System Safety in Healthcare

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Patient Safety from Advances in 3D Printing

A new technology, three-dimensional (3D) printing, has the potential to change the medical world. Objects are made by fusing or depositing materials, such as plastic, metal, powders, liquids or living cells, in layers to produce a 3D object. This technology started in manufacturing and was used to create spare parts for airplanes, eliminating the need for constructing manufacturing prototypes and producing new components within hours instead of weeks.

The application of this technology in healthcare is growing. It is now used in the creation of customized prosthetics, implants and anatomical models. Its usage is expanding rapidly in other areas of healthcare, including pharmaceutical research regarding drug dosage forms, delivery and discovery [Ref. 1].

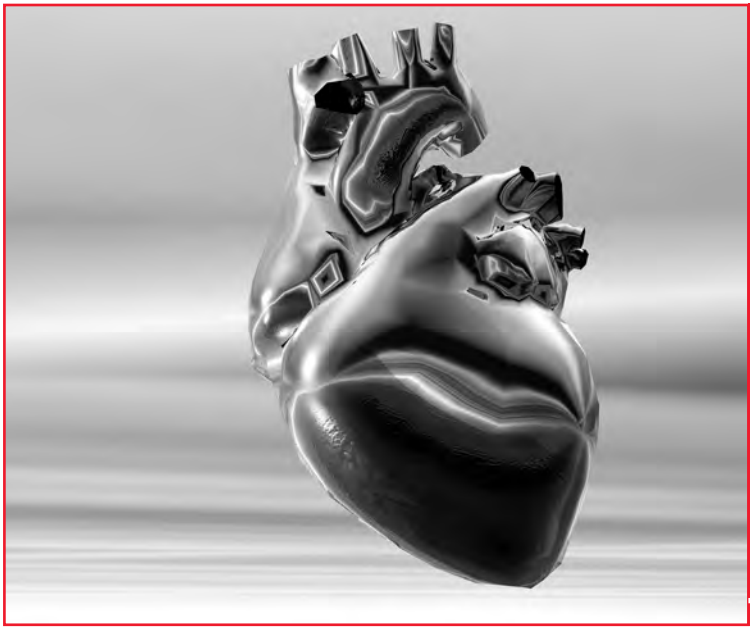
Organovo, a company based in San Diego, California, uses 3D printing to fabricate living human liver and kidney tissues for pharmaceutical research. The company reportedly plans to produce liver and kidney organs generated from a patient's own cells. The company expects it will deliver tissue suitable for surgical therapy and transplantation, with a longer-term goal of replicating entire human organs for transplant. It expects it could print partial livers for human implantation within four to six years [Ref. 2].

Patient Safety Benefits

Current treatment for end organ failure relies mostly on organ transplants from living or recently deceased donors. There is a chronic shortage of human organs available for transplant. This shortage may be decreased for certain indications by using cells taken from the organ transplant patient's own body to build a replacement organ. The transplant organ can be printed within 24 hours from CT scans and MRIs. The technology is not yet mature, but holds promise. It may take several years — likely more than five to six years — to fully develop and clinically validate the transplantable kidney and liver, along with the time it takes to obtain FDA approvals.

Daniel Crawford, the founder of Formlabs, recently explained how this technology can be beneficial to patients. "Doctors can now study highly accurate 3D models of a patient's musculoskeletal system," he said. "These 3D reproductions help medical specialists diagnose ailments, plan for surgery, provide education to the patient and more. Based in Belfast, United Kingdom, Axial3D uses a patient's unique CT and MRI scans to create an exact replica. Axial3D's clients include the public and private healthcare sectors and disciplines that include orthopedics, oncology, oral and maxillofacial, trauma and transplant surgery. Axial3D offers surgeons unprecedented insight beyond conventional 2D patient scans data and, in turn, will potentially elevate patient care across a wide spectrum of disciplines. Custom 3D modeling is transforming every step of the doctor-patient interaction" [Ref. 3].

A leading U.S. manufacturer of 3D printers, Stratasys Ltd., is making big inroads in the surgical field [Ref. 4]. They described their work at the Gates Vascular Institute in Buffalo, New York in a report: "The partnership between neurosurgeon Adnan Siddiqui and a University at Buffalo biomedical engineer, Ciprian Ionita, Ph.D., resulted in the creation of lifelike, patient-specific 3D vascular flow models known as phantoms. Dr. Siddiqui was convinced that 3D printing could create more lifelike vascular models than existing glass and silicone models and believes that the models could be used to plan for difficult endovascular cases. At the same institute, Vijay Iyer, an interventional cardiologist specializing in structural heart disease, asked for a patient-specific, multi-material heart model that he could use to plan a difficult and relatively rare transcatheter mitral valve replacement. They collaborated with Stratasys engineers to create a multi-material 3D structural heart model from the



> "...Vijay Iyer, an interventional cardiologist specializing in structural heart disease, asked for a patient-specific, multi-material heart model that he could use to plan a difficult and relatively rare transcatheter mitral valve replacement. They collaborated with Stratasys engineers to create a multi-material 3D structural heart model from the patient's CTA scan and other imaging studies.... His practice allowed him to better estimate the size of the replacement valve and to see the effect of its placement on blood flow in the aorta."

patient's CTA scan and other imaging studies. After attaching the heart model to a cardiac pump, Dr. Iyer was able to deploy a demo valve under fluoroscopy just as he would in the catheterization lab. His practice allowed him to better estimate the size of the replacement valve and to see the effect of its placement on blood flow in the aorta."

Medical Modeling, a subsidiary of 3D Systems, has developed a Craniofacial Model Skull library. For a few thousand dollars, you can get a collection of 16 skull models detailing the "characteristic dysmorphology of the particular congenital anomaly prior to any intervention" in a wooden display case. The National Institutes of Health even has an exchange where you can share and download medical models and 3D print them [Ref. 5].

According to Massachusetts General Hospital, 3D imaging produces studies that are faster and easier to read [Ref. 6]. They support communication among radiologists, referring physicians and patients. They report that, with no added demand on a patient's time during an exam, 3D imaging can:

- Improve diagnostic confidence
- Replace more invasive and expensive diagnostic procedures, reducing the risk of complications
- Minimize exploratory surgery
- Facilitate non-invasive surgical planning
- Reduce operating time
- Minimize damage to healthy tissue by targeting the treatment area
- Serve as easy-to-read visuals for patient education and communication

Success Example 1

The following case history is a good example of how 3D printing can help patients recover faster [Ref. 7]:

"Ariana, a 17-year-old teen, became the first patient at the Children's Hospital of Michigan, a part of the Detroit Medical Center (DMC), and the first in Michigan, to benefit from a revolutionary 3D printed heart model to aid heart specialists in treating a very large, complex aortic aneurysm.

"In November 2014, Ariana's mom, Jacqueline Foster, decided to have her four children undergo an electrocardiogram (EKG), a test that checks for problems with the electrical activity of the heart, as a precaution since one of her sons had a heart murmur.

"She received a cardiac catheterization, a procedure involving a tube that is placed in her blood vessel, so that doctors could diagnose and potentially treat her condition.

"What looked to be a relatively routine procedure turned into a major turn of events when it was discovered that Ariana had a huge aortic aneurysm, complicated with a tortuous aorta that has a distorted shape or path. This very dangerous condition could take Ariana's life in the future.

"Thomas Forbes, M.D. and Daniel Turner, M.D. collaborated on the use of a revolutionary tool using computed tomography (CT) to generate 3D printed models of Ariana's heart.

"The model was developed by Materialise, a leading provider of 3D printing software and services, based locally in Plymouth, Michigan. Through their Mimics Innovation Suite software and HeartPrint services, Materialise was able to transform Ariana's CT scan into a 3D printed, lifelike replica of her aorta enabling the cardiol-

ogy team to precisely plan treatment and practice the intervention prior to the procedure. This allowed the team of doctors to identify potential issues they might find and precisely pinpoint the placement of the stent without surprises."

Success Example 2

Scientists at Rice University say that 3D printed materials can be designed to better determine how tumors generate, which may make it easier to test treatments for bone cancer [Ref. 8]. Scaffold porosity, which is the percent of empty space created by pores in a structure, along with the size and shape of pores, can change the permeability of nutrients and media, impact cell attachment, and even facilitate cell migration. Therefore, 3D printing lets scientists get closer than ever before to impersonating the architecture of actual bone.

> "3D technology is still in its infancy, and yet it holds a lot of promise. The potential applications are endless and can have a huge impact in transforming patient care. This can potentially also improve patient safety and operational systems while hopefully keeping costs at bay."

Success Example 3

Cornell University researchers recently developed a realistic-looking prosthetic hand — at a cost of just $50 — using 3D printing, soft robotics and lithography. "It can handle decidedly more delicate tasks, because it is the exact opposite of the stereotypical clunky metal robot most people imagine: it can grip, sort and sense what it is touching, and not only resembles, but also feels like a human hand," a report stated. "However, the Cornell research team had not yet been able to connect the hand to brain waves, to give it a real sense of touch." The report goes on to say that a research team at the University of Wollongong (UOW) has introduced soft robotic hands that are extremely close in both function and feel to a real human hand [Ref. 9].

The Future

3D technology is still in its infancy, and yet it holds a lot of promise. The potential applications are endless and can have a huge impact in transforming patient care. This can potentially also improve patient safety and operational systems while hopefully keeping costs at bay.

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