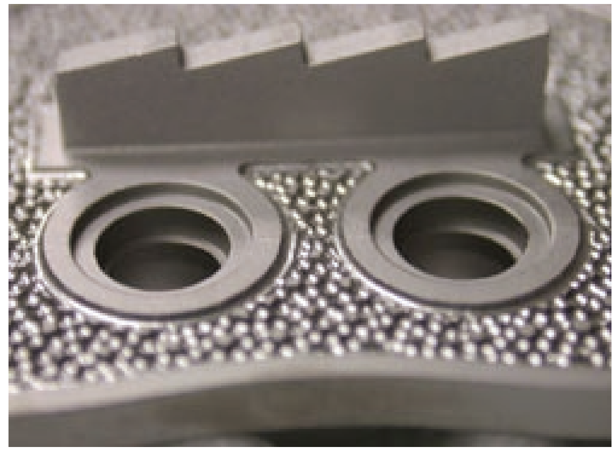
OrthoTec
Orthopaedic trends, technology, and manufacturing

Published: Fall 2010, Volume 1, No. 2

Barely Scratching the Surface

By: Mark Amrich and Art Burghouwt

A close-up of a spinal implant with a proprietary texture etched into the surface.



A close-up of a spinal implant with a proprietary texture etched into the surface.

Until very recently, there were a limited number of surface texture application methods available to designers and manufacturers of metal orthopaedic implants. The most commonly used were porous coated beads and plasma spray to provide on-growth surfaces to orthopaedic implants. Today, an increasing number of manufacturers of orthopaedic implants are turning to photochemical etching technology to apply novel surface textures to smaller and more intricate implants.

Photochemical etching, which has been used to manufacture cranial maxillofacial reconstruction implants such as cranial plates and titanium trauma meshes, has proven to be beneficial for producing burr-free, stress-free, tight-tolerance products. Specifically, the novel etching process has been refined to create two-dimensional and three-dimensional surface texturing capability that helps hold the implant in place for initial fixation. The technology also helps to create a matrix into which the bone can grow (bone on-growth), which may increase long-term stabilization of the device.

The Process

The surface texture applied to medical implants can be an important factor in determining the fit, stability, and bone fixation qualities of the implant during and after surgery. A new class of engineered 3-D surface textures has been designed specifically to provide primary fixation and enhanced bone on-growth utilizing photochemical etching technology. The technology enables OEMs to design and choose specific 3-D surface textures that can be optimized for implant stability, bone adhesion, and surface roughness.

The etching process ensures repeatability and uniformity so that each device delivers identical performance. The etched texture is controllable and has advantages over alternative porous and plasma spray coatings. Potential concerns such as overspray, mechanical weakening, and dimensional changes are virtually eliminated by this process. As a result, the technology is well suited to tight-tolerance product applications with smaller surface areas, including implants for the spine, wrist, ankle, and other small joints.

Another way in which this method differs from traditional ones is that the etching process is not a coating; rather, it is a subtractive process (i.e., it removes a very small portion of the original material surface and leaves the rest intact). A portion of the original implant's surface is preserved and the physical dimensions of the implant do not change. As a result, implants incorporating these etched surface textures will invariably have the same dimensions and fit—exactly as designed by the OEM and as specified by the orthopaedic surgeon.

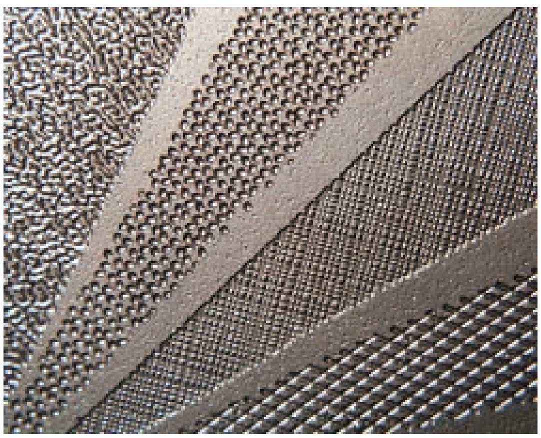
Soft tissue and bone have a propensity for growing onto roughened or irregular surfaces. An engineered texture creates a series of peaks and valleys that is an ideal surface for bone on-growth. The peaks themselves have undercut features that give the surface a rough feel. These undercuts grab onto the bone when the device is implanted. This action creates a strong initial fixation, which is important for stabilizing the implant and enabling new growth onto the textured surface.

How It Works

Texture patterns are first developed by computer-aided design (CAD) techniques and are then applied to the metal implant surface by a photochemical etching process. This process uses sophisticated imaging systems to impart the design onto the implant surface.

CAD enables the development of unique texture patterns, composed of micropeaks and micropores, to suit specific customer and product requirements. These patterns are then reproduced precisely on metal parts of any configuration and complexity. Examples of potential applications include spinal spacers and cages, dental implant posts, wrist stems, and various extremity and trauma plate surfaces.

Photochemical machining is a well-known process used for the production of printed circuit boards, letterset printing plates, encoder discs, flex plates, switches, and other components. Typically, raw metal sheet stock is coated with a photosensitive polymeric etch resist (photo resist). A negative or positive image is then printed onto the photo resist using a CAD-generated photo tool and ultraviolet light to cross-link the polymer and selectively bond it to the metallic substrate. The resist is developed using an aqueous solvent to wash away the unexposed areas, revealing the bare metallic substrate and leaving the remaining areas of the resist coating to protect the underlying metal from chemical attack. The sheet stock is then placed in a chemical etch bath or placed in spray etching equipment to dissolve the exposed bare metal. After chemical etching, the resist is removed with the appropriate solvent. The result is a burr-free, stress-free metallic product that has easily repeatable etched patterns.



A sample of different variations that can be created in the textured surface.

Typically, flat metal parts ranging in thickness from 0.001 to 0.100 in. can be manufactured using this process. The etch process can be used to manufacture products from a range of materials including copper and copper-based alloys, brass, nickel, inconel, nickel and nickel-based alloys, and hafnium. Materials such as molybdenum, tungsten, steels, stainless steels, and titanium are also compatible with the process. Of particular significance to the orthopaedics industry are the stainless-steel and titanium alloys because these are most often used for implants and instruments due to their biocompatibility and corrosion resistance.

As a result of the versatility of this process, orthopaedics OEMs can create almost any imaginable textured pattern, which allows them to choose a surface that is particularly tailored to their specific medical device. The OEM can also specify the depth of the pattern it wants etched into the implant. For example, features as small as 50 μm can be etched onto a surface with extreme accuracy and repeatability; etch depths can be controlled to within 10% of the specified depth.

Application Benefits

The benefits applying implant surface textures include the following.

Accuracy. A photochemical engineered texture can be applied on very small implants (e.g., spinal spacers and disks as well as small-extremity implants) and on complex geometries. Traditional porous and spray-on coatings are not as easily controlled, and accurate placement can be difficult on small implants. Additive coatings can also create dimensional buildup and wear debris, whereas chemical etching is a subtractive process that does not generate wear debris and retains the original datum surfaces.

Repeatability. Whereas plasma and porous coatings are randomly applied, photochemical etching enables the uniform application of a pattern to every part. This process can repeatedly transfer any specified pattern to any flat, concave, or convex surface on any number of implants. Every textured surface on every implant will display the identical pattern with the same micropeaks and micropores in the same locations.

The ability to create and replicate surface textures with unerring accuracy and fidelity to the original pattern design (from the visual appearance of the gross pattern down to the microscopic dimensions and localization of each pore and peak) results in extremely high uniformity from implant to implant, and from production run to production run. From the perspective of the OEM, there are two key advantages. Not only does the part-to-part and lot-to-lot repeatability and uniformity help ensure that every device delivers identical performance, but the process contributes to the overall efficiency for OEMs and helps contain product costs by reducing part rejects and increasing yields.

Flexibility. The process allows manufacturers to create shapes, patterns, and textures with extremely fine detail.

Strength and Durability. The low temperature (less than 500˚F) used in this particular process ensures that there is no change in the mechanical properties of the implant. Conversely, higher temperatures in coating processes typically require secondary machining operations. Not only do these secondary operations result in more work, but those temperatures can also weaken the part. Some patterns and textures offer the benefits of high shear strength; others, the benefits of high tensile strength; and still others, the benefits of combined shear and tensile strength.

Variability. Texture can graduate from fine to coarse, and multiple texture patterns can be applied on a single component at any stage of the manufacturing process. This new class of engineered 3-D surface textures offers a number of unique and valuable technical advantages that make the photochemical etching process appropriate when optimized, repeatable surface textures are required. The process delivers extreme precision with complex, custom designs and extremely fine detail.

Etching versus Coatings

The etching process has the potential to replace porous coatings and plasma sprays for implant applications. Some comparisons of the techniques follow.

Porous Coatings. Porous coatings use high temperatures, i.e., in excess of 2000˚F, to sinter titanium spheres onto the surface of the implant. These spheres or beads can be difficult to place accurately on small implants. There is also the potential for grain growth during the heat process, which can change the mechanical properties and thereby weaken the implant. The implant then has to undergo additional heat treating to restore these lost properties. The dimensional sizes of the implant can also be changed during this process, which may require the implant to undergo additional finish machining. The photochemical etching process is a low-temperature process that allows the implant to maintain its original mechanical properties. The texturing can thus be done after the implant is completely finished, thereby reducing process steps and increasing efficiency.

Plasma Spray. The plasma spray process is often hard to control for small parts due to shadowing effects and overspray. Plasma spray involves lower temperatures than porous beads, but because the titanium powder is sprayed, controlling where the spray goes is difficult and requires labor-intensive masking of the implant. The spray coating may also leave residual material or debris that is not fully bonded to the implant and must be scraped off. Alternatively, the surface created by etching is imaged onto the implant and is tightly controlled through a CAD-generated program. This allows placement of the pattern in a precise location on the implants and eliminates the need for additional masking. Also, because the etching is a subtractive process, there is no chance of material loosening or flaking off.

Although photochemical etching has many advantages, there are some limitations. Currently this process is only available on titanium and stainless-steel alloys. Because the pattern is a precise CAD-generated design that is accurately applied to each individual implant, it is a highly repeatable method that ensures that every implant has the exact same pattern to be characterized and inspected. The other processes involve the random application of material such that the coating on each implant can be somewhat variable and is more difficult to quantify and inspect.

Conclusion

Medical device companies are increasingly finding value in photochemical etching technology and integrating it into their manufacturing processes for texturing small and intricate components. It has been used on cervical, thoracic, and lumbar spinal spacers and similar fusion implants as well as on articulating spinal disks. It is also being considered for use on implants for use in hand, wrist, ankle, and foot surgeries. The key advantage is the accuracy and repeatability of the texturing process and the low-temperature environment in which textures are created.

This engineered 3-D surface texturing process holds potential for implant-tissue attachment in a wide variety of orthopaedic applications. The blending of CAD and photochemical etching technologies makes it possible to create and apply virtually any pattern and surface texture with high precision, repeatability, and superior performance characteristics.

Mark Amrich is vice president of manufacturing, etched products, for Tecomet (Wilmington, MA). Art Burghouwt is director of business development at the company.