Titanium Plasma Spray

Introduction

The goal of any implant coating in total joint arthroplasty is to provide a biologically friendly environment to bone. In turn, this will facilitate bony on-growth/in-growth leading to long-term stability of the implant. This has been achieved at Exactech by offering titanium plasma spray coating on all femoral hip prostheses. This technical monograph will review the method of applying plasma spray coatings and document support of plasma spray coatings and the benefits of this coating as it relates to the FDA plasma spray coating guidelines.

Method

Bio-Coat, of Southfield, MI, is one of the few companies in the world to offer vacuum plasma sprayed coatings for medical implants. This technology provides a unique opportunity to offer porosity throughout the entire coating, without relying on a solid bond coat necessary with inert gas technologies. The Bio-Coat vacuum plasma spray system is equipped with a five axis robotic applicator. The use of a "CNC" controller (a computer assisted process) enables the creation of reproducible programs that guarantee the same quality coating each time on the complex implant surface geometry. The high chemical reactivity of titanium, especially in its powder form, makes it a challenge to spray plasma coatings correctly. The most protective environment for spraying titanium is a vacuum.[1] Typical argon spray systems rarely use robotics and rely heavily on "hand spraying" thus creating much less reproducible results. The Bio-Coat robotic vacuum spray process is applied to all Exactech plasma spray coated femoral stems.

Properly applied titanium plasma spray has been found to encourage both bone on-growth and in-growth. When comparing the porosity percentages of Exactech product plasma spray coatings and traditional sintered beads there is very little difference. Standardized metallographic measurements show that plasma spray provides 34% porosity[2] and sintered beads provide 35% porosity.[3]

- Microstructural Analysis

A significant advantage to vacuum plasma spraying is the ability to alter the velocity of the powder particles being applied. The higher the velocity, the stronger the bond will be between the coating and the implant substrate and the less porosity that will be achieved. With careful balance, the formation of a metallurgical bond will occur (i.e. the substrate and the coating become continuous) and create proper porosity using vacuum plasma spray technology. Conventional argon spray systems are not capable of forming an "as sprayed" metallurgical bond.[2]

Exactech's decision to exclusively offer plasma spray on its femoral stems does not, in any way, lessen the proven success of porous sintered beads. However, strong porous sintered bead coatings require machining of a pocket on the proximal portion of the stem into which the coating is laid. The extra step of sintering titanium beads may create an undesirable amount of thermal insult to the implant. The creation of the pocket and placing the beads increases manufacturing time and cost. A primary benefit of titanium plasma spray is that the coating is applied directly to the implant substrate and temperatures for the process at the substrate are lower.

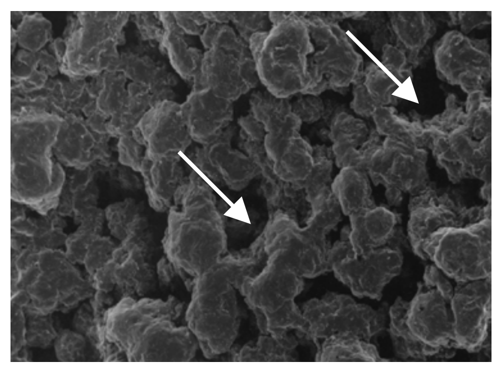

Figure 1: A SEM micrograph of the coating surface reveals areas for potential in-growth and on-growth.

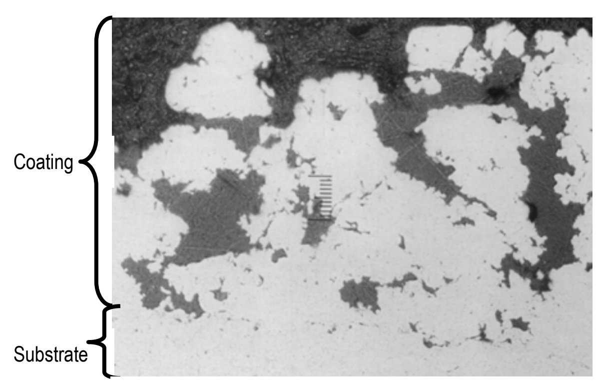

Figure 2: A light micrograph of the Bio-Coat coating cross-section is shown. The coating was found to be metallurgically bonded and crack-free.[2]

- Documented Support of Plasma Spray

Support of titanium plasma spray has been well documented over the past 10 years. Bobyn et al. supported plasma spray when they published data stating that circumferential porous coating (plasma spray) plays an important role in preventing access of wear debris to the endosteal surface of the femur.[4] In addition, Emerson also reported stems that were circumferentially coated with titanium plasma spray provided an effective interface that served as a barrier for migration of wear debris to the endosteal surface of the femur and the greater trochanter.[5] Furthermore, several retrospective studies of stems circumferentially coated with titanium plasma spray have been published that document clinically favorable outcomes resulting in excellent bony in-growth and long-term stability.[6,7]

Results

- Exceeding the FDA Plasma Spray Coating Guidelines

The following chart compares FDA guidelines for tests required to evaluate the titanium plasma spray coating performance and the Exactech titanium plasma spray coating.[2]

Test Performed	Substrate	FDA Guidelines	Exactech C.P. Titanium Plasma Spray Results
Tabor Abrasion Resistance	Ti-6Al-4V	.065, max Grams lost at 100 cycles	0.031 ± 0.012 Grams lost at 100 cycles
Static Tensile Strength	Ti-6Al-4V	3190, min (PSI)	9957 ± 1452 (PSI)
Static Shear Strength	Ti-6Al-4V	2900, min (PSI)	5932 ± 240 (PSI)

The most significant advantage to the vacuum spraying process is the dramatic reduction in the formation of brittle ceramic titanium compounds such as TiC (Titanium Carbide), TiN (Titanium Nitride), TiO_2 (Titanium Oxide), and TiH (Titanium Hydride). While these compounds may be useful for wear resistance, they lack ductility and will create cracking and inclusions in a plasma sprayed coating. As little as 0.8 wt % of oxygen, nitrogen, or carbon create a marked increase in the brittleness of titanium.[8] Inert argon plasma spray technology is limited in its ability to minimize these compounds.[2]

Conclusions

- Both Bobyn and Emerson have reported that titanium plasma spray coating helps to provide an effective barrier that prevents available wear debris from gaining access to the endosteal surface of the femur and greater trochanter.
- Exactech's plasma spray coating is applied using a robotic vacuum spray system rather than relying on "hand spraying" with the benefit of reproducible results and the same quality coating with each application.
- Plasma spray and porous sintered beads encourage both in-growth and on-growth. Exactech implants have plasma spray and porous sintered bead coatings that exhibit 34% and 35% porosity respectively.
- Vacuum plasma spray controls the velocity at which the powder particles are being sprayed, thus creating a robust bond between the coating and the substrate while optimizing the porosity.
- When comparing coating options, direct application of the coating to the surface without a machined pocket and lower heating of the substrate gives titanium plasma spray coatings an advantage over beaded coatings.
- The Exactech vacuum plasma spray coating exceeds FDA guidelines required to evaluate the performance of titanium plasma spray coating.

References

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