Elsevier Business Intelligence

PUBLISHED WEEKLY

"The Gray Sheet"®

MEDICAL DEVICES AND DIAGNOSTICS

NOVEMBER 4, 2013

Vol. 39, No. 44

3-D Printed Implants Hit The Market, Pave The Way For More Personalized Devices

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Multiple companies have recently used 3-D printing to make implantable devices that are customized to specific patients or to improve manufacturing precision and efficiency. The current activity could be a first step toward establishing a new paradigm of personalized implants, FDA and others suggest.

Additive manufacturing, or 3-D printing, employs computer models to build three-dimensional objects by printing layers of materials – including plastics/polymers, metals, powders and liquids – on top of each other. The process can be used to construct materials that more closely meet the specific needs and dimensions of specific patients, and to do so more cost-effectively than conventional manufacturing.

FDA has publicly championed the technique in recent months and is studying the manufacturing process within CDRH's Office of Science and Engineering Laboratories (OSEL). (See *"'The Sky's The Limit' For 3-D Printed Medical Devices, FDA Says" – "The Gray Sheet," Sep. 9, 2013*.) The agency touted 3-D printing in a report issued last week that was intended to draw attention to FDA's broad-based efforts to facilitate "personalized medicine," also focusing on genomic testing, stem cells and other topics. (See "FDA's Upcoming Drug/Diagnostic Co-Development Guidance Could Quickly Become Outdated" — "The Gray Sheet," Nov. 4, 2013.)

"3-D printing is transforming our concept of personalized medicine and medical intervention opportunities," FDA Commissioner Margaret Hamburg said during an Oct. 29 AdvaMedDx and American Association for Cancer Research meeting on personalized medicine in Washington, D.C.

FDA, in particular, emphasizes the promising future of 3-D printing. Its personalized medicine report highlighted a case that has already received significant media attention – a tracheal splint constructed at the University of Michigan to treat a critically ill infant.

The splint, developed by Glenn Green, associate professor of pediatric otolaryngology, and a colleague at Michigan, was made using CT images of the infant's airways and lungs. It was 3-D printed from polycaprolactone (PCL), a polymer that dissolves into the body within three years, and it was approved for use through FDA's emergency-use authorization program.

The splint "offers a glimpse into a future where truly individualized, anatomically specific devices may become a standard part of patient care," FDA states in the report.

"The first things that will be made with 3-D printing are going to be relatively inert tissues, like bone or cartilage," Green said in an interview. "Then, we'll get into increasingly complex tissues. For example, the most complex tissue would be something like the eye or the inner ear, where you've got a neurosensory organ and multiple different types of tissues need to interact correctly. So those are the most far away from creation."

"We can anatomically biomimic... We can mechanically biomimic... And then we can physiologically biomimic," said Oxford Performance Materials' CEO Scott DeFelice, explaining how 3-D printing customizes an implant to a patient.

While some of those applications are far off, the general technique of 3-D printing is being applied by device companies today. More than a dozen 3-D printed devices have already been cleared or approved by FDA.

Many of those are guides used to aid a surgeon in performing a procedure on a particular patient's anatomy. For instance, in October, DePuy Synthes CMF launched its *TruMatch CMF* (craniomaxillofacial) *Solutions*, surgical tools for customized facial reconstruction, orthognathic surgery, distraction and cranial reconstruction. (See *"New Product Briefs: Orthopedic Devices; Point-Of-Care Cardiac Assay; Auto-Injector" – "The Gray Sheet," Oct. 21, 2013*.) The system works with the firm's *ProPlan CMF*, a virtual surgical planning service that provides 3-D visualization of the patient's anatomy and includes 3-D printed patient-specific surgical guides and occlusal splints.

But companies have also recently started to use the technique for implants. "We're quite sure that we're going to see an explosion of devices manufactured by this technology," said FDA's Steven Pollack, director of OSEL.

Getting A Head Start With The Head

One initial foray into 3-D printed implants has been for craniomaxillofacial reconstruction products to fill voids in the skull.

Tissue Regeneration Systems Inc., founded in 2008, gained 510(k) clearance this August for the first of several planned products – its cranial bone void filler used to repair neurosurgical burr holes. The product is made by 3-D printing a bioresorbable polymer (PCL) that is porous and osteoconductive. The implant is covered with a coating to promote bone growth so that it will fully degrade within two to three years.

"To our knowledge, this is the first FDA approval of a coated bioresorbable skeletal reconstruction implant fabricated by means of 3-D printing," TRS President and CEO Jim Fitzsimmons said in an interview.

Fitzsimmons believes companies are starting with non-load-bearing cranial implants because these are easier to get through FDA. "Obviously getting approval of a skeletal reconstruction implant in a non-loading area of the body is much easier than getting approval in a load-bearing area," he said.

"3-D printing provides us with design and manufacturing flexibility, simplicity and the potential to reduce time to market" – Stryker's Patrick Treacy

The executive says TRS plans to use the same technology to create other implants for use in craniomaxillofacial surgery – and eventually those would be load-bearing, such as an implant for mandibular reconstruction. TRS has yet to commercialize its product, waiting until it gets several implants cleared or approved by FDA.

Another company with a 3-D printed cranial implant is Oxford Performance Materials, founded in 2000. The firm gained 510(k) clearance in February for its *OsteoFab* patient specific cranial device for bony voids in the cranial skeleton. The product was launched in the U.S. in March, and is being distributed by Biomet Inc.

OsteoFab is made from *OXPEKK-IG* polymers, which do not degrade and therefore stay intact in the body. The firm plans to use the same polymer to create other skeletal implants in the future, said President and CEO Scott DeFelice.

He explained that 3-D printing allows the company to manufacture products that mimic the body in three different ways.

"We can anatomically biomimic, so we can make it anatomically the right shape so it looks right. We can mechanically biomimic, which means we can make it mechanically similar to the adjacent bone. And then we can physiologically biomimic, meaning we can give it a structure and topography and a substrate that the bone will grow onto. It's a combination of those three things," he said in an interview.

Photo: Stryker

Stryker's 3-D printed *Triathlon Tritanium Tibial Baseplate.*

Stryker Corp. is one large orthopedic firm that has recently starting using 3-D printing to manufacture its implants. It employed the technique for its *Triathlon Tritanium Tibial Baseplate* device, which was launched in June following 510(k) clearance. The baseplate is used with the company's *Triathlon Total Knee System* for total knee arthroplasty. The device is made using laser rapid manufacturing.

Stryker CEO Kevin Lobo specifically highlighted the product and the promise of 3-D printing, particularly as a cost-saving tool, during the firm's 2013 analyst meeting on Sept. 5. 3-D printing has "really exciting potential for us," Lobo said. "The potential for significant cost savings is real, but it's an industry that's kind of in its infancy. So it will take time to play out."

Advantages Of 3-D Printing

Reduced costs are just part of the equation that led Stryker to choose 3-D manufacturing for the product, suggested Patrick Treacy, VP and general manager of Stryker's Knee Reconstruction division.

"3-D printing provides us with design and manufacturing flexibility, simplicity and the potential to reduce time to market," Treacy told "The Gray Sheet." "It allows us to integrate engineered porous metal geometries and solid structures for biologic fixation in specific locations beyond what is achievable through conventional technologies."

Most devices are made from subtractive manufacturing, wherein an object is carved out from a material, such as metal, plastic and ceramic. According to FDA's Pollack, that leads to wasted material that won't be used for the device. And it is difficult to create complex internal structures, he explained in an interview.

"3-D printing is a kind of additive manufacturing where you can – in a computer – create the device in its full form with its internal and external structure, and assemble it in one shot with that internal and external structure all built in," Pollack said.

Photo: Oxford Performance Materials

Oxford Performance Material's 3-D printed *OsteoFab* patient-specific cranial device.

For Oxford Performance Materials, 3-D printing "is a combination of having a really elegant process to manufacture that's highly economic, and being able to have … material that is osteoconductive, which is also a really big deal," for promoting bone growth, CEO DeFelice explained.

One type of 3-D printing used by device firms is called selective laser sintering, which is what TRS employs to manufacture its cranial void filler.

"These lasers pass through powder and drive the heating and cooling of the powder on a very small scale, and thus we are able to fabricate very sophisticated internal pore designs," TRS' Fitzsimmons said. "These types of implants with these internal designs wouldn't be able to be constructed with other more conventional manufacturing techniques."

The next wave of 3-D printing will be in tissue manufacturing, and there's already a company with the capability of printing cells and tissues, FDA's Pollack said during an Oct. 28 media tour of OSEL's 3-D printing lab in Silver Spring, Md.

"There is a company that is now manufacturing a five-nozzle device that can deliver plastic, extra-cellular matrix and collagen analogues – and the idea there is that you could build a tissue construct. So we'll work our colleagues in the Center for Biologics Evaluation and Research when that actually comes in as a technology used to make an artificial organ," he said

"There's a lot of this going on academia, there's certainly a lot of this going on industry," he continued. "We're trying to be there when the devices come to us to ask intelligent questions, questions that will move the technology forward."