

Orthopaedics Manufacturing: It Is Rocket Science

Manufacturers are adapting processes used in the aerospace industry into the orthopaedics industry.

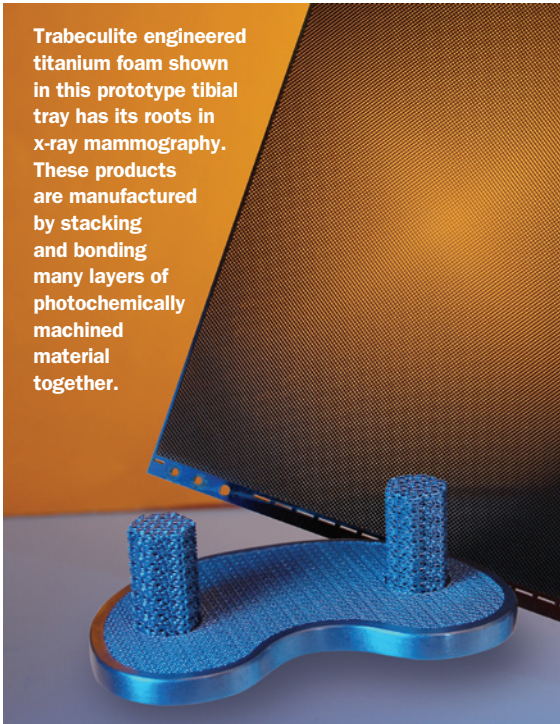
ROBERT LYNCH

Orthopaedic implants demand high-performance and advanced materials with unique designs. Designers also need to consider the use of *extreme manufacturing techniques*, which stretch conventional fabrication processes and proprietary processes to yield new levels of performance or accuracy. Implementing such techniques often requires the development of an entirely new fabrication process. As a result, contract manufacturers must draw from various industries to improve manufacturing processes.

This article highlights the similarities between orthopaedics manufacturing and other high-tech manufacturing fields such as aerospace engineering. It also discusses how manufacturers can learn and benefit from the lessons of an adjacent technology when developing next-generation orthopaedic implants.

Product Requirements

Many medical contract manufacturers have their roots in aerospace component manufacturing. Most manu-



Trabeculate engineered titanium foam shown in this prototype tibial tray has its roots in x-ray mammography. These products are manufactured by stacking and bonding many layers of photochemically machined material together.

facturers have made a natural transition away from aerospace and toward medical manufacturing.

Although the product requirements may be different, the performance requirements are similar for these two industries. Whether a device is used to position a satellite in space or to rebuild a damaged knee,

it requires the ultimate in performance, accuracy, and reliability. Aerospace manufacturing has the same rigid level of quality and traceability requirements as medical contract manufacturing. Orthopaedic design specifications require tight process techniques and controls to maintain narrow tolerance windows.

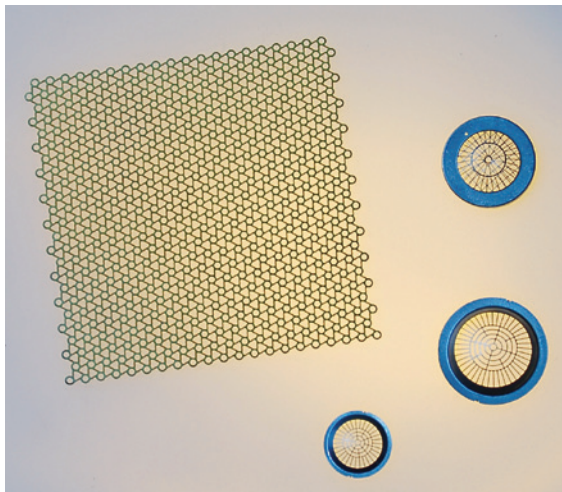
Many orthopaedics manufacturers that build large joints have been accustomed to achieving tolerances in the range of 0.5 mm. In most cases, these are anatomically shaped components designed to mate with or imitate bone. The bone varies from patient to patient, and procedures usually require a great deal of sawing, drilling, broaching, rasping, and shaping by a skilled surgeon. Implants require tolerances of ± 0.01 mm or tighter. Devices that have multipiece precision-fitting assemblies and aerospace-fit specifications drive these requirements.

This trend will also drive the cost of the devices, because achieving tight tolerances can be costly. Providing components with tight tolerances requires expensive machine tools that can meet the part requirement and reliably repeat the process with minimal

drift in dimensional output. In addition, a thorough knowledge of robust process design is imperative. Manufacturers employ process capability studies that measure the ability of the process to keep parts within tolerance limits. It is possible to have a process that complies with print specifications but is out of spec according to the customer's process capability requirements. This process can trigger a time-consuming 100% inspection requirement. Such layered customer requirements increase the complexity and cost of manufacturing components.

Precision manufacturing is critical to device manufacturers. Firms with an aerospace background often have experience with precision. Most aerospace manufacturers have metal-processing equipment that supports or complements device manufacturing requirements. Machine shops have three- and four-axis machining centers, turning equipment, Swiss-style machines, electrical-discharge machines, and grinding equipment. Some manufacturers have moved to advanced machining centers and multi-axis machines. Others have capabilities such as forging, photochemical machining, E-beam welding, and rapid prototyping. A contract manufacturer has the advantage of using these technologies and capabilities to solve a customer's manufacturing challenge.

In the past, developments in aerospace have led to several new technologies and advanced machining processes. For example, many of the computer numerical control machines used today were originally built for the aerospace industry. Machine tool makers have recently begun catering to medical manufacturers with machine tools designed specifically for them. In the last decade, machine tools have moved away from hard tooling for specific products to more-versatile machines with multi-axis capabilities to serve many different product designs. In the last five years, machine-



Photochemical machining in 3-D yields components for a maxillofacial mesh. It was originally used in high energy and high frequency devices for vacuum tubes (right).

tool manufacturers have created an integrated package by incorporating automation bar feeding, part pickers, and robotics into their tools. In many cases, these machines are scaled-down versions of machines that were originally designed for aerospace and now fit the part size and floor footprint to support a medical application.

Design Software

The evolution of design software has been influenced by all areas of manufacturing. Design programs such as Pro-Engineer and Unigraphics (UG/NX) have become preferred platforms in medical manufacturing. These programs allow advanced modeling and finite element analysis to work hand-in-hand to produce effective and complex surface geometries that replace natural biological functions. When the design software works well, the challenge is to translate from a part model to a streamlined machine language that instructs the advanced machining center.

Complex surfaces and multi-axis machining centers have moved beyond converting a computer designed 3-D CAD model to a program that tells the machine which tool and tool path to use to create a part. Medical device manufacturers may not know about these changes, but aerospace contract manufacturers have been using multi-

axis machines for many years to create complex turbine engine components, for example. They have also developed effective post programs, which are the machine's translator. They are designed to interpret the space between the part-model program language and the required machine-tool language.

It is a point of frustration to get a machine to perform an instructed task. The contract manufacturer must design and write programs to fit specific needs. Information sharing can be a challenge in this arena due to the work required to solve problems, write effective programs, and protect intellectual property. Aerospace professionals are accustomed to this process as the evolution of high-performance space-age components has been paralleled by the development of machine tools and related processes and programs.

Materials

Material properties and performance requirements of orthopaedic implants continue to evolve. OEMs are looking for materials that are stronger, have good wear resistance, and exhibit biocompatibility. They also want light, thin, small, long lasting, and inexpen-



Smith & Nephew's forged Oxinium knee femoral combines space age precision forging, machining, and proprietary finishing to manufacture knee implants that can last a lifetime.

sive materials that meet the biological demands of patients. Implant manufacturers must be able to serve bariatric patients, and calculate load implications on an implant. Manufacturers also serve patients who expect to remain active and want to resume daily activities (including the activities that initially damaged their joint) sooner.

The need for long-lasting implants is rising as older patients continue active lifestyles and sports injuries to young patients become a large part of the implant segment of cases. The majority of implant procedures are still performed in patients 65 and older, but this has been driven by the finite lifespan of implants. And the longer a patient waits for the first procedure or the older the patient is, the more likely it is that a patient will require a second or third revision.

For example, Smith & Nephew promotes its Oxinium knee and hip systems to a young patient population, due to the device's claimed 30-year implant life. The extended life of these implants comes from a space-age material. Oxinium was initially used in nuclear power plants that required a ductile metal-bearing material that could withstand a corrosive environment. Oxinium meets the structural and wear requirements of being underwater in the bowels of a reactor.

One of the issues Smith & Nephew faced was the cost-effective fabrication of an anatomical knee component that could pass a proprietary oxidation process. Fabrication was dependent on the upstream processes and controls. It took a few years and a variety of space-age processes to bring that product to market. The knowledge base that the manufacturer established in forging aerospace components and similar materials guided the development successfully through the process.

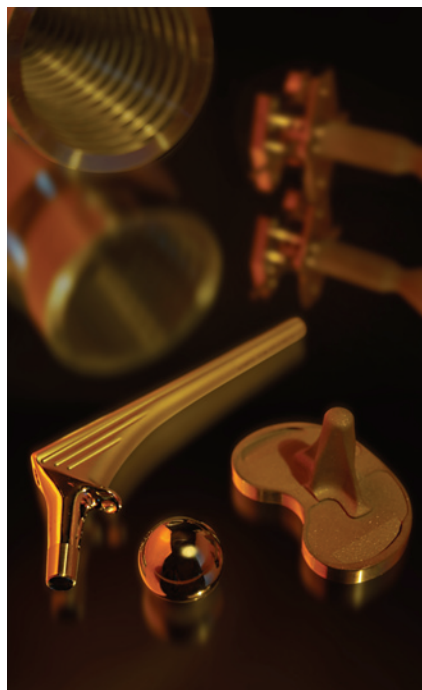
Fabrication Processes

Forging. Forging is one of the oldest metal-forming processes in the world. Early forged pieces have been dated as far back as 4500 BC. During the 10th century, forging was a primary process for making weapons such as

swords. We have come a long way since then, but the procedure continues to be used to create high-performance, high-strength products. Space-age materials benefited from the additional material properties imparted by the forging process.

Jet engines are a good example of an application in which forging is important. The development of rotating blades for turbine engines required the strength and cost benefits delivered by the process. Parts are typically finished in five-axis machining centers that produce a precise part with high quality and reliability within the designated price range. It was an ideal segue to using forging to manufacture medical implants. The requirements were virtually identical. The medical marketplace needed a reliable process to meet an exacting demand within a reasonable cost structure.

The migration to forged medical components is almost complete. Most implant products are now forged when possible. The challenge will be incorporating new materials and adapting



When it comes to advanced materials and demanding specifications, the next generation of orthopaedic implants takes manufacturing cues from an industry that understands performance and reliability.



A forged tibial tray (foreground), a compressor body for a supercooled infrared detector, and a rocket engine injector body have similar quality and reliability standards.

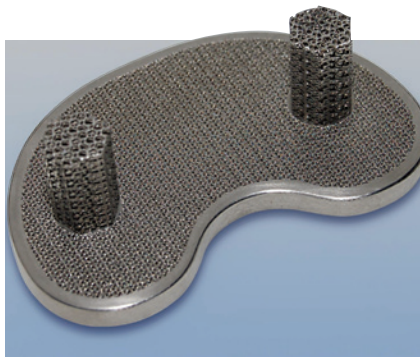
existing processes to form these new materials. Contract manufacturers that keep their creative tools sharp by working on a variety of similar programs, albeit in adjacent markets, could have a distinct advantage in developing new processes.

Photochemical Etching. Another fabrication process that relies on space-age technologies is photochemical machining (PCM). PCM can be found in the manufacturing of many medical devices. For example, in circuit-board manufacturing, which is a form of photochemical machining, PCM has moved away from circuit boards into chemically cutting solid sheet stock of medical-grade stainless steels and titanium up to 2-mm thick. Some of the more advanced electronic and electromechanical devices in the aerospace industry began adopting the PCM process to manufacture components because other conventional processes were either not cost effective or could not meet the physical requirements. The process uses a CAD-generated image of the required part configuration in 2-D. The 3-D aspect is created in the z-direction by the etching process, which can be an economical process for thin components in a variety of biomaterials. It is also a low temperature process that does not impart any

stresses on the parts. The accuracy and true position, especially in the xy direction, is extreme. The process has been embraced in medical manufacturing, especially in the maxillofacial area, where thin sheets of titanium (0.1–1.5 mm thick) are processed to form complex contourable meshes with intricate shapes and through-holes.

Although most companies that provide PCM offer a 2-D flat sheet process, some have been producing true 3-D photochemical etched products for the space and satellite market. This 3-D process has been adapted to provide true 3-D PCM products for medical use. It has been further developed into a process that provides textured surface treatments to enhance the bone-implant interface contact area and provide initial implant stabilization.

Taking the PCM process further, manufacturers have implemented lessons learned from manufacturing x-ray and gamma-ray lenses, which are used in an advanced space telescope that looks at solar flares on the sun, and adapted that manufacturing process to create an engineered titanium-foam product that is being investigated



High-precision photochemical machining coupled with stack lamination and diffusion bonding could enable the development of high strength implants with integral porous areas for bone and tissue attachment.

for use in spinal implants and other areas. This unique process platform gives a product development engineer a broad avenue of design that can combine physical strength requirements and bone integration. Both features are based on the specific design enabled by the titanium foam's porous structure.

Conclusion

In the future, manufacturers must focus on process reliability to yield a product that delivers the value proposition of price and lead time. Manu-

facturers that understand the unique process requirements of materials will lead the pack in producing next-generation implants. Improving the efficacy of bearing materials on light and inexpensive metals or plastics, porous PEEK for bone attachment, porous metal constructs, and patient-specific implants are a few of the technical challenges that exist today.

The evolution of implants during the last few years has involved less radical design change and more advanced materials and processes. These principles should carry implant manufacturing for the foreseeable future. As OEMs look to contract manufacturers to help them solve challenging manufacturing problems, those who understand the challenge, display a willingness to work on the solutions, and provide their valuable knowledge and experience will be the most successful. Space-age technologies and rocket science will play an important role in the success of these programs.

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