With demand for joint replacements exploding as populations age, materials used by medical implant and medical device manufacturers continue to evolve. Metallurgists and materials scientists are seeking more-innovative ways to improve the quality and longevity of surgical implants.

Craniofacial implants made from PEEK polymers with EOS’ laser sintering process offer lightweight, patient-matched solutions.

Materials for Medical Manufacturing

Specialized metal alloys, ceramics, thermoplastics and other newer materials continue to aid aging populations

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Metals such as titanium, cobalt chromium, and other alloys are the materials most commonly employed these days to make the millions of implants used in joint-replacement surgeries. However, many newer materials including PEEK, ceramics, and other nonmetallics are finding a place in knee and hip joint implants and in other medical applications. Specially steels are widely used in spinal-fixation surgeries, with steel screws and other components used in spinal surgeries where the implants are later removed.

Material toughness and fatigue resistance, coupled with favorable biocompatibility properties for implantation in the human body, make metal alloys such as titanium and cobalt-base alloys the choice for medical implants such as total joint-replacement systems and devices for fracture fixation. In the US market, the US Food & Drug Administration (FDA) regulates and approves medical devices, and not the materials from which the devices are manufactured. “There’s no such thing as an FDA-approved material, and the FDA’s most important responsibility is for the safety and for the efficacy of these medical and surgical devices,” notes Howard L. Freese, PE, FASTM, manager, Business Development-Biomedical, at ATI Allvac (Monroe, NC), an Allegheny Technologies company. “The people who make the devices are totally responsible in their submissions to the FDA for the safety and the efficacy of their product, including the machining of it. Ultimately, it’s got to perform. It’s got to be safe and effective.”

Within the auspices of the FDA, and ASTM and ISO standards, there are five types of materials used, he adds. These include implantable metallic materials, implantable polymeric materials, implantable ceramic materials, tissue-engineered medical products, and biological materials. Specialty steels employed include 316 stainless and, typically, vacuum-melted stainless steels, which are commonly used for implants such as screws, pins, plates, and rods.
“If you took all the stainless steel items, it’s not a very large fraction of the total number of long-term implantable metallic biomaterials in the US,” Freese notes. “These things are used as pins, rods, and anchors that are typically implanted for a short period of time, often in fracture fixation, and then removed. But almost from the very instant you put any of these stainless steel components or devices in the human body, they start corroding. So there are some biocompatibility issues, and there are some corrosion issues with these stainless steels. And in the case of metal touching metal, or other things touching metal, there is the possibility of micromotion and wear debris. You don’t like to have a lot of these things, small metal particles or metal ions, loose in the human body.”

“The use of metallics in implants is centuries old, back even to Egypt and India.”

“Your cobalt-base alloys are, generally speaking, stronger alloys, originally aerospace alloys that came out of the jet-engine superalloys,” Freese adds, “and probably some of them have been used since the 1950s, not in large quantities, but in alloys like MP 35N, or R30035. It has been around for a while, and L-605 has been around for a while; probably one of the older ones is R30075, which was the cast version of the cobalt-chromium-molybdenum alloy.”

Cobalt-chromium-molybdenum, or CoCrMo, and other hard alloys now used in implants trace their heritage to use in World War II jet aircraft engine technology. “The stainless steels have been used even before that,” Freese says. “The use of metallics in implants is centuries old, back even to Egypt and India.” Dating to the Civil War area and through about World War II, it was an issue between the patient and the surgeon, he adds. “If a guy had to go down to the local store and get a 10-penny nail, he’d do it. But that was between the surgeon and the patient. Later on, the ASTM F4 committee was established with a lot of orthopedic surgeons, and we started creating the standards for these materials, and started looking at metals more sensibly, and we’ve limited the materials that could and should be used for good outcomes.

“The titanium alloys, and also the cobalt-based alloys, have come out of the aerospace industry, and in particular titanium aluminum vanadium, Ti-6Al-4V, and also Ti-6Al-4V ELI, which is characterized by Extra Low Interstitials [ELI]. There’s a lower oxygen content for 6-4 ELI—it’s almost the
same material. It’s different in what it doesn’t have. It has less iron, less oxygen, fewer interstitials. If you look at the physical chemistry, the microstructure, you have these repeatable ‘cages’ throughout the structure, and it’s what’s within that structure that’s considered to be minor or trace elements, these interstitial components that are specified in the ASTM or the ISO standard.”

For structural orthopedic applications, the metallurgical properties of Ti-6-4 and Ti-6-4 ELI make them the most common of titanium alloys, he adds. “The properties are so very similar, and I would say the machining properties would be much similar.” In medical applications, Ti-6-4 ELI has been around longer and is used more widely because the ASTM F136 standard has been in place longer, he says. “The standard for Ti-6-4, which is ASTM F1472, came along much later, and it’s not so widely used in this country. In the aerospace industry, it’s quite the opposite, however.”

More than half the titanium made worldwide is either Ti-6-4 or Ti-6-4 ELI, he notes, and the choice between titanium or cobalt chrome for implants often tilts toward Ti-6-4 due to its biocompatibility. “The cobalt alloy is strong for a variety of reasons, but most people would offer the opinion that there’s more titanium used than the cobalt-based alloys. That is because of the properties of titanium and its usefulness because of biocompatibility, and corrosion-resistance, which is pretty good, and the material’s bio-integratability.

“The osseointegratability or the biocompatibility is something that each device manufacturer studies, when he develops his new device and makes his submissions to the FDA. Titanium and cobalt chrome are comparable in biocompatibility, but I think titanium would probably integrate better. If you look at the interface between the tissue of the host and the device itself, one finds that titanium does perhaps a little bit better than some of the cobalt-base alloys.”

Specialty alloys abound in medical devices, targeting mainly implants and instrument applications, notes L. Anthony Guitterez, manager, medical products, Carpenter Technology Corp. (Wyomissing, PA). “The two main groups of applications are implants and instruments. A few of the most commonly used materials for implants are titanium, Ti-6Al-4V, stainless steels [Carpenter’s BioDur 316LS alloy], and cobalt alloys [BioDur CCM and BioDur CCM Plus alloys],” Guitterez notes, “and those used for instruments are typically made from other classes of stainless steel [Project 70+, Custom 630, Custom 455 stainless, and Custom 465 stainless].

“In the most recent years, there have not been many truly innovative new materials introduced in the medical field due to continued pressures on cost-containment and risk-mitigation,” Guitterez states. “However, Carpenter Technology recently signed an exclusive licensing agreement with Manhattan Scientifics to produce and commercialize a new class of high-strength nanostructured materials, and the company’s sights are set on both the aerospace and medical markets.”

Technical properties of such newer materials would include a desirable combination of higher strength and toughness, superior corrosion resistance, and improved fatigue resistance, Guitterez explains. New manufacturing processes also may result in materials improvements.
“Many of the implantable materials are produced using the purest raw materials and the latest premium melting and remelting techniques to achieve high alloy purity, fine grain size, and homogenous microstructures,” he adds. “Some of the most difficult challenges are to provide the desired consistency in all required properties and product attributes necessary for our customers to manufacture the finished parts, while improving the performance of the device at the lowest total cost. Oftentimes, improving an alloy’s structure can make the material more difficult to machine, and a customized tool or process needs to be devised to maintain manufacturing efficiencies.”

**Promising processes for implants include laser sintering** for metal implants and high-temperature processes for polymer implants including polyetheretherketone (PEEK), which is being employed in the latest project for craniofacial implant applications using laser sintering techniques from EOS (Munich). EOS provides a process for creating fully dense metal alloy implants using its direct metal laser sintering (DMLS) machines, and the company recently demonstrated test parts made from PEEK using its high-temperature process.

“Historically, a lot of stainless steel has been used, either for instruments or implants,” notes Martin Bullemer, EOS manager, medical business development. “That changed to other materials, and nowadays you’ll find cobalt-chrome alloy, according to the ASTM F75 standard, used mainly for load-bearing applications, primarily for hip and knee applications.

“If you look at your knee and you just count the movements you do a day, then you need a very, very high fatigue lifetime,” says Bullemer, “so one of the mechanical properties requires that the standard cobaltchrome tests for 10-million cycles of fatigue, and that’s just corresponding to a few years’ movements of the human body.”

The EOSINT 280 system uses powder metal alloys, including titanium and cobalt chrome. “There are good reasons for selecting cobalt chrome for load-bearing applications like knee and hip joints,” Bullemer says. “For example, in mechanical properties, it’s stronger than titanium, but titanium is better accepted by the human body.”

**With newer PEEK materials for craniofacial implants,** EOS’ plastic laser sintering on its EOSINT P 800 machine uses different process technology than its DMLS process. “The difference is that metal is a melting process in a cold environment, where we melt the metal with the laser,” he says. “For polymer systems, we have a hot process; we heat up the powder close to melting temperature, then solidify the powder with a low-power laser.”
In February, EOS exhibited at the Medical Design and Manufacturing (MD&M) show in Anaheim, where the company presented tests of the PEEK customized craniofacial implants fabricated in Germany using the EOSINT P 800 laser-sintering system, which operates at up to 385°C for processing high-performance polymers. EOS technology enabled developing a specific geometry for bone replacement that can only realized using additive manufacturing. The new design incorporates a mesh scaffold that promotes improved bone growth, and optimizes infiltration with a hydroxyapatite-filled, bioabsorbable polymer.

For the past two years, the company has been involved with the Custom IMD project (www.CustomIMD.com) in Europe, financed by the European Commission, which aims to make custom implants available within 48 hr. “We have been part of an extended R&D project in Europe. In Europe, we have these framework projects with numerous companies partnering and developing new processes,” Bullemer notes. “Our task was to develop a process for patient-matched PEEK implants, and that's what we have. The situation at the moment is that you can say that it's proven that you can use EOS technology and the material for patient-matched implants. The regulation for patient-matched is easier than for any standard implant.”

PEEK offers advantages over metals for craniofacial and other implants, partly due to its lighter weight. EOS has its own PEEK material, notes Bullemer, as well as others available in its portfolio. “Compared to a standard plastic, the melting temperature is much higher, it has better chemical resistance, and it's more biostable. Because it has a higher melting temperature, PEEK can be sterilized easily.”

Used mainly in non-load-bearing applications, PEEK is a good option for cranial implants, either resulting from car accidents or patients with tumors, he adds. “An advantage is that it corresponds much better to the natural bone than does any metal,” Bullemer states. “That's why it's very well-accepted by the body. And it has good material properties, in strength and in weight.”

The polymer laser sintering is also being employed for medical drills and cutting guides. “It's definitely a growing application,” he adds. “Disposable instruments in plastic are based on CT scans to get a patient-matched instrument which actually fits very well to the patient’s knee, reducing the operation time, so the patient spends less time in the operating room, saving time and money for everybody.”

Ceramics also show promise with new knee implants made from materials such as Smith & Nephew’s oxinium material, a metal/ceramics hybrid that is said to combine the best of metal and ceramics, with fracture toughness like that of cobalt chrome, but using a ceramic surface that offers outstanding wear resistance.

“We make components for implantable devices, and the materials most commonly used in our applications are titanium, platinum, Pt/Ir [platinum/iridium], gold, and Al₂O₃,” notes Christien M. Vaillancourt, new business development manager—Medical Products, Morgan Technical Ceramics (Fairfield, NJ). “Some others used, but not as common, are zirconia toughened alumina, ZrO₂, niobium, and palladium. Other medical devices and structural implants may lean more toward the stainless steels and cobalt chrome.

“There have been many advances over the last few years in the area of powder injection molding,” Vaillancourt adds. “Our sister company in Stourport, UK, does...
ceramic-injection molding for the dental market, and metallic-injection molding components have been used in the manufacture of surgical instruments for the last 10 years or more.

“Medical device manufactures are looking for robust, inert, biocompatible materials. Al₃O₃, titanium, and platinum are good examples of such materials as they have very good strength, are accepted well in vivo, and do not degrade over time. We have a wide variety of ways to produce ceramic including die pressing, isostatic pressing, green and hard machining, and injection molding. Through these methods, we are able to produce a wide variety ceramic shapes and sizes. Most of the medical grade metals mentioned above are rather expensive. Some are also rather hard to machine—they do not process easily. Other materials have weldability issues, i.e., it is difficult to join them to other materials.”

Materials in medical vary widely by the application, notes Hanan Fishman, president, PartMarker Inc. (Fort Washington, PA), developer of PartMarker software. “Medical manufacturing is a very broad term, so the material various manufacturers use depends on the product being manufactured and its application,” Fishman observes. “With implantable orthopedic medical devices, typical materials might be stainless, titanium, or PEEK. For an implantable dental device, like an abutment, titanium, stainless, zirconium, or even gold might be used. For surgical instrumentation, stainless might be more typical—the choice of the material is down to the purpose of the device. Certain materials, based on clinical research, may improve bone calcification when implanted.

“CAD/CAM plays a massive role in the manufacture of medical parts for a number of reasons,” he adds. “First, medical parts today are typically designed via 3-D solid models and require a CAM system to generate NC programs to machine them. Medical parts generally have highly complex geometries, which makes using CAM software the only commercially feasible way to program and manufacture them.”

More and more medical devices are being manufactured on highly complex and sophisticated machines, including multiaxis Swiss-type lathes, five-axis mills, multitasking turn-mill centers, and bar-fed mills, Fishman notes. “CAD/CAM will allow the user to better simulate and program a process. CAD/CAM has become an absolutely essential productivity tool for machinists making medical parts.”

Swiss machines are well-suited to medical device manufacturing because medical devices, especially implants, typically need to be pretty small to fit into the human body, Fishman observes. “Swiss machines offer the unique benefit of dropping parts complete with a plurality of milled and turned features. Small parts with a number of turned and milled features are the bread and butter of Swiss machines. Many still know Swiss machines as ‘screw machines,’ and as it turns out, there are a lot of screws to be made for medical applications including bone screws and other fixation products.” ME