Reviewing Ceramic Advances for Medical Implants

Medical device manufacturers are in a constant search for new and innovative material advances. For implantable devices, they have been seeking alternatives to metal that offer greater advantages. One such material that has been used since the ‘70s is ceramics. This article highlights some of the applications for which this material is being utilized, illustrated through specific products.

By Keith Ferguson

Technical ceramics, with their biocompatibility and resistance to wear, are ideally suited for a wide variety of medical implant applications, from artificial joints to implantable electronic sensors, stimulators to drug delivery devices. For well over a decade, alumina, zirconia, and other ceramics have successfully proven their ability to withstand the harsh environment of the human body.

[1] *Click* here *[1] to enlarge*

Now, driven by the industry’s need for longer-lasting and ever smaller—yet more complex—components, materials scientists are extending the benefits of ceramics for new medical implant applications with innovative techniques, including injection molding, engineered coatings, and ceramic-metal assemblies. This article discusses how these developments in ceramic material and processing are contributing to the evolution of medical implant applications and the key role that Morgan Technical Ceramics (MTC) is playing in this industry. Morgan Technical Ceramics, comprised of Morgan Advanced Ceramics (MAC) and Morgan Electro Ceramics (MEC), is a leading manufacturer of innovative ceramic, glass, precious metal, piezoelectric, and dielectric materials.

Ceramics for Artificial Joints

Advances in the use of ceramics for artificial joints have received a great deal of attention, especially since golf legend Jack Nicklaus received a ceramic-on-ceramic total hip replacement in 1999 in an experimental procedure at New England Baptist Hospital. Ceramic-on-ceramic hip joints received FDA approval in 2003.

Ceramic materials have been used for artificial joints since the 1970s when the first generation of alumina products demonstrated superior resistance to wear, compared to the traditional metal and polyethylene materials. Advances in material quality and processing techniques and a better understanding of ceramic design led to the introduction of second generation alumina components in the 1980s that offered even better wear performance.

Traditional metal-polyethylene hip system wear generates polyethylene particulate debris, inducing osteolysis, weakening of surrounding bone, and results in loosening of the implant, a primary cause of costly revision operations. Ceramic materials generate significantly less polyethylene debris when used in conjunction with polyethylene acetabular components in bearing couples. State-of-the-art ceramic-on-ceramic technology, where an alumina femoral head is mated with an alumina acetabular cup, totally eliminates polyethylene debris and reduces wear significantly. A study of MAC’s HIP Vitox ceramic-on-ceramic hip joints demonstrated a wear rate of just 0.032 mm^3/million cycles. In addition to resolving the problems caused by polyethylene debris, the use of ceramic-on-ceramic hip systems alleviates any concerns over metal ion release into the body if a metal on metal hip system were used.

This superior wear performance extends the life of artificial joints, giving ceramic-on-ceramic joints a predicted life of well over 20 years. Serving the needs of the increasing numbers of younger patients for whom such surgery is now a viable operation, these ceramic-on-ceramic joints allow them to continue leading active lifestyles.

Ceramics for Implantable Electronic Devices

New developments in ceramic technology are playing an equally important role in the evolution of implantable electronic devices. In the 45 years since the first cardiac pacemaker was successfully implanted in the U.S., researchers and doctors have created a wide array of implantable electronic devices, including pacemakers, defibrillators, cochlear implants, hearing devices, drug delivery, and neurostimulators.

For example, medical device companies are testing neurostimulators that pulse various nerves to treat particular medical conditions: the hypoglossal nerve (in the neck) to treat sleep apnea, the sacral nerve to treat bowel disorders, the stomach to treat obesity, the thalamus to treat epilepsy, the vagus-nerve to treat chronic depression, and other regions of the deep brain to treat migraines and obsessive-compulsive disorder.

These devices increasingly rely on ceramic components, such as the feed-thrus that provide the functional interface between the device and body tissue. A feed-thru is a ceramic to metal seal assembly that contains metal pins or small tubes that pass through a ceramic component. These pins allow electricity to pass in or out of the implanted device in order to sense what is going on in the body and/or to administer an electrical charge when needed. A feed-thru can also be used to administer drugs to the patient. The ceramic substrate of the feed-thru acts as an electrical insulator, isolating the pins from each other. MTC can also make ceramic housing assemblies to enclose the electronics for the device, which can attach to a feed-thru.

Feed-thrus for implanted devices must be hermetic, with a leak tight seal around each pin. This ensures that bodily fluids do not work their way into the device and destroy the internal electronics, and that chemicals do not inadvertently escape from drug delivery devices. A braze material, typically 99.99% gold, is used to join each metal pin to the ceramic insulator. To ensure the braze adheres securely, MAC has developed a proprietary process, in which the surface of the ceramic is prepared for brazing by the application of a thin film of biocompatible metal such as platinum, niobium, or titanium via physical vapor deposition.

Developers of new and improved implantable medical devices continually demand smaller and more complex components. For example, MTC has created a one-inch diameter ceramic feed-thru for drug delivery applications that houses 104 separate pins. Voltage passes through each pin activating different combinations of switches allowing a greater number, or more complex combinations, of drugs administered at any given time.

The application of powder injection molding (PIM) has furthered the pursuit of component miniaturization. This method enables the production of intricate features and unusual geometries, most notably for hearing-assist devices, bone screws, and implantable heart pumps. Testing of ceramic injection molded objects has shown that net-shape as-molded parts exhibit significantly less variation in flexural strength than green machined parts of the same formulation. The narrower Modulus of Rupture distribution of the PIM parts can be attributed to lower variability in surface finish than that which occurs with a comparable machined surface.MAC also offers Metal Injection Molding (MIM) technology, which provides a low-cost alternative to machining, investment casting, and stamping. A MIM machine can typically mold parts in about 10 seconds compared to minutes or even hours through conventional techniques. MIM applications are ideally suited for high-volume production of intricate components, ranging from laparoscopic instruments to biopsy jaws and dental brackets.

An additional area of ceramic technical development important to medical implant applications is ceramic-based coatings, such as diamond-like carbon, that provide a biocompatible, sterilization-compatible, non-leaching, and wear resistant surface for key pivot points and wear surfaces. Such coatings are used to reduce friction, increase surface hardness, and prevent ion transfer from metal implant components.

Conclusion

Driven by the rapidly expanding and evolving market for medical implants, material scientists and ceramic component manufacturers will continue to develop new materials and new processes for the smaller, more sophisticated, and longer-lasting implant applications of the future.

ONLINE

For additional information on the technologies and products discussed in this article, visit Morgan Advanced Ceramics at www.morganadvancedceramics.com [2].

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