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Osteointegration of femoral stem prostheses with a bilayered calcium phosphate coating

Eric Goyenvalle[a,b], Eric Aguado[a,b], Jean-Michel Nguyen[c], Norbert Passuti[d], Laurent Le Guehennec[a], Pierre Layrolle[a,*], Guy Daculsi[a]

[a]*INSERM EM 9903, Materials of Biological Interest, Faculty of Dental Surgery, BP 84215, 44042 Nantes Cedex 1, France*
[b]*Unité de Pathologie Chirurgicale, Ecole Nationale Vétérinaire de Nantes Route de Gachet, BP 40706, 44307 Nantes Cédex 3, France*
[c]*Laboratoire de Statistiques et d'Informatique Médicales, Faculté de Médecine de Nantes, 1 rue Gaston Veil, 44035 Nantes Cedex 01, France*
[d]*Pôle ostéoarticulaire, CHU Nantes, Place A. Ricordeau, BP1005, 44035 Nantes Cedex 01, France*

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Abstract

Our purpose was to evaluate the osteointegration of bilayered calcium phosphate (CaP)-coated femoral hip stems in a canine model. A first layer of hydroxyapatite (HA) 20 μm thick and a superficial layer of Biphasic Calcium Phosphate (BCP) 30 μm thick were plasma-sprayed on to the proximal region of sandblasted Ti6Al4V prostheses. Bilayered CaP-coated and non-coated canine femoral stems were implanted bilaterally under general anesthesia in 6 adult female Beagle dogs. After 6 and 12 months, a significant degradation of the bilayered coating occurred with a remainder of 33.1 ± 12.4 and 23.6 ± 9.2 μm in thickness, respectively. Lamellar bone apposition was observed on bilayered coated implants while fibrous tissue encapsulation was observed on non-coated femoral stems. The bone-implant contacts (BIC) were $91 \pm 3\%$ and $81 \pm 8\%$ for coated and $7 \pm 8\%$ and $8 \pm 12\%$ for non-coated implants, at 6 and 12 months, respectively. Our study supports the concept of a direct relationship between the biodegradation of CaP coating and the enhanced osteointegration of titanium prostheses. A bilayered CaP coating might therefore enhance bone apposition in the early stages because of the superior bioactivity of the BCP layer while the more stable HA layer might sustain bone bonding over long periods.

Keywords: Canine hemiarthroplasty; Calcium phosphate coating; Bone apposition; Mineral apposition rate; Biodegradation

1. Introduction

Calcium phosphate (CaP) coatings have been shown to promote early bone apposition at the surface of cementless orthopedic prostheses [1–7] and have given highly successful clinical results [8–14]. Plasma-sprayed hydroxyapatite (HA) coatings applied on to titanium implants have been shown to enhance the quality of bone apposition and the biomechanical fixation of prostheses [3,15]. Under optimal conditions, CaP coatings should enhance bone tissue healing rates in order to ensure primary implant stability and biological fixation of the prostheses [16–21]. It has been shown that this enhanced bone apposition observed with plasma-sprayed HA-coated implants is associated with coating degradation [17]. Following implantation, the CaP coating dissolves and liberates ions into the peri-implant region, increasing the saturation of body fluids and thus precipitating a biological apatite on to the implant. This biological apatite layer serves as a substrate for osteogenic cells producing a mineralized extracellular matrix [22–24]. The coating dissolution rate is related to its composition and crystallinity. Highly soluble and poorly crystalline coatings might accelerate the dissolution–reprecipitation process, and consecutively favor osteoconduction. The stability of a CaP coating on

*Corresponding author. Tel.: +33 2 40 41 29 20; fax: +33 2 40 08 37 12.
E-mail address: pierre.layrolle@nantes.inserm.fr (P. Layrolle).

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prostheses over long periods of time has been a subject of controversy [3,25,26].

Biphasic calcium phosphate (BCP) ceramics composed of a mixture of HA and beta-tricalcium phosphate (β-TCP) present a controlled resorbability depending on the β-TCP/HA ratio. It has been shown that increasing the proportion of β-TCP enhances the dissolution rate while the HA crystals support the biological apatite precipitation [17]. The optimal βTCP/HA ratio for osteointegration of bioceramics has been found to be 40/60 [27].

The present study aims at investigating the effect of a bilayered BCP/HA coating on the osteointegration of implants in a pre-clinical model. The top BCP layer should promote osteoconduction soon after implantation because it is more soluble than HA in vivo. The under layer of HA should sustain biological fixation over long periods of time. Our preliminary results have demonstrated the efficiency of this concept in non-load bearing conditions [1]. In this study, we evaluate the osteointegration of the bilayered BCP/HA coating in conditions similar to those encountered in human practice. Specially designed canine femoral stems were implanted bilaterally in adult female Beagle dogs for 6 and 12 months. Osteointegation of the BCP/HA-coated and non-coated prostheses was evaluated histologically. Coating degradation and bone to implant contacts (BIC) were measured by histomorphometry on backscattered electron (BSE) images.

2. Materials and methods

2.1. Implants

Femoral stem prostheses were specially designed to fit the femoral anatomy of adult Beagle dogs (Fig. 1). The canine femoral stems were machined out of titanium alloy (Ti6Al4V). The proximal area of the prosthesis was sandblasted. The implants were passivated in 30% nitric acid and thoroughly rinsed in demineralized water. The bilayered coating was applied on to the proximal region of the prostheses by plasma-spraying using high-purity stock feed HA and BCP powders. HA and BCP starting powders were prepared by direct precipitation, sintered and ground into 50–60 μm particles (Zimmer, France). Their physico-chemical characteristics are gathered in Table 1. Before plasma-spraying, the BCP was composed of a mixture of 60% HA and 40% β-TCP. The bilayered CaP coating consisted of an initial HA layer of 20 μm and a second BCP layer 30 μm thick. After plasma-spraying, the bilayered HA/BCP coating was analyzed by X-ray diffraction (Philips, PW1050) [1]. The HA layer was composed of 68% HA, 12% α-TCP and 20% of amorphous calcium phosphate (ACP). The BCP layer contained 38% HA, 32% α-TCP and 30% ACP. The coating bonding strength was 5 ± 0.87 MPa [28].

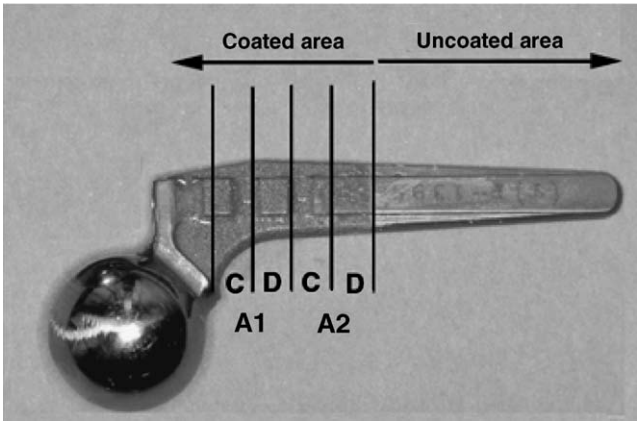

Fig. 1. Femoral titanium prostheses showing the different levels of sectioning (A1 and A2). (C) and (D) indicate, respectively, the blocks for calcified and decalcified histological analysis

2.2. Animal model

All animal handling and surgical procedures were conducted according to European Community guidelines for the care and use of laboratory animals (DE 86/609/CEE). This animal study was approved by the local ethical and animal care committee of the Nantes National Veterinary Faculty. Six female Beagle dogs, aged between 3 and 8 years (body weight 10–14 kg) were purchased from a professional breeder (CEDS, Toucy, France). After 2 weeks' quarantine, the animals were prepared for surgery and radiographs of the hip joints were taken. Antibiotic prophylaxis was administrated by intravenous injection of cefalexine (30 mg/kg, Rilexine, Reading) 30 min before, 2 and 8 h after surgery. General anesthesia was performed by subcutaneous injection of atropine sulfate (0.025 mg/kg), intramuscular injection of levopromazine (4 mg/kg, Nozinan, Specia) 15 min later and intravenous injection of sodium thiopental (15 mg/kg, Nesdonal, Rhône Mérieux). Anesthesia was maintained by using a gas mixture of 60% O_2, 40% N_2O and halothane (Fluothan, Coopers Veterinary) with a breathing machine (Bird, Mark 8). The animal was positioned in lateral decubitus and the skin was disinfected with iodine solution (Vetedine, Vetoquinol). The animal was then covered with sterile surgical drapes. Skin and muscular incisions were performed to expose the femoral proximal region via a posterior approach. The femoral head was cut using an oscillating saw (Aesculap, GA140, Germany) under constant cooling with saline solution. The medullary canal was taken by using an underdimensioned rasp and the femoral prosthesis was press-fit impacted with an anteversion angle between 0° and 5°. The head of the femoral stem was directly inserted into the acetabulum. Finally, the tissues were closed in different layers using resorbable sutures (Ligadex 3.5). The metaphyseal coated femoral stem was implanted first into the left femur. Four weeks later, the uncoated implant was impacted similarly into the right femur. For 15 postoperative days, the operated limb was placed in a non-weight-bearing position by application of an Ehmer sling. After this period of restricted activity, full-weight bearing activities were authorized. All the animals used in this study were kept under observation at the Nantes National Veterinary Faculty.