Technical Data on HA Coatings

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ISO 13485 Registered

The Bio-Coat Hydroxylapatite Coating

The following information describes the Bio-Coat hydroxylapatite coating.

X-Ray Diffraction

A three year average has shown the Bio-Coat hydroxylapatite coating to have an HA content of 98.3% with a percentage crystallinity of 68.2%.

Chemical Analysis

Trace elements - The Bio-Coat hydroxylapatite coating meets the requirements established in ASTM F-1185 (Composition of Ceramic Hydroxylapatite for Surgical Implants).

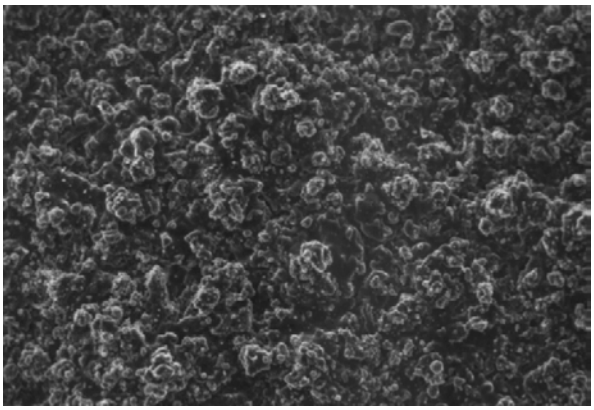
Calcium to phosphorous (Ca/P) Ratio - The theoretical value for the Ca/P ratio is 1.67, the Bio-Coat Hydroxylapatite coating has a Ca/P ratio of 1.67, confirming the fact that little transformation to resorbable phases such as α-TCP, ß-TCP or CaO occurs. The fact that there was little transformation observed is confirmed by the high percentage of hydroxylapatite as determined by x-ray diffraction.

Density

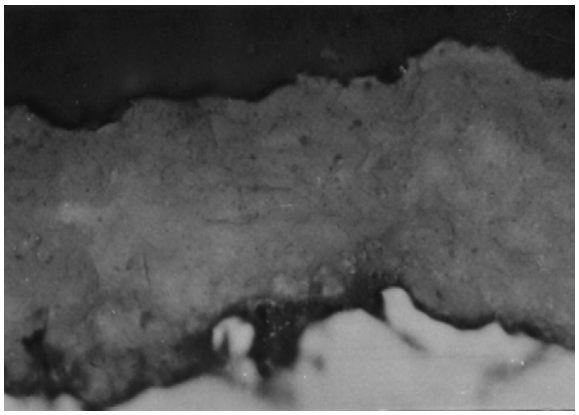
The density of the Bio-Coat HA is 99% of the theoretical density for solid HA. This makes the coating less likely to resorb, due to the minimal porosity.

Microstructure

The HA coating has less than 5% porosity, with a minimal amount of cracking.



SEM of the HA Surface (750x)



Light Micrograph of the Coating (500x)

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Mechanical Testing Subsequent to Immersion in Saline

Tensile Testing

The tensile strength of the Bio-Coat HA is 9429 ± 1595 psi. (65 ± 11 MPa.) on Ti-6AI-4V and 8673 ± 724 psi. (59.8 ± 5 MPa.) on a Co-Cr-Mo substrate. On porous Ti-6AI-4V and Co-Cr-Mo coatings, the Bio-Coat HA had a tensile strength of approximately 8000 psi. (55.2 MPa.).

Shear Testing

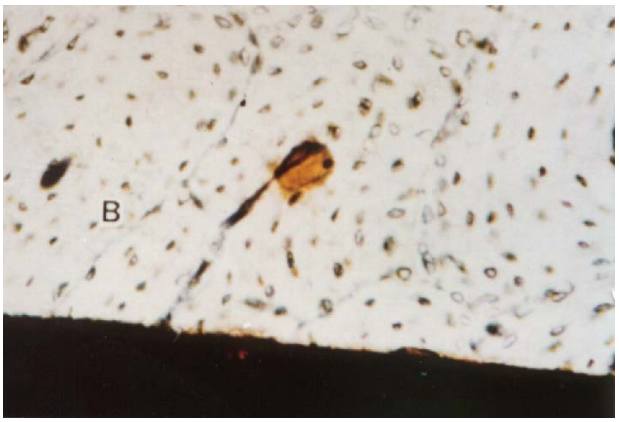
The shear strength of the Bio-Coat HA on Ti-6AI-4V is 6122 ± 532 psi. (42.2 ±3.7 MPa.) and is 6804 ± 193 psi. (46.9 ± 1.3 MPa.) on Co-Cr-Mo. On porous coated Ti-6AI-4Vand Co-Cr-Mo substrates the shear strength of the Bio-Coat HA is between 5000 and 5900 psi. (34.5-40.7 MPa.).

Shear Fatigue Testing

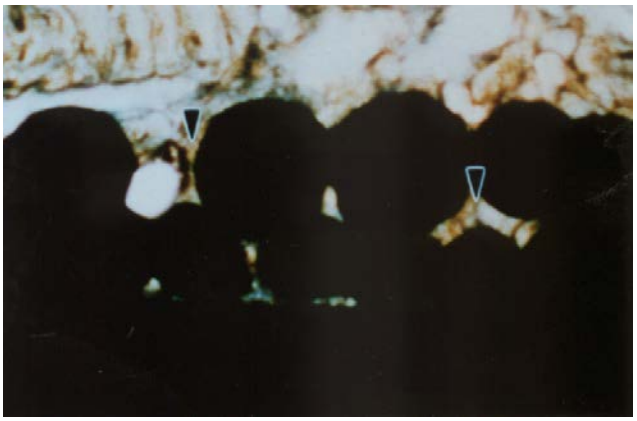
Shear fatigue testing of the Bio-Coat HA on Ti-6AI-4V revealed a fatigue strength of 2500 psi. (13.8 MPa.) at 10 million cycles. The shear fatigue strength on the Co-Cr-Mo substrate was found to be 3000 psi. (20.7 MPa.).

Animal Data

Transcortical implantation data in the canine model revealed the Bio-Coat HA coating on solid Ti-6AI-4V to be 8.69 ± 2.64 MPa., 11.60 ± 2.12 MPa., 13.90 ± 1.97 MPa. and 13.80 ± 4.00 MPa. at 3, 6, 12 and 52 weeks, respectively. Testing performed on the Bio-Coat HA coating on porous coated Ti-6AI-4V revealed an interfacial shear strength of 14.33 ± 3.01 MPa., 20.01 ± 2.12 MPa., 29.62 ± 1.83 MPa. and 34.35 ± 4.81 MPa. at 3, 6, 12 and 52 weeks, respectively. The percentage of bone in growth increased at each time period to 92% at 52 weeks. The mean values found at these intervals are at the upper end of literature citations for HA, using similar methods.



3 Weeks Histology HA/Ti-6Al-4V



12 Week Histology HA/Porous Ti-6Al-4V

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Advantages of the Bio-Coat Hydroxylapatite Coating

The starting powder used by Bio-Coat is a highly pure dense powder with a tightly controlled size distribution. Powders with a large distribution of particle sizes are likely to undergo transformations to resorbable phases.

The dense starting powder combined with the surface preparation and spray technology developed by Bio-Coat produces a highly dense coating (99% of theoretical density). This is important for adhesion and maintaining the optimal resistance to resorption of the coating.

The liberation of plasma gun debris (copper and tungsten) is virtually eliminated by Bio- Coat's use of internal injection systems.

The tensile strength of the Bio-Coat material is comparable to other reported literature for HA on Ti-6AI-4V (i.e. Bio-Interfaces reports 40-60 MPa, CAM reports 60-70 MPa. and Osteonics reports 50.8 MPa)

The shear strength of the Bio-Coat HA is superior to all reported literature references for HA on Ti-6AI-4V (Bio-Interfaces reports 10-20 MPa. and CAM reports 20-25 MPa.).

The shear fatigue strength of the Bio-Coat HA is very competitive with reported values for the fatigue strength commonly reported for porous materials and the bone/bone cement interfaces.