3D Printing and Medical Devices

Is the Future Just a Button Away?

About the Author

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It was the kind of news that required a double take: a surgical patient has 75 percent of his skull replaced with a one-piece polymer implant? And that implant was created on a printer? Really?

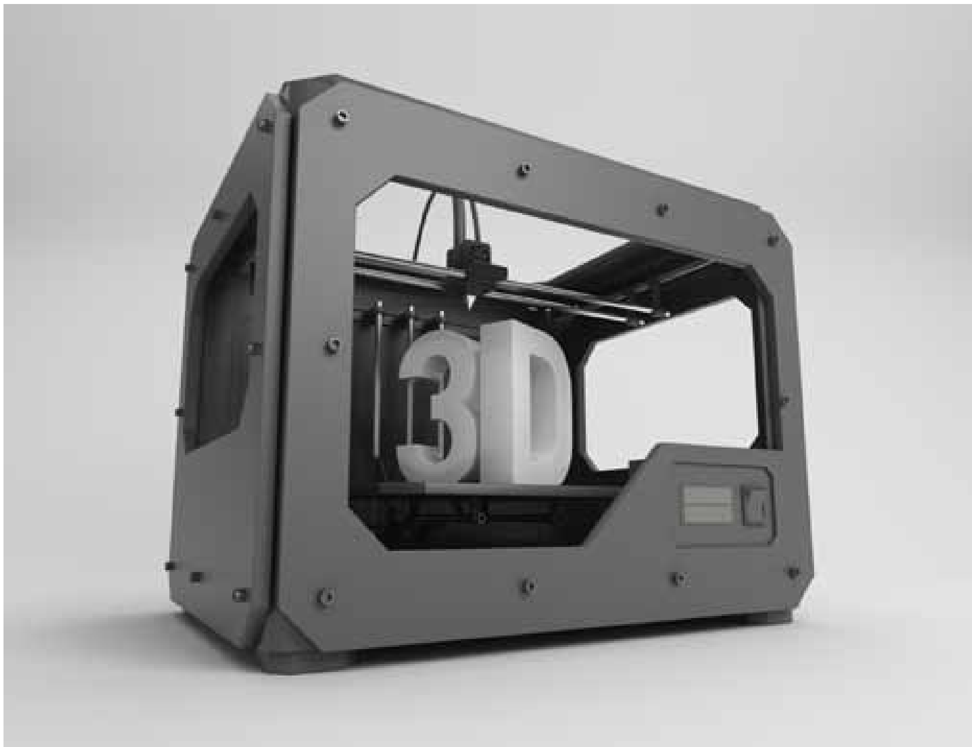
Really. The surgery took place on March 4, 2013, and the implant—made from a biocompatible material called polyetherketoneketone or PEKK—was designed and fabricated by the Connecticut-based biomedical outfit Oxford Performance Materials, or OPM. Over five days and working off a digitally scanned model of the patient's skull, the company used a process known as additive manufacturing, or 3D printing, to build the implant layer by layer so it would fit exactly in the void it was meant to replace. Once it was installed, because the implant was osteoconductive, it would stimulate bone growth—first along its perimeter, where it met the bone that was there, and eventually across its entire surface. This replacement, that is, would eventually become a part of the patient's head.

It was remarkable news, certainly; but in the end the most remarkable thing about it had less to do with the technology than where the surgery took place—in the United States. OPM, in fact, had been supplying patients in other countries with 3D-printed implants for more than a year, and 3D printing itself has been a work in progress for decades. This laser-sintered implant, on the other hand, on this particular patient, had only been made possible two weeks earlier when OPM's OsteoFab Patient Specific Cranial Device received 510(k) approval from the U.S. Food and Drug Administration. With that thumbs-up the medical device manufacturer could now sell its technology here on its own soil, and as this Long Island, NY, patient could attest, it wasted no time in doing so. The first 3-D printed skull implant in the United States? Now that was news.

A Solution Looking for Problems

Of course, anyone following the news these days, or even poking around on YouTube, knows at least something about 3-D printing. The technology, notes Craig Lanning, an instructor in the Department of Bioengineering at the University of Colorado Denver, "has really started to gain a lot of public attention." Lanning says he uses 3D printers to create medical device prototypes for the school's many researchers and medical professionals. "A couple of years ago it was very difficult to find someone who knew what I was talking about," he notes. "Now it's everywhere."

If you're new to the game (and a visit to one of the state-of-the-art leaders in this technology, such as the University of Texas at Austin's Laboratory for Freeform Fabrication, is out of the question), here's a primer: 3D printing, also known as additive manufacturing, creates three-dimensional objects from digital models. Often those models are rendered using computer-aided design software (CAD), but they can also originate from a 3D scanner—either a device specifically designed to work with 3D printers or, more commonly in the medical world, an MRI machine or CT scanner. Once a 3D printer receives its digital directions to print, it does so layer by specially formulated layer, fusing those layers, which range from soft composite materials to metal, as it goes. J. Tobey Clark, director of instrumentation and technical services at the University of Vermont and president of the nonprofit Healthcare Technology Foundation, describes 3D printing as a unique technology "in that you're able to build things that you can't build with any of the typical techniques that are used to make objects or parts." Those techniques are known as subtractive processes, explains Clark, because they take material away from whatever you started with until you have what you need. 3D printing, on the other hand, is an additive process, which permits the creation of "very complex shapes and parts."



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Given that cutting-edge capacity to create, the potential applications for 3D printing are enormous. GE, for example, has turned to 3D printing to produce fuel injectors for its jet engines. In the medical world, in addition to skull implants, the technology has been used to make a wide range of prosthetics, assistive devices like crutches and canes, artificial hips and kidneys, surgical models for physicians to use in complicated cases, and crowns, bridges, and a variety of other dental products. And researchers are now experimenting with so-called 3D bioprinting, through which bones, tissues, and organs may eventually be built layer by layer from living cells.

It's enough to make one's head spin, and perhaps not surprisingly, some have called the technology a LEAN replacement for traditional manufacturing, with its energyhungry factories and assembly lines and dependence on shipping across vast swaths of the planet. But those in the industry, like Matt Havekost, director of additive manufacturing sales at Advanced Technology Systems, Inc., in Minneapolis, MN, tend to think otherwise. His company has been selling 3D printers since 1996, Havekost says, and while over the years he's certainly watched the industry grow, he's never thought of it "as a replacement for traditional manufacturing." Instead, "it's a new opportunity that gives customers a way to produce fewer parts, more complex parts, and customized parts differently than they've ever been able to do before."

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— Craig Lanning, Department of Bioengineering, the University of Colorado Denver

For example, Havekost says, one of his customers uses 3D printing to produce MRI scan coils in custom sizes. "In the past they would have had two or three different tools they needed just to produce a one-size-fits-all coil; having the tools to make a hundred different sizes would have been just too expensive." With a 3D printer, he notes, "they can just do one-offs. They'll get an order for five different sizes and design and build them overnight. That's what this technology can do. It can make parts specifically for the customer's needs, and it can do it quickly and efficiently. And that's what is changing the game here. We're not replacing an existing manufacturing technique. It's a new one that has new offerings and new capabilities."

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— Purna Prasad, Stanford University Medical Center

UC Denver's Lanning agrees, but he also cautions that those "new capabilities" may be overblown. Just a few years ago, he points out, the preferred term for 3D printing was "rapid prototyping"—which, he says, more accurately describes the most common use for the technology: to quickly fabricate scale models that may or may not have the structural strength to be functional. Lately, though, in both the marketing materials of printer companies and in much of the media coverage, the "prototyping" aspect has been all but buried beneath the hype of object creation. "So now there's this common misunderstanding about what this technology was meant for and what its limitations are. Because a lot of people now see 3D printing as, 'Oh, I can just get the file for this part and print it out and boom, I'm done.' Well, that may be the case, it may not be the case, because it may be functional or it may just be a prototype." Lanning says that when given the chance, he likes to set the record straight. "It's like, '3D printing in the medical device world is growing so fast!' Well, yeah, it's gone from one use to two, so a 100 percent increase!" The fact is, he says, "it's still not a staple in the industry; for the most part it's still just rapid prototyping, and now it's slowly becoming 3D printing of usable parts."

Purna Prasad, director of clinical technology and biomedical engineering at Stanford University Medical Center, calls 3D printing "very promising," but he too suggests fascination with the technology may be blinding us to its current limitations—as well as limiting our vision of what it may ultimately prove most useful for. "It's really still in an experimental stage," he says. "Think about single-dimensional printing and how long that's been around, and what have we used it for? We've constricted ourselves to printing documents and sketches and things like that. There are so many more possibilities just with single-dimensional printing, I think we've hardly scratched the surface." In that light, Prasad says, 3D printing should be looked at as more than a novel means of producing solid structures.

"I see it as the future of medical imaging. Imagine a 3D printer with a built-in laser that can do a 3D rendering in thin air. A doctor having a telemedicine conference with a patient could show him how his heart is doing right there with a hologram in three dimensions. The impact of that—'look, here is what's happening, it's blocked and you have

The items shown here were all created on an in-house 3D printer at the VA Medical Center in Minneapolis, MN. The first photo shows an adjustable safety rail guide for a patient lift used during standing foot ultrasounds. The second photo shows a wall-mounted scope holder for use in the center's dermatology clinic. The third photo shows two versions of a prosthetic ankle for patients who spend more time standing than walking. The model allows normal ankle function when walking, but has a keychain remote control, allow the wearer to "lock" the ankle for long periods of standing. Photo Courtesy of April Eilers, Medical Media Service, VA.

only 25 percent left'—that would be huge." Prasad also envisions a world where medication patches and one-time-use, microprocessor-powered vital signs monitors could be printed out by patients in the comfort of their own homes. "Your doctor would send the prescription to your printer and you'd just print the device yourself. You'd never have to go to the pharmacy." Or, continues Prasad, imagine a scenario where 3d-printed EKG sensors, glucose-level sensors, or temperature sensors include imbedded patient-identification information that allows results to be transmitted instantaneously to the electronic medical record. It could be the clinical-technology or biomedical engineer's job to print those sensors, he notes, which may result in a shift "in the entire healthcare process, with clinical engineers doing more and more bedside care."

The bottom line, Prasad says, is that 3D printing "is a solution looking for a good problem. I think the solution is very good, and it has enormous applications. We just have to use it for the right problems. We need to use it where it will add value. If we just use it to manufacture parts, I don't think it will have much economic value." If, on the other hand, we think outside the box, "the whole playing field may change," says Prasad.

Another Tool in the Toolbox

One man who has been thinking outside the box is Steve Morin. Morin, the in-house "instrument maker" at Minneapolis VA Medical Center in Minnesota, has used a scanner, CAD, and a 3D printer to design and build everything from a centrifuge basket for low-temperature centrifuging to a prototype of an intubation device. "When a product is not available, my job is to make it a reality," he explains. He's also created a special window-blind knob that adds security in rooms of at-risk patients (the knobs have no sharp edges and cannot be pried); a wall-mounted radon test canister holder; and many prototypes for the facility's team of prosthetics research investigators. "That's where it really shines," he says, "is in proof-of-concept and prototyping for clinical research" where the products he's built would have been too expensive to create using traditional manufacturing techniques.

The printer, Morin adds, "allows us to keep lots of equipment in service long after OEM [original equipment manufacturer] support ends." The medical facility is more than two decades old, he explains, "and many of the companies that supplied the original products for the building are no longer around. So we're doing a lot of obsolete parts and engineering services for buildings facility management." And then there's the center's

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— Steve Morin, Minneapolis VA Medical Center

expensive biomedical equipment, Morin notes, some of which is also no longer supported. Replacing such equipment may not be an option, says Morin, "because we're often invested pretty heavily into it. So instead it becomes my job to try to stretch the service time for those devices."

One of his very first jobs using rapid manufacturing (Morin also has a full line of conventional machine tools in his shop) involved exactly that sort of problem. "We had an infusion pump and the one part that kept breaking was the latch that held the syringe in." It was a two-armed latch, he explains; one arm would break, leaving the entire load from the latch's spring on the other arm. Clinicians would typically continue using the latch with one arm—until it broke, too. "Well, we couldn't get that latch from the vendor, and it we couldn't find it anywhere. And it was a complex part with multiple curves that wouldn't have been practical" to build using conventional tools. So instead, Morin says, they worked with an outside contractor who had a 3D printer, "and since I had the chance to redesign the part from the get-go, I made it so it wouldn't fail." The latch that came off that printer was just a prototype, "but it was enough to prove the design well enough" that they then hired a molder to make 200 new latches. "So we proved the concept before we committed the money for tooling."

"We definitely don't rely on it on a day-to-day basis to produce parts for us, but I think it does give us a little more reach and a little more capability than most other biomed departments."
— Mike Phelps, Minneapolis VA Medical Center

That experience was enough to convince Morin and others at Minneapolis VA, including his supervisor—Mike Phelps, the facility's director of biomedical instrumentation and technology—that an in-house 3D printer would be worth the investment. Phelps says he sees the printer not as the answer to every problem his department faces, but as another tool in Morin's toolbox. When he needs a part, he says, "sometimes we go to the original equipment manufacturer, sometimes we buy it from a third party, and sometimes we go to Steve and he builds it for us." If Morin decides the 3D printer is the machine for the job, notes Phelps, then that's fine with him. "We definitely don't rely on it on a day-to-day basis to produce parts for us, but I think it does give us a little more reach and a little more capability than most other biomed departments."

Sometimes the product that rolls off the printer is exactly what Phelps needs—strong and durable enough to do the job. Other times "it's relatively fragile, so we can't actually use it for production purposes, but it does help us determine whether the shape and configuration and sizing are correct. It gives us a really good idea whether our design is going to work for us without having to spend a lot of money to have it fabricated out of a more traditional material or through a more traditional processing method."

When he was in graduate school, Phelps recalls, he had friends working at other companies who introduced him to 3D printing and rapid prototyping, so when it was his turn to pitch the idea to his facility's leadership, the concept wasn't new to him. "I talked about it as this 21st-century kind of technology," he says, one that would take them beyond the "traditional sheet-metal cutters and drill presses and CNC machines you'd see in a regular industrial setting." And to have that technology and that capability in-house, he said—"that would be a huge advantage to us, especially in terms of our research projects," but elsewhere, too, "including biomed." 3D printing, says Phelps, offers "versatility and affordability" in cases where other avenues of production are either too complex, too expensive, or both. "It's been a very good investment from our medical center's standpoint."

The Fine Print

That investment, obviously, may not be for everyone. While relatively low-quality, consumer-level 3D printers can now be purchased for under $2,000 on eBay and elsewhere, professional printers cost much more and industrial-level "machines that are producing quality parts start at around $200,000," says UC Denver's Craig Lanning. "And that is very difficult to justify [for a medical facility] when you consider how the devices that need maintenance are failing." Still, Lanning notes, as the price for 3D printers comes down, that equation might change, and at some point in the future there may be a scenario where "when something breaks, for example, they could just contact the company, have the company send them the part file, and then they'd have a room with a 3D printer that is FDA certified to make that part." With a set-up like that, says Lanning, there would be less need for inventory and space, less environmental impact (no overnight shipping via jet), and parts would be produced only when they were needed.

Until prices do come down, larger operations such as the VA system, as well as research facilities where investigational work may be aided by the rapid-prototyping capabilities of the machines, may have better financial leverage. "I could even see different VA hospitals coordinating with each other," says Steve Morin, "so that the VA in Denver, which has a printer that works with metal, and a VA-affiliated facility in Pittsburg, which

Craig Lanning, an instructor in the Department of Bioengineering at the University of Colorado Denver, holds a 3D printed model that is used to explain heart defects to young patients at Children's Hospital Colorado.

3D AND THE FDA

According to Craig Lanning of the University of Colorado Denver, he and others who rely on 3D printers to create medical device prototypes would like to see any regulations governing such devices "focus not so much on the device itself but on manufacturing practices and using good laboratory processes." It should remain up to the physician, says Lanning, to determine whether a one-time-use device is appropriate in a given situation for a given person. "I think we need to get that really well hammered out, and maybe put it into law—that when these devices are made and used, here's how it's done and here's who is liable and who is not." Only then, Lanning predicts, will printed devices designed for direct contact with patients really gain acceptance in the medical world.

The FDA, meanwhile, is using 3D printing in its own offices (see http://blogs.fda.gov/fdavoice/index.php/2013/08/fda-goes-3-d/) to develop "new tools, standards, and approaches to assess the safety, effectiveness, quality, and performance of FDA-regulated products." And in the agency's Office of Science and Engineering Laboratories, scientists are "investigating how the technology may affect the manufacturing of medical devices in the future," as well as "how different printing techniques and processes affect the strength and durability of the materials used in medical devices." According to agency spokeswoman Susan Laine, as the FDA learns more about the 3D process it may consider "drafting guidance to address specific additive manufacturing questions." Meanwhile, she says, standardization issues are already being considered by the Committee on Additive Manufacturing at ASTM International (formerly known as the American Society for Testing and Materials; see www.astm.org/COMMITTEE/F42.htm).

uses another form of additive manufacturing, and then our facility here in Minneapolis—if we all knew each other's capabilities" digital files could be sent from one facility to another for production.

Tobey Clark of UVM thinks it will take prices dropping "below $10,000 or $5,000 for high-resolution printers" before they become standard equipment in clinical engineering departments. He also sees a need for significant improvement in materials quality ("we need hard materials that don't deform at high temperatures") and price. His group works with one company that is collecting used 3D printer materials for re-use. "I think that kind of recycling is going to lead to a reduction in cost," Clark says.

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— Jennifer Jackson, Decars-Sinai Medical Center

But there are others costs that have to be considered as well, notes Jennifer Jackson, director of clinical engineering and device integration at Cedars-Sinai Medical Center in Los Angeles. Her facility does not have a 3D printer (although one of her colleagues has turned 3D printing into a hobby and recently delivered a presentation on the technology), but she could see one landing there eventually—given the right conditions. "My guess is vendors are going to want their piece. They're probably going to sell their very specific 3D printer that is the only printer that will produce parts a certain way and that the FDA has signed off on, and you will need to take a $10,000 training course in order to learn how to make their specific parts. Unfortunately, it has the potential to become a very, very expensive enterprise very quickly."

There's liability related to use of a product on or around patients, of course, but then there's also the risk associated with building replacement parts for other companies' devices.

Still, says Jackson, she's willing to keep an open mind. "I love the idea of introducing new technologies and playing around with new service models, including how do we support the parts in our system, but I'm enough of a businesswoman to know that this could be an opportunity or it could be a threat to the current producers of parts. I know we're a long way away from having what is basically a hobbyist's tool to a professional part of the supply chain. I would love if the technology and the industry would get to the point where it would be an acceptable alternative to our current sourcing models, but I'm not expecting it to happen next year."

Scott Skinner, director of clinical engineering with Norton Healthcare, feels similarly. He can imagine 3D printing finding a home in his wing of the company some day, he says, but not yet. "But I do find it exciting because it really may be one of those 'disruptive innovations'—it could fundamentally change the way things work. If we had a business problem related to the design of a product and we could quickly develop a functional model of a device that might solve that problem that we could evaluate ourselves," this would turn the vendor-hospital relationship on its head. "Historically that process has been mostly vendor driven," says Skinner, "where vendors reach out to hospitals" and ask for input on their devices. "This could change it to a completely different paradigm where the hospitals could instead be pushing information into the medical device industry." Hospitals, in other words, would essentially become manufacturers. "And obviously, that then raises some interesting regulatory and risk-related questions." For example, Skinner asks, "if we innovate a product within our organization and a vendor decides to leverage a component of it to give us a workable solution, what happens if they market that to other hospitals? At that point what liability do we have for the input that we gave for the design?"

That issue—liability—is what some have pegged as 3D printing's "elephant in the room." There's liability related to use of a product on or around patients, of course, but then there's also the risk associated with building replacement parts for other companies' devices. "If you're a biomedical equipment technician and you're repairing a device and you use a part that is not approved by the company to repair it," says Lanning, "you may then take on some responsibility if the device fails again." For now, at least, most if not all facilities that use 3D printers in conjunction with biomedical services are limiting their application to parts and devices that do not directly impact patients. And it's likely to stay that way for some time. "In the medical world," Lanning notes, "people are very hesitant to go out on a limb. Everyone knows what can happen if you do."

3D and HTM

The ways in which 3D printing might impact healthcare technology management professionals such as clinical engineers and biomedical equipment technicians (BMETs) are generally up for debate. Advanced Technology Systems' Matt Havekost believes that HTM pros are unlikely to be tasked with maintaining printers, as companies like his, which sell the printers, also "provide maintenance people who take care of the machines." (Interestingly, 3D printers are often used to print out replacement parts for other printers.) Materials supply would also be a non-issue, says Havekost, as companies like his provide those materials in spools of filament in smart chip-embedded canisters. (The smart chip communicates with the printer, adjusting settings and parameters and "managing everything it needs to know related to that material.") Loading canisters into the machine is a simple process, says Havekost, and some machines even switch automatically between canisters according to project demands.

Many HTM professionals will wonder whether having a 3D printer on hand will actually help them with their jobs. As Craig Lanning notes, most hospitals use standardized devices, so "if you have one IV pump, all the others are exactly the same." When something breaks, that is, it's very easy to either grab a new part from inventory, to temporarily replace the entire device with an identical unit from elsewhere in the facility, or, worst case, order the part from the manufacturer and have it delivered overnight. But as Morin, of the Minneapolis VA, points out, because things seem to work well the way they are doesn't mean there's not a better way. "In our case," he recalls, "it was sort of this chicken-and-egg scenario. We didn't really know what the machine could do until we actually began to put it through its paces."

Still, Morin says, he's not so sure that every HTM professional out there would leverage the technology in a way that justified the investment. "The problem is that biomed techs are very specialized in their training. To ask them to do parts manufacturing, you're really asking for a different discipline." That said, he adds, "every biomed tech who works in a hospital has access to 3D scanning capability with MRI machines and CT scanners, and they're already used to using that equipment and handling 3D image data. What they're not familiar with is how to take that data and turn it into a CAD model and into hard objects." Clark agrees. Often the files that come out of a CT scanner aren't compatible with the 3D printer, he says, "so you have to do a file conversion and some manipulations to get it into CAD. And that's the hard part—producing the 3D files that you send to the printer."

Training is available for all of this, and vendors typically offer it for free. Even so, notes Cedars-Sinai's Jackson, the technology may not be for everyone. "There is such a wide range of technical skill with the BMET professionals out there," she says. "There are some who could probably do everything without a problem—design the parts and devices they needed and build them with the printers, but others wouldn't be so comfortable doing that kind of work, or even learning those skills."

A Glimpse of the Future

To get an idea just where 3D printing might ultimately find its home in healthcare, consider its place now, in one of the country's leading medical facilities, Rochester, Minnesota's Mayo Clinic. There, Tom Halvorsen manages the facility's mechanical engineering team and machine shop, which he describes as a medical device and manufacturing house. "We support the whole medical practice and we support the researchers , so we're always making custom devices." And to facilitate that work, in addition to all the standard machining tools one would expect to find in a "full-blown

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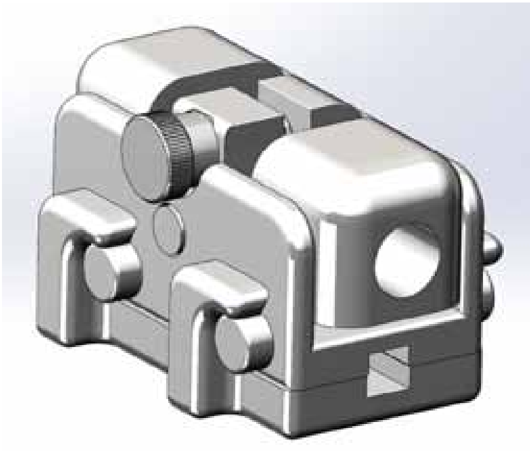
— Tom Halvorsen, the Mayo Clinic



Here are two examples of additive manufacturing devices made at the Mayor Clinic. The first image shows a surgical arm cover used to hold a patient's arm in place for imaging. The second image shows a keeled spine graft burr holder, a surgical tool used during disk replacements.

machine shop," they have three 3D printers. "We're very committed to 3D printing," Halvorsen says. "The primary way we've been using them is to create pre-surgical planning models for our orthopedic surgeons. We've done hundreds of those."

Many of those models are strictly prototypes, he explains, "more show and tell," but one of the machines uses manufacturing-grade materials and can create "complex contours and real manufactured parts that we're delivering to customers." Typically Halvorsen and his team use the 3D printers

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only when it makes sense to do so—for complex designs, for example, that would be too difficult to machine; but the speed at which the printers work also plays a factor, "so we're using them more and more."

While doctors and researchers most often place the work orders, biomedical technicians usually provide support for the products that Halvorsen's department develops. "So when we design something, a custom device, we create a support package that includes a user manual and turn it over to the biomed technicians to do support, repair, and maintenance." In some cases, technicians with experience in the area for which the product is being designed provide input and help develop requirements for the part. Halvorsen says a recent project entailed creating a small centrifuge insert—"a piece that would really solve a need they had for centrifuging blood products." His department received input on how to design the insert from both the clinical users and the equipment-services users, he says. "They actually made an initial prototype out of RTV silicone, and then we designed and printed a rapid prototype that worked out great."

Other creations from his 3D printers include cable connectors and cable housing, says Halvorsen. "Quite often our equipment-services people will need a custom-made cable. These aren't things you can go to a Digi-Key catalog and find. So we'll make up a cable and print out a 3D cover or enclosure for it." Halvorsen calls 3D printing an "enabling technology." It's "kind of onesy-twosy stuff, but it allows you to break through some barriers where you used to say, 'We can't do that.' Well, now you can ."

Interestingly, Halvorsen adds, almost everything his department does falls outside the purview of the FDA. "When we make things for infrastructure, like the centrifuge insert, there is no FDA involvement there." And when a device is made for a single physician working with a single patient, "the doctor can do almost anything he or she wants, and they assume liability" for the device (the device would go through a series of internal safety reviews first, says Halvorsen). "Investigational devices," meanwhile, would typically qualify for FDA exemptions. "The work we do for research purposes does not usually involve the FDA."

Cleaning and sterilization, however, are other issues altogether. "Those are Joint Commission concerns," Halvorsen says, "and they're becoming really particular about it." As the department develops custom devices for use in clinical practice, "we have to be very conscientious and very thorough in developing instructions for use and for cleaning and sterilization." With 3D-printed models, Halvorsen adds, porosity can be a problem, mainly because of the material itself. "And pores are places where bugs can reside and grow." Halvorsen calls this a "technical hurdle," something "the whole 3D printed market in the medical arena is really serious about addressing."

Halvorsen thinks that as 3D printing becomes more common, HTM professionals will increasingly be called upon to provide requirements and support to those "doing the designing and developing." They should "understand both the capabilities and limitations" of the technology, he says. And above all, they should embrace it. "You know, you can go ahead and make a request for something that would have been inconceivable to make just a few years ago. You look at a device and say, 'there is no way that I can machine that,' but now that limitation is off the table. Now you can print it. You can print contours and you can print profiles that were never even possible before. So in some ways, as you're thinking about solutions to problems, 3D printing really opens up a lot of new doors."