



HX® Surface Modifications

Applications on LINK® Joint Prostheses

HX® Coating at a Glance

Advantages

- Excellent biocompatibility
- Minimal layer thickness, thus preserving the underlying surface structure and functionality
- Microfine, microcrystalline structure with large free surface area and high capillary effect on body fluids
- Optimal solubility, controlled absorption and replacement by endogenous bone
- Faster and better healing^{1,2}
- Standard shearing resistance and bonding strength

Properties

Test criterion	Result
Color	light gray
Layer thickness (EN ISO 2360)	15±5 µm
Bond strength (ASTM F 1147-99)	>14 MPa
Ca/P ratio (EN ISO 11885-E22)	1.1±0.1
Phase composition	>95% brushite
Cytotoxicity	not cytotoxic (as per DIN EN ISO 10993-5)
Soluble	86% of the total released CaP after 1 week

Tab. 1 Summary of the tests

Range of Applications

In orthopedics, the HX® layer can be applied to various substrates and surface roughnesses/topographies. The prosthesis components listed below are available with an HX® coating.

- LCU®, T.O.P.®, T.O.P.® II, SP-CL®, C.F.P.®, CONTOUR® Ribbed II, MP® and Gemini®
TiCaP® = Ti-plasma coating + HX®



Fig. 1a:
HX®-coated hip stem



Fig. 1b:
HX®-coated acetabular cup



Fig. 1c:
TiCaP® (Ti + HX®)-coated femoral component

Basic Principles

A key requirement for durable and stable integration of a joint prosthesis is primary stability plus rapid and sustained osteoconduction (secondary stability, beginning with attachment of bone precursor cells). Achieving secondary stability quickly during the critical healing phase is essential for the lifetime of the joint prosthesis, free of loosening in the implant bed.

Rapid osteoconduction at the implant surface in the bone tissue depends decisively on stable primary fixation that permits micromovements of $<28\text{ }\mu\text{m}$ in the implant bed and optimal long-term osseointegration behavior. Both parameters are influenced to a large degree by the surface structure and chemistry of the joint prosthesis. The optimal surface has a complex, microporous topography with differing degrees of roughness³. According to Bobyn⁴, the pore sizes should preferably be between 50 and 450 μm . The surface is then biocompatible and osteoconductive.

The osteoconductive properties of calcium phosphate coatings have been known for many years⁵. Today it is possible to apply an extremely thin coating of calcium phosphate, which allows the

positive characteristics of the calcium phosphate to be utilized, while at the same time maintaining the underlying topography and associated large-pore structure of the surface.

The HX[®] coating developed by LINK is a thin, bioactive calcium phosphate coating designed primarily to meet the specific requirements as the interface between living bone and implant. It also accelerates osseointegration via elution into the surrounding medium^{1,2}. A special electrochemical process is used to apply the HX[®] layer to the large-pore PoroLink[®] surface.

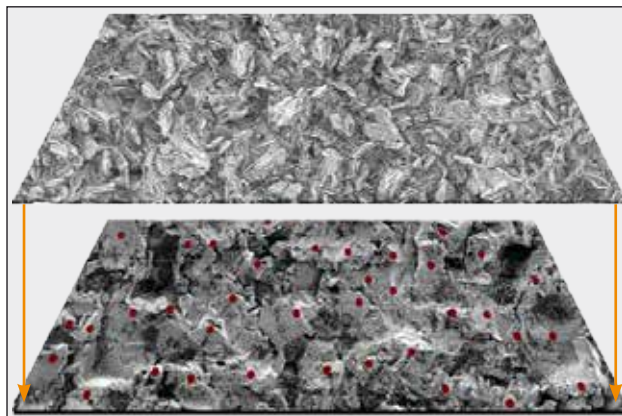


Fig. 2:
REM images of PoroLink[®] microstructure (below) with an average distance of 160 μm between the roughness peaks and a subsequently applied HX[®] coating (above)

Properties

In the current technology, HA (hydroxyapatite) is the standard coating used for implants. But other calcium phosphate phases, which promote bone ongrowth on the implant surface and ensure controlled solubility of the coating, perform the tasks of the conventional HA coating quicker and more advantageously⁶⁻¹¹. For osteogenesis following implantation, low-calcium phases, which serve as the precursor to the low-solubility HA in the body, are most suitable for promoting osseointegration. Over 95% of the HX[®] coating consists of the low-calcium HA precursor brushite (readily soluble), making it an ideal basis for contact osteogenesis.

Our implants are electrochemically coated, in contrast to the conventional plasma spray method. This means that a crystalline and microfine structure with outstanding solubility and absorption properties is produced. Furthermore, our coating technology ensures an absolutely even and complete coverage of the complex implant shapes, while retaining the surface structure and its functionality. This is achieved due to extreme thinness of the coating, at just $15\pm5\text{ }\mu\text{m}$.

Color and Structure of the HX® Layer

The fine calcium phosphate phases appear macroscopically as a light gray, finely textured surface (Fig. 1a-c & 3: Implant examples).

Fig. 3:
HX®-coated hip stem

HX® Coating Topography

The HX® coating is an osteoconductive layer with a thickness of $15 \pm 5 \mu\text{m}$. It is applied by an electrochemical process, resulting in extremely high mechanical strength, which is advantageous during the implantation procedure. The substrate topography in the coarse-micron range $>10 \mu\text{m}$ (coarse blasting), in combination with calcium phosphate nanocrystals, provides an excellent basis for the attachment of bone cells. (Fig. 4)

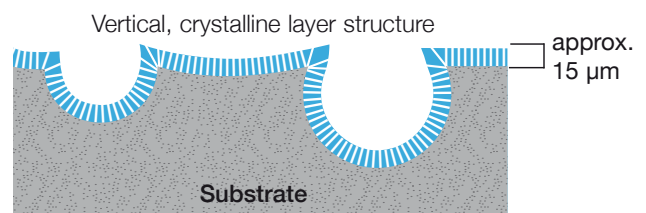


Fig. 4:
HX® layer: schematic cross-section of coated surfaces

Crystallography of HX®

The topography of the coating surface is defined by fine crystal structures, both rod-shaped and plate-like, which align themselves almost

vertically on the surface of the implant during the coating process. (Fig. 5a-b).

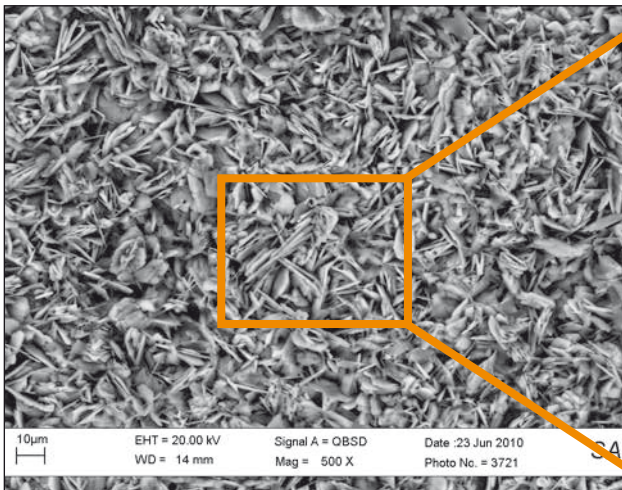


Fig. 5a:
SEM image of the HX® surface at 500x magnification

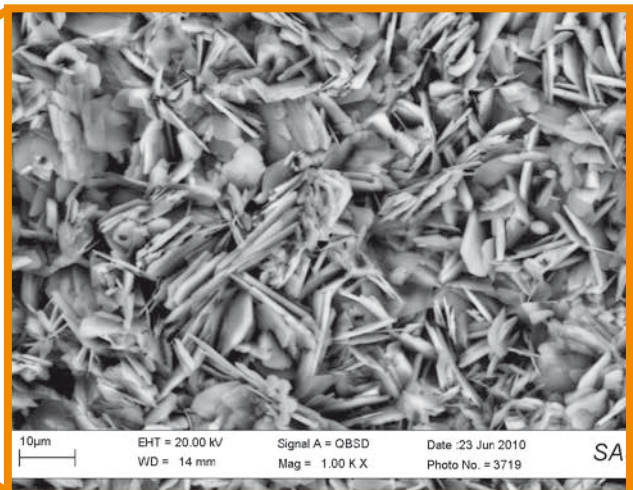


Fig. 5b:
SEM image of the HX® surface at 1000x magnification

Capillarity

The HX® coating forms fine crystal structures on the surface of the prosthesis, which in turn creates a large free surface area. The result is a high degree of hydrophilicity with very good capillarity in contact with liquids, and large-area wetting within a few seconds.

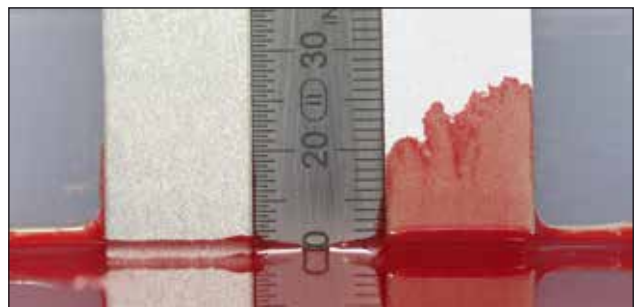


Fig. 6:
Example of experimental run. On the left uncoated, on the right CaP coated specimens after 300 seconds.



Fig. 6a:
... capillarity of HA coating after 60 seconds

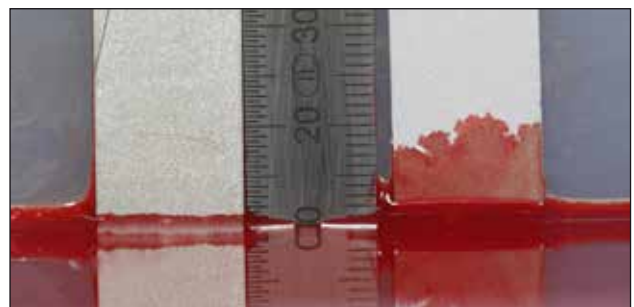
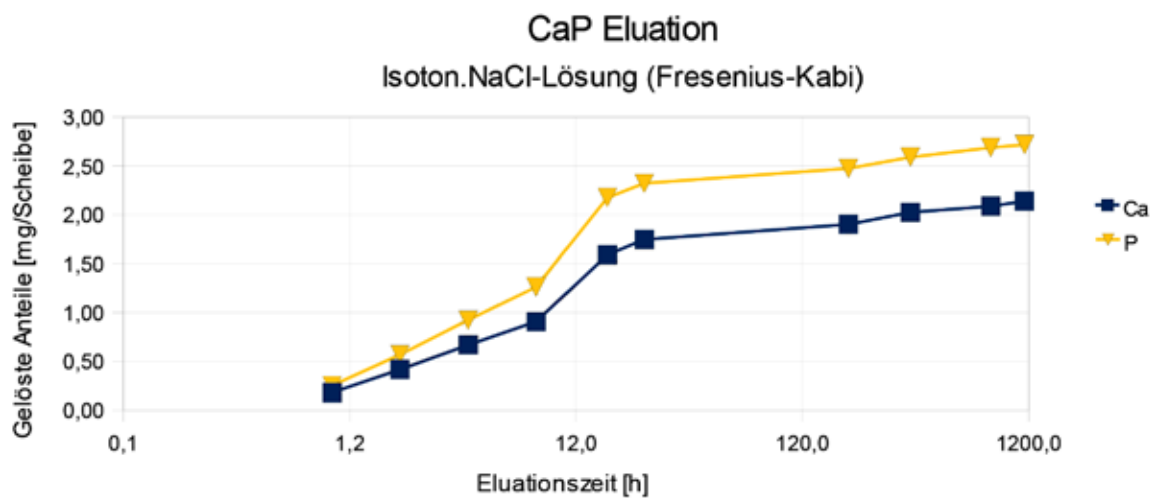


Fig. 6b:
... capillarity of HX® coating after 60 seconds

Solubility of the HX® Layer

The solubility behavior of the HX® layer was determined using SEM^a and EDX^b analysis. The elution solution used was an isotonic NaCl solution (Fresenius-Kabi) at a temperature of 37°C, in which the coated test specimens were placed for defined periods of time.

Subsequently, ICP-OES^c was used to analyze the Ca and P content of the solutions, and the values obtained were correlated with the elution times. These investigations showed an increase in the Ca and P content over the entire elution period.



Tab. 2:
CaP elution

- a - SEM = Scanning Electron Microscopy
- b - EDX = Energy Dispersive X-ray Spectroscopy
- c - ICP-OES = Inductively Coupled Plasma Optical Emission Spectrometry

Biocompatibility

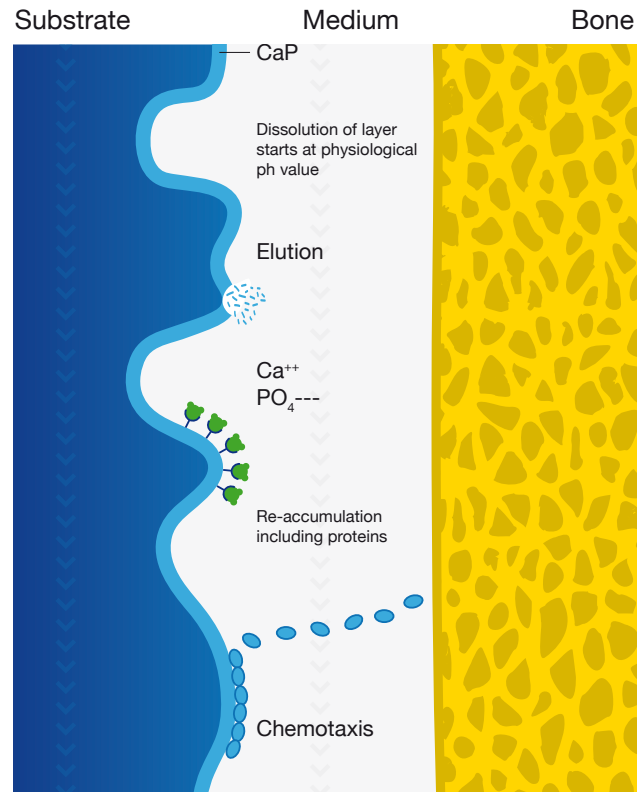
The HX® layer was tested for cytotoxicity by an accredited laboratory using a growth inhibition test, in conformity with ISO 10993-5. In addition, this laboratory confirmed the result by carrying out a cytotoxicity test in direct contact, in accordance with ISO 10993-5.

The final test results show that standard specifications were exceeded and that the HX® only reacts cytotoxic at extremely high concentration.

Process of Osteoconduction¹²

- Lowering of the pH
- Partial dissolving of the coating in the medium
- Ca + P ion increase
- Ion exchange with the medium
- Renewed deposition of crystals with included proteins
- Extracellular ions are trapped in the apatite crystals
- Formation of collagen matrix and new bone
- Increasing concentration of Ca + P ions stimulates chemotaxis

Theory of osteoconductive processes, according to Overgaard¹²



References

1. H.B. Wen, F.Z. Cui, Q.L. Feng, H.D. Li, X.D. Zhu, Microstructural Investigation of the Early External Callus after Diaphyseal Fractures of Human Long Bone, *Journal of Structural Biology*, Volume 114, Issue 2, March 1995, Pages 115-122
2. F.Z. Cui, H.B. Wen, X.W. Su, X.D. Zhu, Microstructures of External Periosteal Callus of Repaired Femoral Fracture in Children, *Journal of Structural Biology*, Volume 117, Issue 3, November 1996, Pages 204-208
3. John E. Davies, Elnaz Ajami, Rahim Moineddin, Vanessa C. Mendes, The roles of different scale ranges of surface implant topography on the stability of the bone/implant interface, *Biomaterials*, Volume 34, Issue 14, May 2013, Pages 3535-3546
4. P.H.D. Bobyn, J.D. et al.: "The Optimum Pore Size for the Fixation of Porous-Surfaced Metal Implants by the Ingrowth of Bone.", *Clin. Orthop. and Related Research*, No. 150, July-August, 1980
5. Yang C., Effect of calcium phosphate surface coating on bone ingrowth onto porous-surfaced titanium alloy implants in rabbit tibiae, *J Oral Maxillofac Surg.* 2002 Apr;60(4):422-5.
6. Redepenning J, et al., Electrocrystallization of Brushite Coatings on Prosthetic Alloys, *Chemistry of Mater.* 1990; 2: 625.
7. Johnsson MS, et al., The role of brushite and octacalcium phosphate in apatite formation, *Critical Review in Oral Biology & Medicine* 1992; 3: 61.
8. Redepenning J et al., Characterization of electrolytically prepared brushite and hydroxyapatite coatings on orthopedic alloys, *J Biomed Mat Res* 1996; 30: 287.
9. Neumann H-G et al., Multilayer systems for corrosion protection of stainless steel implants, *Surface and Coatings Technology* 1998; 98 : 1157.
10. Kumar M et al., Electrodeposition of brushite coatings and their transformation to hydroxyapatite in aqueous solutions, *J Biomed Mat Res* 1999; 45: 302.
11. Campbell AA., Bioceramics for implant coatings, *materials today*, November 2003; 26.
12. Overgaard S., Calcium phosphate coatings for fixation of bone implants, *Acta Orth. Scand.*, Suppl. No. 297, Vol. 27, December 2000



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