DEVELOPMENT OF A 3D-PRINTED PCL-TiAlNb MATERIAL COMPOSITE WITH ANTI-MICROBIAL ZnO COATING FOR NEXT-GENERATION MAXILLOFACIAL IMPLANTS

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[ENGINEERING OF BIOMATERIALS 163 (2021) 15]

Introduction

Jawbone resection is the final surgical treatment for ~5500 patients in EU27 with maxillofacial benign and malignant tumours. The resulting large bone defects lead to scarred, mangled facial appearance and the loss of mastication and speaking function, requiring aesthetic and functional reconstruction as basis for physical and physiologic rehabilitation. Although autologous vascularized bone from fibular or iliac-crest autografts is current gold standard, the portion of transplantable bone is limited and subsequent high-dose anti-cancer chemo-/radiotherapy often results in tissue necrosis.

Alternatively, a final reconstruction was based in current research activities on patient-specifically manufactured maxillofacial implants without autografts, whereby the neoformation of vascularized bone in such implants occurs within the patient's own body as "bioreactor" as the safest approach in tissue engineering. Compared to the state-of-the-art Ti implants, the metal-polymer hybrid implants were targeted on fulfilling the functional (mastication, speaking, etc.) and aesthetical jawbone reconstruction needs together with strongly improved accuracy (dental interocclusion), mechanical strength, antimicrobial protection, low irritation of surrounding tissue and the possibility for CT imaging in oncological re-checks.

Materials and Methods

The hybrid implants were manufactured by following additive manufacturing techniques:

- selective laser melting (SLM) of V-free TiAlNb alloys and isostatic pressing for the fatigue- and corrosion-resistant metal CORE
- fused filament fabrication (FFF) of polycaprolactane (PCL, PolyMed Inc.) with in vivo biodegradation duration of >1 year for bone neoformation within the biomimetic pore structure (60% open porosity with >0.7 mm pore size) for the bioresorbable polymer scaffold SHELL

The surfaces (including the open porosity) were optimized by ZnO coating deposition (low-temperature thermal atomic layer deposition, ALD) for anti-microbial protection over >12 weeks.

The presented biomaterial characterization was based in vitro on cytotoxicity testing (direct contact and eluates in contact to fibroblasts), genotoxicity testing (MILLIPLEX® MAP 7-plex DNA Damage/Genotoxicity Magnetic Bead) and anti-microbial testing for Staph. aureus & epidermidis, E. coli according to ISO 22196. In vitro testing used the sheep model (3 months implantation in femur bone).

Results and Discussion

The in vitro results showed no cytotoxicity in direct contact as well as to eluates for the tested fibroblasts and all material combinations (uncoated as well as ZnO coated surfaces). The anti-microbial behaviour of the ZnO coated PCL and TiAlNb surfaces revealed a decrease from 1E5 to <1E1 Staph. aureus and E.coli species within 24 h, while bacterial growth occurs on non-coated surfaces. Genotoxicity assay results don't indicate any impact on gene expression.

In vivo tests are currently ongoing and will be finalized till November 2019. Interim results, obtained by microCT, do not show any adverse effect on the in-ingrowth of the specimen into femur bone for all the tested combinations as well as the reference materials (pure Ti). The comparison of in vivo and in vitro results will mainly be based on comparison of histological and microCT findings with the found mechanisms of dissolution of the bioresorbable PCL substrate and ZnO coatings including scanning electron microscopy studies, e.g. structure formation on the surface during dissolution, interface formation between bone and biomaterials.

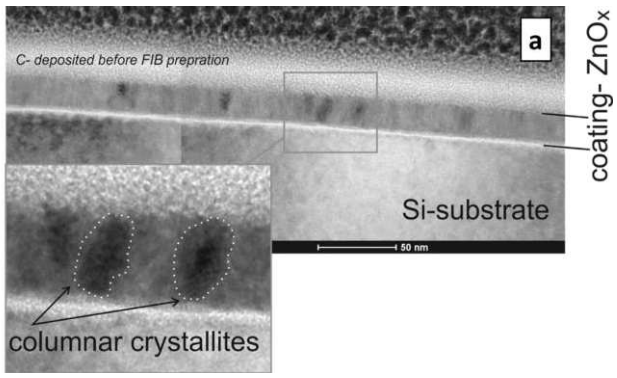

FIG. 1. (a) Transmission electron microscopy image of the ZnO coated surface. (b) Final prototype of the composite implant.

Conclusions

These comprehensive developments will have crucial material, technological & biomedical impact on maxillofacial tumour surgery.

Acknowledgments

Highly acknowledge is Austrian FFG and Polish NCBR for funding the "jawImplant" project in the frame of the European H2020 "M.ERA-NET" initiative.