Tissue response to HA-Coated Carbon Composite Intramedullary Rods in the Rat Femur

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Submitted

on September 05, 09:22 AM

for ors2008

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Introduction: Arthroplasty patients are living longer, more active lives. As a result, total hip replacement (THR) is subject to greater patient expectations and demands. For elderly, patients, implant survival rates for THR exceed 90% at 10 years but thereafter decline, e.g. to 15% after 15 years and 20% after 20 years [1]. For men younger than 55 when implanted, these rates fall to 80% at 10 years. Retrieval studies generally attribute the overall increased failure rate to aseptic loosening and/or fixation failure resulting from stress shielding. Progress at the bearing couple has reduced the particulate burden associated with osteolysis, but the same advances have not been made to reduce stress shielding. Typical femoral components undergo millions of load cycles per year with loads averaging 4X body weight. The combination of alloys and implant designs capable of withstanding these demanding conditions for 15-20 year periods results in relatively robust implants. In such cases, stress shielding is unavoidable and results in a loss of bone adjacent to the implant and a concomitant increase in the risk of fixation failure. Recent manufacturing advances [2-4] have enabled the development of fatigue resistant, carbon fiber (CF) composite implants with stiffness characteristics matching those of the human femur. A femoral component made of a CF composite, an intermediate polymer layer and a hydroxyapatite (HA) coating was developed for cementless fixation. As a preliminary evaluation of this device, the present study was designed to investigate the tissue response to the 3 femoral materials in normal and failure-mode scenarios.

Materials and Methods: A bilateral rat femoral rod was used to evaluate the tissue response to the 3 different implant components (CF composite, HA coating and carbon to HA bonding layer) of the implant. The "CF" rods were manufactured by compression molding a composite made of a polyamide 12 (PA12) matrix reinforced with 68wt.% of long CF (Schappe Techniques, France). The rods representing the intermediate layer were made from a blend of HA and PA12. These "blended" rods were produced by compounding of HA particles (Plasma Biotal, UK) and PA12 (GE Polymers, USA). The "HA coated" rods were made from the previous onto which an atmospheric plasma spray HA coating was deposited [3,4]. All rods were 10 mm long and 1.5 mm wide. A subgroup of the CF and blended rods were further processed by blasting the entire surface with 24 grit alumina oxide to simulate abrasive wear of the implant core. 15 Sprague-Dawley rats (250-300 g) received 30 femoral rods. 6 rats each received a CF and a textured CF rod, 6 rats each received a blended (HA and PA12) and a textured blended rod and 3 rats each received 2 identical HA coated rods. Using a retrograde approach, a small 1.2 mm drill bit was manually passed into the femoral canal between the knee chondyles. The canal entrance was expanded slightly with the aid of a

tapered awl. Post operatively rats were administered Cefazolin (50 mg/kg for 7 days) and Buprenorphine (0.16 mg/kg for 2 days). Implants were fabricated in a controlled environment and decontaminated by dipping in 100% ethanol then rinsing in sterile PBS prior to insertion into the distal diaphyseal region of the femur. After 6 weeks the rats were sacrificed, the femurs harvested and radiographed, then processed for undecalcifed thin-section histology. Femurs were dehydrated in ascending solutions of ethanol followed by ether acetone before infiltrating and embedding in methylmethacrylate. Multiple 5 µm-thick sections were obtained from 2 points on the implant, 3 and 7 mm from the distal end and stained for mineral (Von Kossa, VK) and tissue (H&E) response. For each implant, the percentage bone apposition from each of the 2 unique sections was determined. 4 high power images (randomly selected and excluding bone) from each of the 2 H&E sections per implant were analysed (8 images per implant) to determine the predominant peri-implant tissue response.

Results: All 30 rats returned to normal activity within 24 hours. Most post explanation radiographs revealed a thin line of bone adjacent to the implant [Image 1] with no obvious signs of osteolysis. Analysis of the VK stained sections [Image 2] showed some degree bone apposition to all femoral rods. The HA coated rods (37.07%±13.01) had the greatest amount of bone apposition, followed by the blended (14.71%±8.02) then the CF (12.09%±6.63) rods. Areas of non-osseous response were predominantly marrow (59.26%) and dense fibrous tissue (29.63%) for the HA coated rods, for the blended rods marrow (69.35%) and loose fibrous tissue (29.03%), and marrow (56.45%) and loose fibrous tissue (14.52%) for the carbon fiber rods. Intracellular peri-implant debris was noted in a small number of the blended and HA coated implant sections. Debris were visible in nearly all of CF sections, often inside macrophage-like cells. Intense immune reactions to debris were however not noted. Texturing of the implants did not significantly alter tissue response but increased the amount of debris found among the CF and blended rods.

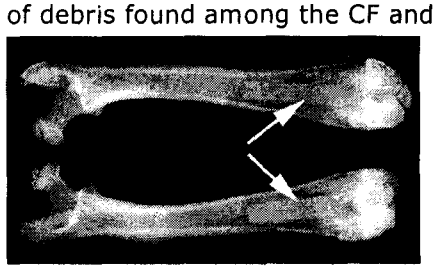

Fig 1. Radiograph of rat femurs with rods (arrows).

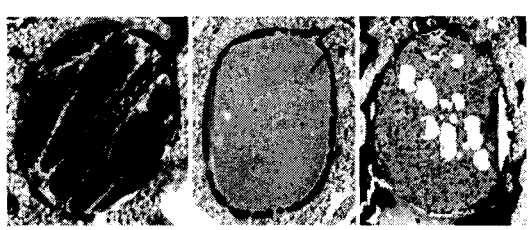

Fig 2. VK stained sections demonstrate bone (black) apposition from (left) CF, (center) blended and right HA coated rods (25X).

(No Table Selected)

Discussion: This in vivo study evaluated the response to 3 different material components of a new CF femoral stem. Overall the 3 different materials were well tolerated and presented low to moderate levels of tissue response under less than ideal conditions. These findings support continued evaluation of composite technology for use in THR.

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Acknowledgements: Financial support from NSERC is greatfully acknowledged.
CONTROL ID: 391382

PRIMARY CATEGORY: Hip
Primary Discipline: Engineering
Secondary Discipline: Biological
AWARDS:
KEYWORDS: hip arthroplasty, bone formation, biomaterials, implant.

I. IRB Statement - Human Subjects: Human subjects not involved in this investigation
II. REVIEW OF MATERIAL: author/co-authors have reviewed this abstract and agree with the material
MANDATORY DISCLOSURE STATEMENT:
M. Bureau: III. MDS - No
S. Hacking: III. MDS - No
T. Pauyo: III. MDS - No
J. Legoux: III. MDS - No
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