



SURFACE ENGINEERING

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Engineered 3-D Surface Texturing Process Enhances Fit and Stability of Metal Orthopedic Implants

Precisely Reproducible Patterns Insure Optimal Part-to-Part Uniformity

Introduction

One of the most important considerations when designing and manufacturing metal orthopedic implants, such as knees, hips, and shoulders, is the surface texture applied to the components of the implants that will be affixed to a patient. In particular, the surface texture directly influences the fit, stability and bone fixation qualities of the implant during and after surgery.

Since the advent of implant surgery, various modes of applying surface textures (for example, machining, sintering, plasma spraying and etching) have been adapted or developed. Generally speaking, each new generation of surface texturing technology has contributed to improved performance characteristics and extended useful life of the implants.

Representative of the current state of the art in surface textures for metal implants is a new class of aggressive, engineered 3-dimensional surface textures (trade name: "Tecotex®"). These textures are designed to optimize implant fit, stability, bone adhesion, and service life.



Example of Tecotex® surface textures

This texturing process offers a number of significant benefits pertaining to the creation and application of implant surface textures, and to the subsequent surgical fit and post-surgical bone fixation of implants that employ these textures. It was first presented as an implant fixation technology to members of the American Academy of Orthopedic Surgeons (AAOS) in February 2002.

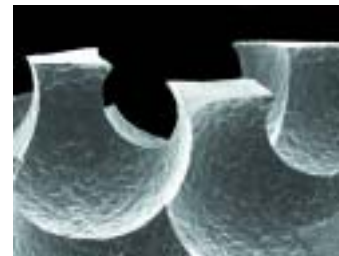
Repeatable Patterns

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

that is comparable to the sophisticated, high-end production techniques used to fabricate semiconductor devices.

CAD enables the development of unique texture patterns, comprised 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 treated parts include acetabular cups, hip and shoulder stems, knee femoral and tibial components, spinal cages, and dental implant posts.

The process can transfer any specified pattern to any flat, concave, or convex surface on any number of implants repeatedly. Every textured surface on every implant will display the identical pattern with the same micropeaks and micropores in the same places.



SEM of Tecotex® showing undercut surface

To Tecomet's knowledge, all other commonly employed surface texturing and coating processes create patterns randomly (i.e., at the microscopic level, no two patterns will ever be alike) and, hence, may introduce subtle variations in the quality of surface texture across a given production run, or series of runs, of otherwise identical implants.

The ability to create and to 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 exceptional uniformity from implant to implant, and from production run to production run.

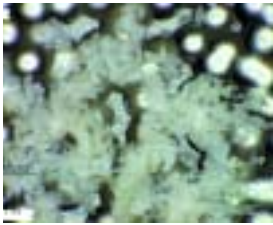
Part-to-part and lot-to-lot repeatability and uniformity help ensure that every device type that incorporates a texture applied by this process will deliver identical performance with regard to the implant's fit, stability and bone fixation qualities. In addition, the process contributes to improvements in overall production efficiency for OEMs and helps contain production costs by reducing part rejects and increasing yields.

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Aggressive Surface Textures

Surface textures applied by this process are often described as feeling “sharp to the touch.” This characteristic has important ramifications with regard to bone fixation. Photomicrographs of a representative treated surface reveal etched micropeaks with sharp undercut edges, which make the textures ideal for orthopedic implant surgery.

In applications where cementless fixation is permissible, the sharply undercut surface shaves off bone microchips as the implant stem is inserted into the bone. This characteristic (termed “Scratchtite®” fit) has been observed in animal and cadaver studies.



Shaved autograft bone in Tecotex®

Studies by OEMs using surface textures produced by this process, indicate that the pulp of live bone cells packs itself into the micropores of the texture during implantation. It is believed that this characteristic fosters regeneration of the bone inside the texture.

Over both the short and long terms, the combination of the surface texture and the integral bone regeneration may contribute to the stabilization of the implant and may minimize or even eliminate implant micro-motion problems. This, in turn, may help reduce the incidence of pain and/or loosening of the implant in the recipient.

No Risk of Heat Damage

The photochemical etching aspect of the process is “low heat”, which suits it well for use on implants fabricated from materials that might experience undesirable changes to their metallurgical properties if subjected to high heat.

For example, the application of a high-heat surface coating treatment might potentially embrittle or otherwise weaken the stem of a small-sized hip implant, resulting in a shorter-than-expected service life. By contrast, the process described in this article poses no thermal risks to the implant, thereby preserving all desirable metallurgical properties, such as, grain structure, fatigue resistance, tensile strength, shear strength, and hardness.

Preservation of Original Datum Surface

The etching process is subtractive (i.e., it removes only a very small portion of the original material surface, and leaves the rest intact). Consequently, the original datum surface of the implant is preserved, and the physical dimensions of the implant never change (unlike the situation with additive processes). Hence, implants carrying these etched surface textures will invariably have the same dimensions and fit — exactly as designed by the OEM and as specified by the orthopedic surgeon.

No Secondary Machining or Contaminant Removal Requirements

Another attribute of the etching process is that it produces an “open clean surface.” There are no final machining requirements

and, hence, no opportunities to entrap contaminants introduced by such procedures in either the surface texture or the structure of the implant.

Elimination of final machining, cutting oils, and the various byproducts (i.e., metallic residue and sludge) helps shorten the production cycle, trims the cost for secondary operations, and removes yet another processing step in which the implant might otherwise run the risk of being damaged and having to be reworked or scrapped altogether.

Equally important, unlike typical additive surface texturing processes, this etching process poses no risk of particulate matter sloughing off the substrate during subsequent fabrication procedures or during and after implant surgery.

Conclusion: A Widely Adaptable Surface Texturing Process

As described in this article, this engineered 3-dimensional surface texturing process holds enormous potential for implant-tissue attachment in a wide variety of orthopedic, medical and dental applications. The blending of CAD design and photochemical etching technologies makes it possible to create and apply an unlimited variety of patterns and surface textures with high precision, excellent repeatability, and superior performance characteristics.

Indeed, new patterns and textures are continually being developed. Some afford the benefits of high shear strength; others, the benefits of high tensile strength; and still others, the benefits of combined shear and tensile strength.

These patterns may be very coarse for orthopedic applications, such as joint replacements, but they may also be very fine if, for example, the application will involve delicate neuro-cranial surgery. Beyond the realm of joint implants, there are many other potential applications, such as dental implant posts, spinal implants, and even soft tissue engaging surfaces to support ligaments and cartilage during and after surgery.

Thus, this new class of engineered three-dimensional surface textures offers a number of unique and valuable technical advantages that make the process worthy of serious consideration whenever optimized, repeatable surface textures are required.

Editor: Mark Amrich, Program Manager for Etched Medical Products at Tecomet, has a 25-year background in photochemical etching and biomechanics. He has been with the company for 15 years and has helped bring etched technology into other medical areas, such as maxillofacial mesh products, X-ray mammography, and spinal applications. Tecomet has been a provider of innovative reconstructive and trauma products for the orthopedic industry for more than thirty years. The Tecotex® process is proprietary and patent pending. To facilitate the regulatory work of OEMs, a master file for this process has been registered with the Food and Drug Administration.

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