

Imparting osseointegrating properties to the surface of PEEK implants with hydroxyapatite and titanium plasma spray coating while maintaining the substrate material's original chemical and physical properties

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Introduction: Polyaryletheretherketone (PEEK) is gaining acceptance by designers for use in medical devices. Of particular interest are its biocompatibility and mechanical properties. For example the modulus of elasticity is a close match to that of bone, enabling PEEK devices to guard against stress shielding. However PEEK surfaces are not inherently osseointegrating, so there is a requirement for a viable method for applying coatings to enhance the biocompatibility and durability of cementless PEEK implants, similar to that provided on metallic implants today. The series of regulatory testing to gain approval for metal and hydroxyapatite coatings on metallic implants is well documented. There is no reason why any less stringent testing should be required of PEEK devices. In addition, any processing should take into consideration, and guard against, the potential detrimental modification of the PEEK material. Designers should not be forced to take a judgement to lose substrate integrity over the benefit of an applied osseointegrating plasma coated surface. Accentus Medical has overcome these concerns by developing a modification to their established Acusure[®] range of inert / reducing gas plasma spray coatings for metallic implants. The modified Acusure[®] technology enables the deposition of viable hydroxyapatite and titanium coatings at a low enough temperature to produce a coating that meets essential regulatory requirements and that does not impact on the structure and composition of the PEEK substrate. The effects of Acusure[®] lower process temperature plasma coating has been evaluated by Invibio, the major PEEK supplier, using their proprietary testing methods on PEEK-OPTIMA[®] material. Test results show that coating with Acusure[®]'s modified method with titanium, hydroxyapatite or combination of both substances does not adversely affect or degrade the substrate material. A suite of design validation testing has been conducted which demonstrates that the coatings meet the best practice guidelines and the relevant ASTM and ISO standards for metallic substrates.

Methods and Materials: The application of a thermal sprayed coating onto metallic materials relies upon the heat of the process to provide a well adhered coating. The physical and chemical properties of the coating are dependent on the process conditions. The development of a lower temperature coating process to apply calcium hydroxyapatite onto PEEK has been performed at Accentus Medical. Good understanding of plasma process technology, the properties of PEEK, and process validation methodology has been used to provide a lower temperature coating process. For HA coating, comprehensive testing has been performed of the

mechanical properties (static shear, static tensile and shear fatigue), physical properties (sectioning, thickness measurements and quantitative metallography), chemical properties (Ca:P ratio, trace element analysis, solubility, dissolution, X-ray diffraction and infra red spectroscopy). In addition a suite of tests has been performed to analyse the PEEK substrate material (physically and chemically), and to specifically investigate any transfer of material between the PEEK and the coating.

Results: The chemical, physical and mechanical properties of the HA coating on PEEK demonstrate compliance with the regulatory standards. The mechanical tests are lower in strength than on metallic devices, though remain in excess of the minimum regulatory requirements for coatings on metallic devices. There is no evidence of transfer of material from PEEK to the detriment of the HA coating. Similarly the PEEK substrate has been independently tested by the PEEK manufacturer, Invibio. Results demonstrate that neither the deposition of titanium nor of hydroxyapatite have adversely affected, modified or degraded the PEEK material.



Hydroxyapatite plasma spray coating on PEEK with no adverse effects on the substrate

Discussion: A modified lower process temperature plasma spray coating has been developed and calcium hydroxyapatite successfully applied to PEEK test pieces. A series of tests have been performed to demonstrate compliance of the coatings with the regulatory requirements currently used for coatings on metallic devices. Designers do not need to take a judgment to lose substrate integrity over the benefit of an applied osseointegrating plasma coated surface. Likewise there is no requirement for separate ASTM and ISO standards for the application of osseointegrating surfaces onto PEEK. Regulatory dossiers, including a FDA masterfile, are being updated to include PEEK as a validated substrate for Accentus Medical's Acusure[®] titanium and hydroxyapatite coatings.