3D-Printed Prosthetics Roll Off the Presses

Sujata K. Bhatia, M.D., P.E.
Harvard Univ.
Shruti Sharma
Massachusetts Institute of Technology

From implant design to scaffold development and prosthetic construction, 3D printing offers unique solutions for complex problems in the biomedical sciences.

Three-dimensional (3D) printing, also referred to as rapid prototyping (RP), is an emerging technology that has the potential to revolutionize the medical landscape. Developed over 30 years ago, 3D printing has only recently started receiving attention from clinicians and biomedical engineers. Unlike traditional printers that produce two-dimensional objects, 3D printers layer plastics, metals, or other polymers to create a three-dimensional object.

Chemical and biological engineers are harnessing the potential of 3D printing through the development of new inks, 3D printing software, and multi-nozzle printers. Considering 3D printing's rapid development, the near future promises growing utilization and development for 3D-printed prostheses for individual patient care.

This article discusses the key features of 3D printing and the various 3D printing techniques. It focuses on the clinical applications of this technology, specifically the use of 3D printing to create bone implants and prosthetic sockets.

3D printing basics

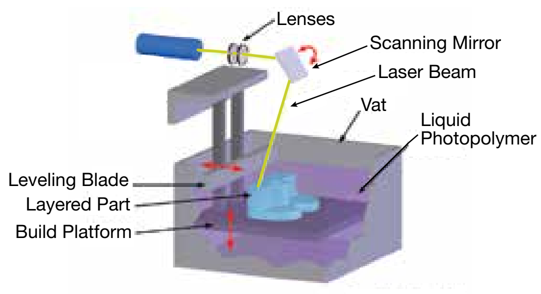
The first 3D printer was developed by Charles Hull, executive vice president and chief technology officer at 3D Systems, who obtained a patent in 1986 for stereolithography — the process of printing successive layers of material on top of each other to create a three-dimensional object *(1)*. Hull also developed the STL (standard tessellation language) file format, which is still the gold standard for data transfer between computer-aided design (CAD) software and 3D printers. In 1993, Michael Cima and Emanuel Sachs of the Massachusetts Institute of Technology patented the first 3D printer capable of printing objects made of plastic, metal, and ceramic *(2)*. Since then, several companies have formed to create 3D printers and their associated inks.

There are four major 3D printing methods: stereolithography, inkjet printing, selective laser sintering, and fused deposition modeling.

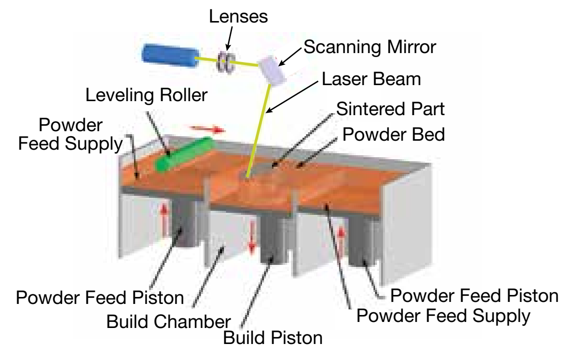
Stereolithography employs ultraviolet (UV) radiation to initiate the curing of defined photoresin layers. In one setup (Figure 1), a UV laser traces a 2D cross-section that is then submerged in a tank of liquid photoactive resin, which polymerizes upon illumination. After one section is complete, another 2D cross-section is traced and then layered on the previous section. This process is repeated until the composite slices form the completed 3D object. Another stereolithography layout does not depend on a bath of resin, but instead uses a movable platform suspended above a resin reservoir.

Both designs are limited in that they can only use one resin at a time, because there is usually only one reservoir or tank of ink. Moreover, because the resins need to be liquid, they are made of either acrylic or epoxy, both of which can be brittle and shrink upon polymerization *(3)*.

Inkjet printing, a concept that was originally patented



▲ **Figure 1.** Stereolithography uses a highly focused (via lenses and mirrors) UV laser to trace out (solidify) cross-sections of a 3D object in a vat of liquid photoactive polymer. Once a layer is traced and solidified, a leveling blade moves across the surface to smooth it out. The platform is then lowered by a distance equal to the thickness of each cross-section and the next layer is formed. This process is repeated until the object is complete. Image courtesy of CustomPartNet.



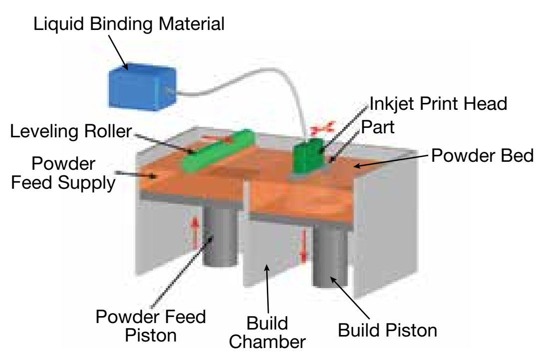
▲ **Figure 3.** Selective laser sintering uses lenses and mirrors to focus a laser beam that sinters powder into each cross-section of the 3D object. A platform moves down, exposing the part to a thin layer of powder, which is then leveled and smoothed by a roller. A laser beam then traces out the target shape, sintering the powder in that area. Once the layer is built, the platform moves down and the process continues. Image courtesy of CustomPartNet.

for 2D printers, has also found application in 3D printing. In 3D inkjet printing (Figure 2), solid powder particles are bound together by a printed liquid material to create a 3D object. The 3D inkjet printer consists of a platform, onto which the printing powder is placed, and an inkjet printing head, which deposits (or prints) liquid binding material onto the powder to form one layer of the object. After a layer of powder has been evenly placed on the platform, droplets of binding material are printed onto the layer and then solidify. The unbound powder is released and a second layer is printed and bound to the previous layer.

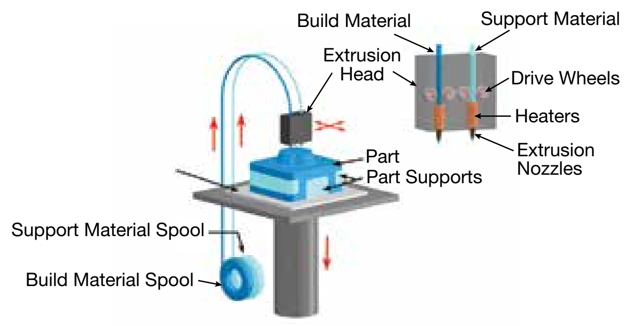
An advantage of inkjet printing is that it is does not require photopolymerization, which allows for the use and development of a broad range of printing inks. Furthermore, powders of different materials can be combined to generate a heterogeneous 3D model. However, the polymer glues that bind the powders are toxic *(4)*.

Selective laser sintering (SLS) is similar to inkjet printing in that it uses powder-based materials. SLS (Figure 3), however, utilizes high-power lasers to sinter polymer powders, avoiding the problem of glue-related toxicities *(5)*. Objects made by SLS are easily deformed by the repeated heating and cooling associated with the laser's cycling, which makes it difficult to produce an object of a precise size and shape. The ability to control these aspects of the object is essential for medical devices and prosthetics to fit exactly in specific locations.

Fused deposition modeling (FDM) uses a printer (Figure 4) that consists of a printing head, which heats the ink to a semi-molten state, and a stage, onto which the semi-molten thermoplastic inks are deposited in successive



▲ **Figure 2.** In inkjet printing, a platform moves down to expose a thin layer of powder, which is then smoothed and leveled by a roller. A print head deposits the liquid binding material onto the targeted region of the powder layer. This area solidifies, forming the first cross-section of the 3D object. After a layer is built, the platform is lowered and a new layer of powder is added and leveled, then the print head deposits the binding material to solidify that layer. This process continues until the entire object is built. Image courtesy of CustomPartNet.



▲ **Figure 4.** In fused deposition modeling, a polymer is extruded through a nozzle and deposited onto a platform to form each layer of the 3D object. The print head, which is heated, can be supplied with the build material (the material that makes the final part; dark turquoise) and support material (used to support the object while it is being built; light blue) as filaments or plastic pellets. Once a layer is completed, the platform is lowered, and the process begins again. The layer thickness is determined by the diameter of the extruder die. Image courtesy of CustomPartNet.

layers to form the 3D structure. An advantage of FDM is its ability to print objects from multiple types of material, including ceramics, polymers, metals, and biodegradable materials. However, heterogeneities arising during the melting process may create internal defects, an issue that is under active investigation *(6)*.

Digital imaging

Medical implants and prosthetics have been created with RP technology in recent years, as patient-centered care is demanding a patient-specific approach to medicine. In essence, virtual models created by CAD are converted into physical models by breaking the object into a series of slices of finite thickness. The 3D printer fabricates each slice, sometimes using a combination of inks of various materials, and unites them to form a complete object.

The digital representation of the part to be printed can be sourced from individual patient data that depict soft tissue, vasculature, and other structures. With the evolution of multi-detector computed tomography and magnetic resonance imaging, high-resolution 3D image data can be acquired within a single breath-hold. The spatial resolution of such images made with high-quality contrast is 400–600 μm *(7)*. Cone-beam computed tomography, positron computed tomography, single-photon-emission computed tomography, and ultrasonography are other noninvasive imaging techniques that can acquire data for RP *(8)*.

The 3D images captured from the patient are computationally transformed into a 3D triangle mesh, which is comprised of a set of triangles connected by their common edges or corners. The 3D mesh is further processed using CAD software. Once the data have been optimized, they are sent to the 3D printing machine for production.

Medical applications

Three-dimensional printing provides opportunities for customization and precision not realized before. Vascular networks *(9)*, bandages *(10)*, bones *(11)*, ears *(12)*, exoskeletons (Figure 5) *(13)*, windpipes *(14)*, and dental prosthetics *(15)* are just a few examples of 3D-printed devices in clinical use.

To create a vascular network, Miller, *et al.*, printed rigid 3D filaments of carbohydrate glass. The filaments were used as a cytocompatible sacrificial template in engineered tissues containing living cells to generate cylindrical networks that could be lined with endothelial cells and perfused with blood under high-pressure pulsatile flow *(9)*.

To make customized wound dressings, Jeong, *et al.*, printed bandages containing living cells. When placed on the wound, the bandage, which the researchers call a microvascular stamp, releases angiogenic factors that promote the growth of blood vessels. Built of layers of hydrogel made of polyethylene glycol and methacrylic alginate, the stamp contains pores that allow the growth factors to leak out and deposit in a defined pattern on the wound *(10)*.

▲ **Figure 5.** A 3D-printed robotic suit has given a woman who was paralyzed from the waist down after a ski accident the ability to walk again. Debuted in February 2014 by 3D Systems, the robotic suit is the first of its kind. To construct the components, Valencia, CA-based 3D Systems obtained scans of the patient's thighs, shins, and spine, and then printed these using an SLS-type printer. The printed parts were then integrated with mechanical actuators and controls manufactured by Ekso Bionics. Image courtesy of 3D Systems.

An ear (Figure 6) was also created by 3D printing a cell-seeded hydrogel matrix in the shape of a human ear, along with an intertwined conducting polymer consisting of infused silver nanoparticles. The printed ear exhibits enhanced auditory sensing for radio-frequency reception, and complementary left and right ears could listen to music in stereo *(12)*.

A customized bioresorbable tracheal splint was 3D-printed using a computer-aided design based on a computed tomographic image of the patient's airway. The splint (Figure 7) was used to treat a toddler with tracheobronchomalacia, a life-threatening disease that leads to respiratory insufficiency *(14)*.

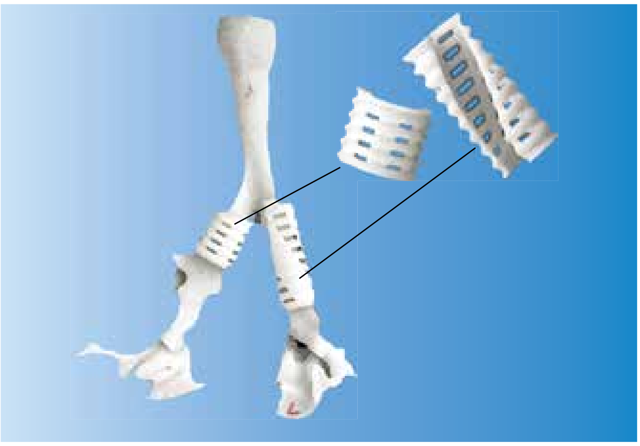
▲ **Figure 6.** Scientists at Princeton Univ. used a 3D printer to fabricate a bionic ear that was able to receive signals across a frequency spectrum of 1 MHz–5 GHz (beyond the 20 Hz to 20 kHz range of a human ear). Image courtesy of Michael McAlpine, Princeton Univ.

The application of rapid prototyping to design prosthetics and bone implants is an exciting and expanding area for 3D printing.

Implant and tissue design

When bone is lost due to injury, the defects are filled with natural bone. Studies have shown that an artificial material with the same properties (*e.g.*, density, porosity, strength, flexibility) as bone can replace bone for grafting *(16)*. Standard bone implants are already commercially available, but they are available only in standardized sizes, and fitting for a particular patient may not be adequate.

RP overcomes both of these limitations, because it can create a bone that is customized to the patient based on imaging of the original bone or a mirror image of a contralateral (on the opposite side of the body) bone. RP technology focuses on creating scaffolds, which are 3D biocompatible structures that provide a template for cellular attachment and stimulate the formation of bone tissue. Once a scaffold is implanted into the body, blood vessels and host bone form on and throughout the structure. Research on the use of RP in bone tissue engineering focuses on methods to synthesize scaffolds with architecture similar to that of natural bone to improve their functions *in vivo*.



▲ **Figure 7.** A team of scientists at the Univ. of Michigan led by Glenn Green, associate professor of otolaryngology, 3D-printed a bioresorbable airway splint for a 3-yr-old child who suffered from tracheobronchomalacia, a rare condition that causes the person's airway to collapse. Using CT scans of the child's trachea and bronchus, the scientists designed and printed a tiny sleeve that could slip over the affected part of the airway. Image courtesy of Glenn Green, Univ. of Michigan.

Hydroxyapatite (HA) is a natural material found in bone that is being investigated as ink for bone implants made by 3D printers; other bone-replicate materials include calcium phosphate ceramics (tricalcium phosphate), calcium phosphate cements, monetite, and brushite *(17, 18)*, as well as composite materials such as polyetherketoneketone (Figure 8). Combinations of these materials are now being tested to increase the ink's biocompatibility and bioresorptivity *(19)*.

Three-dimensional printing of HA into scaffolds has been observed to help promote the formation of vessels, as well as homogeneous osteoconduction (the guiding of reparative growth of the natural bone) from central channels *(20)*. It has also been used successfully to create various anatomical structures for facial surgery and to make customized prostheses for hip, knee, femur, and hemi-knee reconstruction *(21)*.

For bone tissue engineering, 3D printing is well suited to generate complex-shaped porous ceramic materials directly from ceramic inks *(16)*. Because bone is a porous composite structure consisting primarily of HA, the printing of HA inks with porosity that has been tailored (based on a CAD file) to mimic the architecture of bone can be used to make implants and scaffolds that aid in the regeneration of bone *(22)*. One challenge is to increase porosity to allow for greater implant adhesion, bone ingrowth, and biodegradability. Thus, find-

▲ **Figure 8.** Oxford Performance Materials received approval from the U.S. Food and Drug Administration last year for its 3D-printed skull implant. The implant is made of polyetherketoneketone (PEKK) — a semi-crystalline thermoplastic. Image courtesy of Oxford Performance Materials.

▲ **Figure 9.** Scientists at the MIT Media Lab have successfully 3D-printed a variable-impedance prosthetic socket for trans-tibial amputees. Image courtesy of David Moinina Sengeh, MIT Media Lab.

ing an ink or a combination of inks that enhance porosity is a major goal of research in this area. The ideal porosity to encourage bone ingrowth is 30–70% with a pore size of 500–1,000 µm *(23)*.

The mechanical properties of 3D-printed scaffolds also heavily depend on the porosity of the scaffolds. HA is known for its strength, but it is extremely brittle — a major challenge in the 3D printing of ceramic scaffolds. However, Kikuchi, *et al.*, showed that an interlayer of collagen between layers of HA increases the toughness of the scaffold because the collagen absorbs energy during stress *(24)*.

Prosthetic sockets

A prosthetic socket is a device, tailor-made to match the unique geometry of a patient's residual limb, that connects a prosthesis with the limb. The traditional method of manufacturing sockets via mold creation not only is time consuming, but it produces a socket that is uncomfortable because it does not fully imitate the natural joint. It is estimated that over 95% of amputees experience socket discomfort *(25)*.

Although the use of computer-aided design and manufacturing (CAD/CAM) technology has improved socket performance, the addition of 3D printing would allow sockets to be made more quickly, and the size and shape of a 3D-printed socket could more accurately match the bone it is replacing *(26)*.

A 3D-printed socket is made by first obtaining scans of the limb and performing image processing and reverse engineering to construct a 3D model of the residual limb *(27)*. This approach can accurately reproduce both the internal and external structures of the residual limb, and enables customized sockets to be customized for an individual patient.

Hugh Herr, head of biomechatronics research at the MIT Media Lab, used a 3D inkjet printer to construct components of a variable-impedance prosthetic socket (Figure 9). To reduce the pressure experienced by the patient at the interface of the socket and the residual limb, the components were made of different materials, each with a different stiffness. This approach produces more-comfortable, better-fitting prosthetics *(28)*.

Companies such as Bespoke Innovations and Not Impossible are using 3D printing for commercially available prosthetics. Bespoke Innovations manufactures prosthetic coverings that fit the body form, and Not Impossible has developed a low-cost, 3D-printed prosthetic arm *(29, 30)*.

Looking ahead

The application of 3D printing to medicine requires optimization on several fronts. For one, printing speed needs to be improved. Creating RP models can sometimes take hours to days, which is problematic for emergency cases.

The number and diversity of materials used for 3D printing must be increased to meet the demands of complex cases. Moreover, the materials need to have the desired physical qualities and demonstrate biocompatibility. Rejection of the material by the body or seepage into the vascular supply may cause significant morbidity or mortality.

Current 3D printers require inks that are powders or low-viscosity liquids that can flow through the printer's

SUJATA K. BHATIA, M.D., P.E., is a physician and bioengineer who serves on the biomedical engineering teaching faculty at Harvard Univ. (Phone: (617) 496-2840; Email: sbhatia@seas.harvard.edu). She is the Assistant Director for Undergraduate Studies in Biomedical Engineering at Harvard, and an Assistant Dean for Harvard Summer School. She is also an associate of the Harvard Kennedy School of Government, for the Science, Technology, and Globalization Project, and she teaches in the Harvard Kennedy School executive education program on Innovation for Economic Development. She received bachelor's degrees in biology, biochemistry, and chemical engineering, and a master's degree in chemical engineering, from the Univ. of Delaware, and she received an M.D. and a PhD in bioengineering, both from the Univ. of Pennsylvania. Prior to joining Harvard, she was a principal investigator at the DuPont Co., where her projects included the development of bioadhesives for wound closure and the development of minimally invasive medical devices. She has written two books, *Biomaterials for Clinical Applications* (a textbook that discusses opportunities for both biomaterials scientists and physicians to alleviate diseases worldwide) and *Engineering Biomaterials for Regenerative Medicine*. She received an award from the Harvard Univ. President's Innovation Fund for Faculty in recognition of her innovative approaches to biomedical engineering education, and the John R. Marquand Award for Exceptional Advising and Counseling of Harvard Students, and is a member of AIChE. She is a registered P.E. in the state of Massachusetts. She was voted by the Harvard College Class of 2014 as a Harvard Yearbook Favorite Professor.

SHRUTI SHARMA is an undergraduate student in the Materials Science and Engineering Dept. at the Massachusetts Institute of Technology, where she conducts research on the use of 3D printing for prosthetic prototyping and production. She is also involved in improving the accessibility of medical devices in low-resource countries through developing policy and is currently working with the World Health Organization's Dept. of Medical Devices on the *2014 Compendium of Innovative Health Technologies for Low-Resource Settings*. Sharma is the President of the MIT student body, and she founded the Girls Leadership and Mentorship (GLAM) program.

nozzle. Thus, both new printer designs and new inks need to be developed. Increased printing resolution would be beneficial, especially in light of the intricate structures and surfaces of implants and prosthetics. And, physician-friendly programs should be developed that improve the translation of medical imaging data to CAD and then STL formats.

A database of CAD and STL files would also be useful, as descriptions of device fabrication are currently only found in journal articles. Sharing of the digital data files would enable better collaboration and enhance the design and development of prosthetics.

With such advancements, it would not be surprising to find, in the coming years, 3D printing being employed widely in clinical settings. Medical device manufacturing has traditionally been limited by time and resource constraints; 3D printing has the potential to overcome these limitations to speed the prototyping and production of novel prosthetics. CEP

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