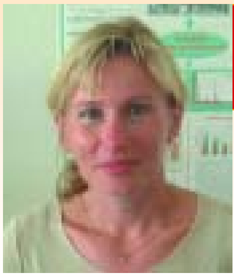


Petra Becker
Peter Zeggel
DOT GmbH, Rostock, Germany

BONIT®
A Biomimetic Calcium Phosphate Coating Connects Bone and Implant Surfaces

Introduction

To a great extent, implant functioning depends upon the properties of the implant surface. The effect of surface properties on the interface between the implant and surrounding living tissue is particularly important for implant longevity and functionality. Manufacturers strive to develop implant surfaces that are compatible with the body's metabolism. To this end, bioactive surface coatings utilizing calcium phosphates (CaP) are widely used in coatings for both orthopaedic and dental implants because of their unique advantages, especially as they relate to "gap crossing" and osteoporosis. These coatings enhance osseointegration in poor bone quality and exhibit greater resistance to micromotion.

Disadvantages of technical coatings

For two decades, plasma spraying with calcium phosphate "hydroxyapatite" (the CaP phase of mature human bone) has been considered a state-of-the-art process. However, long-term drawbacks associated with plasma-sprayed HA-coated implants may outweigh the short-term achievements. Some disadvantages of plasma-sprayed HA include: (1) thermal decomposition during the coating process; (2) low coating-substrate bond strengths; and (3) unpredictable dissolution of the coating.

Should the coating be stable?

More and more, literature suggests that, in general, coatings are only necessary during the first healing period of osseointegration as a matrix for the early immobilization of osteoblast-like cells, and for the development of vascularized bone tissue on the implant. In other words, coatings don't need to remain after osseointegration has been achieved.

Electrochemically deposited CaP-coatings match such efforts. This new generation of bioactive coatings offers an opportunity to transition from technical coatings (i.e., plasma spray) to biological coatings that allow the implant to more closely mimic the normal conditions found in human body balance. Due to their microporous morphology, electrochemically-deposited CaP coatings provide favorable solubility and resorbability.

Biomimetic coating BONIT®

Developed in 1995, BONIT is an electrochemically-deposited CaP coating (see patent WO 0205862) based upon a biomimetic process in which implants are coated in an electrolytic bath with a ~20µm thin bioactive layer of calcium phosphate. The room temperature procedure provides for complete coverage of complex shapes and porous surfaces. As opposed to the monolithic crystalline structure representative of plasma-sprayed coatings, this process employs a fine crystalline structure whereby CaP crystallites are affixed to the implant surface in the shape of platelets or pins that are in near vertical alignment. This micro-crystalline coating accelerates bone on-growth at the implant surface, thereby allowing faster and improved integration of the implant with controlled coating solubility.

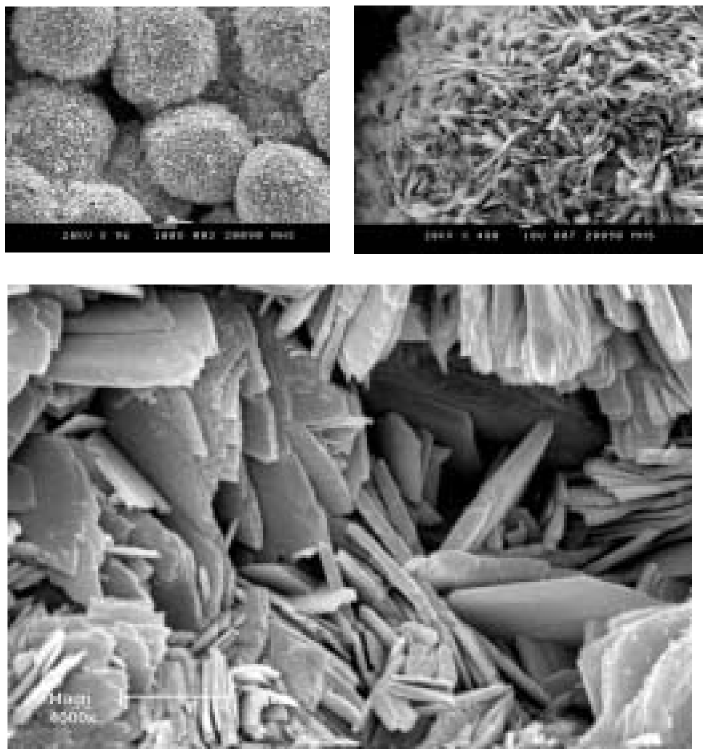

Figure 1. SEM micrograph of BONIT® on porous coating at x100, x500 and x4000

Chemistry
The CaP phase of BONIT is a composite of Brushite with less HA (<5%). Brushite is a CaP with a Ca/P ratio of 1.0. This phase is postulated as an intermediary phase in bone mineralization in vivo. Compared to HA, Brushite is an easily soluble calcium phosphate that implies the presence of a high local ion source of calcium and phosphate ions. This high ion concentration is the reason for rapid contact osteogenesis and high mineralization; thus, the coating supports the natural healing process of a bone implant. This morphology creates an exceptional capillary effect that facilitates complete moistening of the implant surface upon the slightest contact with body fluids.

Figure 2 : Capillarity of BONIT® at dental implants

Testing
During shear testing, this coating on smooth surfaces shows no abrasion. The CaP crystals remain unchanged and form a layer. During shear testing on severely-structured rough surfaces (e.g. porous-sprayed titanium coatings, TPS), abrasion occurs only to a limited extent at the outer marginal zones or peaks—the internal areas of a porous surface remain unaffected in their morphology.

BONIT® ***in vitro***
In cell culture experiments, this coating shows excellent results relative to biocompatibility and functionality. We investigated the behaviour of osteoblast-like cells (cell line MG-63) on the coating with SEM. Cells were cultured on BONIT“ coated titanium samples in Dulbecco's modified Eagel medium with 10% fetal calf serum at 37°C and 5% CO2 atmosphere. Figure 3 shows osteoblast-like cells on the coating after eight hours. After 30 hours (figure 4), the appearance of the osteoblast-like cells on the coating is dramatically different—neither the initial, needle-like structured surface of the coating nor the cells themselves are directly visible, as they are covered by new mineralized, fine-structured CaP phase.

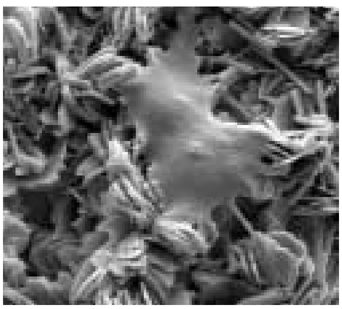

Figure 3

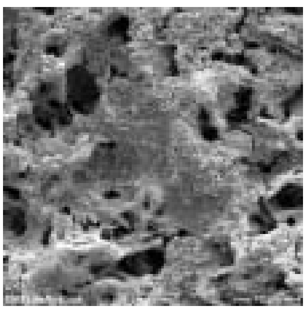

Figure 4

Other cell culture tests show very good results in terms of cell adhesion and proliferation. Negative control without BONIT revealed significantly smaller cell distribution, and a considerably-reduced cell morphology. Cell metabolism was considerably higher due to the soluble coating.

BONIT® ***in vivo***
In a series of animal experiments, BONIT demonstrated excellent behaviour in terms of osseointegration. Figure 5 shows extensive new bone apposition at the surface of a dental implant (pig model) after six weeks, demonstrating the osteocoductive capacity of the coating[1].

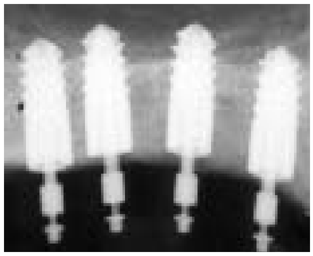

Figure 5

Figure 6 represents the histomorphometrical evaluation of various surfaces on titanium test bodies placed into femora of the Göttinger Minipig[2]. It shows that additional coating with BONIT yielded a significant increase in osseointegration. Also in mechanical pull-out tests the best results has been achieved with the combination of BONIT with a porous surface (TPS) (data not shown).

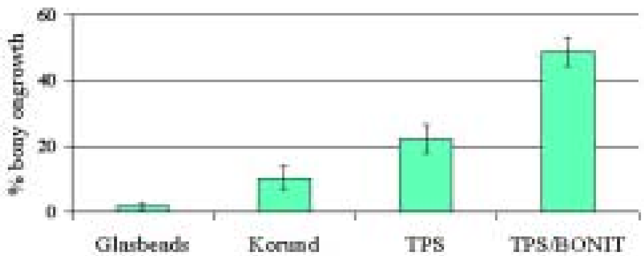

Figure 6

Summary
The in vivo results can be summarized as follows:
- controlled resorption of BONIT and simultaneous substitution by new bone
- no inflammatory processes or foreign body reactions
- osseointegration without problems in shorter times

1. Szmukler-Moncler S. et.al., Bioceramics Vol. 13 Bologna, 2000, 395-398.
2. Schwarz M.L. et.al., 49th Annual Meeting of the ORS, New Orleans, 2003 (P 1378).

Editor: DOT GmbH develops medical coating technologies for orthopaedic and dental implants and provides PVD, TPS, Electro-Chemical CaP Deposition (BONIT®), and Anodic Oxidation (DOTIZE®) surface treatments. DOT subsidiaries offer machining of dental and orthopaedic implants, as well as laser marking and clean room packaging services.