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Tissue response to the components of a hydroxyapatite-coated composite femoral implant

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Abstract: Bone loss around femoral implants used for THA is a persistent clinical concern. It may be caused by stress shielding, generally attributed to a mismatch in stiffness between the implants and host bone. In this regard, a fatigue resistant, carbon fiber (CF) composite femoral implant with bone-matching stiffness has been developed. This study evaluated the tissue response to the three material components of this implant in normal and textured (blasted with 24 grit alumina) surfaces: the hydroxyapatite (HA) coating, the CF composite and the intermediate crystalline HA particulate composite layer to bond to the HA coating (blended). Sprague-Dawley rats underwent bilateral femoral implantation each receiving two rod-like implants. Bone apposition to the HA (37%) and textured Ti (41%) implants was not significantly different. Bone apposition to the untextured CF (14%) and blended (19%) implants and polished Ti (8%) implants was significantly lower. Bone

apposition to the textured CF (9%) and blended (11%) implants was lower (but not statistically from the as received or untextured counterparts). Nearly all sections from femurs containing CF implants presented CF debris. There was no evidence of localized bone loss or any strong immune response associated with any of the implant materials. All materials were well tolerated with minimal inflammation despite the presence of particulate debris. The high degree of bone apposition to the HA-coated composite implants and the lack of short-term inflammation and adverse tissue response to the three material implant component support continued evaluation of this composite technology for use in THA. Published 2010 Wiley Periodicals, Inc. *J Biomed Mater Res Part A*: 94A: 953–960, 2010

Key Words: hip implant, carbon fiber composites, hydroxyapatite coating, tissue response, bone apposition

INTRODUCTION

Patients who underwent arthroplasty are living longer, more active lives, and receiving joint replacements at younger and younger ages.¹ As a result, total hip arthroplasty (THA) in this younger population is subject to greater physiologic stresses and survivorship is a persistent clinical concern. In general, clinical outcome measures reach their maximum at 3–5 years postimplantation and thereafter decline.² For older patients, implant survival rates for THA exceed 95% at 10 years but thereafter fall to 80–85% after 18 years.^{3,4} This is in contrast to younger patients undergoing THA, where reported survival rates fall to 72–88% at 10 years for patient under 60⁵ and to 68% at 20 years⁶ for patients under 55. Poor Harris scores have also been reported for 26 and 35% of the patients surveyed (mean age of 48.4 years) after 11.2 and 19.4 years, respectively.⁷

Retrieval studies generally attribute the overall increased failure rate in younger patients to aseptic loosening, specifically a loss of fixation related to peri-implant bone loss.^{5,8–10} There are two general modes of peri-implant

bone loss, each of different origin and attributed to different factors.¹¹ First and foremost, osteolysis is bone loss that results from an immune-mediated response to wear particles usually generated by articulation at the THA bearing couple.^{8–11} Stress shielding is the second, and describes bone loss adjacent to an implant, generally occurring in the proximal femur in the calcar region and is attributed to lower than physiologic bone loading or disuse.^{11–18} At the bearing couple, improved materials and manufacturing techniques are likely to reduce the long-term particulate burden associated with osteolysis and related complications.^{19–23} However, the potential for peri-implant bone loss and subsequent loss of fixation due to stress shielding still remains.

One of the primary goals of THA is to improve or restore patient mobility by reducing joint pain or by restoration of normal joint anatomy. Walking generates considerable forces at the hip joint with joint forces averaging 4× body weight.^{24–26} For the average THA recipient, femoral components undergo millions of load cycles per year, the combination of biocompatible alloys and resulting implant

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FIGURE 1. Photograph of (A) the composite femoral prototype stem and (B) its three material components. Components of the femoral stem from the inside to the surface: the composite carbon fiber load-bearing structure (CF, bottom), the composite to hydroxyapatite bonding layer (blended, middle), and the hydroxyapatite coating (HA, top). [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

designs capable of withstanding these repetitive loads for 15–20 year periods (and beyond) without catastrophic failure resulting from fatigue, has necessitated the development of relatively stiff and robust implants.^{27–29} Stress shielding is likely to occur with “stiff” implants that are well fixed distally.^{11,13,16–18,29,30} This is because distal fixation permits load transfer from the bearing couple through the implant,

bypassing the proximal femur. In studies where load transfer to the proximal femur is varied, a reduction in cortical bone is generally attributed to the mismatch in the modulus of elasticity between the relatively stiff femoral implant and the more flexible proximal femur.^{17,30,31}

The potential clinical complications associated with a reduction in peri-implant bone are an increased likelihood of femoral fracture, implant migration and an increased complexity for revision surgery that may involve bone grafts and a longer or customized femoral component.^{3,16,32,33} In cases where patients younger than 55 years of age undergo THA, a revision is likely to be necessary during their lifetime^{5–7} and implants that preserve proximal bone stock are of obvious clinical interest.¹⁶

One potential solution to reduce bone loss associated with stress shielding is the use of implants with an overall reduction in bending stiffness. Although femoral implants of increased flexibility are clinically available³⁴ or have been proposed,^{35,36} it seems that they are not widely used in clinical practice. Recent manufacturing advances have enabled the development of fatigue resistant, carbon fiber (CF) composite implants with stiffness and geometric characteristics better matching that of the human femur.^{37,38} In this respect, a femoral component fabricated from a CF composite with an intermediate polymer layer and a hydroxyapatite (HA) coating was developed for cementless fixation (Fig. 1). A previous study by our group evaluated the tissue response to HA-coated CF composite intramedullary rods placed in the rabbit femur that mimicked the composition and fabrication of the clinical prototype.³⁹ This study demonstrated that the HA-coated CF composite implants supported extensive bone attachment. It remained unclear, however, if wear on the implant surface, potentially penetrating and exposing some of the implant layers would significantly and adversely affect tissue response. The purpose of this study is to evaluate the tissue response to the materials in each of the layers of the prototype composite

FIGURE 2. (A) Photograph of the three implant rods: hydroxyapatite-coated (top), as-received untextured carbon fiber rod (middle), and as-received untextured carbon fiber rod (bottom). Scanning electron micrographs of the implant surfaces (1000×), (B) hydroxyapatite-coated rod, (C) as-received untextured carbon fiber rod, (D) textured carbon fiber rod, (E) textured titanium alloy rod, and (H) polished titanium alloy rod.

TABLE I. Femoral Rod Materials and Surface Characteristics

Femoral Rod Composition	Surface Treatment
Hydroxyapatite on blended substrate	Plasma sprayed
Blended substrate	As-received, untextured
Blended substrate	Textured by grit blasting
Carbon fiber	As-received, untextured
Carbon fiber	Textured by grit blasting
Titanium alloy	Textured by grit blasting
Titanium alloy	Polished

femoral implant with surfaces representing normal and abraded or worn conditions, in a *in vivo* assessment of the potential of this composite implant technology.

MATERIALS AND METHODS

Femoral implants

A bilateral rat femoral rod model was used to evaluate the tissue response to the three different implant components of a prototype composite femoral implant [Fig. 1(A)] consisting of a carbon fiber composite (CF), a plasma-sprayed hydroxyapatite coating (HA-coated), and an intermediate crystalline HA particulate composite layer to bond to the HA coating (blended) [Fig. 1(B)]. These three as received or untextured implants were collectively referred to as the “composite group” and are shown in Figure 2(A). A group of titanium implants were included as controls. Femoral rods and surface characteristics are described in Table I.

The CF rods were manufactured by compression molding a composite made of a polyamide 12 (PA12) polymer matrix reinforced with 68% (wt.) of long CF (Schappe Techniques, France) using an hydraulic press (WABASH MPI, Presses 100 T, Wabash, IN) at 250°C under a pressure of 1.35 MPa for 10 min. The rods representing the intermediate layer were made from a blend of 100% crystalline HA and PA12. These

blended rods were produced by mixing 100% crystalline HA particles (Captal 30, Plasma Biotol, UK) and PA12 pellets (GE Polymers, USA) at 220°C using a twin-screw extruder at 150 rpm (Werner & Pfleiderer, ZSK-30 model, Stuttgart, Germany) and compression molding at 220°C under a pressure of 690 kPa for 5 min using the hydraulic press used previously. The “HA-coated” rods were fabricated from the previous “blended” rods onto which an atmospheric plasma spray coating of HA particles (Captal 30, Plasma Biotol, UK) was deposited. A SG-100 plasma gun (Praxair, Danbury, CT) was used with argon at a flow rate of 60 L/min (applied current of 500 A and voltage of 31 V). The coatings had a thickness of 80 µm, a crystalline index of 0.60 and a surface roughness of 4.6 µm, as previously reported.^{38,39} All composite rods were 10-mm long and 1.5-mm wide. To simulate an abraded surface, a subgroup of the CF and blended rods were further processed by blasting the entire surface with 24 grit alumina at 80 psi. The surface morphology of the HA coated, textured and untextured carbon fiber rods, textured and untextured blended rods, and polished and textured titanium rods are shown in Figure 2(B–H).

HA-coated implants were fabricated in a controlled environment and sterilized at the time of surgery by soaking for 60 s in 100% ethanol then rinsing three times in sterile PBS. CF and blended implants (as-received and textured) were cleaned by sonication (Crest, Tenton, NJ) for 30 min in a 1% (v/v) solution of Liquinox (White Plains, NY) and distilled water. Following cleaning, the rods were rinsed three times in distilled water. Like the HA-coated implants, the CF and blended rods were sterilized at the time of surgery by soaking for 60 s in 100% ethanol then rinsing three times in sterile PBS immediately prior to implantation.

A group of polished and textured titanium (Ti6Al4V) alloy rods (Ti), 20-mm long and 1.5 mm in diameter were included as controls. Textured titanium alloy rods were prepared by blasting the entire surface with 24 grit alumina at 80 psi until evenly textured. Rods were cleaned by

FIGURE 3. Radiographs of femoral implants after 6 weeks *in situ*. Composite rods are radiolucent so their location within the femoral canal is indicated by arrows. (A) Hydroxyapatite-coated rod, (B) hydroxyapatite-coated rod, (C) textured carbon fiber rod, (D) as-received untextured carbon fiber rod, (E) textured blended rod, (F) as-received untextured blended rod, (G) textured titanium alloy rod, and (H) polished titanium alloy rod.

FIGURE 4. Tissue response to femoral implants. Overview of transverse sections of femoral implants after 6 weeks in situ. (A–F) Thin sections stained for bone (black, von Kossa) and fibrous tissue (blue, toluidine blue). (A, B) Hydroxyapatite-coated rod, (C) textured carbon fiber rod, (D) as-received untextured carbon fiber rod, (E) textured blended rod, and (F) as-received untextured blended rod. Backscatter scanning electron micrographs of (G) textured titanium alloy rod and (H) polished titanium alloy rod. Implant is white and bone is gray. Hydroxyapatite-coated sections had the tendency to “curl” during sectioning however tissue interface remains clearly visible. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

sonication for 30 min in a 1% (v/v) solution of Liquinox and distilled water. Following cleaning, the titanium alloy rods were passivated for 30 min in a 35% (v/v) solution of nitric acid (Fisher Scientific, Ottawa, ON, Canada) then rinsed three times in distilled water. All titanium implants were steam sterilized at 135°C for 20 min prior to implantation.

Experimental design and surgical and terminal procedures

Twenty-one male, Sprague-Dawley rats (250–300 g) each received two femoral rods (one per femur). Six rats each received both a polished and textured titanium implant, six rats each received both an as-received CF and a textured CF rod, six rats each received both an as-received blended and a textured blended rod, and three rats each received two identical HA-coated rods.

Using a retrograde approach, a 1.1-mm drill bit (Synthes, Mississauga, ON) was manually rotated and guided into the femoral canal between the chondyles of the knee after a 3-mm incision had been made below the patella. An implant was then placed in the expanded entrance of the distal femur and pressed then tapped into the canal until the distal end of the implant was recessed 3 mm from the joint space. All implants achieved a firm “press-fit.” The wound was irrigated and the tendon and skin incisions were closed with 4.0 vicryl. Postoperatively rats were administered Cefazolin (50 mg/kg, BID for 7 days) and Buprenorphine (0.16 mg/kg, BID for 3 days).

After 6 week femurs were harvested and radiographed and processed for undecalcified thin-section histology. Briefly, femurs were fixed in a 4% solution of para-formaldehyde, dehydrated in ascending solutions of ethanol followed by a 1:1 mixture of ether:acetone then 100% ethanol before infiltrating and embedding in methylmethacrylate. Once cured, the femurs containing the composite implant materials were sectioned transversely on a microtome and successive 5- μ m thick sections were obtained from two locations, 3 and 7 mm from the distal end of the implant. Thin sections were prepared for light microscopy and stained for mineral with von Kossa (VK) and counter stained for soft tissue with toluidine blue or for general tissue response with hematoxylin and eosin (H&E). The femurs containing the titanium rods were sectioned at 1.5 mm intervals on a diamond saw (Buehler, Markham, ON) and the implant interface was analyzed by back scattered electron microscopy (BSEM, JEOL, Peabody, MA).⁴⁰ The percentage bone apposition from each of the 2 VK stained sections (CF, HA-coated and blended implants) or BSEM images (Ti implants) was determined using a digital image analysis package (ImageJ, Bethesda, MD). First the implant shape was outlined and the perimeter automatically determined. The length of each discrete portion of bone in direct contact with the implant surface was determined, then summed and expressed as a percentage of the implant perimeter.⁴¹

Four high-power images (400 $\times$) of a portion of the composite implant perimeter that excluded bone were selected from each of the two H&E sections per implant. This

TABLE II. Bone Apposition to Femoral Rods ($n = 12$ per Implant) and Sections

Implant	Overall Bone Apposition (%) ^a	Lowest Bone Apposition (%) ^b	Highest Bone Apposition (%) ^b
Titanium rod (polished)	7.6 ± 3.1	0	11.2
Titanium rod (textured)	40.88 ± 18.73	0.3	65.91
HA rod	37.07 ± 13.01	23.20	61.35
Carbon rod (untextured)	13.86 ± 6.97	3.50	24.87
Carbon rod (textured)	8.86 ± 4.93	1.52	17.50
Blended rod (untextured)	19.30 ± 8.13	9.43	28.19
Blended rod (textured)	11.37 ± 6.36	1.89	23.78

^a Bone apposition to femoral rods.^b Bone apposition to sections.

resulted in eight images per implant from the two different levels (48 images in total) that were assessed to determine the predominant peri-implant tissue response. The tissue

response was compared with nonimplanted rat femurs that were used to establish a histological baseline. The tissue response per portion of each section analyzed was classified

FIGURE 5. Tissue response to regions of femoral implants generally devoid of bone. Asterisk (*) denotes tissue region adjacent to implant. (A, B) Hydroxyapatite-coated rod, (C) textured carbon fiber rod, (D) as-received untextured carbon fiber rod, (E) textured blended rod, and (F) as-received untextured blended rod. Hematoxylin and eosin; scale bar at bottom left indicate 100 μm . [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

TABLE III. Predominant Tissue Reaction to Femoral Rods Expressed as Percentage of Sections (*n* = 48 per Implant Type)

Implant	Marrow	Neutrophils	Loose Fibrous Tissue	Thick Fibrous (≥5 Layers)	Thin Fibrous (≤4 Layers)	% Sections with Debris Visible
HA rod	59	–	11	30	–	22
Carbon rod (untextured)	51	19	20	–	–	81
Carbon rod (textured)	57	19	13	7	4	100
Blended rod (untextured)	71	–	29	–	–	0
Blended rod (textured)	68	–	32	–	–	10

as “marrow” if it predominantly contained typical marrow cells (adipocytes, RBC, neutrophils), “neutrophils” if it predominantly contained a higher than control density of neutrophils, “loose fibrous tissue” if it predominantly contained loose unorganized fibrous cells, “thick fibrous” if it contained five or more layers of organized fibrous cells at the implant surface, and “thin fibrous” if it contained four or less layers of organized fibrous cells at the implant surface. Any section with debris adjacent to the implant surface was noted.

RESULTS

Postoperative period

No rats died during the postoperative period and there were no postoperative complications. The bilateral surgery was well tolerated and all rats were ambulatory postoperatively and returned to normal activity within 24 h. On harvest, crossexamination of the dissected femora did not reveal any sign of infection or unusual tissue formation.

Histology

High-resolution radiographs did not demonstrate localized bone loss (Fig. 3) or any unusual bone response. Histological analysis of the VK stained sections (Fig. 4) indicated varying degrees of bone apposition to all femoral rods and surface treatments (Table II). The HA-coated rods had a statistically significantly greater amount of bone apposition ($37.07\% \pm 13.01\%$) than the overall apposition to the blended rods ($15.33\% \pm 7.19\%$, $p < 0.001$) and the overall

apposition to the CF rods ($11.36\% \pm 5.95\%$, $p < 0.001$) rods. Overall bone apposition to the textured Ti rods ($40.88\% \pm 18.73\%$) was slightly higher than the HA-coated rods, but the difference was not statistically significant. Bone apposition to the polished Ti rods was statistically significantly lower ($7.6\% \pm 3.1\%$, $p < 0.01$) than that of the textured titanium rods. For the CF and blended rods, surface texturing reduced the amount of bone apposition but in each case the difference was not statistically significant. Bone apposition to the textured CF rods was reduced to $8.86\% \pm 4.93\%$ from $13.86\% \pm 6.97\%$ for the untextured CF rods. Bone apposition to the textured blended rods was also reduced to $11.37\% \pm 6.36\%$ from $19.30\% \pm 8.13\%$ for the untextured blended rods. This was in contrast to the textured Ti rods where application of a surface texture greatly enhanced the bone apposition.

The predominant tissue response was determined by analysis of the H&E stained thin sections of the different composite rod materials and surface states (Fig. 5). Results are presented in Table III. For the HA-coated rods, the areas of nonosseous response were predominantly marrow (59.3%) and dense fibrous tissue (29.6%), for the untextured blended rods predominantly marrow (71.4%) and loose fibrous tissue (29.0%), and for the untextured CF rods predominantly marrow (51.3%) and loose fibrous tissue (20.2%). The areas of nonosseous response to the textured blended rods were predominantly marrow (68.3%) and loose fibrous tissue (32.0%). Tissue response to the textured CF rods was varied with the predominant response

FIGURE 6. Debris associated with (A) textured carbon fiber rod and (B) as-received carbon fiber rod. White arrows indicate presence of debris in tissue adjacent to implant. Debris appears to be more prevalent with textured carbon fiber rod. In all cases, particulate debris is within 1–5 μm in diameter. Hematoxylin and eosin; scale bar at bottom left indicate 100 μm . [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

being marrow tissue (57.1%), followed by neutrophils (19.6%) and loose fibrous tissue (13%) then thick fibrous (6.5%) and thin fibrous (4.4%) tissue encapsulation. Debris was noted for a relatively small number of the HA (22.2%) and blended rods (9.8%) and was generally present in the extracellular space and not associated with immune cells. However, debris was clearly visible in nearly all of the CF sections, in 100% of the textured and 81% of the as-received sections. Some debris from CF containing sections appeared to be located within cells, but specific cell type was not determined (Fig. 6). Despite the predominance of debris associated with CF rods, an intense immune reaction to this debris was not observed. Texturing of the implants did not alter tissue response but did increase the amount of debris found among the CF and blended rods. No debris was visible adjacent to the Ti rods or the untextured blended rods.

DISCUSSION

This *in vivo* study evaluated the tissue response to seven femoral rods, five of which were manufactured from the three different material components of a new carbon fiber composite femoral stem and two which were fabricated from titanium alloy. The femoral rod model has been widely used to evaluate and approximate the peri-implant environment, specifically the tissue response to femoral components in a simplified non load-bearing environment (canine and rabbit).

All materials demonstrated some degree of bone apposition. Bone apposition to the HA-coated composite rods and the textured Ti rods was not different and overall bone apposition was similar to bone apposition reported elsewhere for HA-coated, polished, and textured titanium femoral rod models in rabbits^{42,43} and canines.⁴¹ Bone apposition to the carbon fiber and blended rods was not modulated by surface texture; mean value for bone apposition obtained was slightly higher than bone apposition to the polished titanium rods, although this trend was not statistically significant. In this 6-week study, no gross adverse tissue reaction was observed nor was there any radiographic, or histologic indication of bone resorption.

With respect to nonosseous response, all materials were well tolerated with minimal inflammation despite the presence of particulate debris. Histologic results presented low to moderate levels of adverse tissue response in light of the debris prevalence. Hydroxyapatite particles were visible in 22% of the HA-coated sections but were not associated with any specific cell type. For the blended rods, the absolute amount of debris released after texturing remained small, and when present, it was not associated with any specific cell type either. Debris from the as-received blended rods was the lowest overall, with no debris detected.

Eighty percent (80%) of sections from the as-received carbon fiber rods showed visible carbon debris. This suggests that the carbon fiber rods even when nonabraded (and unloaded) are prone to release debris into the surrounding tissue space, which also suggests that carbon fiber, if implanted in the body, should be encapsulated or

enclosed by a material that is not susceptible to debris formation or release. Debris from the textured carbon fiber rods was present in all (100%) of the sections analyzed. Debris from both the carbon fiber rod types was sometimes associated with and found within cells. These sections however did not exhibit an adverse tissue reaction.

The presence of polymer debris at the bone-implant interface has been shown to stimulate bone resorption, leading to osteolysis and potentially loosening of the prosthesis.¹⁰ Particles can come from the cement mantle in the case of cemented implants, the bearing couple or from the implant surface.⁴⁴ In terms of bone loss, particulate size and density are modulating factors as is material composition.⁴⁴ In this model, texturing of the carbon fiber and blended implant surfaces resulted in a statistically significant release of peri-implant debris, however evidence of osteolysis was not observed. Despite the presence of particulate debris, the lack of bone lesions may have been a result of the relatively short 6-week study period, insufficient particle concentration or resulting particle size. In addition, the textured surfaces of the carbon fiber and blended implants should not be considered as a "worst-case scenario," since they do not, among other factors, include the accompanying particulate concentration that wear through the implant would generate.

A lack of inflammation with the CF and blended materials and particulates may also be a result of the materials used in the study. Prior cytotoxicity assessment (ISO 10993-5) has demonstrated that these three material components did not affect cellular viability (L929 fibroblasts) when cells were exposed to leachable products (MTT assay) after 24, 48, and 72 h and in direct contact (Alamar Blue assay) after 1, 3, and 7 days. The current results support these previous findings.

CONCLUSIONS

The high degree of bone apposition to the HA-coated carbon fiber composite implants and the lack of short-term inflammation and adverse tissue response to the as-received and textured carbon fiber composite implants and HA/polymer blended implants support continued evaluation of this composite technology for use in THA.

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