OSTEOCONDUCTIVE COATINGS

History

Prosthesis fixation in bone is a technical challenge on which the durability of the orthopedic implants depends. The first hip prostheses were fixed with PMMA cements. The "uncemented" implants were developed in the Seventies. The fixation of these implants is done by direct growth of the bone on the surface of the implant. This kind of fixing is also called: "biological fixation".

Biological fixation is carried out mainly by the following methods:

- *Sandblasting of the implant:* the roughness obtained by sandblasting enables the growth of the bone on the surface of the implant. This type of fixation is mainly used for the titanium implants because this material, even if it cannot be qualified as osteoconductuctive, allows the direct apposition of the bone on its surface (other metals used in the manufacturing of implants such as stainless and cobalt-chrome lead to a fibrous encapsulation). The disadvantage of this technique is that it is very difficult to avoid an incrustation of sand at the surface of the implant, less favorable to bone growth.
- *Titanium plasma spray coating:* These rough and porous coatings are able to lead to bone growth. Bone growth

into the pores of the coating allows a firm and durable fixation.

- *Hydroxyapatite (HA) coating:* This synthetic calcium phosphate, which formula is $Ca_{10}(PO4)_6(OH)_2$ and constitutes the mineral portion of natural bone, is known to be "osteoconductive". It is recognized by the cells of bone remodeling (osteoblasts and osteoclast) which make bone grow on its surface. This type of coating allows a bone growth faster than titanium coatings. On the other hand the disadvantage of this coating is that it is resorbed at long term. After resorption, the bone is in contact with the sandblasted surface of the prosthesis, which may contain sand incrustation.
- *Double layer Titanium and HA coatings:* this type of coating allows the combination of the osteoconduction of HA coating and the durability of the titanium coating.

We can also mention other types of surface treatments allowing a biological fixing: textured surface in the mass of the implant (Mesh, Trabecular…), porous coatings by beads sintering, thin layer of calcium phosphate by electrodeposition…

Market share

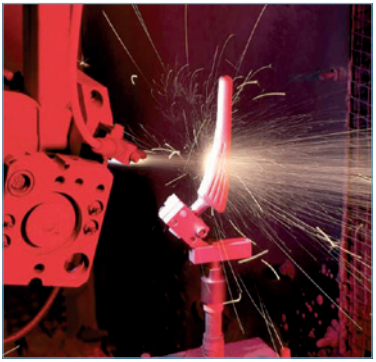
Currently, 40 to 50% of the orthopaedic implants are cemented. 50 to 60% are with biological fixation (uncemented). The majority of the implants with biological fixation have a plasma sprayed coating.

Plasma spray process

Cleaning	It ensures that there will be no impurities trapped in the interface substrate/coating. May be completed with a passivation.
Masking	Protects the surfaces that should not be coated.

Sand blasting	Allows the mechanical adherence of the coating to the implant surface.
Plasma spraying	The coating is processed in one or two steps depending on whether it is a simple or double layer coating.
Bead Blasting	Metal coatings: It removes the badly hanged sprayed particles in order to prevent their releasing in the body of the patient.
Cleaning	Physicochemical decontamination and also microbiological decontamination if the product will afterwards enter in a clean room for its final packaging.

There are two types of plasma spraying installation: most of the coatings are done by atmospheric plasma spraying (A.P.S), it is also possible to make coatings with vacuum plasma spraying (V.P.S).



The VPS can limit the interaction of the powder with the gas of the atmosphere (nitrogen, oxygen, hydrogen) during spraying. For titanium coatings, it is possible by this technic to limit the formation of titanium nitride and thus to increase the mechanical strength of the coating.

Manufacturing costs of VPS coatings are higher than APS coatings, because the spraying cycle is longer and installation much more expensive.

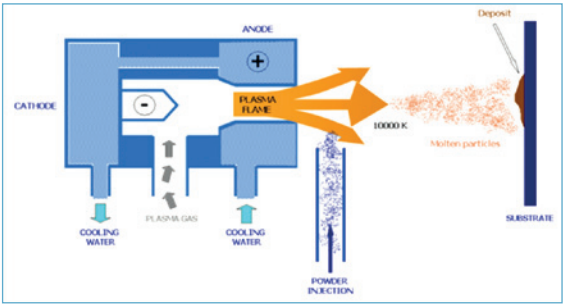
THE OPERATION OF A PLASMA SPRAY GUN

Formation of the plasma flame:

The plasma flame consists of dissociated and ionized gas. It is created by ionization of the gas (Argon, hydrogen, nitrogen, helium...) in the electric arc formed between the electrodes of the plasma gun.

Powder spray:

The powder of coating material is introduced into the plasma flame. Particles are thus melted and sprayed at high velocity on the substrate.



Coating characteristics, reference standards, testing methods

Market referential for plasma coating characteristics for orthopedic implants is mainly the following:

- ISO13779-2 standard for HA coating.
- ASTM F1609 standard for HA coating.
- FDA guidelines for HA and metallic coatings.

FDA – Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements (February 2, 2000).

FDA – 510(k) Information needed for Hydroxyapatite coated orthopedic implants.

Composition

	CONTROL METHOD	COATING TYPES / LIMITS	REFERENCE DOCUMENTS
Chemical composition	**ICP-AES** (Inductively coupled plasma - atomic emission spectrometry)	**Titanium –** O, Fe C, H, N	ASTM F1580 (powder)
		Cobalt-Chrome alloy – Cr, Mo, Ni, Fe, C, Si, Mn, W, P, S, N, Al, Ti, Bo	ASTM F1377 (powder)
		HA – As, Hg, Cd, Pb, Heavy metals	ISO 13779-2 /ASTM F1185 / ASTM F1609
Composition	**XRD or ICP/AES**	**HA –** Ca/P between 1.67 and 1.76	ISO 13779-2 / ISO 13779-3
Qualification and quantification of crystalline phases	**XRD** (X ray diffraction)	**HA –** Crystallinity index ≥ 62% **Crystalline phases :** Tricalcium phosphate $\alpha \leq 5\ \%$ Tricalcium phosphate $\beta \leq 5\ \%$ Tetracalcium phosphate $\leq 5\ \%$ $CaO \leq 5\ \%$	ISO 13779-2 ISO 13779-3
The detection of functional groups and impurities	**FTIR** (Fourier Transform Infra-red Spectrometry)	**HA** All the hydroxyapatite functional groups shall be detected. No impurity shall be detected. Few or no quantifiable Oxyapatite	ISO 13779-3
Dissolution	**Dissolution test**	**Dissolution test**	ASTM F1926
Dissolution	**Solubility product (Ksp)**	**HA**	NIST SRM 2910

Mechanical strength

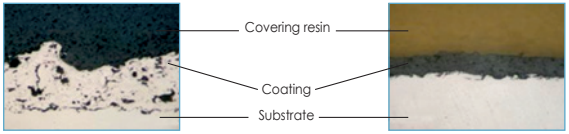
The mechanical strength is an essential parameter to control in order to guarantee the long-term durability of the coating.

	CONTROL METHOD	COATING TYPES / LIMITATS	REFERENCE DOCUMENTS
Tensile strength	Tensile strength test	**Metallic coatings** ≥ 22 MPa	ASTM F1147 ISO 13779
		HA ≥ 15 MPa	
Static shear strength	Static shear strength test	**Metallic coatings** ≥ 20 MPa	ASTM F1044
		HA	
Fatigue shear strength at 10^7 cycles	Fatigue shear strength test	**Metallic coatings**	ASTM F1160
		HA	
Abrasion resistance after 100 cycles	Taber® test	**Metallic coatings** ≤ 65 mg of loss	ASTM F1978

Morphology

Coating morphology (thickness, porosity, roughness), with the composition, is an essential parameter for an efficient bone growth. Thickness and porosity are controlled according to ASTM F 1854.

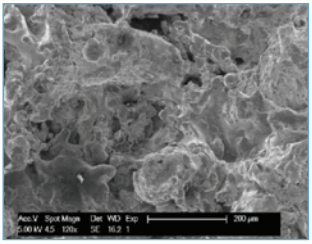
Metallographic cut



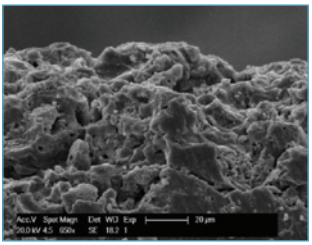
Titanium coating

Hydroxyapatite coating

(S.E.M) Scanning Electron Microscopy



Titanium coating



Hydroxyapatite coating

Partner

MedicalCoating, Subsidiary of MedicalGroup, is specialized in biomedical coatings on orthopaedic, spine and dental implants. These coatings (Titanium, Cobalt-chrome and Hydroxyapatite) are manufactured by plasma spraying APS or VPS. All the processes are validated IQ-OQ-PQ. MedicalCoating is present in more than 30 countries, including USA, where a Master File (MAF-1633) was filed and reviewed by FDA.

MedicalLab is a specialist in realizing coating characterization tests. ISO17025 (COFRAC) accredited laboratory, MedicalLab carries out all ISO or ASTM tests on coatings and assists its customers in their regulatory approval approach or process validation.

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