Electron beam melted Free Form Fabricated titanium alloy implants: A 6 months in vivo study in Sheep

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Introduction

A functional load bearing implant should possess properties such that fixation, in terms of bone ingrowth, and load bearing capacity are fulfilled without producing destructive bone remodelling. Thus, design and material must be carefully optimized. Electron Beam Melting (EBM), a Free Form Fabrication (FFF) technology, offers a highly productive process for producing complex shaped implants. EBM produced titanium implants have been shown to be biocompatible and encourage substantial short-term (6 weeks) bone ingrowth in porous structures[1].

The aim of the current study was to evaluate the long-term biocompatibility of porous FFF Ti6Al4V implants compared to non porous in sheep.

Materials and Methods

Implants were manufactured in an Arcam EBM S12 system, using a standard Arcam Ti6Al4V Extra Low Interstitial (ELI) powder, with a powder particle size of 45 -100 µm. The layer thickness of the build process was 0.07 mm and all implants where manufactured in one single build with the same process controlling settings. Two different designs were made, macro porous (500-700 µm) and solid, which were subsequently blasted, cleaned and sterilized.

Surface characterization was performed to assess the surface topography, material density, porosity and oxide thickness (examples of which are shown in Fig. 1).

Implants were installed in the distal femoral epiphyses (bone tissue) and the subcutaneous tissue of the dorsum (soft tissue) of sheep and retrieved after 6 months healing.

The soft tissue implants were evaluated for histology and fibrous capsule formation while the bone tissue in contact with and inside implants were evaluated by histology, histomorphometry, scanning electron microscopy and micro-CT.

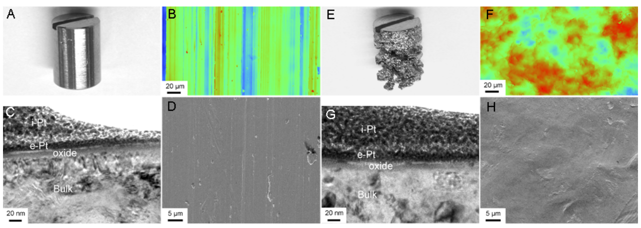

Figure 1: Foto, interference microscopy, cross-section TEM and SEM analysis of the implants. A-D) Solid sample. E-H) Porous sample.

Results

The surgical sites in all animals healed uneventful In soft tissues, the porous samples demonstrated a thinner fibrous capsule compared to the solid sample. As judged by histology, no inflammatory cell infiltration was detected. Similar amount of bone tissue was found around (~80 %) and in direct contact with both types of implants (~60 %). Histomorphometry demonstrated a substantial bone ingrowth in the porosities of the macroporous design. A major observation was the detection of bone in direct contact with the surface of the walls of the macropores (Fig. 2).

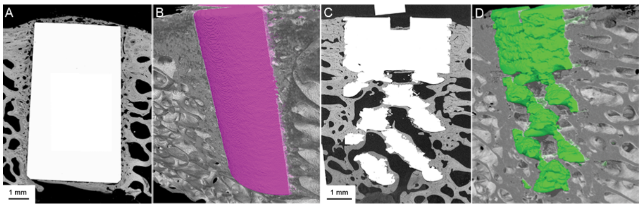

Figure 2: Micrographs of the bone implant unite using electrons and x-rays. A-B) Solid sample. C-D) Porous sample. Large amount of bone tissue was observed around and in direct contact with the implants. Further, a large amound of bone ingrowth along the walls of the porosities was deteced in the macroporous implants.

Discussion

A major observation in the present study was the detection of a high degree of bone implant contact, i.e. osseointegration, of Free Form fabricated Ti6Al4V porous scaffolds. This observation extends previous findings of osseointegration of FFF Ti6Al4V at early time period[1]. Interestingly, an equal, high degree of osseointegration was detected both at inner and outer surfaces of the scaffold. Moreover, an equally high amount of surrounding bone outside and in direct contact with the implant was found for solid and porous scaffolds.

Conclusion

The present study shows the possibility to manufacture implants with a complex geometry with a controlled interconnected porosity using EBM FFF technique. After 6 months, a high degree of osseointegration and adequate soft tissue biocompatibility was demonstrated. These observations suggest that the EBM FFF technique is of considerable value for the design of implants and prostheses where intentional, macroporous features are required in order to promote osseointegration and bone ingrowth.

References

1 P Thomsen, J Malmström, L Emanuelsson, M René, A Snis, *J Biomed Mater Res B Appl Biomater*, 2009, **90(1)**, 35.