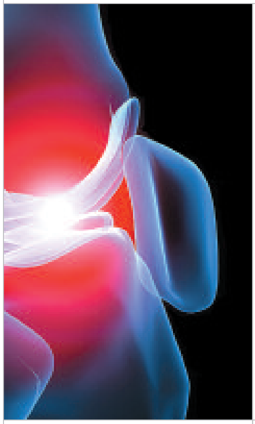

Turning Convention On Its Head
Using Abrasion for Material Deposition

For the first time, it is possible for new and novel functionalities to be added to the surface of metallic implants in a manner devoid of complications. The developers of this abrasion process believe that this capability will lead to the development of new ideas and product concepts not heretofore considered.

John O'Donoghue is the principal founding member of the EnBIO team. He was until recently a Principle Engineer with Guidant/Boston Scientific. There he was responsible for conceptualizing and implementing new approaches to the manufacture of medical devices as well as designing and implementing several product improvement changes. He also has extensive regulatory and medical device validation experience.

Liam O'Neill is the Research and Development Manager for EnBIO. He has 13 years experience in coatings and surface analysis technology, including three years developing coatings for the aerospace industry and six years developing novel plasma-based surface treatments with Dow Corning.

Abrasion is one of the tremendous forces of nature that has helped to shape our world, ranking alongside water and ice in terms of its sheer erosive power. In dry climates, sand-laden winds have sculpted the rock with a raw cutting force, creating shapes and features that awe and inspire. These same forces are often considered to be destructive, defacing the efforts of man to shape his world—literally so in the case of the Sphinx of Giza whose facial features have succumbed to the ravages of erosive sandblasting.

In recent times, abrasion has been tamed and controlled to take its place among the many industrial processes available for the purposes of shaping and fabricating materials into the goods that ease and improve our lives. Abrasive blasting (as distinct from shot peening, which is used primarily to modify the mechanical properties of metals) is used to abrade the uppermost layers from the surfaces of a myriad of metallic and ceramic substrates for the purposes of cleaning, or to prepare the surface for a subsequent process step. It does not logically follow then that abrasion can be used as a means for material deposition on certain select surfaces. Yet EnBIO, a surface modification company based in Ireland, has achieved just that.

CoBlast: A new deposition technique for select metals

EnBIO (an acronym for Enhancing Biomaterials) incorporated in 2006 with a focus on exploiting the use of abrasive blasting to produce surface modifications for the medical device and dental sectors. The company developed a patent-pending technique called CoBlast™ to incorporate dopants (a dopant is a substance which is added to a crystal lattice with the intention of changing its conductive properties) in the uppermost layers of reactive metals like titanium and its alloys, nitinol, cobalt chrome and select stainless steels. These metals, used to manufacture implants for the human body, quickly form a thin protective oxide layer on their surface in air as a result of their inherent reactivity. Ironically, it is this action that renders these metals passive and consequently suitable for use as structural replacements for many diseased body parts. Applications range from commonplace orthopedic prosthetics to stents—tiny scaffolds deployed to hold arteries and ducts open. Also, not surprisingly, the use of titanium in dental implants has led to an explosion of interest from manufacturers in this field.

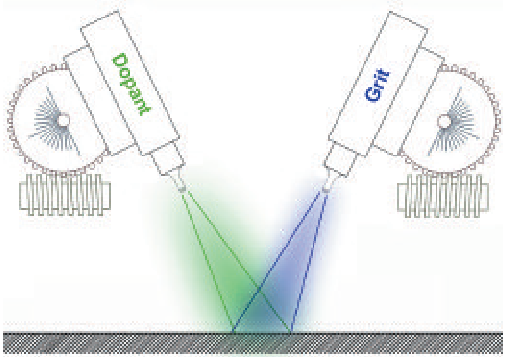

Figure 1: Schematic of the CoBlast process

One of the features of natural oxide formation on reactive metals is the incorporation of airborne contaminants into the newly constructed oxide layer. Carbon and traces of elements deriving from the titanium processing steps are naturally found in the oxide film on the surface. CoBlast exploits this natural effect by loading the immediate atmosphere with appropriate materials when the oxide is forming, thereby incorporating materials of choice into the surface. CoBlast derives its name from the process of simultaneously blasting a surface with two media: one stream is a conventional abrasive jet to disrupt and remove the oxide layer on the immediate surface while the second jet stream delivers the dopant material required in and on the surface. Disrupting and removing the resident oxide layer exposes the underlying metal reactivity; the resulting oxide healing process— which completes itself in a fraction of a second—naturally incorporates the dopant material that is flooding the area. The reconstituted layer is a composite of natural metal oxide and the introduced dopant—usually a bioceramic in the case of an orthopedic implant.

Benefits of CoBlast

In addition to its simplicity (and thus its low cost), the scalable process has many inherent advantages. The main advantage is the room temperature application. As we know, it is extremely difficult to apply a material to the surface of a metal in the adherent manner required for most coatings. High temperature methods such as plasma spray or sputtering are usually used, resulting in damage to the material being deposited. This has serious implications for the use of such techniques in implant coatings where control of materials is paramount. EnBIO has successfully deposited a range of bioceramics on metal substrates without changing the physical or chemical properties of those materials or the substrate in any way. As well as the obvious regulatory advantages to such a process, the full potency of the material is brought to bear on the surface for its intended function.

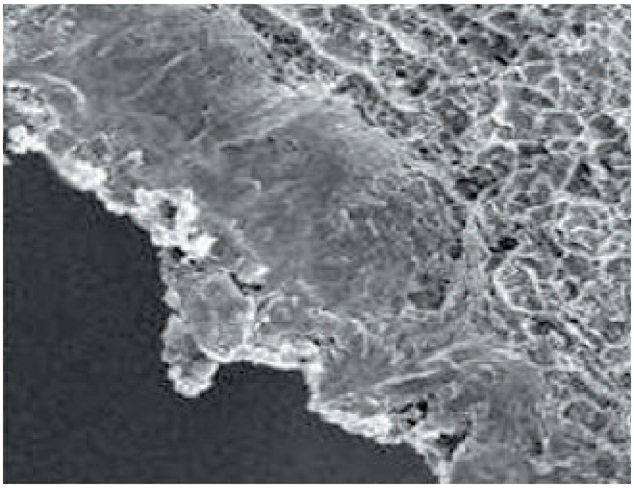

Figure 2: Cross-sectional profile of a surface modified using CoBlast (Hydroxyapatite on Ti)

The straightforward nature of the CoBlast™ process means that it can easily be added to any production process and at a favorable cost relative to conventional deposition techniques in the medical device sector. Abrasive blasting is already well regulated in medical device manufacturing, and this coupled with the fact that all the materials—dopants and substrates—are also well established gives precedence for regulatory approval and hence sector acceptance. It also means that there is already appropriate equipment and expertise available within the industry.

In addition, ceramic materials incorporated via the oxide cannot be delaminated or chipped off as with conventional coatings. In the same way that the natural oxide layer on a metal is considered to be part of the metal, so too is the bioceramic loaded oxide layer resulting from the CoBlast surface treatment. An analogy frequently used by EnBIO is that of the difference between a wood stain and a varnish: the stain is the surface modifying element in the case of wood, while the varnish constitutes the coating that sits on top of the wood. The varnish can be removed off the top but removal of the stain requires removal of wood. Such is the case with reactive metals having undergone the CoBlast process. Removal of the dopant materials is only possible if the uppermost substrate layers are also removed. CoBlast results in a thin layer of incorporated material without adding substantial volume to the part being treated. This adhesion is demonstrated by the superior results of the CoBlast surface to ASTM tensile and shear tests.

Applications: Medical and non-medical

The coating material preferred by the medical device and dental communities is Hydroxyapatite (HA), a bioactive bioceramic used

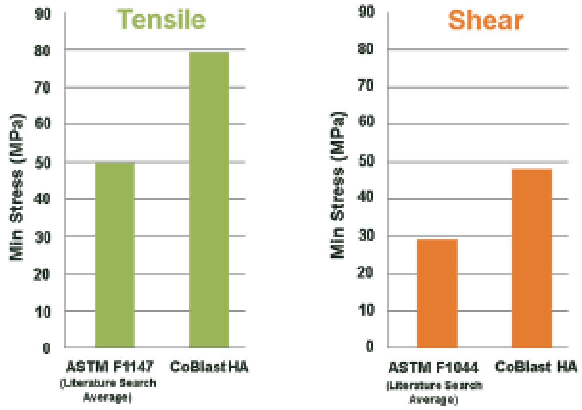

Figure 3: Adhesion of CoBlast HA (measured) vs plasma sprayed HA surfaces for ASTM F1147 tensile test and ASTM F1044 shear test (average from literature search)

mainly in orthopedic and dental applications. XRD analysis of hydroxyapatite (HA) demonstrates that the deposited HA is fully crystalline—an important feature for the implant stakeholders, but indicative of the material-friendly manner embodied by the technique. In vitro and In vivo testing indicates that the CoBlast deposition technique competes favorably with contemporary HA coating methods while offering mid- to long-term benefits due to the highly adherent HA finish. EnBIO has succeeded in depositing HA on Nitinol stents that have successfully survived a 50 million cyclic fatigue test without losing the HA from the surface.

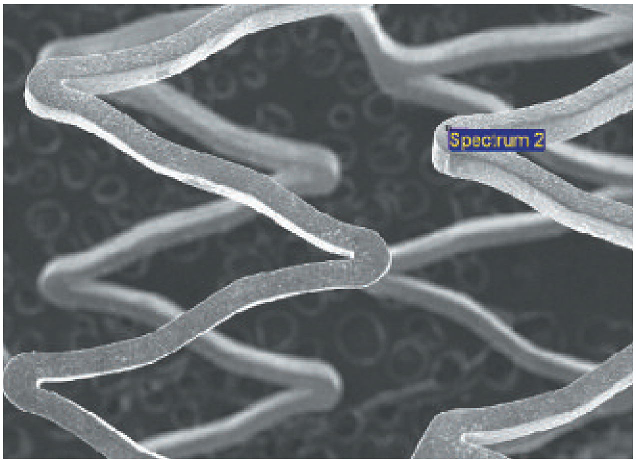

Figure 4: Image of coronary stent with CoBlast modified surface

Other work has demonstrated that using CoBlast to apply various materials to the surface of titanium can significantly improve the hardness and wear resistance of the titanium, which is an inherently soft metal. EnBIO believes that this novel and cost-attractive approach of modifying the surface of titanium will have countless applications as the use of titanium becomes more widespread. EnBIO's focus has expanded into a number of aerospace and military sectors.

With advances in abrasion techniques like these, even the ancient Egyptians would be impressed!