Coating Dossier SBTC ®

Dental Applications

SGS Dental
Swiss Implant System

Contents

1. General Information

The primary requirements for joint replacement-implants are good primary stability and a durable friction-locked connection to the surrounding bone tissue. The basic prerequisite for the above is the formation of a strong, direct contact between bone and implant. Osseointegration of the implants, in addition to the design and the selection of the material, is primarily determined by the design and the properties of the implant surface. Immediately after implantation the interaction between the implant surface and the surrounding tissue exerts an important influence on the degree of acceptance by the body. Modification of the surface can have a positive influence on the primary reaction in the body and also on the long-term stability (1, 2). Today, an implant surface is considered optimal if it is both macroporous and biocompatible to the bone metabolism, and therefore supports osseointegration of the implant into the surrounding bone tissue. Innovative implant surfaces for cement-free anchorage have been made with a porous titanium coating in combination with a bioactive calcium phosphate coating for many years. Calcium phosphates are used in medical coating technology because they ensure fast growth of bone tissue and promote a very strong connection between the implant and the surrounding tissue, and thus reduce the healing phase (3). Since the 1980s the state of the art has been considered the combination of sprayed titanium and the poorly soluble calcium phosphate phase, hydroxyapatite (HA), which has been applied to the implant surfaces at a thickness of > 50-200 µm by the plasma-spray process (sprayed HA). While the porous TPS coating is responsible for mechanical anchorage of the bone, the CaP coating generates a quick contact osteogenesis. Although these coatings have many positive properties, the use of sprayed HA coatings also has a range of disadvantages. Examples include thermal decomposition of the HA powder during the spraying process, which results in local differences in solubility as well as other problems, and may cause infiltration or separation of the coating. Amorphous calcium phosphate in particular with its very high solubility in vivo may result in coating delamination and flaking. One consequence of coating delamination may be the formation of a connective tissue capsule in the resulting gap, which would culminate in an aseptic loosening of the implant (4). Because of what is referred to as the line-of-sight process, this coating process is less suitable for porous surfaces and complex implant geometries. These facts have caused a rethinking of the necessity for the long-term stability of the calcium phosphate coating. According to current knowledge, bioactive coatings are required on the implant surface only until the implant has become osseointegrated (5,6). The professional scientific literature of recent years agrees with this statement with a change from the use of hydroxyapatite as the standard to other CaP modifications such as brushite, monetite, OCP or TCP, which with the recognition of controlled solubility promote bone growth on the implant surface as the coating dissolves (7, 8, 9, 10, 11,12). Complete and controlled resorption of the calcium phosphate coating requires thin coatings, which are not possible with conventional spraying technology. To achieve these requirements the target is a high degree of crystallinity combined with optimal solubility.

The SBTC® coating, developed by SGS, is a thin, bioactive calcium phosphate coating that meets the necessary requirements for accelerated formation of new bone. It is applied to the implant by electrochemical deposition and creates a microporous structure with an optimal solubility and resorption. Unlike the highly crystalline, poorly soluble plasma-sprayed HA coatings, the electrochemical coating technology yields a fine crystalline structure. The process eliminates hard particles and flaking of the coating. The coating process from a liquid phase ensures absolutely even and complete coverage of structured surfaces and complex implant shapes with a very thin coating (20 ± 10 µm). The chemical composition of the SBTC® coating is a composite of brushite and hydroxyapatite (HA). Brushite, an easily soluble calcium phosphate phase, is noted for very good biocompatibility (13). Biologically the easily soluble brushite forms a reservoir for calcium and phosphate ions, which can be used for bone apposition. The formation of new bone and also the healing of a fracture start with low-calcium phases such as brushite, monetite or octa-calcium phosphate, which all represent the more soluble calcium phosphate modifications. In the course of mineralization, the more easily soluble modifications are converted into less soluble HA. This means that low-calcium phases are a precursor of the bone mineral HA and as a coating support the natural osseointegration process of a bone implant (14, 15). With these properties the thin, bioactive SBTC® coating acts as a connection between the living organism and the implant.

2. Features of the SBTC® coating

2.1 Shape & structure of the SBTC® coating

SBTC® is an electrochemically deposited calcium phosphate coating, which is primarily defined by its chemical composition and the associated properties. Macroscopically the SBTC® coating forms a light-gray, finely structured surface (Fig. 1).

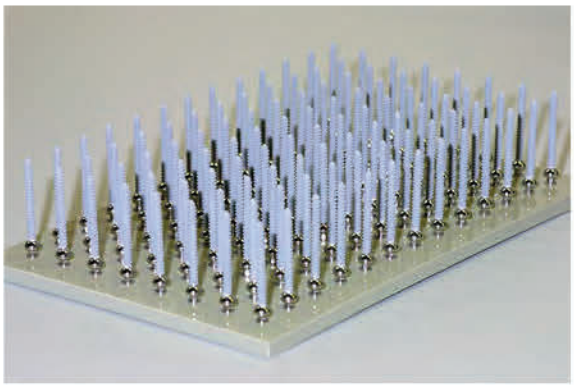
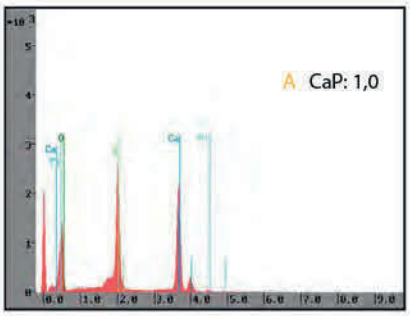


Fig. 1a: SBTC®-coated dental implants

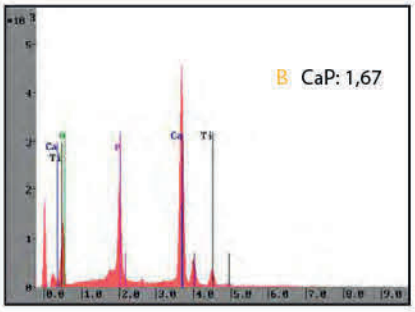
2.2 Phase composition and Ca:P ratio of SBTC®

The phase composition of the SBTC® coating can be derived from the molar Ca:P ratio. It is the mass-fraction-weighted total of the Ca:P values of the brushite and hydroxyapatite constituents. The calcium phosphate of the bioactive SBTC® coating is a composite (Fig. 2), the majority of which is the easily soluble calcium phosphate brushite phase [$CaH(PO_4)$ x 2] and a small proportion is the less soluble hydroxyapatite phase [$Ca_5(PO_4)_3OH$] (16). Both compounds, the brushite and also the hydroxyapatite, are naturally occurring inorganic compounds.

Fig. 2a: REM image of SBTC® (vertical)



2b: EDX spectrum of the outer phase A (brushite)



2c: EDX spectrum of the inner phase B (HA)

The molar calcium-phosphate ratio of the SBTC® coating is 1.1 ± 0.1 and is calculated by quantitative evaluation of the EDX (Energy Dispersive X-Ray) spectroscopy (17). The x-ray radiation is measured by the electron beam excited by a semiconductor detector. The energy is typical for that specific element, and the intensity depends on the mass fraction of that element in the sample. It is an important factor for quality as surance and process monitoring.

2.3 Crystallographic properties of SBTC®

In contrast to plasma-sprayed HA coatings, the structure of the SBTC® coating is not monolithic but fine crystalline. It consists of a wide range of platelets and needle-shaped microcrystals, which are aligned verti cally on the implant surface and are firmly anchored (Fig. 3a-b).

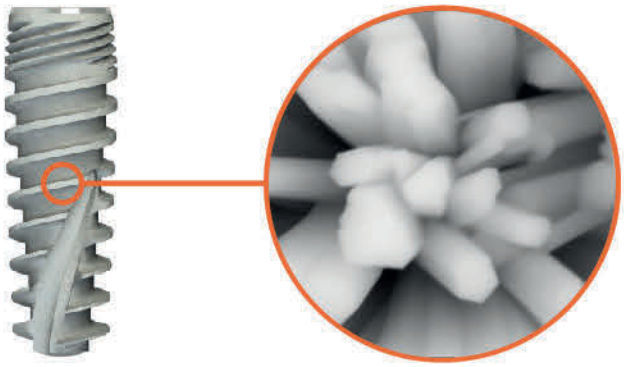


Fig. 3a: SBTC®-coated dental implant

Fig. 3b: REM image of the SBTC® surface, *magnification 2000x*

2.4 Description of physical properties

The coating process in the electrolysis bath enables the deposition of extremely thin coatings with absolutely even and complete coverage of microstructured surfaces. The porosity of the substrate is not reduced.

2.4.1 Coating thickness

The SBTC® coating is only 20 ± 10 µm thick.

2.4.2 Capillarity

„The wetting, marginal or contact angle formed by a liquid on a coating material defines the wettability of its surface" (Fig. 4) (18).

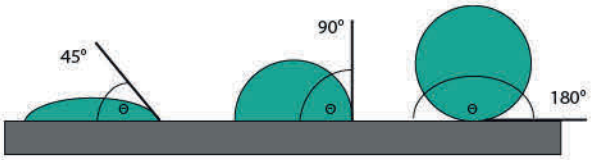


Fig. 4: Schematic view of various wetting angles 45° hydrophilic; 180° hydrophobic

The hydrophilia also influences the degree of contact with the physiological environment. The smaller the angle the greater the hydrophilia of the surface. The structure of the SBTC® coating makes it a strongly hydrophilic coating with an angle of contact to water of 0° (Fig. 5).

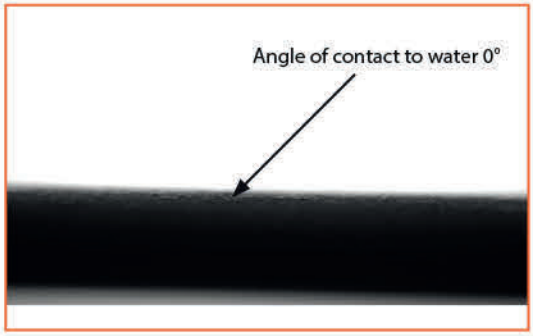


Fig. 5: Water-contact angle of SBTC®, drops aspirated, contact angle = 0°

The virtually perpendicular, closely packed calcium phosphate crystals and the associated large area of open surface give the implant surface a high degree of capillarity for blood, which ensures com plete wetting of the implant surface at the sligh test contact with body fluids (Fig. 6). The capillary effect transports growth factors from the blood to the coating, and therefore also directly to the me tallic implant surface where they are immobilized. As a result of the bone-like chemical environment, stem cells are stimulated to form osteoblasts and initialize the formation of new bone tissue. The capillary effect in vivo therefore forms a very important basis for successful osseointegration of SBTC®-coated implants.

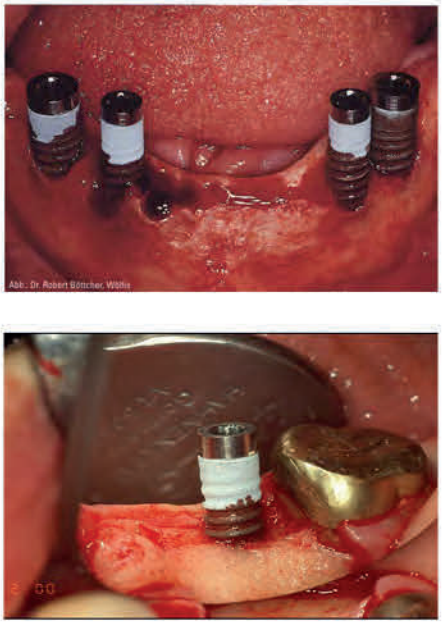


Fig. 6a-b: Capillary effect of in vivo

2.4.3. Adhesion strength

The fine, even crystalline deposition results in an adhesion strength greater than 15 MPa. A screw test in cortical swine bone was conducted to confirm the adhesion strength of the SBTC® coating. The results of the screw test demonstrate very minor shearing in the outer thread regions (thread flanks). Although the platelet and needle-shaped crystals were partially compressed or laterally displaced (Fig. 7a-b), the calcium phosphate crystals still formed a thin, strongly adhesive film on the implant surface. Coating delamination or cracking was not observed, which once again confirms that the coating adhesion is retained even under severe torsional loading, and the SBTC® coating can retain its bioactive, bone-forming function to its ful-

lest extent during osseointegration of the implant (17). Adhesion strength testing of the adhesion strength of the SBTC coating in accordance with ISO 13779-2 was conducted in accordance with the ASTM F1147 standard.

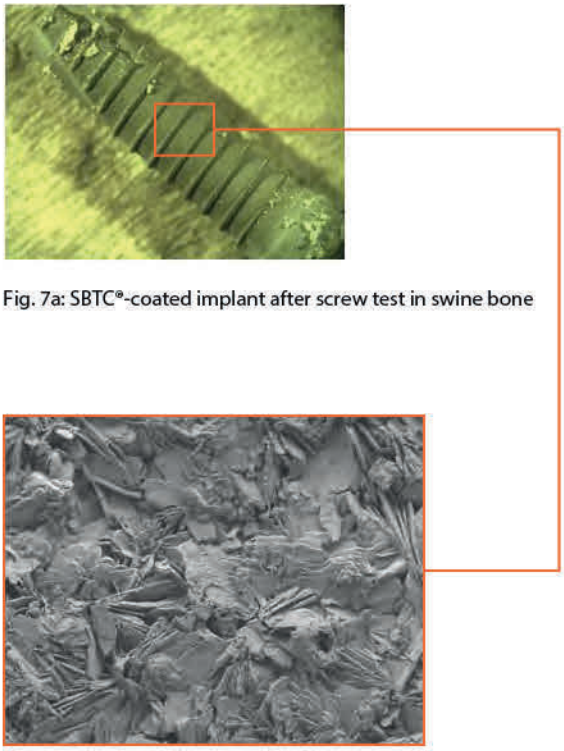


Fig. 7a: SBTC®-coated implant after screw test in swine bone

Fig. 7b: SBTC® coating after screw test in swine bone

2.5 Description of the biological properties of the coating

The SBTC® coating is a bioactive calcium phosphate coating that supports the adhesion of osteoblast cells and simultaneously promotes their proliferation. The cells demonstrate good adhesion on the SBTC® surface and a typical morphology for osteoblasts (Fig. 8a-b). Under the scanning electron microscope the integration of the cells into the material is clearly visible (Fig. 8c).

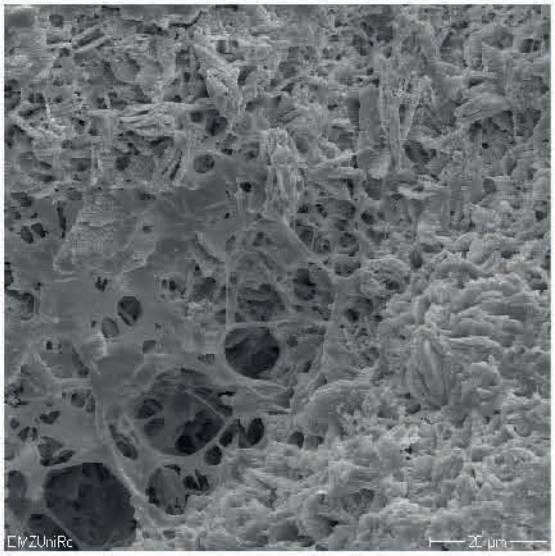


Fig. 8a: Bone tissue formation on SBTC® in vivo

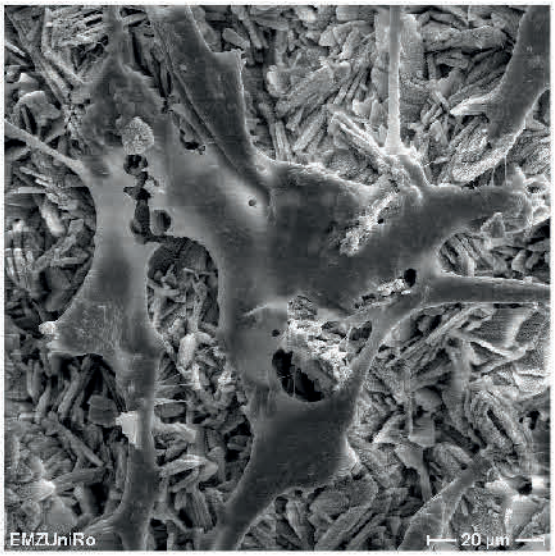


Fig. 8b: Human osteoblasts on SBTC® in vitro

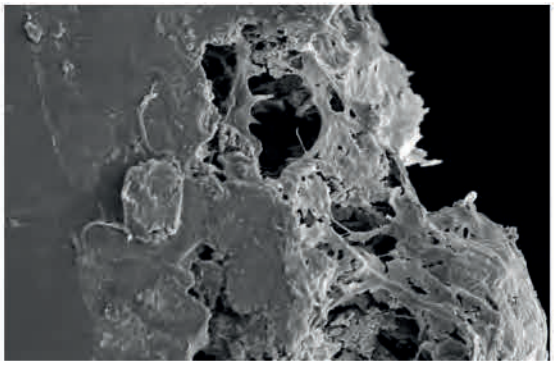


Fig. 8c: MG 63 osteoblast cells on SBTC®, Side view

The SBTC® coating consists of two calcium phosphate phases with different solubilities. The more easily soluble outer calcium phosphate phase, brushite, occurs in natural bone as an intermediate stage during calcification of new bone tissue (19). When brushite dissolves, calcium and phosphate ions are released in a high concentration, and they are the cause of fast contact osteogenesis and the high mineralization rate (20). Brushite is therefore in a position to stimulate the body to its own bone synthesis in the short term, and to accelerate the osseointegration of the implants, particularly in the primary phase. The inner calcium phosphate phase, the fine crystalline hydroxyapatite, is resorbed more slowly and releases ions that promote the formation of new bone over a longer period. The SBTC® coating is fully resorbed over a period of 6-12 weeks after implant placement and is simultaneously replaced by newly formed bone tissue, with the ultimate result that an optimum bond between bone and implant has been formed in place of the coating. This osteoinductive property combined with the controlled resorption is the primary advantage of the bioactive SBTC® coating.

2.5.1 Differentiation of cells *in vitro* under the influence of SBTC ®

The influence of the SBTC® coating on cell differentiation was examined by a Co culture of the hFOB1.19 osteoblast cell line with TPS/SBTC®-coated platelets of $TiAl_6V_4$. The osteoblast-specific collagen synthesis was analyzed at various points during incubation. The result after 6 days and after 10 days of incubation showed increased collagen synthesis on the SBTC®-coated test bodies (Fig. 9).

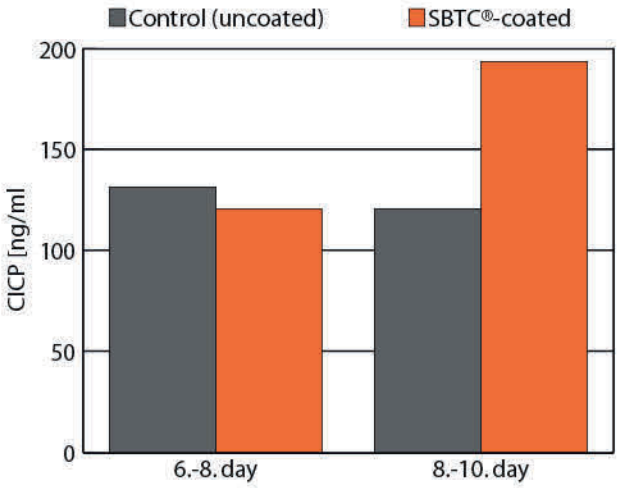


Fig. 9: Influence of the coating on the collagen synthesis in vitro

2.5.2 Mineralization *in vitro* under the influence of SBTC®

The influence of the SBTC ® coating in the mineralization was analyzed by incubating test bodies coated with SBTC® in cell culture medium (DMEM) for seven days. The extract was added to a confluent cell layer and the mineralization was confirmed by van Kossa staining. With van Kossa staining mineralized areas are stained black. Figure 10 shows the difference between the control medium and the SBTC® extract. While a slight mineralization could be confirmed in the cells in the control medium, strong mineralization could be confirmed with the SBTC® extract (Fig. 10).

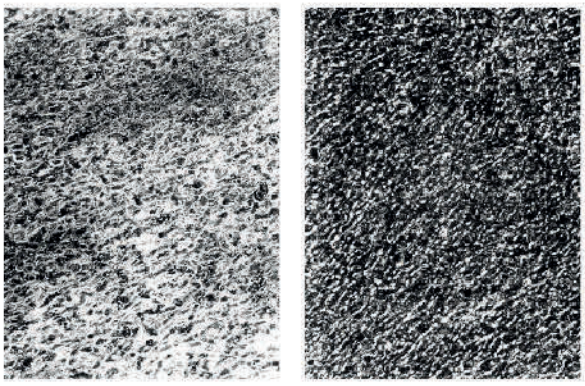


Fig. 10: Mineralization pattern of osteoblasts under various culture conditions (van Kossa staining)

This indicates that the calcium-phosphate phases in the SBTC® coating stimulate the mineralization of human osteoblasts.

2.5.3 Immunological reactivity *in vitro* under the influence of SBTC ®

The effect of the SBTC ® coating on the immunological reactivity was analyzed by the release of interleukin 1ß (IL-1ß). IL-1ß is a typical enzyme, which is released during the early inflammation phase and influences bone resorption. The test was conducted with monocytes and macrophages of the mouse cell line J-774A.1, which were cultured either with control bodies ($TiAl_6V_4$/TPS) or with SBTC®-coated test bodies. After three days of culture the expression of IL-1ß was analyzed. The SBTC®-coated samples in comparison with the uncoated control demonstrated a significant reduction of IL-1ß release (Fig.11). This means that the coating with SBTC ® triggers virtually no inflammation parameters, and as a result can be classified as very biocompatible.

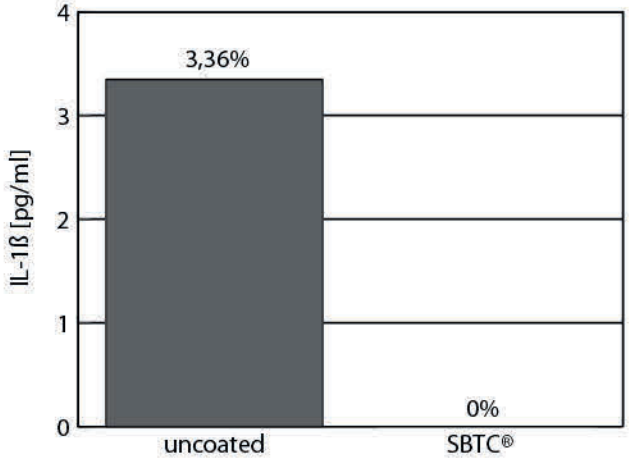


Fig. 11: Release of IL-1ß under various culture conditions

2.5.4 Analysis of the protein adsorption *in vitro* under the influence of SBTC ®

The protein adsorption or immobilization of proteins at the implant surface is, clinically viewed, an important step in the osseointegration of implants. To determine the protein adsorption SBTC®-coated test bodies and uncoated control bodies were incubated in fetal calf serum for several hours. After various incubation times (1h and 4h) the protein adsorption on the different test bodies was analyzed. As can be seen in Figure 12, the coating with SBTC ® significantly increased protein adsorption in comparison with the uncoated test bodies.

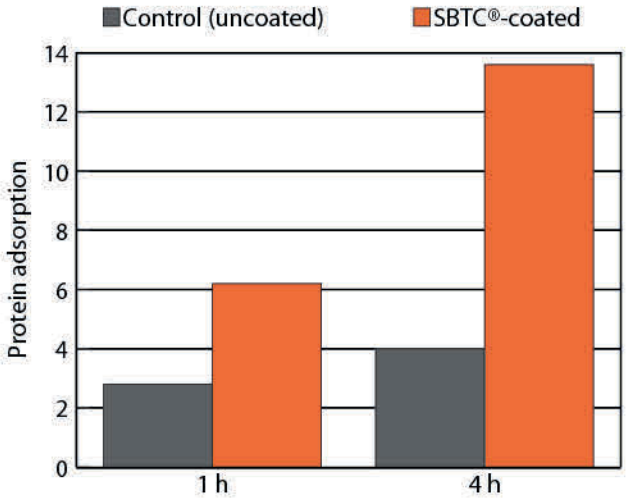
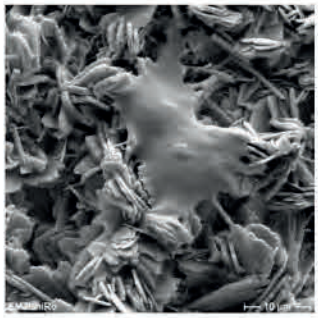


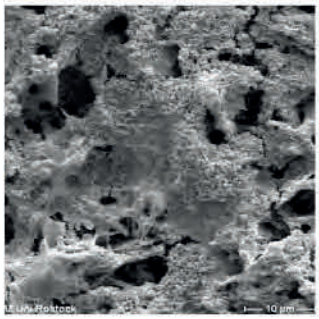
Fig. 12: Influence if the coating on the protein adsorption in vitro

2.5.5 *In vitro* precipitation tests with SBTC®

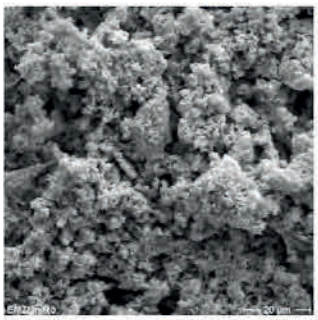
In in vitro tests SBTC®-coated test bodies were colonized with osteoblast cells of the cell line MG-63 and cultured in cell culture medium for 48 hours. After 30 hours in the culture a fine crystalline precipitation could be observed on the coating surface. The cells on the SBTC® surface were partially covered with the precipitate (Fig. 13a-c). As could be shown by EDX analyses, the precipitate was also a calcium-phosphate compound. After 48 hours the cells were completely covered. Visualization of the actin cytoskeleton (Fig. 13) of the bone cells showed that the morphology of the cells remained virtually unchanged during the re precipitation.



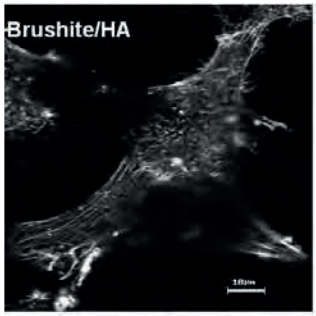
after 8 h



after 30 h



after 48 h



Actin-Cytoskeleton of a bone cell

Fig. 13: Reprecipitation of a new calcium phosphate phase in vitro

Comparison test bodies that were coated with hydroxyapatite only did not show this behavior. The in vitro results lead to the conclusion that there is a precipitation on the surface during dissolution of the coating, in particular because of the presence of the easily dissolved brushite phase. It can be concluded that these processes also take place in the body and there is therefore a calcium phosphate phase directly on the SBTC® surface in the body.

2.5.6 *In Vitro* examination of bone growth behavior on SBTC®

Titanium clasps were coated with TPS to examine the growth of bone tissue on different surfaces. Some of the clasps were also covered with a SBTC® coating (coating thickness 20 µm) (Fig. 14a-b).

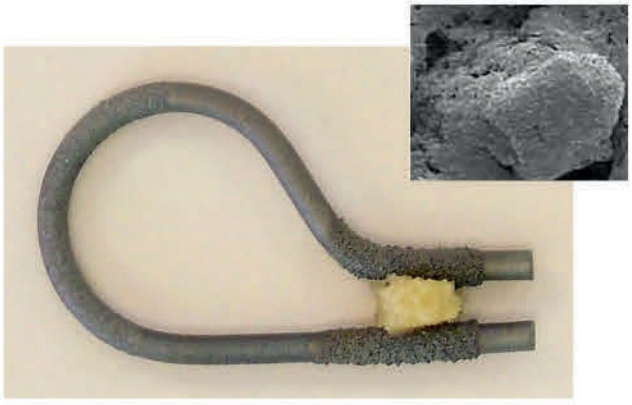


Fig. 14a: Clasp with TPS

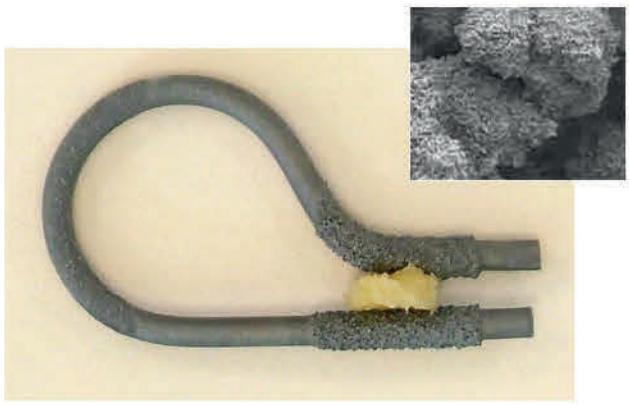


Fig. 14b: Clasp with TPS + SBTC® coating

Human bone tissue (explantation from the acetabulum) was clamped between the clasps and the test setup was transferred to a tissue culture slide. The incubati on period was 10 days. Then the contact area between the human bone and the implant surface was examined, and the spread and growth of the osteoblasts was examined under an electron microscope. After 10 days of culture, the clasps that had been given an additional coating of SBTC® showed widespread bone cells on the implant surface (Fig. 15). In comparison the uncoated clasps showed only marginal bone growth. This shows that the biomimetic calcium phosphate coating forms an ideal temporary matrix for bone regeneration and the osseointegration of implants (21).

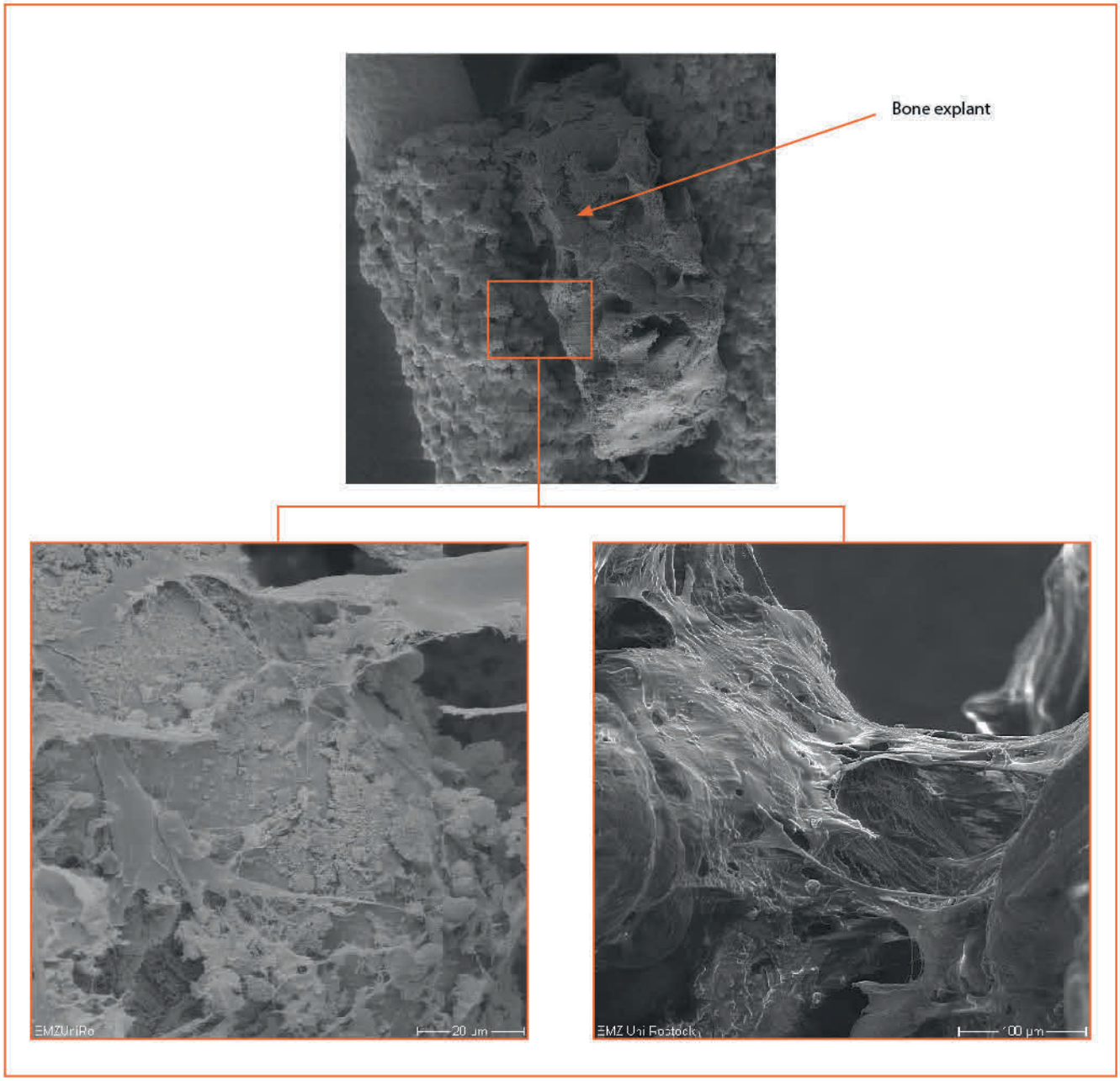
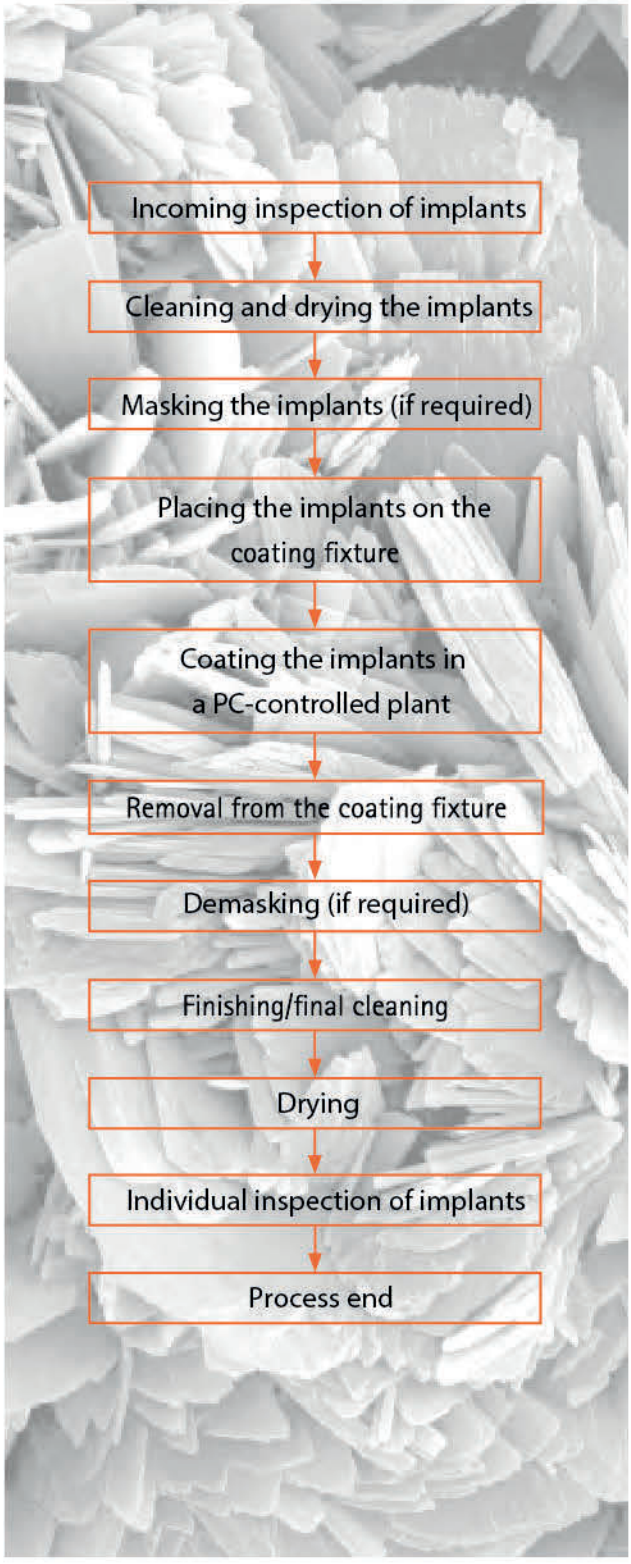


Fig. 15: Growth behavior of cells on SBTC® in vitro

3. Process of SBTC® coating

Before the electrochemical coating the implants were given a thorough cleaning in the ultrasonic bath. If the implant had areas that were not to be coated, those areas were masked before the coating process (25). The process of SBTC® coating is a combination of an electrochemical reaction, an acid-base reaction and a precipitation reaction (13), in which calcium-phosphate coatings are electrolytically precipitated onto the implants from a calcium-phosphate solution. The process is conducted at room temperature under virtually physiological conditions and creates a new surface quality on implants. The coating from a solution enables complete coverage of porous implant surfaces and complex implant shapes. In contrast with the highly crystalline, poorly soluble HA coatings resulting from the plasma-spray process, the electrolytic coating technology creates a fine crystalline structure that does not reduce the porosity defined by the substrate. Hard particles or wide-area delamination of the coating do not occur with this technique. Process-optimized control programs ensure the consistently high quality of the SBTC® coating.

Description of the individual process stages:



4. Testing

4.1 Chemical testing

4.1.1 Analysis of starting materials

The SBTC® coating consists of the two inorganic calcium phosphate components, brushite and hydroxyapatite. The proportion of heavy metals (Cd, Hg, As, Pb) is determined by the quality of the starting materials. The supplier guarantees the compliance with defined concentrations of the above heavy metals. This is below the requirements of the US standards ASTM F 1185 and ASTM F 1609. In addition, every batch of starting materials is analyzed for purity before adding it to the coating process. The proportion of heavy metals has also been analyzed directly in the SBTC® coating as part of the validation process.

4.1.2 Phase composition and Ca:P ratio of the SBTC® coating

The SBTC® coating consists primarily of brushite [$CaH(PO_4)$ x 2] and a smaller proportion of hydroxyapatite [$Ca_5(PO_4)_3OH$]. The molar calcium-phosphate ratio of the SBTC® coating is determined by quantitative evaluation of the EDX (Energy Dispersive X-Ray) spectroscopy (17). The x-ray radiation is measured by the electron beam excited by a semiconductor detector. The energy is typical for that specific element, and the intensity depends on the mass fraction of that element in the sample. The molar ratio of calcium to phosphate is 1.1 ± 0.1 and identifies the phase composition of the SBTC® coating. It is an important factor for quality assurance and process monitoring.

4.1.3 Solubility of the SBTC® coating

After an incubation period of seven days at 37°C in a simulated Ca:P-free physiological buffer solution, the dissolution of the SBTC® coating was 18.3%. The dissolution rate is greatest in the first six hours after placement in the fresh buffer solution. After the initial dissolution and the associated presence of calcium and phosphate ions in the solution, the solution process becomes significantly slower. This state corresponds to the physiological processes in the body after placement of an implant, because the body fluid also contains calcium and phosphate ions.

4.1.4 Shelf life of the SBTC® coating

The SBTC® coating can be stored for at least five years when stored in dry conditions at a normal storage temperature. The coating is free from chemically unstable organic or inorganic compounds. The qualitative XRD tests have not shown any phase-dependent change in the coating after the gamma-radiation sterilization.

4.2. Physical testing

4.2.1 Adhesion strength

The adhesion strength of the SBTC® coating was calculated in accordance with ASTM F 1147 and is in the range > 15MPa. An influence of the SBTC ® coating on the fatigue strength of the implant body could not be detected.

4.2.2 Coating thickness

The thickness of the SBTC® coating is tested by the eddy current test method in accordance with EN ISO 2360 and is an inductive, non-destructive test procedure. The coating process with SBTC® yields a thin, even coating with a thickness of 20 ± 10µm.

4.3 Biological testing (biocompatibility)

SBTC® is a coating for implantable medical devices (dental implants) that are in contact with soft tissue and bone tissue. Because the duration of contact is over 30 days, the tests for cytotoxicity, sensitization, irritation and acute systemic toxicity are all conducted in accordance with the applicable standard.

4.3.1 Cytotoxicity

The cytotoxicity test for the SBTC® coating was conducted in 2001 by an accredited laboratory in accordance with DIN EN ISO 10993-5. The test was conducted on a murine fibroblast cell line by analysis of the inhibition of the mitochondrial activity. The results showed that mitochondrial activity was not inhibited on the SBTC®-coated test bodies. This means that the testing of the coating for biological evaluation found no indication of any relevant cytotoxic effect. The test report confirms that the tested material is not cytotoxic (22). This result has been confirmed by additional tests in 2004 (23), 2005 (24) and 2010 (25) (Annex 1).

4.3.2 Sensitization

The test for sensitization is recommended in the standard 10993-1 to enable an assessment of allergic and sensitization reactions triggered by soluble constituents of the material. In the test for sensitization in accordance with DIN EN ISO 10993-10 the SBTC® coating gave no indication of any sensitizing properties (26) (Annex 4).

4.3.3 Irritation

The test for irritation is conducted in accordance with standard 10993-1 to discover any irritation effects caused by the product or substances released by it. SBTC®-coated samples were subjected to an irritation test under GLP conditions (intracutaneous reactivity) with polar and non-polar extraction agents as specified by DIN EN ISO 10993-10. The test report confirms that the tested SBTC® coating does not have an irritant effect (27) (Annex 2).

4.3.4 Acute systemic toxicity

The test for acute systemic toxicity was conducted in 2010 by an accredited and GLP-certified laboratory. The result of the test shows that the SBTC®-coated samples have no detectable acute systemic toxicological properties (28) (Annex 3).

4.4 Summary of tests

5.1 Number of SBTC®-coated implants

Test criterion	Result
Color	light-gray
Coating thickness (EN ISO 2360)	20 ± 10 µm
Adhesion strength (ASTM F 1147-99)	> 15 MPa
Ca:P ratio (EN ISO 11885-E22)	1.1 ± 0.1
Phase composition	≤ 70% Brushite/ ≥ 30% HA
Cytotoxicity	not cytotoxic (in accordance with DIN EN ISO 10993-5)
Sensitization	no sensitizing effect (in accordance with DIN EN ISO 10993-10)
Acute systemic toxicity	no acute systemic toxicity (according to DIN EN ISO 10993-11)
Irritation/intracutaneous reactivity	no irritation (in accordance with DIN EN ISO 10993-10)
Shelf life	5 years
Solubility	18.3% after 7 days in physiological buffer solution
Analysis of starting materials	starting material are subject to the requirements of the US standards ASTM F 1185 and ASTM F 1609.
Abrasion	no layer delamination after screw test in swine bone

Table 1: Summary of tests

5. Clinical data

5.2 Animal-experimental tests

5.2.1 Formation of new bone in the minipig

Animal tests were conducted on the minipig animal model at the laboratory for biomechanics and experimental orthopedics of the University of Mannheim to investigate the formation of new bone with SBTC®-coated implants (29). SBTC®-coated titanium pins were press-fitted into 21 animals. The follow-up period was 12 weeks. The results of the study show significantly increased bone deposition with the SBTC®-coated implants (Fig. 17) and subsequently significantly better anchorage of the implant in the early postoperative phase (Fig. 18).

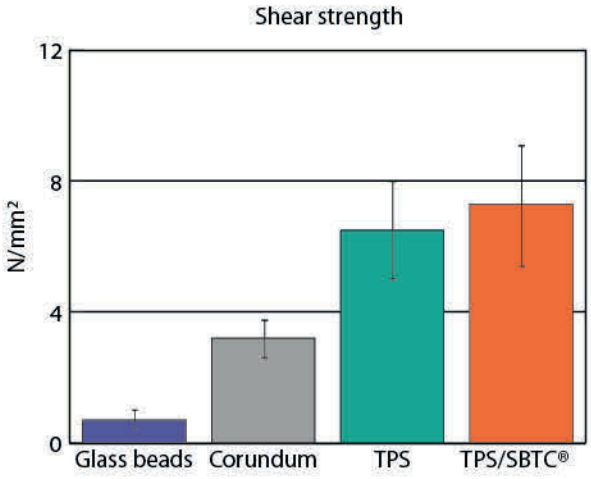


Fig. 17: Shear strength of different surfaces after implant placement

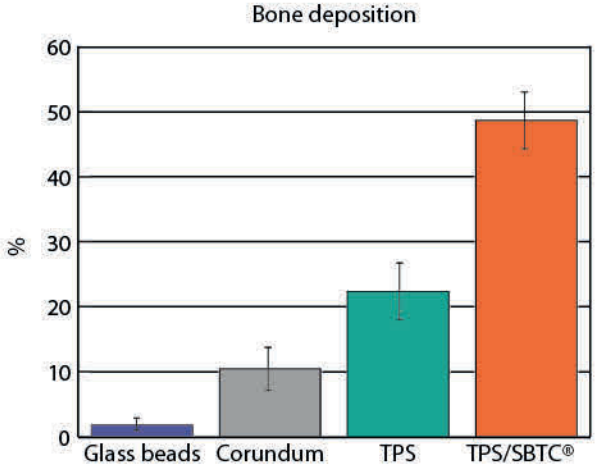


Fig. 18: Bone deposition of different surfaces after implant placement

5.2.2 Effectiveness of the SBTC ® coating in the animal model

In this animal experiment the osseointegration of test implants with the TPS surface was compared to implants with the TPS/SBTC® coating. The implants were placed in the maxilla of domestic pigs (Sus scrofa domestica). The direct bone contact in both test groups was analyzed six weeks after implant placement. The results of the test show significant differences in the bone contact between the two groups. The average bone contact for the control implants was 49.8%,

while a direct bone contact of 73% was measured for the SBTC®-coated implants (Fig. 19).

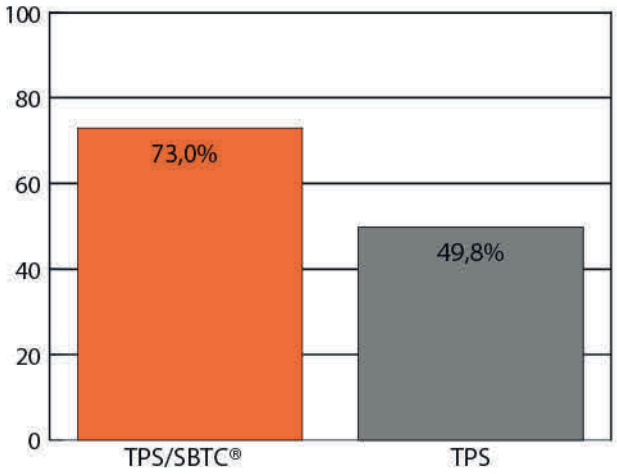


Fig. 19: Bone contact values of the different surfaces

A high proportion of bone was found, particularly between the threads of implant, and a clear osteoconductive effect as a result of the presence of the SBTC ® coating (Fig. 20a-c). The SBTC® coating was almost completely resorbed during the study period of six weeks.

No reactions to foreign bodies were detected, which is another indication of the very good biocompatibility of the surface (30).

5.2.3 Study of SBTC®-coated implants in the canine model

The goal of the study was to determine the effect of the SBTC® coating on osseointegration over extended periods with immediate loading. Implants with different surfaces were placed in the mandibles of dogs (beagles). The surfaces of the implants consisted of a TPS surface, a plasma-sprayed HA surface and a TPS+SBTC® surface. The implants were immediately restored with a crown and placed under immediate loading. The crowns were not in contact with neighboring teeth or other implants. The follow-up period was seven months. The results of the trial show that the SBTC® coating was fully resorbed after seven months and had been replaced by newly formed bone tissue (Fig. 21,22).

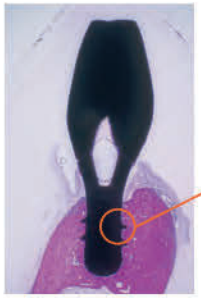


Fig. 21: Inserted dental implant with restoration under immediate loading

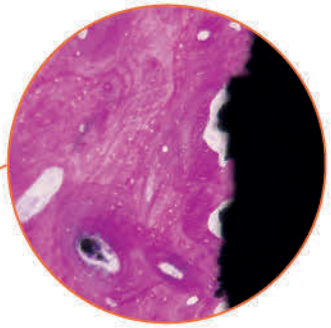


Fig. 22: Bone and implant interface (TPS/SBTC)

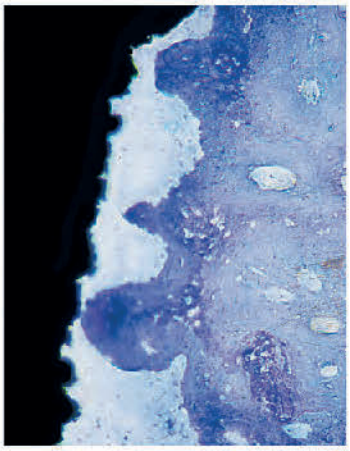


Fig. 20a: Implant with TPS surface (control group)

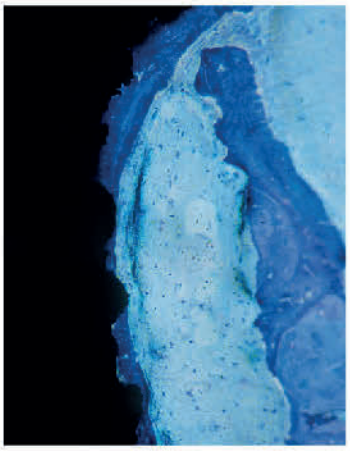


Fig. 20b: Implant with TPS/SBTC® surface (test group)

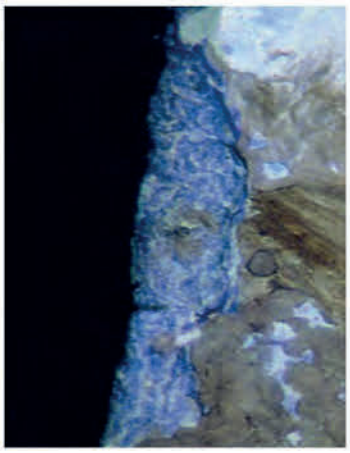


Fig. 20c: Formation of new bone by SBTC®

In contrast, fragmentation of the coating and unho mogenous resorption could be observed with the HA-plasma-sprayed surface. Isolated HA particles were also found.
The SBTC®-coated implants also demonstrated the highest bone deposition density (Fig. 23). However, the difference between the surfaces decreased with increasing implant placement time (31).

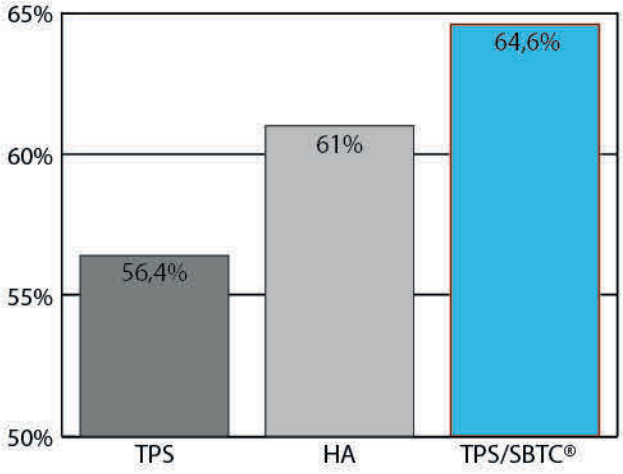


Fig. 23: BIC values of the different surfaces under immediate loading

5.2.4 Effect of differently applied CaP coatings on the osseointegration of implants
The effect of differently applied CaP coatings on the osseointegration of titanium implants was investi gated in the animal model. The study included three groups with different surface modifications. Group 1 had a rough surface, group 2 had a biomimetic CaP coating and group 3 had an electrochemically deposi ted CaP coating. A total of 36 implants were placed in the tibias of 18 rabbits. The study period was 6 and 12 weeks. The influence of the different implant surfaces on the osseointegration was analyzed. REM images of the different surfaces were prepared and analyzed. On the biomimetically deposited CaP coating the crystals were arranged as flakes, while the electrochemically deposited CaP coating had rod-shaped crystals with a hexagonal cross-section. The histological analyses after six weeks showed bone growth along the sur faces. On the electrochemically deposited CaP coating the significantly largest BIC values were measured and compared with the rough and biomimetically deposi ted CaP surfaces. The study showed that the electro chemically deposited CaP coating appears to improve osseointegration, and as a result can ensure a long-term and stable fixation of the implants in the bone tissue (32).

5.3 Clinical results

5.3.1 Immediate loading of CaP-coated dental implant - results of a multicentric study

A multicentric study, which included universities and private practices, investigated PITT-EASY implants (Oraltronics) with SBTC® coating (FBR surface on a porous TPS surface). The implants were placed in the maxilla and the mandible. The study protocol inclu ded immediate loading. A total of 156 implants were placed in 62 patients, with 40 implants placed in fresh extraction alveoli. After 6 months 8 implants in 6 pati ents had been lost, 6 in the mandible and 2 the maxilla. After 6 months under load 94.9% of the implants were osseointegrated and functional (33).

5.3.2 Early loading of endosseous implants with SBTC® coating

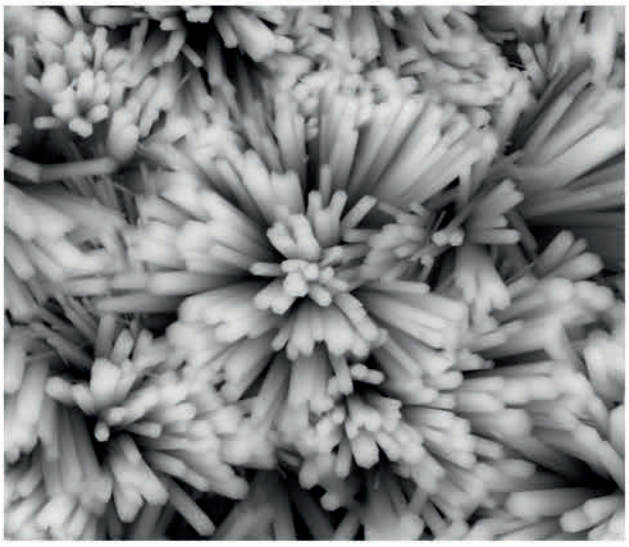
55 patients received 159 SBTC®-coated (FBR surface) Pitt-Easy implants. The average age was 55.6 years. The healing phase in the mandible was 7 weeks and in the maxilla 12 weeks. The healing phase was exten ded to 18 weeks in poor bone quality (D4 bone) and in combination with a sinus floor elevation. At the time of exposure 3 implants were poorly osseointegrated. The cumulative survival rate of the remaining implants after 30 months was 98.11%. Coating the implants with the electrochemical calcium-phosphate coating reduced the healing phase by half (34).

6. Range of applications

- Orthopedic implants (joint implants: ankle joint, knee joint, hip joint, shoulder joint, hand joint, spinal implants and finger implants)
- Dental implants

7. Advantages at a glance

- Fine crystalline (not monolithic!) structure with large free surface
- Complete, controlled resorption and replacement by autogenous bone
- Microporosity with high capillary effect on body fluids
- Thin coating
- Outstanding biocompatibility
- Optimal solubility and controlled resorption front
- Complete and even coverage of porous surfaces and complex implant shapes by „non-line-of-sight" process
- After surgery a large, free calcium and phosphate reservoir on the implant surface - ideal proliferation conditions for osteoblasts
- Faster and better healing
- No mechanical release of particles or coating



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