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Chris Trembath
Associate Editor

FEATURE

Applying the Finishing Touch

High-tech surface modifications keep implants fluid and functional, resulting in more durability and better patient outcomes

Painting a wall, or staining a piece of wood...these are just a couple of colorful analogies that have been used to describe orthopedic surface modifications. The process, of course, is much more demanding than fixing up the old barn with a brush.



Hip heads used in prosthetic hip implants. Photo courtesy of Spire BioMedical, Inc.

Orthopedic device manufacturers rely on companies that provide sophisticated surface modifications for their devices to operate efficiently with minimum wear and risk of infection to the patient. As a result, development of highly refined surfaces and biomaterials for bearing surfaces is a leading movement in orthopedics.

Minimizing Wear

Joint replacement wear is the primary factor that limits the life of an implant, and the major focus of surface modification is minimizing debris migration from the artificial joint. As an orthopedic implant receives stresses from movement, especially in hip joints, tiny particles build up and migrate away from the joint into the surrounding tissues. Naturally, the human body identifies these tiny particles as foreign bodies and reacts. As a result, infections can form and cause a host of medical problems for the patient.

In the case of a metal/polyethylene joint, for example, debris comes from the polyethylene because there is metal/plastic articulation, according to Eric Tobin, chief operating officer of Spire Biomedical in Bedford, MA. "The plastic component wears over time due to abrasion from the mating component or, in some cases, sub-surface stresses that cause material to flake or crack off from the polyethylene," he explained.

Tobin further noted that when the polyethylene particles migrate into the interface between the implant and the bone, it triggers a hyperimmune response and leads to osteolysis, a process in which the native bone

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begins deteriorating, ultimately causing gaps and subsequent loosening of the implant.

To reduce this wear, proprietary processes have been developed, such as implants made from an oxygen-enriched composite material of zirconium metal with a zirconia ceramic surface, or more widely known as Oxinium.

The early use of ceramics (a material less susceptible to wear than metal/polyethylene combinations) has been haunted by a reputation of experiencing failures (fractures). Although ceramics have made substantial strides in durability over the past 10 years through newer processing techniques and improved chemistry, industry experts report that the material is not currently in widespread use in the orthopedic industry.

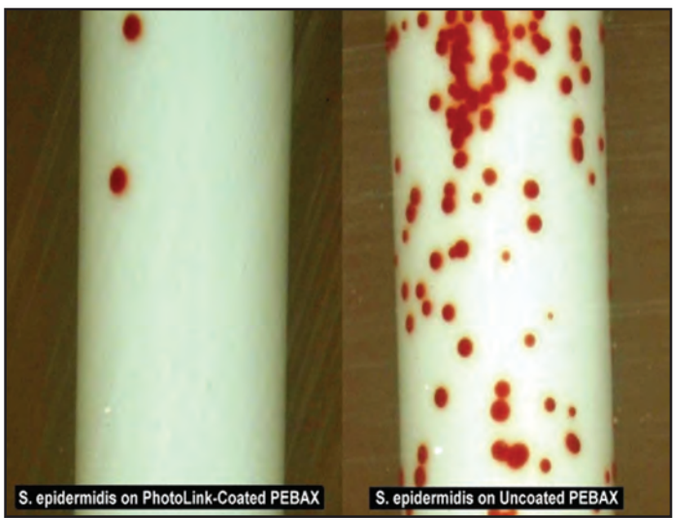
Oxinium, however, has given new life to the use of ceramics in orthopedic joints. The advantage of this material over metals, experts noted, is that the Oxinium surface is substantially harder and much more resistant to scratches. Additionally, Oxinium is more lubricious than cobalt chrome and therefore reduces friction between the femoral implant and plastic tibial bearing surface. As a result, the Oxinium replacement will not generate the quantity of debris that cobalt chrome does, and the implants last considerably longer.

Introduced by Smith & Nephew (Memphis, TN), Oxinium oxidized zirconium is a metallic alloy with a ceramic surface that provides wear resistance without brittleness.

Oxinium is created through a proprietary manufacturing process that allows zirconium alloy to fuse with oxygen and transform into ceramic on the surface. The resulting material combines the best attributes of ceramic and metal while leaving the limitations of each behind.

"Debris is the number one cause of failure in an implant, so any debris that would get in between the implant and the mating part would act like sandpaper and wear it down much faster," said Ray Harris, director of sales for The Electrolizing Corporation of Ohio (based in Cleveland).

"The idea in general is to try to get the metallic surfaces to be more like the ceramics, and I think that's what most surface treatment modification coating companies have tried to do," said Tobin. "The benefit of metal is it's generally less expensive than ceramic bulk components."



Coatings on PEBAX tubing. Photo courtesy of SurModics, Inc.

Tobin added that, ultimately, the ideal material would be one that combines the properties of the metallic bulk material with ceramic surface properties because the result would be better smoothness and higher hardness.

Of course, reducing the wear of an orthopedic implant will create a longer lasting hip or joint replacement, but if the body rejects the implant due to biological factors, another type of surface modification is required.

Biocompatibility Issues

Since the human body only reacts to the immediate surface of a foreign object, biologically compatible surface modifications can be made to facilitate implant acceptance without rejection. Additionally, biocompatible modifications allow for faster osseointegration (bonding between the implant and host tissue or bone) and are thus driving forward a major trend in the orthopedic industry to decrease the recuperation period needed before a patient can place any load on the implant.

Certain alloys, such as silver, titanium and stainless steel, are used in surface modifications because they possess inherent biocompatibilities (ie, they do not adversely react with human tissue). Silver, for example, has actual disinfectant properties, which aid in the elimination of bacteria that may develop due to metal debris. Titanium, on the other hand, is biologically inert and does not cause a reaction in the human body.

"From an infection standpoint, there are silver-based coatings where a very thin layer of silver is deposited on medical devices," said Tobin. "The thing that is appealing about silver is that it has a fairly high differential toxicity between mammalian cells and bacterial cells. It's much more toxic to bacterial cells than it is to the native cells of the body."

Although durability and biocompatibility have been the focus of joint implants for many years, a third characteristic that recently has been of

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focus is the property of bioactivity—surface modifications using materials that promote cell adhesion.

For an implant to mimic a human bone, the surrounding tissue must be able to penetrate the implants. The quicker this occurs, the shorter the recuperation period needed before a patient can apply pressure on the implant.

To meet these needs, the orthopedics industry is increasingly using hydrophilic polymer, a coating that promotes cell adhesion by emulating the structure and function of a cell. Water molecules are able to attach to the polymer, thus "tricking" the human body into thinking the implant is a natural bone. Hydrophilic polymer also increases lubricity and can be altered to attract albumin or other biologics that encourage cell growth.

Much like a drug-eluting stent, orthopedic surface modifications are becoming pro-active, rather than reactive. Certain coatings are being developed that will allow the timed release of pharmaceuticals such as antimicrobials and peptides to ward off infection and increase cell adhesion, respectively. (See sidebar, "Which Is It—Drug, Delivery Mechanism or Device?" on page 38.]

"We're seeing much more interest in site-specific, antimicrobial capabilities, whether from durable film coatings or in a classic drug release approach," said Steven Keough, senior vice president and general manager of the orthopedics business unit at Eden Prairie, MN-based Surmodics, Inc. "We're also seeing newer classes of very specific peptides, or proteins. Look for designer antimicrobials appearing on the horizon."

Keough also noted that one of the most promising areas of research in the surface modification industry is in internal coatings.

"When you discuss surface modifications and coatings, most people think of 'external' coatings," he explained. "But what can go inside of structures that can be helpful in orthopedics? Stem cells can. You can't just think of the external surface of a device as something that is active or modified—think of all surfaces in a device."

Nanotechnology coatings, such as super-hard combination alloys, also are expected to lead the way for a new generation of surface modifications.

Furthermore, researchers at Southwest Research Institute, headquartered in San Antonio, TX, have

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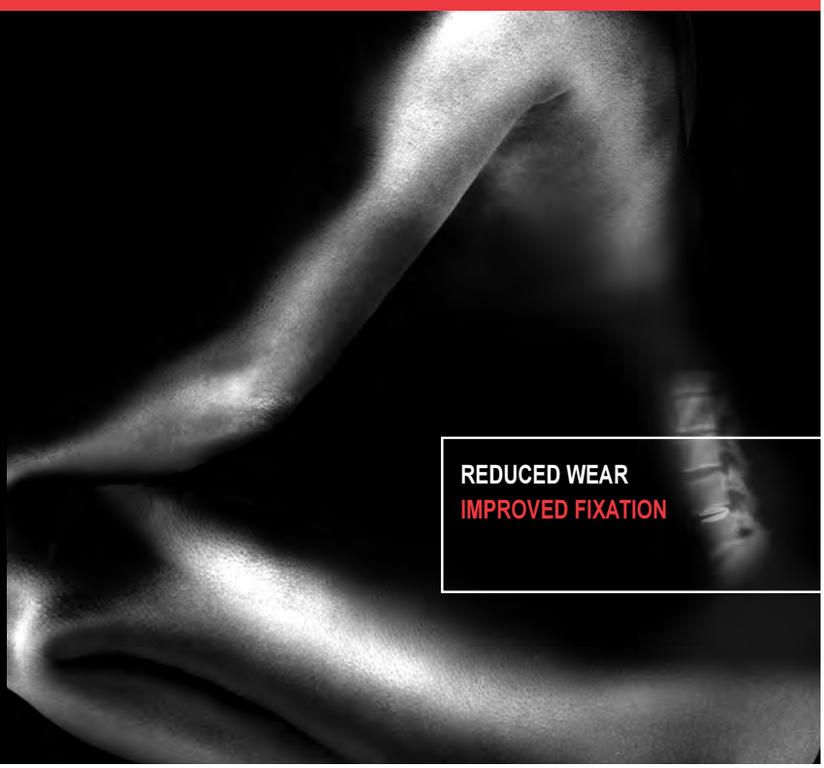

Spire Biomedical, Inc.
One Patriots Park,
Bedford, MA 01730
T 781.275.6000
1.800.510.4815
F 781.275.7470
biosales@spirecorp.com
www.spirebiomedical.com

spire Biomedical

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Which Is It—Drug, Delivery Mechanism or Device?

As pharmaceuticals and medical devices become more intertwined and, thus, increase functionality, new issues are rising to the surface for orthopedic device manufacturers who rely on bioactive surface modifications. Is the device now considered a drug, drug delivery or merely a device?

"As you see more and more active agents being used in surface coatings, you must ask yourself, 'What are the requirements under the combination device guidelines?'" said Steven Keough, senior vice president and general manager of the orthopedics business unit at Eden Prairie, MN-based Surmodics, Inc.

According to the research firm of Frost & Sullivan, the US antimicrobial coatings markets earned revenues of $175.4 million in 2005 and expects revenues to reach $558.7 million by 2012. With this rate of projected growth, overcoming regulatory hurdles is a critical challenge for coating developers. For example, developers of combination products (ie, those that combine drug, device and/or biologics) would not only have to select a drug that they have little experience with, but also demonstrate its acceptable toxicity and mechanism to understand the release into the body—and, finally, its shelf-life. Further, developers would have to carry out preclinical and clinical evaluations to validate the safety and efficacy of such products.

With the establishment of the new Office of Combination Products, an FDA agency which will review hybrid drug-device products according to their primary function, it is still yet to be decided how bioactive surface coatings will be classified; in fact, they may even be subject to both drug and device regulations. As multiple advances are being made in surface coatings, it is clear that the FDA will simply be scratching the surface.

developed a novel silver-doped, diamond-like coating with significant potential to reduce device-related infection. DLC is a highly biocompatible and blood-compatible material that provides additional resistance to bacterial adhesion.

However, with numerous new methods and materials being investigated for surface modifications, it is difficult to pinpoint the next trend in surface coatings.

"There's so much experimentation going on that it's almost impossible to say which technology is really going to take off," said Wayne Roberts, chief chemist at Electrolizing Corporation of Ohio. "Whatever one succeeds first is probably going to be the way it goes, although it might not even be the best one."

Paint or Stain?

Of course, not all surface modifications are coating processes. Etching and chemical manipulation of a surface also can introduce beneficial properties to a device.

Whereas surface modifications aim to coat (paint) an orthopedic device with a material, etchings (stain) physically alter the surface to create a modification.

Laser etching is a method of surface modification that eliminates the need for additional materials to be added to an implant or the need for additional heat, a factor that can inadvertently alter the physical properties of an implant.

"Laser technology has been investigated for surface modification because of the non-contact and low heat input exhibited by the process," said Kevin Hartke, manager of sales and marketing for Mound Laser & Photonics Center in Miamisburg, OH. "The short pulse width allows for good ablation of material from the part without putting extra heat into the part."

Hartke says that by using a laser to create small "dimples" on a surface of an implant, wear debris that would normally migrate away from the joint and cause a negative biological reaction are held in the pockets, thus increasing the life span of an implant.

Other methods of surface modification, such as sintering and plasma deposition alter the surface of an implant by depositing a rough coating on the surface, which allows for better bone adhesion.

Below the Surface

As the baby boomer generation ages, the orthopedic implant industry is expected to grow significantly in the next 10 years. Another contributor to this growth is the increasing use of minimally invasive surgery.

"Two things are happening; you've got a widening customer base, but you also have an advancing technology," said Hartke. "The technology is becoming more and more minimally invasive, which is making the technology available to a much wider customer base, and at the same time your customer base is growing."

Harris concurred as he noted that surgeries once considered too traumatic and risky for elderly patients are now being performed regularly on the older generation due to the movement towards more minimally invasive surgery.

"You have two ends of growth in orthopedics—the older generation and the younger generation," Harris explained. "If you increase the amount of surgeries you can do for the older generation, you increase your market. And if products last longer because they're better, you can put it in a younger patient, knowing

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that you're not going to have to replace it again in 10 years. So you're increasing your market from both ends of the spectrum."

As device makers continue to identify patient markets based on demographics and age groups, techniques are becoming much more specific and, at the same time, viable where they might not have been in the past.

For example, as the technology integrating anti-microbial surface coatings has become more refined, hip resurfacing, a technique that has not been widely accepted in the United States, is becoming more prominent as an option for younger patients.

"As the Europeans have shown us, there is a much better outcome for younger patients who usually have more healthy femoral head tissue remaining in the hip than an older patient," said Keough. "And it speaks to why we are focusing on surface modifications—to maximize the retention of the native healthy bone and tissue wherever we can."

Not surprisingly, encouraged by their doctors to engage in daily exercise routines for their health, scores of younger patients are filling orthopedists offices in record numbers. According to an article published in The New York Times, the Consumer Product Safety Commission examined emergency room visits in 1998 and found that sports-related injuries to baby boomers had risen by 33% since 1991.

Just as your favorite piece of furniture would deteriorate over time if you didn't give it a coat of stain or paint, orthopedic devices would corrode and weaken without surface modifications. And as the orthopedic market continues to grow, the ever-changing field of highly engineered surface modifications has just started to scratch the surface, but in the end will yield longer-lasting results and better patient outcomes. ❖

In the July/August issue:

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Contact Howard Revitch
(201) 825-2552, howard@rodpub.com **Ad Closing Date: July 3**

