COATING TECHNOLOGIES REVIEW:

How Orthopedic Implants Get Coated

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Twenty-five years ago, orthopedic implants featured large spherical beads, averaging 0.0022 to 0.0025 inches in diameter. Since then the technology has moved from even smaller beads, to more porous structures and now to rough surfaces that are non-spherical or irregular with high porosity. This evolution in implant needs has also relied on coating and sintering technologies to evolve. Most recently, we've seen the development of additive manufacturing, which allows customized porosity, as well as customized shapes of the overall implant.

Orchid Orthopedic Solutions focuses on both bone on-growth coatings and bone in-growth coatings with expertise in sintered coatings, spherical, asymmetric and porous foam used in on-growth coatings. In-growth coatings are usually done with plasma spray, using titanium hydroxyapatite, or titanium on PEEK (polyethertherketone). This article provides some background on the technologies and discusses the benefits and limitations for each process.

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Sintered Coatings

Sintering is just a fancy word for bringing materials to a temperature that is fairly close, but not at the melting point of the bulk material. In essence, powder is applied to the implant and then heated up to close to melt temperatures. The surface melt (called incipient melting) forms a bond between the adjacent beads and the substrate.

Applications can range from hip, knees and shoulder components. Lately there has been a call for sintering spinal implants, cones and sleeves, and even wedges that are used as augments in surgery. The benefit of the technology is that its been used in the marketplace now since the 1970s; it has a very well-understood clinical history.

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SPHERICAL BEADS. Applying spherical beads is a process that has been around for more than 30 years and are used for both titanium and cobalt chrome substrates. One of the limitations of the process is that only titanium can be used with titanium substrates. Likewise, only cobalt chrome coating can be used on cobalt chrome implants.

Particles used in this type of coating can range in size from 88 um to 707 um. However, the industry has veered away from the largest bead sizes and usually use only the medium-sized beads. Very small particles are used in cardiovascular applications, where both the inner diameter (ID) and outer diameter (OD) of the vascular assist device is coated with porous beads.

The process is simple. The manufacturer supplies the implant, and the coating surface is prepared through cleaning and masking. Beads are applied using proprietary binders and sealers. The part is inspected and then sintered either under high vacuum, or partial pressure in an inert environment like argon.

Alternatively, some titanium implants undergo other thermal treatments such as solution treat anneal (STA) or broken-up structure (BUS). Cobalt chrome implants typically undergo HIPing (hot isostatic pressing), followed by solution annealing. Finally, there is testing and inspection of the implant, and any representative test material that went through the process, and the product is then shipped to the customer, or stays in-house for finishing and final machining.

It is important to remember that both spherical and non-spherical coatings must meet requirements when tested according to conventional standards for coating thicknesses that can be tailored based on the implant requirements. The thinnest coating is about ½ mm and the thickest is usually 1 ½ mm. The volumetric porosity can range from 30-70 percent, depending on the size of the beads used. The pore size, or mean void intercept, ranges from 50-500mm.

Further, coatings must pass test requirements for tensile and shear testing. Shear fatigue is typically done as the customer requires. Abrasion resistance testing is done to meet FDA requirements.

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There are some limitations of sintered coatings. The process requires high temperature. The heat causes the grains of the underlying substrate to grow significantly, which can reduce the strength of the material. This should be taken into consideration during the design phase and adequately addressed to ensure the strength of the final implant. As mentioned earlier, dissimilar metals cannot be coated. If the part design calls for dissimilar metals, a plasma spray coating might be a better option. For spherical coatings, the coefficient of friction is typically about 0.5. With a non-spherical bead coating, such as Asymmatrix®, can achieve a much greater coefficient of friction, up to 1.

NON-SPHERICAL BEADS. Asymmatrix® is a non-spherical bead. The particles are jagged, specifically to achieve that higher coefficient of friction.

Particle sizes can range from 177-500um, but can be tailored as needed. The coefficient of friction is usually about 0.9, but can go as high as 1.1. The enhanced feature provides better initial stability.

The coating can be customized to particle size and the number of layers. The particles can be packed tightly or loosely to control both porosity and pore size. In some cases, Asymmatrix® can be combined to create a hybrid coating that adds spherical beads in some layers and irregular beads in others to provide more customized properties.

The benefits of Asymmatrix®, compared with spherical beads, is that it's a rough, scratch-fit type of a coating, which provides better initial fixation. The prevailing theory, also, is that the roughness of coating can grate bone during implantation, and can aid in osseointegration later on.

Similar to spherical coating, the application is a high temperature process, and substrate strength is reduced during the sintering process.

FOAMS. Osseomatrix® is a fully interconnected, fully porous titanium foam. This foam can be machined into small wedges or other implant shapes.

The process of sintering to the implant requires additional heat treatment. The parts are then tested and inspected, as well as cleaned, passivated, packaged and sterilized.

The foam option allows greater tailoring of the volumetric porosity over traditional sintered coatings.

The foam option allows greater tailoring of the volumetric porosity over traditional sintered coatings. It can accommodate both very small and very large sizes. Osseomatrix® can achieve nearly 70 percent porosity for the material, with pore sizes ranging from 400-600um.

Applications for Osseomatrix® include flat surfaces, such as in tibial baseplates. These flat surfaces are machined using wire EDM from bulk materials, followed by sintered attachment onto the implant. It is also suited for stand-alone wedges and bone grafts.

The main drawback of using the material is that it requires additional processing and machining from raw, fully porous bulk material. The process is more complex than sintering the coating, so there are lead times and costs associated with the process that are different from more traditional coatings.

Plasma Spray Coatings

The plasma spray process falls under a broader category of thermal spray processes. In thermal spray, there are two major components: the heat source and the wire or powder metal that is being merged and formed into a coating. The plasma process can involve either a vacuum spray or atmospheric spray. The vacuum spray operates at lower pressure than the atmospheric spray process. Orchid provides two types of plasma spray coatings, titanium and hydroxyapatite.

TITANIUM. Titanium coating is a porous coating applied though vacuum plasma spray. The process involves two electrodes, an anode and cathode, held at very high voltage, and an inert gas, such as argon or helium. The high voltage ionizes the inert gas to take it to a plasma state. The plasma spray process is basically the spraying of molten or heat softened material onto a

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surface to provide a coating. Material in the form of powder is injected into a very high temperature plasma flame, where it is rapidly heated and accelerated to a high velocity. The hot material impacts on the substrate surface and rapidly cools, forming a coating. This energy melts the particles and the tremendous pressure coming from these plasma gases move the melted particles towards the substrate, and creates the coating.

In both processes, prep of the implant includes masking and roughening the substrate surface to allow the coating to adhere properly. Once the blasting is done, the parts are cleaned, masked again and then coated. For the titanium plasma spray, it is necessary to remove particulates that are left sitting atop the coating. These particulates are removed using a blast process.

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The titanium plasma spray coating is characterized by a rough surface of peaks and valleys and a very well connected interporosity. The open porosity provides a rough topography for bone growth. The biggest advantage to the plasma spray process is that titanium can be applied to dissimilar materials.

The disadvantage of titanium plasma spray coating is that it is a line-of-sight process, and any shadowed region will be missed.

HYDROXYAPATITE. Hydroxyapatite (HA) is a phase of calcium phosphate, an inorganic material found naturally in bones. It is used in spraying hip stems, knee components, extremities and baseplates. Because there is little risk of oxidation, the process can be done at atmospheric pressure. A plasma plume is created to melt the particles. The temperature at the core of the plasma is very high, but drops as the plasma moves away from the spray gun. The particles travel at high velocity and can be stacked to form either a porous or dense structure, as needed.

Otherwise, the process for applying the coating is similar to any thermal plasma process. The major difference is that the coating is thin and very dense. The thickness is limited to between 25 and 150 um.

The coating is osteo-conductive and can be applied to a variety of substrates including titanium alloy, cobalt chrome, and stainless steel. This is the biggest advantage HA offers. It can also be applied to porous substrates without blocking the pores, meaning it can be laid over a sintered bead coating or a plasma spray coating, thereby incorporating the bone on-growth properties of the HA with the bone in-growth properties typically coming from the porous structures.

As any plasma spray process, line-of-sight is a limitation.

PLASMA SPRAY COATED POLYMERS. One of the newest processes to the market is spraying titanium on polymeric implants, typically PEEK (polyethertherketone). PEEK is used extensively in spinal implants. The process is similar to the regular titanium spray process described earlier, and can be used on PEEK, carbon-reinforced PEEK and UHMWPe (ultra-high-molecular-weight polyethylene).

PEEK has a tendency to flex, so it is critical to ensure the coating flexes in the same manner.

Some key differences are that the coating will not be as thick as standard titanium plasma spray. Porosity runs between 30-60 percent and the thickness ranges from 50-200 um. One issue of the coating is that it is iso-elastic in nature. This means if the coating is stiff, and additional materials are added to avoid delamination from the underlying structure. PEEK has a tendency to flex, so it is critical to ensure the coating flexes in the same manner.

There is a limit to how much heat a polymer can absorb. The process Orchid uses is designed to maintain the structural and chemical integrity of the underlying material. It is a completely automated coating process, and as with any plasma spray process, has line-of-sight limitations.

Market Challenges and Next-gen Coatings

The next generation of coatings for the orthopedic implant market will need to improve bio-activity as well as overcome limitations of the application processes. Orchid continues to work on how to overcome those limitations while adding benefits to functionality.

Meeting these market changes might require updates to the regulatory guidelines, specifically in the area of bone on-growth and in-growth, wear resistance and micro- and nano-coatings. This is a real challenge because new technologies are often compared with plasma spray technologies, with mixed results, if the regulatory structure does not apply.

Orchid is in the process of developing new coating standards and test methods that can accurately assess the efficacy of the coatings. These standards are usually done through ASTM or ISO, with help from industry experts. Once

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rulebooks or guidelines are developed, it will help industry grow and bring new coatings to the market.

One of the technologies Orchid is currently working on is titanium plasma spray on UHMWPe. The process could help eliminate the need for a metal substrate. Another intriguing technology is anti-wear ceramic that can be used on any articulating surface. Orchid's initial testing on this process show impressive wear properties.

As bone growth technology advances, it will rely on coating processes, both old and new, to provide surface structures that promote healing and preserve or improve use over time. The orthopedic coatings industry is waiting for new standards to evaluate efficacy. These tools will help us explore new and exciting methods for coating implants.