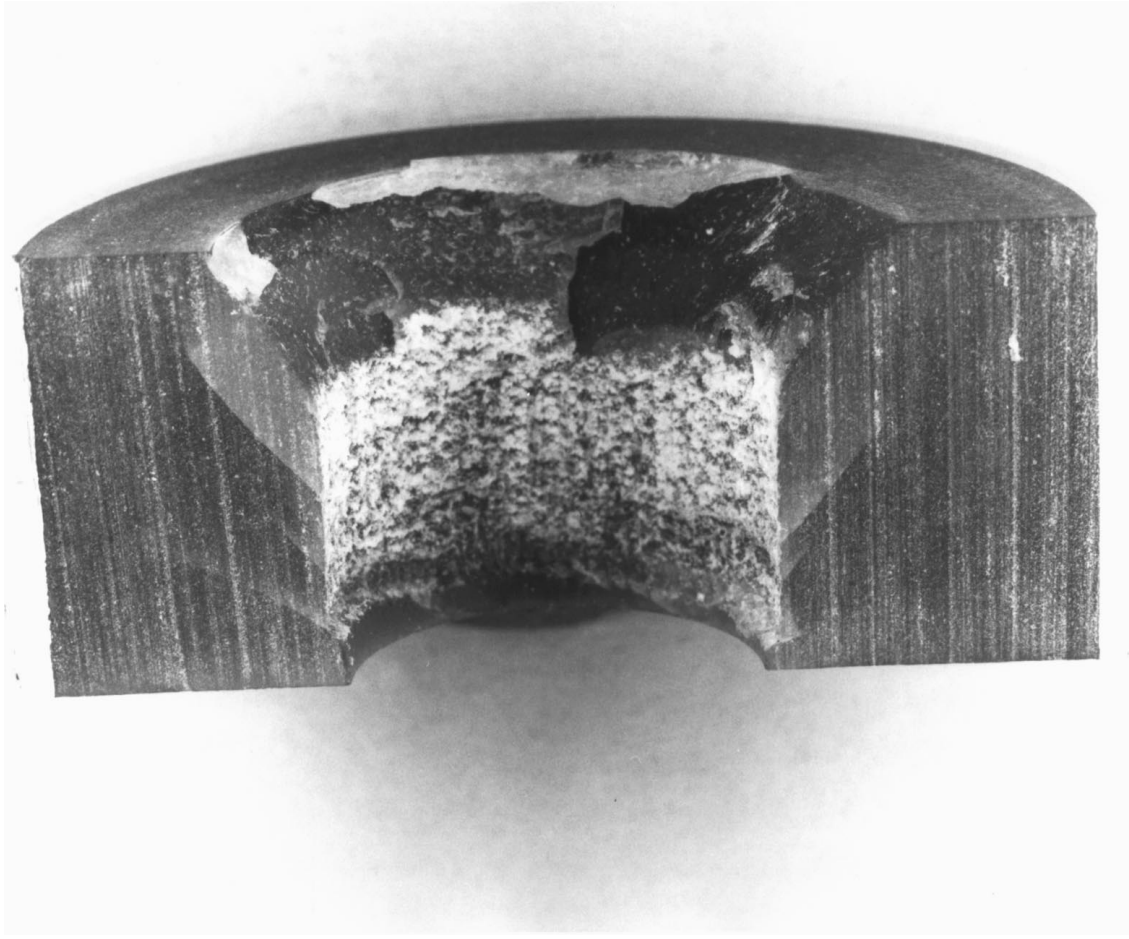
Composite technology permits the tailoring of material properties to create a composite segmental bone replacement implant that will reduce or eliminate problems associated with metal implants. The properties of the chosen E-glass/PEEK composite were accurately predicted through the use of composite modeling software. The PEEK matrix has a mechanical stiffness lower than that of bone, and the E-glass fibers were added to control the increase of the modulus. The final implant will have approximately the same stiffness as bone. Although the materials chosen for this study are considered to have optimal biocompatibility, cost effectiveness, and mechanical properties, other fiber and matrix materials may be substituted to create a composite implant with similar results. The 10% E-glass/PEEK random fiber composite material used in this study has not yet been proven to be suitable for *all* orthopedic implant devices. Tests studying fatigue life, creep resistance, and wear resistance should be performed before applying these materials to implants that are subjected to more complicated load conditions and fatigue than the segmental bone replacement implant.

Evaluation and characterization of the processed materials and parts provided data in support of the initial assumptions and predictions of the composite's material properties. A comparison against commercial standards (through tensile testing) verified that the composite retained its original mechanical properties, even after being subjected to the less than optimal conditions of the in-house fabrication processes.



(a)

Figure 8 A section of the 10% E-glass/PEEK implant with the metal coil embedded in the surface, shown after being pushed out of an epoxy setting. The coil remained fixed in the surface as it was sheared out (a), and the only failure was in the surrounding epoxy (b). (*Continued*).



(b)

Figure 8 (*Continued*).

Nondestructive ultrasonic C-scanning showed that the in-house molding and processing of the prototype preforms were successful in creating relatively solid parts. Any minor air pockets or voids would easily be eliminated in the proposed commercial injection molding processing. Commercial equipment can produce the final implant shape in a one-step mold, eliminating the need for additional machining. A completely molded part will have sealed surfaces, where the fiber-resin interface will not provide an easy ingress for the penetration of moisture.

The porous surface created by wrapping a tightly coiled wire around the implant has distinct advantages over the current practice of sintering tiny particulates or wires onto metal implants. The surface of the implant is exposed to wear and friction, from pre- and interoperative handling and the loads naturally seen by bone. Particulates and wires sintered onto the surface have high stress concentrations at their points of attachment. They are much more susceptible to being pulled off the implant than a coil wrapped and embedded into the surface as one continuous piece. Loose particles and wires *in vivo* trigger the body's defense mechanism, which encapsulates them and causes an inflammatory response. It is unlikely, if not completely impossible, for the wrapped coil to be broken into sections and released into the body.

Push-out tests confirmed that the C.P.Ti coil has a strong mechanical lock in the surface of the implant. The most damaging strain the implant/coil interface experiences *in vivo* is from shear stress, [1] as duplicated by these tests. The coil proved to be relatively permanent in the implant's surface, even when subjected to high impact loads. The pore size and space allowed the epoxy to grab the coil and remain in the pores, even after the part was completely pushed through. The ideal pore size for the ingrowth of bone cells is 150–200 μm [2, 8, 33, 34]. The surface porosity created for these tests has not yet been quantified. If necessary, the porosity can be modified simply by altering the size of the coil when wound.

5. Conclusion

A composite segmental bone replacement implant of PEEK and short, chopped, randomly oriented E-glass fibers was fabricated and characterized. Composite technology and software programs were used to develop a material with a stiffness slightly lower than that of cortical bone. In-house fabrication methods were designed to produce prototype parts, which were destructively and nondestructively characterized to validate material properties and processing techniques. The prototype in-house produced PEEK/E-glass parts had mechanical properties similar to those of bone and agreed with vendor-supplied properties. Ultrasonic C-sanned parts indicated that the in-house fabrication technique produced parts with minimal void volumes.

The push-out tests demonstrated that the Ti embedding process was extremely successful and would allow bone ingrowth without the Ti/bone interface pulling out of the composite implant.

The use of a composite implant, as proposed in this study, will have a great impact on the orthopedic industry. Long-term advantages include a decline in the amount of revision surgeries necessary, providing a reduction in rising health care costs. The new implant would have a longer *in vivo* life, which would better serve the younger patient population. Patients would have a lower probability of recurring pain and surgery.

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