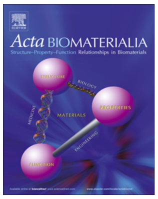
Acta Biomaterialia 36 (2016) 296–309

Contents lists available at ScienceDirect

Acta Biomaterialia

journal homepage: www.elsevier.com/locate/actabiomat



Full length article

Long-term osseointegration of 3D printed CoCr constructs with an interconnected open-pore architecture prepared by electron beam melting

Furqan A. Shah [a,b,*], Omar Omar [a,b], Felicia Suska [a,b], Anders Snis [b,c], Aleksandar Matic [d], Lena Emanuelsson [a,b], Birgitta Norlindh [a,b], Jukka Lausmaa [b,e], Peter Thomsen [a,b], Anders Palmquist [a,b]

[a] *Department of Biomaterials, Sahlgrenska Academy at University of Gothenburg, Göteborg, Sweden*
[b] *BIOMATCELL VINN Excellence Center of Biomaterials and Cell Therapy, Göteborg, Sweden*
[c] *Arcam AB, Mölndal, Sweden*
[d] *Department of Applied Physics, Chalmers University of Technology, Göteborg, Sweden*
[e] *Department of Chemistry, Materials and Surfaces, SP Technical Research Institute of Sweden, Borås, Sweden*

ARTICLE INFO

Article history:
Received 1 December 2015
Received in revised form 11 March 2016
Accepted 17 March 2016
Available online 18 March 2016

Keywords:
3D printing
Additive manufacturing
Electron beam melting
Osseointegration
Alloy
Cobalt chromium
Titanium

ABSTRACT

In orthopaedic surgery, cobalt chromium (CoCr) based alloys are used extensively for their high strength and wear properties, but with concerns over stress shielding and bone resorption due to the high stiffness of CoCr. The structural stiffness, principally related to the bulk and the elastic modulus of the material, may be lowered by appropriate design modifications, to reduce the stiffness mismatch between metal/alloy implants and the adjacent bone. Here, 3D printed CoCr and Ti6Al4V implants of similar macro-geometry and interconnected open-pore architecture prepared by electron beam melting (EBM) were evaluated following 26 week implantation in adult sheep femora. Despite higher total bone-implant contact for Ti6Al4V (39 ± 4%) than CoCr (27 ± 4%), bone formation patterns were similar, e.g., densification around the implant, and gradual ingrowth into the porous network, with more bone in the outer half (periphery) than the inner half (centre). Raman spectroscopy revealed no major differences in mineral crystallinity, the apatite-to-collagen ratio, or the carbonate-to-phosphate ratio. Energy dispersive X-ray spectroscopy showed similar Ca/P ratio of the interfacial tissue adjacent to both materials. Osteocytes made direct contact with CoCr and Ti6Al4V. While osteocyte density and distribution in the new-formed bone were largely similar for the two alloys, higher osteocyte density was observed at the periphery of the porous network for CoCr, attributable to slower remodelling and a different biomechanical environment. The results demonstrate the possibility to achieve bone ingrowth into open-pore CoCr constructs, and attest to the potential for fabricating customised osseointegrated CoCr implants for load-bearing applications.

Statement of Significance

Although cobalt chromium (CoCr) based alloys are used extensively in orthopaedic surgery, stress shielding due to the high stiffness of CoCr is of concern. To reduce the stiffness mismatch between CoCr and bone, CoCr and Ti6Al4V implants having an interconnected open-pore architecture were prepared by electron beam melting (EBM). After six months of submerged healing in sheep, both alloys showed similar patterns of bone formation, with densification around the implant and gradual ingrowth into the porous network. The molecular and elemental composition of the interfacial tissue was similar for both alloys. Osteocytes made direct contact with both alloys, with similar overall osteocyte density and distribution. The work attests to the potential for achieving osseointegration of EBM manufactured porous CoCr implants.

---

* Corresponding author at: Department of Biomaterials, Sahlgrenska Academy at University of Gothenburg, Göteborg, Sweden.
E-mail address: furqan.ali.shah@biomaterials.gu.se (F.A. Shah).

http://dx.doi.org/10.1016/j.actbio.2016.03.033
1742-7061/

1. Introduction

Cobalt chromium (CoCr) based alloys are extensively used in orthopaedic reconstructive surgery for their high strength and wear properties [1–3]. Uncemented, CoCr femoral stems, with a sintered porous surface have shown promising clinical results [4], allowing bone ingrowth into the porous coated surface [5]. However, periprosthetic bone loss around femoral stems is a problem, even with Ti6Al4V alloys, which otherwise have an outstanding clinical record. And while limited postoperative weight-bearing and aseptic loosening contribute to bone loss [6], bone resorption as a direct consequence of stress shielding due to the high stiffness of CoCr has been reported [7]. The extent of stress shielding experienced by bone around a bone-anchored device depends on the interfacial bonding characteristics, e.g., whether it is cemented or uncemented, the presence of a coating, and the possibility for bone ingrowth [8]. Furthermore, stress shielding is also dependent on the structural stiffness, which is principally related to the bulk and the elastic modulus of the material [8]. Indeed, the overall stiffness of a metal implant and the stress shielding experienced by bone may be reduced by appropriate design modifications.

Additive manufacturing is an emerging fabrication technique, with the potential to overcome the challenges faced in traditional machining. Structures are built up by melting successive thin layers of powder. Material is added, rather than being removed, and complex innovative designs can be produced in an intentional, controlled, and pre-determined manner. Medical implants with an integrated open-pore architecture could be readily produced from a computer-aided design (CAD), enabling either mass production of well-defined implants or customised implants based on patient-specific X-ray imaging [9]. Electron beam melting (EBM) is one of the most promising additive manufacturing techniques for load bearing metal implants [10], allowing modulation of the overall stiffness of the porous structure using both cobalt and titanium based alloys [11].

Osseointegration and biomechanical fixation of CoCr are often considered inferior to titanium (typically Ti6Al4V) alloys [12,13]. Therefore, attempts have been made to improve the biological response to CoCr implants by the use of different coating procedures [14,15]. Interestingly, no differences have been demonstrated between uncoated, solid Ti6Al4V and CoCr implants on the histological [16] and the ultrastructural [17] levels. Furthermore, recent findings have revealed that osseointegration occurs without adverse tissue reactions for EBM-manufactured, solid, CoCr implants [18]. Nevertheless, bone ingrowth into porous CoCr constructs has not yet been evaluated, and little is known about the precise biological and tissue response to such materials.

Bone ingrowth into porous Ti6Al4V implants prepared by EBM [19,20] has been demonstrated previously. The current work aims to evaluate: (i) whether porous CoCr exhibits properties compatible with long-term bone ingrowth similar to Ti6Al4V, and (ii) if there are site-specific differences in bone formation, composition and ultrastructure, depending on the location within and outside the porous network.

2. Materials and methods

2.1. Powder materials, implant fabrication, and surface characterisation

For the Ti6Al4V implants, a plasma-atomised Ti6Al4V ELI powder (Grade 23; ASTM F136 standard) of particle size < 100 μm was used (Fig. 1a). For the CoCr implants, a low carbon gas-atomised CoCr powder (ASTM F75 standard) of particle size < 100 μm was used (Fig. 1b). The chemical compositions of the alloy powders were within the limits of the relevant ASTM standards for medical grade implants (Table 1).

The Ti6Al4V implants were built first, in a single build cycle, followed by the CoCr implants in a separate build cycle in an Arcam EBM A1 system (Arcam AB, Mölndal, Sweden). The upper part of each implant consisted of a solid top whereas the lower part consisted of an interconnected, cylindrical, porous network having a diamond-shaped lattice structure (Fig. 1c, d). Using standard Arcam process parameters for preheating and bulk melting of Ti6Al4V and CoCr, respectively, the implants were built in the z-direction of the cylindrical coordinates with the porous part built on top of the solid part using the same 3D CAD drawing for both materials. The average build temperatures were approximately 680 °C for Ti6Al4V and 780 °C for CoCr, respectively. The melting of CoCr contours and net structures was carried out with the same beam current as for Ti6Al4V, while the beam speed and the contour offset of the 2D polygons were optimised so that the CoCr parts were fully melted and displayed similar dimensions as the Ti6Al4V implants.

All implants were blasted with the same powder as they were built of and machined in the x-y plane to obtain a 2 mm height of the solid top. A shallow notch was machined in the top surface in order to facilitate implant placement. All implants were ultrasonically cleaned in ethanol and visually inspected to ensure that any loose particles and flakes had been removed. After inspection, the implants were cleaned in Extran MA01® (Merck Millipore, Darmstadt, Germany) prior to sterile packaging and subsequent autoclaving.

The macroscopic design and the macro porosity of the implants were evaluated by X-ray micro computed tomography (micro-CT). Three implants of each type were scanned in a (Skyscan 1172, Bruker micro-CT, Kontich, Belgium) operating at 100 kV energy with an Al/Cu filter, for a complete 360° rotation at a step size of 0.7° with an averaging of 5 frames and an image pixel size of 11.88 μm. Reconstruction, analysis, and visualisation were performed using associated Skyscan software. Analysis of porosity and structural dimensions of the porous network was performed for a defined volume of interest confining the porous network only.

The surface chemical composition of the Ti6Al4V and CoCr implants was analysed by X-ray photoelectron spectroscopy (XPS, AXIS Ultra DLD, Kratos Analytical, Manchester, UK) equipped with a monochromatic Al X-ray source. Two implants of each type were analysed. Survey scans were performed for analysis of the atomic composition of the surface, while detailed high-resolution scans were performed to evaluate the oxidation states of specific elements.

The surface morphology was evaluated by scanning electron microscopy (SEM; Leo Ultra 55 FEG SEM, Leo Electron Microscopy Ltd, UK) in the secondary electron mode, operated at 5 kV accelerating voltage. Two implants of each type were evaluated at 100–100,000× magnifications.

2.2. Animal surgery

The animal surgery was conducted in accordance with the provisions of the OECD, EU and US FDA Good Laboratory Practice (GLP) regulations. No deviations from the protocol, standard operating procedures or GLP regulations were considered to significantly affect the outcome. A total of five sheep were operated and each received test and control implants bilaterally in the distal femora ($n = 10$).

Prior to the surgery, the sheep were fasted 24 h for food and 12 h for water. Each sheep received pre-operative analgesia with buprenorphine (Buprecare®, Axience SAS) and flunixine (Meflosyl® Injectable, Fort Dodge, France). At the time of surgery, anaesthesia