



*Bioengineers  
Needed:  
Expansive  
Growth in  
Medical 3D  
Printing  
Industry Creates  
Demand for  
Experts*





## Public Health Priority

From prosthetics to tissues, there is a remarkable opportunity for additive manufacturing (AM), commonly known as 3D printing, to benefit public health and drive business results. Expected to be a \$1.21 billion market by 2020,<sup>1</sup> medical 3D printing has evolved from science fiction wonderment to a mainstream tool used in hospitals around the world.

There is a challenge, however, to meeting this potential: a lack of skilled professionals who combine the diverse expertise in biology and engineering that is needed to imagine, design and produce complex anatomical models and other medical innovations using 3D printing.

With rapid growth and potentially life-saving benefit, there is urgency around recruiting and training bioengineers who can handle what is, in theory, a new occupation with unique skillsets.

These bioengineers will have the exciting challenge of not just addressing current medical application needs — but of developing innovations that propel us into a future of enhanced healthcare.

This white paper, developed by SME, will discuss the opportunities and challenges in the crossover between engineering and biology, and explain the need for the industry to rely on an industry Competency Model to help hospitals and device manufacturers recruit and retain the next generation of biomedical experts.

*COVER: Members of the Mayo Clinic team include (left to right) Dr. Kevin Arce, Maxillofacial Surgeon; Amy Alexander, Biomedical Engineer; and Dr. Jonathan Morris, Radiologist.*

Photos courtesy Mayo Clinic; Metal cranial and hip implant courtesy EOS

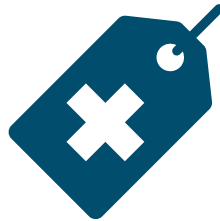
# By the Numbers

Nearly \$9 trillion is spent each year globally on healthcare. Versatile and flexible, 3D printed devices, equipment and tools can help address medical needs.

## FUTURE OF GLOBAL HEALTHCARE<sup>2</sup>

**\$8.7 TRILLION**

Global healthcare spend projected by 2020

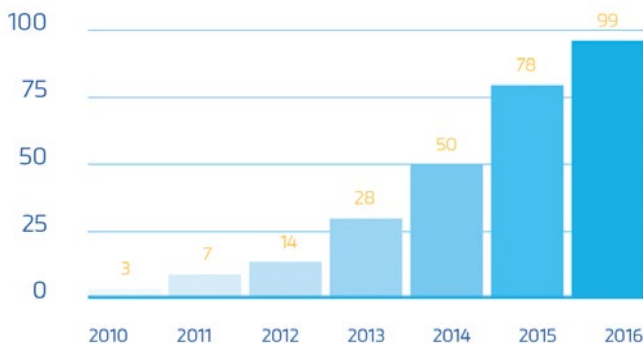


**8%**

Increase in the number of people over 65 years of age between 2015 and 2020

## HOSPITALS IN THE US WITH A CENTRALIZED 3D PRINTING FACILITY

*Using Materialise Mimics technology*



Graph courtesy Materialise

## OVERALL 3D PRINTING/AM GROWTH<sup>3</sup>

**17.4%** Compound annual growth rate (CAGR) of AM industry in 2016

**\$6.063 BILLION** 2016 AM market size

**11%** Approximate revenue from medical/dental pieces

## 3D PRINTING IN HEALTHCARE

**\$1.21 BILLION**

Global market by 2020<sup>4</sup>

**3200%**

Increase in the number of hospitals in the U.S. with a centralized 3D printing facility between 2010 and 2016 (using Materialise Mimics technology)<sup>5</sup>

**16**

Number of hospitals out of the top 20 as ranked by U.S. News and World Report that have implemented a medical 3D printing strategy (using Materialise Mimics technology)<sup>6</sup>

## Medical 3D Printing Applications

With an aging population and increase in chronic diseases, the healthcare industry is turning to innovations such as 3D printing to provide quality care to patients at a reasonable cost.

Current medical applications for 3D printing are diverse such as anatomically correct models for surgical planning, custom tools, and scaffolds. There is also great potential for future uses with the improvement of segmentation software – which allows medical imaging data from CT or MRI to 3D print patient-matched implants or surgical tools.

Already, this 3D printing technology is helping combat rare diseases through precision medicine, where doctors match treatment precisely to a patient. For instance, engineers and doctors at the University of Michigan (U-M) developed a successful 3D-printed tracheal splint for a 20-month-old child to treat tracheobronchomalacia (TBM), a disease that causes the windpipe to collapse and prevent breathing.

According to Glenn Green, MD, associate professor, pediatric otolaryngology, U-M, who worked on the project, “This engineering design has worked as intended... the first child to receive this implant three years ago appears to be cured of tracheobronchomalacia with a splint that has now functionally degraded.”<sup>7</sup>

Life-saving developments like this, through 3D printing, would not be possible in the past due to the costs of traditional manufacturing.

To accelerate this progress, bioengineers are needed to address both existing applications — as well as develop innovations through precision medicine that will come in the future.



*Patient-matched tracheal splint to treat TBM developed at the University of Michigan.*

### MEDICAL 3D PRINTING APPLICATIONS<sup>8</sup>

- **General** (non-personalized instruments or prototypes)
- **Anatomical Modeling** (patient-matched anatomical models from medical imaging studies like CT/MRI)
- **Surgical Planning** (templates, guides and models after preparing a patient-specific surgical plan in a software environment/3D printed items brought into operating room)
- **Precision Prosthetics** (patient-matched implants, prosthetics, or orthotics)
- **Permanent Implants** (“off-the-shelf” implants)
- **Active & Wearable Devices** (devices that include electronics or other active elements)
- **Bioprinting/Tissue Fabrication** (materials that incorporate living cells)

## Factors Contributing to Medical 3D Printing Increases

The need for this new bioengineering skillset grows as 3D printing applications in medicine increase due to many factors:

- **Precision medicine:** Better patient outcomes and lower costs from developing treatment plans and devices specifically for the patient
- **3D printing processes:** More accessible technology becomes mainstream
- **Materials:** Workable materials from polymers to metals allow for varied applications
- **Software:** Improved software allows for faster and more accurate segmentation of medical imaging files
- **Resources:** Industry rallying behind potential and sharing body of knowledge
- **Studies:** Growing evidence of patient outcomes and cost-effectiveness

## Government Support: NIH 3D Print Exchange

Seeing extraordinary potential, the U.S. government is also on board to propel medical 3D printing forward. To facilitate applications in bioscience, the U.S. Department of Health and Human Services' National Institutes of Health (NIH) has created the 3D Print Exchange.

The Exchange is a free resource for doctors, scientists and the general public, providing scientifically accurate or medically applicable 3D printable models in formats that are readily compatible with 3D printers. Exchange users can also tap into tools to create and share their own 3D printable models related to biomedical science.<sup>9</sup> This veritable crowdsourcing solution will help to accelerate use of 3D printing for better, cost effective patient outcomes.

### EXAMPLES OF 3D PRINTED MEDICAL APPLICATIONS

- Personalized 3D model of pelvis for preoperative plan
- Airway splint for baby with tracheobronchomalacia
- Wearable electrocardiogram (EKG)
- Replica of a human hand for medical school use
- Patient-matched cutting guide
- Bioprinting (printing with cells)
- Skin for burn victim
- Hearing aid case
- Dental implant



*Pediatric heart model used for surgical planning and patient education.*

## Profile: Device Manufacturer Perspective

**Dan Fritzing**  
Manager, Global Instrument Innovation  
DePuy Synthes

The use of medical 3D printing technology has the potential to transform healthcare delivery, resulting in truly personalized healthcare solutions for patients and consumers, according to Dan Fritzing, manager, Global Instrument Innovation for DePuy Synthes, part of the Johnson & Johnson family of companies. To better serve patients and consumers, J&J established the 3D Printing Center of Excellence to pursue and rapidly advance this new avenue of technology. 3D Printing offers several benefits over traditional manufacturing, including:

- **Customization.** With 3D printing technology, components and instruments can be created in new ways, produced with customized designs and materials rather than via large-scale, one-size-fits-all manufacturing.
- **Efficiency.** 3D printing technology enables the creation of products and tools layer by layer, thereby reducing lead times, manufacturing costs, inventory, and waste.
- **Personalization.** The technology creates opportunities to move from a “made for the masses” approach to a personalized, “made for me” model.
- **Globalization.** Through decentralized manufacturing made possible with 3D printing technology, solutions can be created and delivered with a global reach that was once impossible.

Fritzing noted that 3D printing for healthcare is different than for non-medical uses, so training is critical.

“Traditional (medical device) machine shops know medical devices and standards, but when it comes to additive manufacturing, there are differences in terms of everything



*Dan Fritzing designs a cutting tool to be produced with additive manufacturing*

from validation to material handling,” said Fritzing. “Engineers shouldn’t assume that the mechanical properties from additive manufacturing materials will be the same as from their bar stock equivalents.”

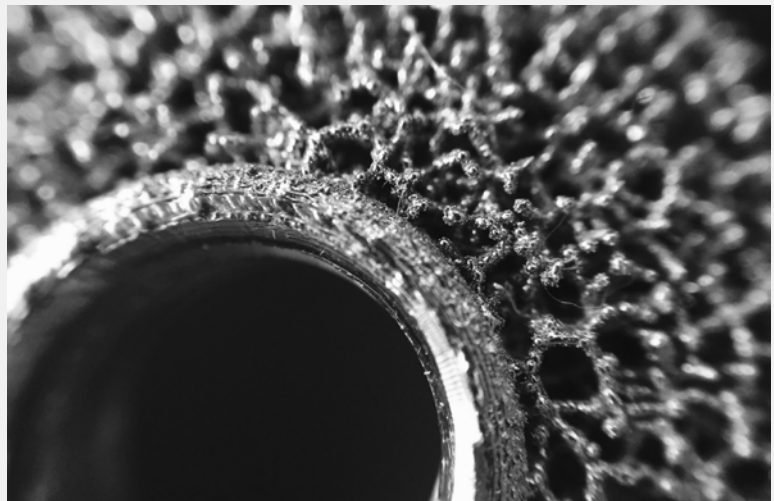
A standard curriculum and training can bring bioengineers to a basic level of competency, Fritzing said, supplemented by company-specific training.

This is especially important when it comes to the segmentation portion of 3D printing — the virtual part where, through patient scans, the customization happens due to the variety of imaging methods (CT, MRI, etc.).

On the device side, some of the common job titles in the medical 3D printing area are Segmenter/Senior Segmenter, Designer/Senior Designer/Principal Designer, and various levels of engineers.

“3D printing was once an innovation of the future and is now an exciting reality,” said Fritzing. “This technology presents enhanced career growth opportunities for each new generation of engineers and manufacturers entering the workforce.”

*Detailed view of metallic porous surface on acetabular cup for hip replacement.*



## Challenges for Medical 3D Printing Growth

From a stringent regulatory environment to funding, this burgeoning industry is seeing challenges, which the industry is actively addressing:

- **Regulatory environment:** With little history of medical 3D printing applications, regulations are still being formulated. The U.S. Food and Drug Administration has issued draft guidance related to 3D-printed medical devices. (see sidebar).
- **Funding, capital.** The industry is building guidelines to support standards of care that will become reimbursable. For instance, the Radiological Society of North America (RSNA) 3D Printing Special Interest Group (SIG) is leading a collaborative effort to develop appropriateness guidelines for the use of anatomical models by condition and treatment plan including surgery.
- **Reimbursement:** Costs are not reimbursed through health insurance. Typically, hospitals will cover the cost as it saves time/ costs later. For surgical planning, for instance, it's cheaper in the long run since it saves time in the operating room. Device manufacturers may include a patient-matched device as part of an implant kit without separate reimbursement because it adds value to their implant, providing them with an edge over other device manufacturers.
- **Technology:** Materials, processes and software for 3D printing for medical applications are evolving. Manufacturers are continually learning more about interaction between materials and the 3D printer, biocompatibility, validation processes, creating standards for raw material suppliers, and more. Segmentation is complicated and requires specialized expertise. The segmentation software is costly.
- **Qualified workforce, recruiting, talent:** The blending of biology and engineering is a relatively new need and there is a strong demand. Educators, industry, and medical institutions are working together to make recruiting and training a priority.

### FDA DRAFT GUIDANCE

The U.S. Food and Drug Administration (FDA) issued draft guidance for Industry and FDA staff on the topic, "[Technical Considerations for Additive Manufactured Devices](#)," on May 10, 2016.<sup>2</sup>

The draft guidance covers both Design and Manufacturing Considerations and Device Testing Considerations. It is considered a "leap-frog guidance," intended to "serve as a mechanism by which the Agency can share initial thoughts regarding emerging technologies that are likely to be of public health importance early in product development," according to the FDA. These recommendations may change as more information becomes available.

As with the airway splint created by U-M described earlier, the FDA has been able to review and regulate certain devices under existing regulations. According to an article in *3D Printing in Medicine*, they have done this "by proactively identifying similarities with existing technologies and key differences that needed to be evaluated."<sup>11</sup>

For instance, the FDA's Center for Device and Radiological Health (CDRH) has reviewed and cleared additively manufactured medical devices for more than 10 years.<sup>12</sup>

It will be important for those coming into the field to understand the regulatory environment and become part of the stakeholder conversation in order to continue developing innovative health solutions through 3D printing.

## Opportunity: Skilled Professionals Needed

Job titles unimaginable 10 years ago are now popping up frequently on career sites: 3D Printing Biomedical Engineer – Cardiovascular; Scientific 3D Printing; Clinical Engineer in hospital setting; Visualization Specialist for supporter of National Institutes of Health and other government agencies; Senior Segmenter for a medical device manufacturer.

According to those in the industry, these positions are difficult to fill, due to the specialized combination of skills needed, covering biology, engineering and 3D printing.

To build a common language among employers and job candidates, the SME Medical Additive Manufacturing/3D Printing Workgroup, comprised of medical device manufacturers, clinicians, technology providers, and educators, has developed a Competency Model that covers these three main job roles:

- Medical 3D Printing Engineer:** This advanced position, found in a clinical setting such as a hospital, creates, implements, updates and verifies/validates processes within a 3D Printing lab, working primarily with polymer systems. Knowledge and experience from both a medical and engineering perspective are needed. A basic understanding of the quality systems needed for

regulatory and HIPAA compliance is needed. Typically this role requires 2+ years experience working as a biomedical engineer.

- Medical AM Engineer:** This advanced position with a device manufacturer covers the same job responsibilities as the Medical 3D Printing Engineer and most of the same knowledge and skills. Candidates should have a strong understanding of the quality systems needed for regulatory compliance (21CFR820). Some skills are not needed such as an advanced medical image processing skillset. These engineers work in both metal and polymer systems. Typically this role requires 2+ years experience working as an engineer.
- Medical AM/3D Printing Technologist:** This is an entry-level position found in both clinical/hospital and device manufacturer settings. As with the more senior roles, knowledge of everything from anatomy to HIPAA compliance to understanding of 3D Printers/AM machines for polymer systems is needed but may be addressed with on-the-job training (OJT). Hospital or manufacturing experience is preferred but not required.

The downloadable Competency Model is available at no cost. Please visit [www.sme.org/am3dpjobmodel](http://www.sme.org/am3dpjobmodel)

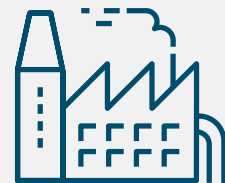
### MEDICAL 3D PRINTING ENGINEER



### MEDICAL AM/3D PRINTING TECHNOLOGIST



### MEDICAL AM ENGINEER



**SETTING:** Clinic/Hospital

**LEVEL:** Advanced

- Advanced understanding of 3D printers/AM machines, primarily polymer systems
- Understanding of anatomy
- Working with IRB to generate and execute protocols
- EHR/PACS integration
- Advanced medical imaging processing
- 2+ years experience working as a biomedical engineer
- SME Additive Manufacturing certification preferred

**SETTING:** Clinic/Hospital or Device Manufacturer

**LEVEL:** Entry

- Basic understanding of 3D printers/AM machines, primarily polymer systems
- Understanding of anatomy
- Medical imaging processing
- Bachelor's degree or relevant experience

**SETTING:** Device Manufacturer

**LEVEL:** Advanced

- Advanced understanding of 3D printers/AM machines, metal and polymer systems
- 21 CFR 820/ ISO 13485 Compliance
- Risk analysis ISO 14971
- Understanding of clinical / surgical Procedures
- Medical imaging processing
- 2+ years experience working as an engineer
- SME Additive Manufacturing certification preferred

## Building the Talent Pipeline

The Competency Model is part of efforts by industry and educational institutions to create clear career pathways for those entering the medical 3D printing/AM field in both traditional and non-traditional manufacturing.

Regardless of a healthcare or medical device environment, progression moves from a Bachelor's degree (a Master's degree is preferred) in Engineering to OJT through internships and/or full-time job experience.

Some Knowledge, Skills and Abilities (KSAs) cover:

- Image Acquisition
- Segmentation
- 3D Model Refinement and/or Design
- 3D Printing
- Post-Processing
- Regulatory Compliance
- HIPAA Rules
- Quality Systems throughout the process

The Competency Model helps with the development of job descriptions as well as curriculums and job training programs, and is part of the process for ensuring consistency for engineers and technologists pursuing careers in medical 3D printing.

Another resource is [SME's Additive Manufacturing Body of Knowledge](#) that serves as the basis for the Additive Manufacturing Fundamentals Certification program. This assessment will serve as a prerequisite for the next phase, the Additive Manufacturing Technician Certification, which will be rolled out later this year. These stackable certifications can lead to an additive manufacturing apprenticeship such as those through the U.S. Department of Labor's Registered Apprenticeship Program.

### Where Are The Jobs?

As the market for medical 3D printing grows, there are a number of manufacturers, all of which need bioengineers to help them develop and produce products, and propel innovation.

Traditional manufacturers such as device manufacturers make up the bulk of the industry, often partnering with contract manufacturers. Larger research hospitals may have their own in-house 3D printing laboratories while smaller hospitals may work with contract manufacturers for segmentation and to prepare files for 3D printing.

There is also an ongoing need for bioengineers doing research as industry looks at continuing innovation for applications such as bioprinting and tissue fabrication. While 3D printing of organs and scaling up production of tissues are decades away, research can be accelerated with additional focus.

### Here's where the jobs are:

#### TRADITIONAL MANUFACTURERS

Device  
Manufacturers

Contract  
Manufacturers

#### POINT-OF-CARE MANUFACTURERS

Hospitals  
- Government  
- Non-profit  
- For-profit

Hospitals  
connected  
to university  
engineering  
departments

Contract  
Manufacturers

## Profile: Amy Alexander, Biomedical Engineer

### 3D Anatomic Modeling Lab Department of Radiology Mayo Clinic

Amy Alexander is a biomedical engineer in the Mayo Clinic Department of Radiology's Anatomic Modeling Lab in Rochester, Minn. In her role, Alexander converts 2D radiological images into 3D models. These life-size, patient-specific models help surgeons from different specialties prepare for complex procedures. Additionally, these models form a communication bridge and education for patients regarding their surgical plan. Alexander also designs and 3D prints individualized surgical tools, like cutting guides, which improve accuracy and efficiency in the operating room.

Alexander came to the Anatomic Modeling Lab in early 2015 with a Bachelor of Science in Biomedical Engineering from the Milwaukee School of Engineering (MSOE) and several years of work experience. Her diverse background covered radiology, medical engineering, 3D printing, and information technology. Through the tremendous support of Radiology Department Head, Dr. Kent Thielen, strong administrative backing from Dr. Ronald Menaker and Linda Nesberg, and fierce dedication and drive from the lab co-directors, Dr. Jane Matsumoto (Pediatric Radiologist) and Dr. Jonathan Morris (Neuroradiologist), Alexander was able to join the team.

Alexander said much of her training was on-the-job. "I am very fortunate to be mentored by Drs. Matsumoto and Morris, and privileged to work alongside expert radiologists and CT technologists to learn medical modeling. Over time, I learned how to best utilize the functions of the software and run the printers more efficiently to build a high volume of anatomic models and surgical guides within a fast-paced clinical setting."

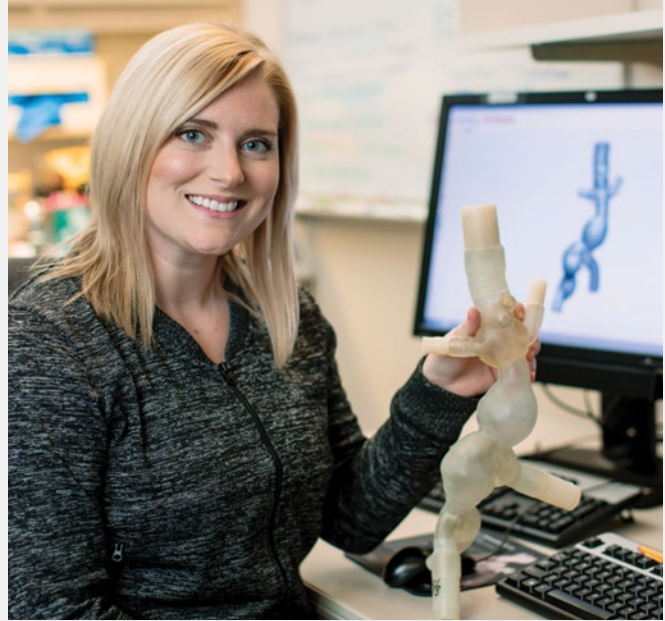


Photo courtesy Mayo Clinic

*Amy Alexander holds an aortic simulation model created from medical imaging data. This model is connected to a water pump to allow surgeons to catheterize the model under fluoroscopy and deploy a device, effectively simulating the procedure for an individual patient.*

She noted that there are several steps to anatomical modeling for which training is required:

- Manipulate DICOM data to segment anatomy/pathology
- Generate 3D model from segmentation and prepare model for 3D printing
- Clean, post-process, photograph, and keep record of printed model
- Observe and participate in discussion and delivery of the model between radiologist and surgeon

"There is a big demand for this kind of medical design at hospitals, universities and device manufacturers. There is a great need for bioengineers who know 3D printing," said Alexander. "Students who intern here at Mayo are getting offers from all over the U.S."

She added that, "The best thing newcomers can do to familiarize themselves with the landscape is take SME's Additive Manufacturing Fundamentals Certification exam, which covers all 3D printing technologies, applications, major vendors, materials, secondary processing techniques, economics, and history."

"3D printing in the medical field demonstrates the fascinating intersection of medical imaging, surgical insight, engineering, and human artwork," said Alexander. "It's an important and growing tool for individualized medicine."

## Bioengineers: Unique Skillsets

While engineers in manufacturing roles outside the medical area share much of the same knowledge and skillsets, bioengineers must be trained in a variety of specialized areas including biology, regulatory, biocompatibility, and sterilization. Knowledge and skills related to AM processes, materials, software, segmentation and design approach must be adapted for patient care.

Still, the similarities are much more significant, allowing crossover career opportunities.

Job candidates should consider cultural differences when pursuing a position. A clinical environment creates an intense and quickly changing environment, requiring adaptability and flexibility. Similar work in other industries such as aerospace or automotive may provide a more traditional office environment with a more predictable workflow.

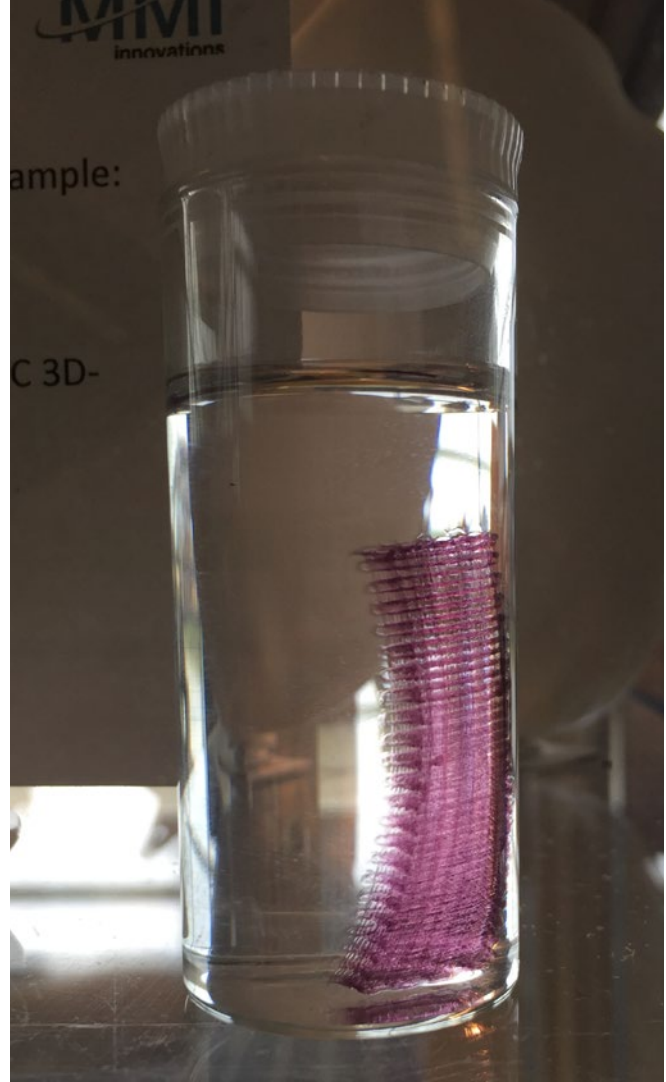
For those interested in the challenge of combatting rare diseases and saving lives, the medical 3D printing area offers expansive opportunities to make a difference and have an impact on this growing field.

Consider two examples of developing applications in the medical 3D printing world: bioprinting and wearables.

### BIOPRINTING

While once deemed science fiction, producing or growing human tissue that can avoid the immune response of donor tissue is now a reality. For instance, a study in *Biofabrication*, outlined the use of a 3D bioprinter to generate bioengineered skin to treat burns and other wounds.<sup>13</sup>

The push is on to achieve a scalable bioprinting production process. With biologists and engineers both



*Bioprinted gelatin for tissue repair and regeneration including bioprosthesis developed at Northwestern University.*

pursuing solutions from different perspectives, this innovation is accelerating.

Biologists have had great success with using decellularized tissues to obtain an extracellular matrix (ECM) scaffold of the original tissue.<sup>3</sup> Wake Forest Institute for Regenerative Medicine has been able to successfully create and implant things like bladders and urine tubes by seeding an ECM scaffold with a patient's own progenitor or adult stem cells. The same process has potential to create hearts, livers, kidneys, and more on a very small scale.<sup>14</sup>

On the engineering side, experts over the last 25 years have made astounding advancements in AM/3D printing which are applicable to bioprinting. Today, engineers can print nearly any shape using a wide range of materials including biomaterials that can be used as scaffolds and more. Improvements in segmentation continue to provide new opportunities.

*Continued on next page*

Still, according to Ken Church, managing partner for Sciperio, a research and development think tank, and research scientist for nScript, a developer of equipment for tissue engineering, the printing of organs is decades away.

“Bioprinting is not just the printing of organs which has received much hype...grow a heart, a bladder and other organs. How realistic is that and can we make that much of a leap from where we are today? Maybe we shouldn’t talk organs. That’s like talking about colonizing Mars. It is certainly interesting to talk about. The U.S. government is putting some money in, but the rest of the world is working new rockets, space stations, the moon, studying Mars, and many hard problems that must be solved long before we colonize. What are the ‘new rockets’ for bioprinting?”

These “new rockets” are the areas that bioengineers are focused on to move us closer to reality: finding functional 3D bioreactors, determining very different logistics of the supply chain, and training doctors in the use of unfamiliar technologies.

Most important, however, is ensuring biologists and engineers learn to speak the same language. Engineers’ experience in automation, controls, feedback, precision, speed, repeatability and extreme size scales will enable biology. However, engineers are not biologists. They do not know the relationships between cells and tissue, the complexity of cells, their diverse purposes, or how to divide or maintain these cells. Growing complex organs on a production scale will take both expert biologists and engineers.

## WEARABLES

There is a growing market for “wearables,” which can include remote patient monitoring devices. These devices benefit from 3D printing technology that allows manufacturers to print pieces smaller, faster, and of various materials.

For instance, Wyss Institute for Biologically Inspired Engineering at Harvard University, Harvard’s John A. Paulson School of Engineering and Applied Sciences (SEAS), and the U.S. Air Force Research Laboratory developed a new hybrid 3D printing technique for flexible wearable sensors. The new AM technique “integrates soft, electrically conductive links and matrix materials with rigid electronic components into a single, stretchable device,” according to a news release.<sup>16</sup>

“Because the ink and substrate are 3D-printed, we have complete control over where the conductive features are patterned, and can design circuits to create soft electronic devices of nearly every size and shape,” said Will Boley, Ph.D., a postdoctoral researcher in the Lewis lab at SEAS and co-author of the paper, published in *Advanced Materials*.

These flexible wearable sensors can move with the body and offer increased programmability at a lower cost.

As wearable technology continues to develop, diverse skills are needed covering medical devices, 3D printing and electronics. Industry and educators must work together to recruit and train skilled workers to specialize in this area.

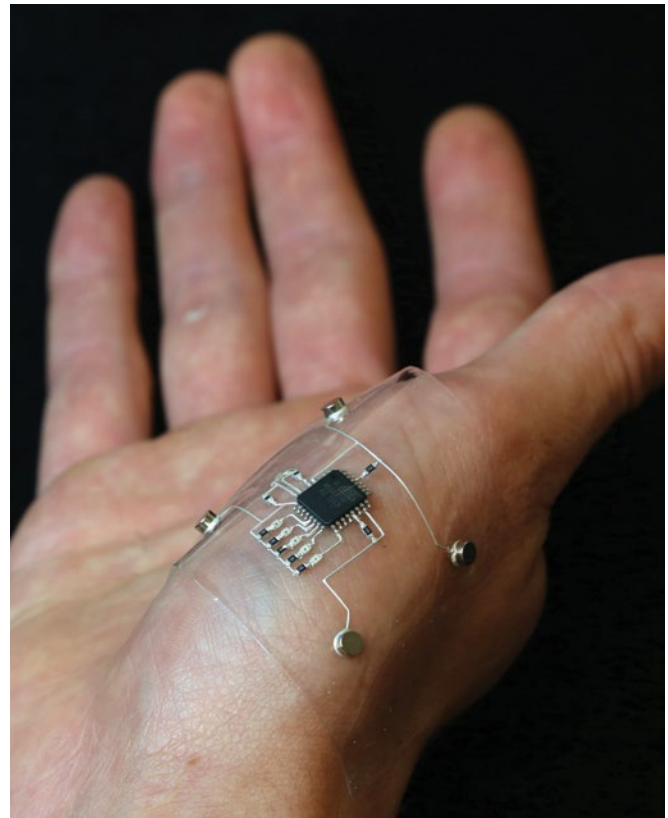


Photo courtesy Alex Valentine, Lori K. Sanders, and Jennifer Lewis/Harvard University

*Potential application of 3D printing flexible sensors include custom printed strain and pressure sensors to track post-surgery rehab progress with direct measurement of joint angles, body position, and extremity deflection.*

## Profile: Clinical Perspective

**Jonathan M. Morris, MD**  
**Associate Professor of Radiology/Co-director**  
**of the 3D Anatomic Modeling Lab**  
**Mayo Clinic**

“The medical 3D printing market has been steadily and rapidly growing,” said Jonathan M. Morris, MD, associate professor of radiology and co-director of the 3D Anatomic Modeling Lab, Mayo Clinic. “Due to the intersection of many factors, there is great opportunity for businesses, medical manufacturers, physicians, and the next generation of engineers.”

Mayo Clinic has been using 3D printing for 11 years including for preoperative planning, patient specific simulation, medical education, and discussing complex surgeries with the patients themselves.

“There are extensive educational uses for medical 3D printing at all levels, with different levels of knowledge,” he said. “For example, training of radiology technologists requires knowledge of anatomy for positioning in imaging suites which is a different level from a surgical fellow needing a closer look at a patient with a congenital anomaly of the heart.”

Surgeons across multiple specialties regularly use accurate 3D printed models based on patient CT or MRI scans to plan complex surgeries. This has led to improved care and better outcomes through innovative approaches, less time under anesthesia and in the operating room (OR), shorter hospital stays, smaller incisions, and a more efficient use of overall resources.

Dr. Morris said that although the cost is not typically reimbursed, hospitals absorb the cost since it can save money in the long run while increasing value.

In addition to large research hospitals like Mayo Clinic, which have their own in-hospital 3D printing labs, medical device makers such as G.E., Siemens, Johnson & Johnson, Stryker, and contract manufacturers are rapidly increasing the uses of 3D printing in prototyping and manufacturing devices.

All of these facilities need skilled workers to fill jobs associated with this technology. The challenge is finding the personnel with these unique skillsets.



Photo courtesy Mayo Clinic

*Dr. Morris discusses a surgical planning model with Amy Alexander, biomedical engineer, and Dr. Kevin Arce, maxillofacial surgeon.*

Dr. Morris said there is a clinical need that covers multiple areas of knowledge: anatomy and physiology, engineering, medical imaging, medical device manufacturing, 3D printing, and more.

“Bioengineers need a variety of skills that cover everything from tolerance and stress testing to, say, cardiac physiology,” said Dr. Morris. “Where do we find the people who have these diverse skillsets?”

Dr. Morris points to the importance of the Competency Model developed by the SME Medical Additive Manufacturing/3D Printing Workgroup that can be used by universities to develop courses and training programs.

“We still need medical 3D printing courses and curriculum at the university level which can incorporate clinical internships at medical centers to meet the future needs of employers,” said Dr. Morris.

The cultural divide between medical and engineering mindsets must be addressed as well. Engineers must embrace the uncertainties of a workplace where medical diagnosis and treatment options are continually evolving vs. one linear “engineered” solution. Mayo Clinic has made great strides in this area, with engineers incorporated into daily clinical workflow, meeting with clinicians, and going to the ORs to gain experience.

Dr. Morris added, “It has been rewarding for both parties when they are allowed to integrally work together with respect and bring solutions that benefit a patient’s life because that is what we are here for. . . the needs of the patient.”

## University Biomedical Engineering Programs

A consistent curriculum at the university level is part of the movement to build a talent pipeline of biomedical engineers. Fortunately, the country has a number of strong programs including those at Harvard University, University of Michigan, Johns Hopkins University, Duke University, Wake Forest University, and University of California San Diego (UC San Diego).

Some bioengineering programs are part of the School of Medicine, however, more are integrating biology and engineering like at UC San Diego where the Department of Bioengineering falls under the Jacobs School of Engineering.

AM/3D Printing is an important part of the curriculum along with traditional engineer sciences, biology, physiology and other biomedical sciences.

3D printing is also playing an important role in research at these institutions. For instance, for a recent study in

collaboration with physicians from Rady Children's Hospital, a team of bioengineers from UC San Diego created a 3D-printed model from scans of the young patients' pelvis and created a computerized model of bone and growth plate for 3D printing. Through their research, published in the *Journal of Children's Orthopaedics*,<sup>17</sup> they found surgical planning using a 3D-printed model of a patient's hip joint cut the time needed for surgery by about 25 percent. The team estimated a cost-savings of at least \$2,700 per surgery from reduced time in the operating room.

"Being able to practice on these 3D-models is crucial," said Dr. Vidyadhar Upasani, pediatric orthopedic surgeon at Rady Children's and UC San Diego and the paper's senior author, in a UC San Diego news release.<sup>18</sup>

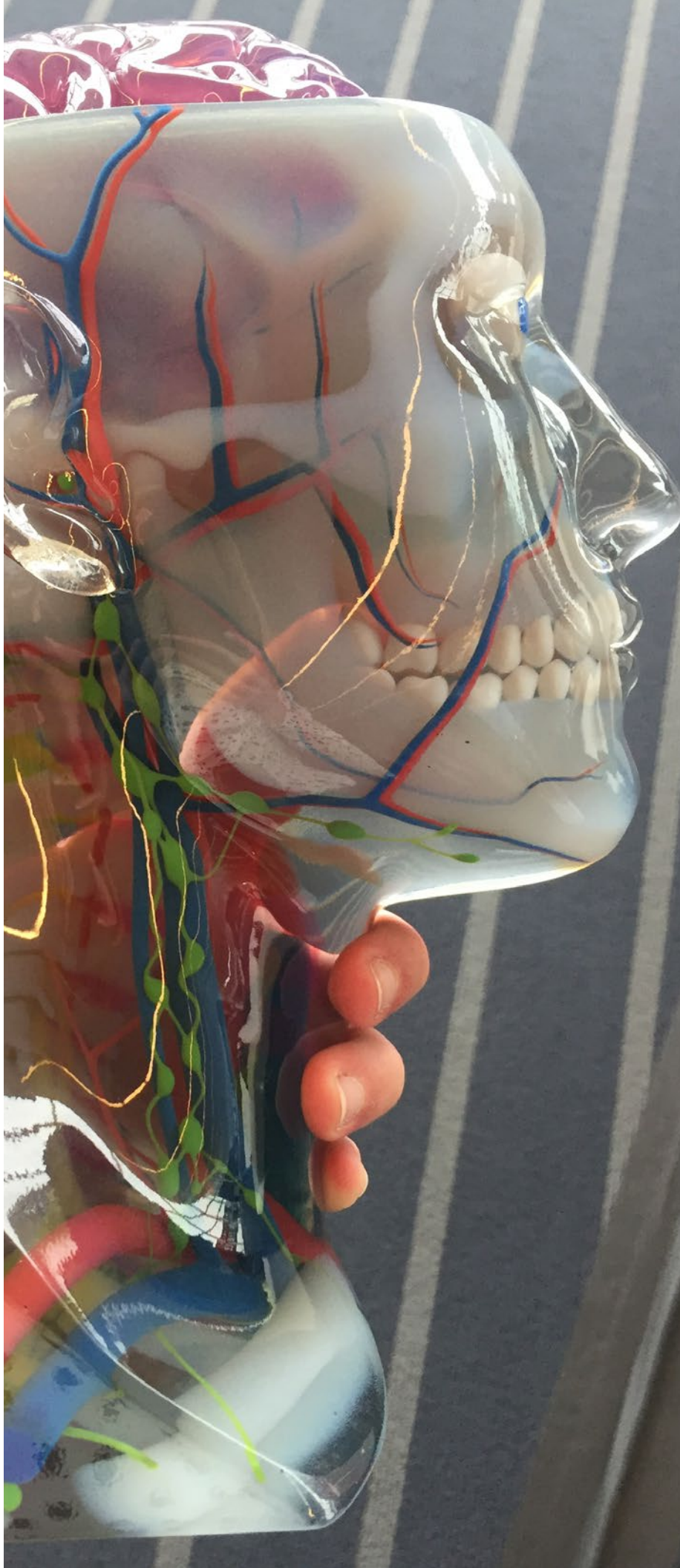


Photo courtesy 3D Systems

*Cranial conjoined twins model and guide for use during separation surgery.*

## Call to Action

As 3D printing in healthcare grows, industry, clinicians and educators need to access to a universal Competency Model for biomedical experts that ensures consistent training from University level to OJT. This will ensure a full, consistently trained pipeline of skilled workers who can fulfill the current opportunity and innovate into the future, benefiting business and, most importantly, public health.



## References

- 1 McConnon, Aili. ["How Printing is Changing Health Care."](#) *The Wall Street Journal*, September 13, 2017.
- 2 Deloitte's 2017 [Global Health Care Outlook](#) report
- 3 Wohlers Associates, Inc
- 4 McConnon, *The Wall Street Journal*
- 5 Materialise. "Essential Facts about Medical 3D Printing in the Top U.S. Hospitals."
- 6 Ibid.
- 7 McDaniel, Lauralyn. ["3D Printing Adds the Fourth Dimension \(Time\)."](#) *Manufacturing Engineering* (April 2015)
- 8 SME Medical Additive Manufacturing/3D Printing Workgroup
- 9 NIH 3D Print Exchange (<https://3dprint.nih.gov>)
- 10 U.S. Food and Drug Administration, ["Technical Considerations for Additive Manufactured Devices."](#) May 10, 2016.
- 11 DiPrima, M., Coburn, J., Hwang, D., Kelly, J., Khairuzzaman, A., Ricles, L. ["Additively manufactured medical products — the FDA perspective."](#) *3D Printing in Medicine*, May 18, 2016.
- 12 Ibid.
- 13 Cubo, Nieves, Garcia, Marta, del Cañizo, Juan F., Velasco, Diego, and Jorcano, Jose L. ["3D bioprinting of functional human skin: production and in vivo analysis"](#) December 5 2016, IOP Publishing Ltd *Biofabrication*, Volume 9, Number 1
- 14 McDaniel, Lauralyn. ["What's Needed to Achieve Scalable Production of Tissues."](#) *Manufacturing Engineering*, April 28, 2015.
- 15 Ibid.
- 16 Brownell, Lindsay. ["Low-cost wearables manufactured by hybrid 3D printing."](#) *The Wyss Institute, Harvard University*, Sept. 6, 2017.
- 17 Cherkasskiy L. Caffrey J. P. Szewczyk A. F. Cory E. Bomar J. D. Farnsworth C. L. Jeffords M. Wenger D. R. Sah R. L. Upasani V. V. "Patient-specific 3D models aid planning for triplane proximal femoral osteotomy in slipped capital femoral epiphysis", *Journal of Children's Orthopaedics*, 11, no. 2 (April, 2017): 147-153.
- 18 UC San Diego Jacobs School of Engineering, ["Engineers harness the power of 3D printing to help surgeons, shorten surgery times."](#) August 2, 2017.
- 19 "McConnon, *The Wall Street Journal*

## Medical 3D Printing Growth Creates Demand for Bioengineers

Expected to be a \$1.21 billion market by 2020,<sup>19</sup> medical 3D printing, also known as additive manufacturing (AM), is revolutionizing healthcare by improving patient care and lowering costs.

To meet the current opportunity — and that of the future — skilled professionals with knowledge and training in both engineering and biology, are urgently needed to imagine, design and produce complex anatomical models and other medical innovations using 3D printing.

In order to accelerate the recruiting process, medical device manufacturers, clinicians, technology providers, and educators are teaming up to create clear career pathways with an industry Competency Model for those entering the medical 3D printing/AM field in both traditional and non-traditional manufacturing.



Photo courtesy Mayo Clinic

## About SME

SME connects all those who are passionate about making things that improve our world. As a nonprofit organization, SME has served practitioners, companies, educators, government and communities across the manufacturing spectrum for more than 80 years. Through its strategic areas of events, media, membership, training and development, and the SME Education Foundation, SME is uniquely dedicated to the advancement of manufacturing by addressing both knowledge and skills needed for the industry. Learn more at [sme.org](http://sme.org), follow @SME\_MFG on Twitter or [facebook.com/SMEmfng](https://facebook.com/SMEmfng).

## Building a community of practice

### *Creating a home for additive manufacturing/3D printing users*

More than 25 years ago, SME's rich history of supporting manufacturers led the pioneers and innovators of 3D technologies to make SME the home for their new Rapid Prototyping technical group.

Today, SME connects some 200,000 people in additive manufacturing, continuing the original group's vision of — and commitment to — creating an extensive community. [www.sme.org/3D](http://www.sme.org/3D)

## Medical additive manufacturing/3D printing

### *Making a difference through collaboration*

The SME Medical Additive Manufacturing/3D Printing Workgroup supports users of medical and biomedical application technology. Members represent medical device manufacturers, clinicians, technology providers and more, including Mayo Clinic, Biomet, University of Michigan, Smith & Nephew, Materialise, nScrypt, Leuven Medical Technology Centre, DePuy Synthes, Stryker Orthopaedics, Phoenix Children's Hospital, Johnson & Johnson and Northwestern University. By providing content to address the latest industry developments, identify gaps in standards, and build evidence for additive manufacturing applications in medicine, the group helps drive technology to improve and save lives. [www.sme.org/medical-am3dp-workgroup](http://www.sme.org/medical-am3dp-workgroup)

## Contact

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