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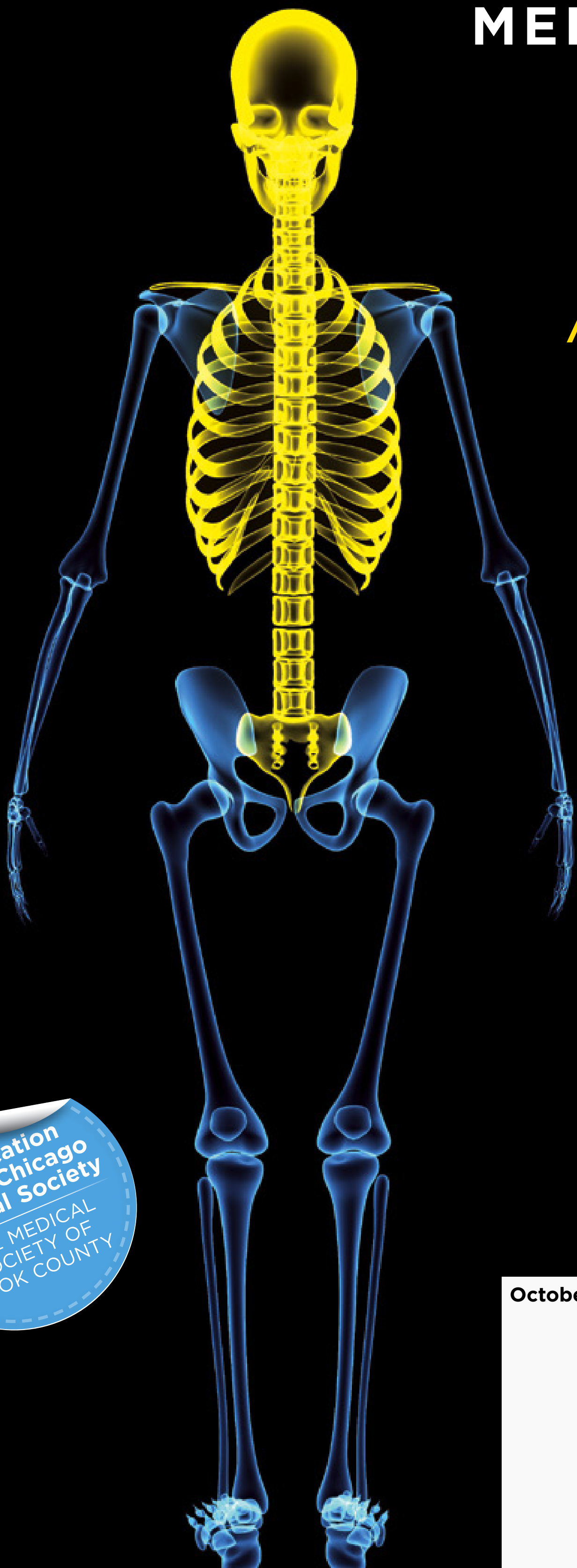

3-D Modeling Adds an Extra Dimension

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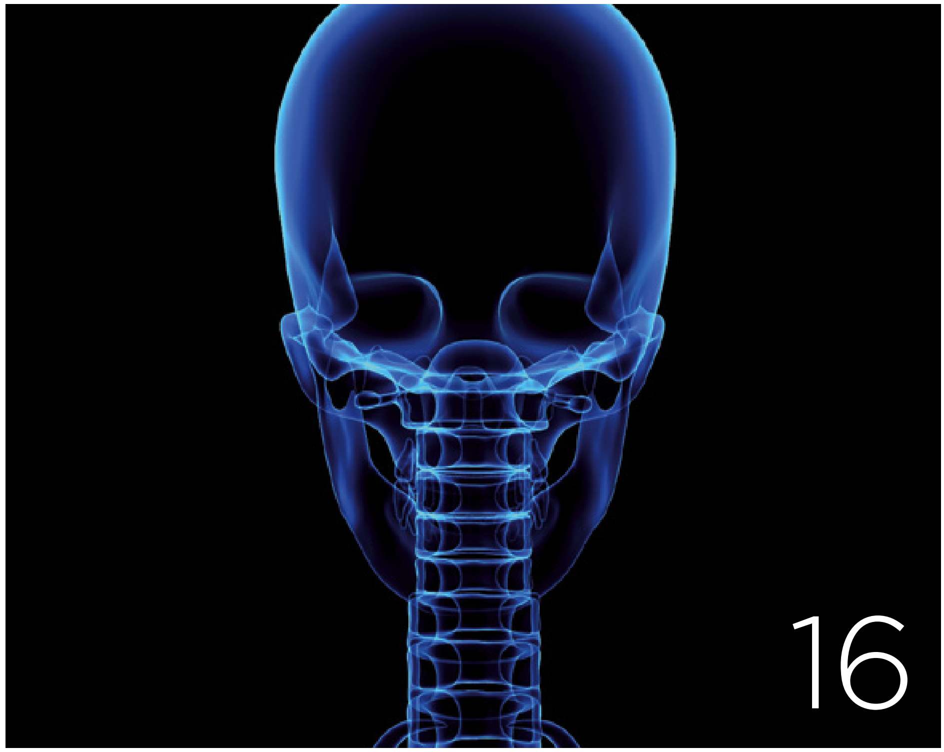
Chicago MEDICINE

Volume 117 Issue 10

October 2014

FEATURES



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Publication Title: Chicago Medicine
Publication Number: 0009-3637
Filing Date: 10/22/20014
Issue Frequency: Monthly
Number of Issues Published Annually: 12
Annual Subscription Price: $20 members/$30 non-members.
Complete Mailing Address of Known Office of Publication: 515 N. Dearborn St., Chicago, IL 60654-4302.
Complete Mailing Address of Headquarters or General Business Office of Publisher:
515 N. Dearborn St., Chicago, IL 60654-4302.
Full Names and Complete Mailing Addresses of Publisher, Editor, and Managing Editor: Scott Warner/Elizabeth Sidney, Co-Editors, Chicago Medicine, 515 N. Dearborn St., Chicago, IL 60654-4302
Owner: Chicago Medical Society, 515 N. Dearborn St., Chicago, IL 60654-4302.
Known Bondholders, Mortgagees, and Other Security Holders Owning or Holding 1% or More of Total Amount of Bonds, Mortgages, or Other Securities: None.
Tax Status: Has Not Changed During Preceding 12 Months.
Publication Title: Chicago Medicine Date for Circulation Data Below: October 2014
Extent and Nature of Circulation:
15a. 5,290 (avg) / 5,000 (actual)
15b1. 372.9 (avg) / 164 (actual)
15b2. 4,631.1 (avg) / 4,521 (actual)
15b3. 0 (avg) / 0 (actual)
15b4. 0 (avg) / 0 (actual)
15c. 5,004 (avg) / 4,685 (actual)
15d1. 0 (avg) / 0 (actual)
15d2. 0 (avg) / 0 (actual)
15d3. 0 (avg) / 0 (actual)
15d4. 0 (avg) / 0 (actual)
15e. 0 (avg) / 0 (actual)
15f. 5,004 (avg) / 4,685 (actual)
15g. 2866 (avg) / 315 (actual)
15h. 5,290 (avg) / 5,000 (actual)
15i. 100% (avg) / 100% (actual)
Publication of Statement of Ownership: If the Publication is a General Publication, Publication of this Statement is Required.
Publisher/Editor 10/22/2014
Scott Warner

Welcoming Technology

HEALTH information technology encompasses a wide range of tools. This month's cover feature looks at 3-D modeling and its amazing uses as a training tool and visualization aid. As the technology advances, it can mean only good things for patient care. As a psychiatrist who treats patients via telemedicine, I believe that technology will make it easier for physicians to do what we do best. Especially in the era of value-based care, where we are asked to do more with less.

With the race on to bring new data driven technologies to health care, I got to thinking about the need for hands-on physicians. Why? As reported in *The New York Times* (Sept. 20, 2014), at least a few Silicon Valley entrepreneurs would prefer an artificial intelligence doctor, presumably a computer with perfect knowledge.

As least one third of attendees at a conference, held in San Francisco, agreed with a professor and technology visionary who said, "I would trust AI over a doctor any day." Reporter Elisabeth Rosenthal, a former physician, made this the topic of her column.

The prospect of artificial-intelligence doctors seems unlikely given that cognitive skills are difficult to automate, and the demands of complex technology require thinking individuals to keep it running. More doctors will be needed to advance the technology.

More likely, technology will streamline the rote work that doctors do, freeing us up to be more productive. Writing in *The Health Care Blog* (Sept. 23, 2014), health care speaker and futurist Joe Flower gave several scenarios in which technology would simply clear the deck of "wasteful procedures and unnecessary administrative tasks."

For example, as EMRs become more transparent across platforms and organizations, doctors will no longer have to search for and re-enter records, images, and lab results. There will be no need for a separate coding caption function, Flower says.

As interoperability improves, applications and devices across all health systems will have the ability to capture and share all patient data, no matter where treatment takes place.

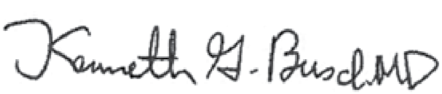
Big data has many potential uses: identifying causal relationships and trends; comparative effectiveness research, safety monitoring investigations, long-term studies on patient outcomes, and management of patient populations. We can expect many debates about individual privacy versus the public good.

Hospitals could offer single-price bundles for services like hip and knee replacements, thanks to deep and automated real-time cost analyses per case and procedure, Flower suggests. Cost analytics could cut by one third the amount of time spent "driving revenue streams," particularly fighting with insurance companies.

Mobile devices and apps would increasingly enable real-time monitoring of patients, thereby reducing the need for acute interventions. Time-pressed physicians and home-bound patients would benefit greatly.

Ultimately, IT-enabled tools would help clinicians make more informed life-saving decisions. Physicians would return to their core mission. "That strong, trusted patient relationship is by far the most efficient communication structure in all of medicine," Flower concludes.

Through our ongoing educational programs, CMS will help you master the tools you need to manage cutting-edge technology and improve patient care outcomes.



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Chicago MEDICINE

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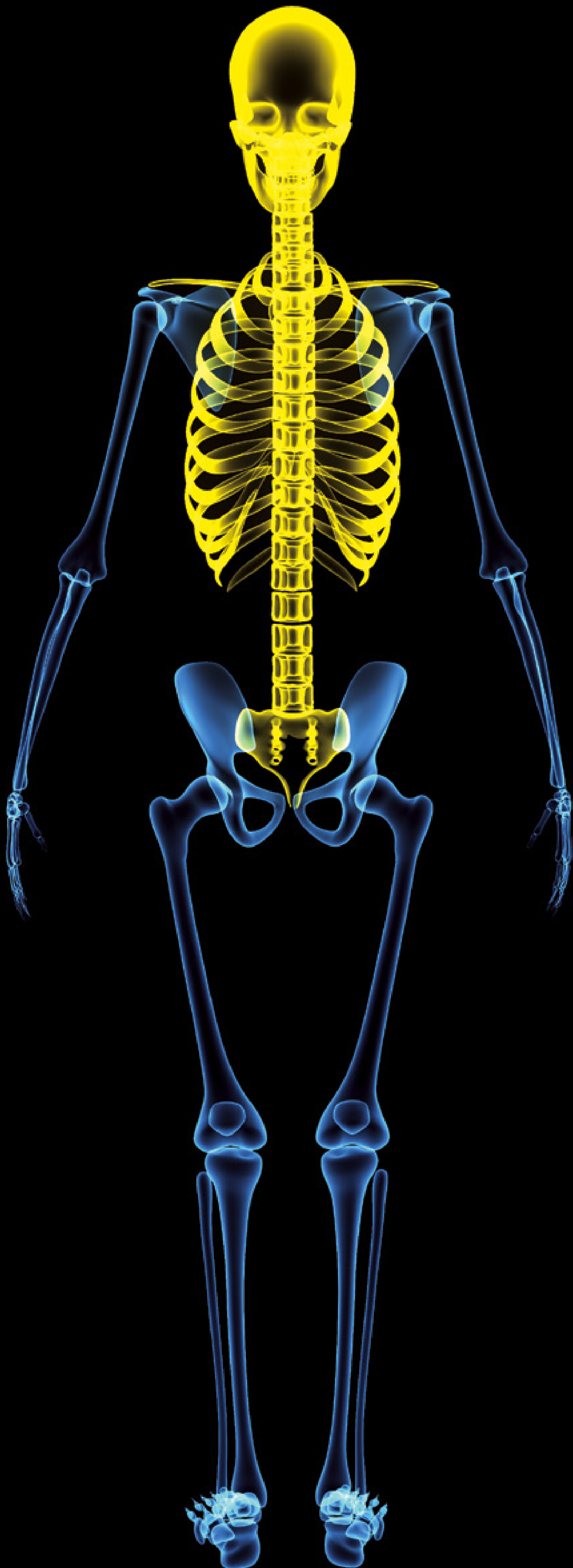
Chicago Medicine (ISSN 0009-3637) is published monthly for $20 per year for members; $30 per year for nonmembers, by the Chicago Medical Society, 515 N. Dearborn St. Chicago, Ill. 60654. Periodicals postage paid at Chicago, Ill. and additional mailing offices. Postmaster: Send address changes to Chicago Medicine, 515 N. Dearborn St., Chicago, IL 60654. Telephone: 312-670-2550.



3-D Modeling Adds an Extra Dimension in the OR

Intricate physical models of human anatomy help physicians gain ground

BY HOWARD WOLINSKY

THE CT SCAN showed the patient had a complicated form of spine-twisting scoliosis. In making his surgical plans, David Roberts, MD, a pediatric orthopedic surgeon specializing in correcting spinal deformities at NorthShore University HealthSystem, wanted to get an extra dimension—a 3-D view—before performing surgery. During his fellowship training at Texas Scottish Rite Hospital for Children in Dallas, he routinely worked with models of spines created from 3-D printouts from inkjet printer-like devices. He wished he had the same capabilities here.

LEFT: Orthopedic surgeon Dr. David Roberts, and partner Dr. Srdjan Mirkovic, refer to a 3-D model of the spine during surgery. RIGHT: Researchers use these 3-D printed models to fill a gap in medical education—the lack of pediatric surgery simulators to repair rare congenital defects in newborns.

Then in June, Dr. Roberts heard that NorthShore was studying a new high-end, $200,000 multi-material 3-D printer made by Stratasys. The printer was supplied via a corporate partnership between NorthShore and ProofX, a Chicago-based 3-D printing startup.

The ProofX Bio FabLab, located within the Center for Biomedical Research Informatics at NorthShore in Evanston, produced a scale model of the spine of Dr. Robert's patient within 24 hours of analyzing CT scans. The plastic model, which took several hours to print, was used by Dr. Roberts for surgical planning and referred to in the operating room real-time.

"3-D printing is such a useful tool because for orthopedics, just like many other specialties, 3-D anatomy is very important. For a long time, we've had 3-D reconstruction like CT scans, but the use of the actual physical model is useful for a lot of things. I don't think it's standard, but it's becoming more common in orthopedics," Dr. Roberts said.

He said the model he received was very intricate with the interior and other structures. "It helped us understand the deformity and then when you're in surgery you're able to refer to the model directly, which makes you more efficient in a way that you can understand where things are and know the anatomy."

He said referring to a CT in surgery is difficult because his hands are occupied. But a 3-D model reveals angles and details of the delicate spinal cord and nerves. "You are able to check the anatomy and know exactly where you are. Anatomy is everything in surgery, meaning that to have the most precise understanding is good." He said a model is like GPS in a car calling out turns while viewing CTs is comparable to unfolding maps. "You could do things the old way, but the new way has advantages," he said.

Consumers Leading the Way

3-D printing has been available in medicine since the 1970s. Recently, 3-D printing has been gaining a rapid foothold in the consumer market as libraries. 3-D print shops and even individual consumers have bought devices for as little as a couple hundred dollars to make parts for bikes, cars, jewelry, busts, virtually anything.

3-D printing has been used to rapidly build houses. There even was the controversy in 2013 in which a Libertarian publisher created a file for printing out the "Liberator" handgun using the First Amendment for cover. The U.S. State Department used a technicality to shut down distribution.

General surgeon Jonathan Silverstein, MD, vice president, clinical research informatics at NorthShore, said the consumer revolution in 3-D printing has resulted in people using printers to make toys, jewelry and statuettes at home, in libraries and in storefront businesses. Hobbyists share files online and can build homemade printers for a couple hundred dollars.

He said this consumer movement has reenergized interest in 3-D printing in medicine. But a high-quality printer still can cost $200,000. "3-D printing could have been used seven years ago but the printers would have cost ten times as much," Dr. Silverstein said.

"Today, the 3-D printers have enormous capabilities, printing internal anatomy in varying materials and hues to give the surgeon a road map."

Innovative Anatomical Models

Research scientist Nigel Parsad, who directs 3-D anatomical printing and visualization research at

Dr. Katherine Barsness, assistant professor of surgery at the Feinberg School of Medicine, holds 3-D printed organs used to train surgeons to repair congenital defects in newborns.

the ProofX Bio FabLab, has created 3-D anatomical models for surgical innovation, including the spine, for Dr. Roberts. Other 3-D life-sized models have been used in jaw reconstruction following cancer surgery and in orthopedic surgery to repair patella-femoral dysfunction.

Amy Pittman, MD, an otolaryngologist at Loyola University Medical Center in Maywood, said CT scans are printed out to both plan surgery and to make bars into which fibula bone from the lower leg is transplanted to fill the gap in the jawbone. Surgeons use the model to bend the reconstruction bar, joining the transplant to the spared jawbone, to fit that particular

The Next Step: Bioprinting Organs Cell by Cell

3-D PRINTING, an additive process using inkjet-type printers to put down layer after layer of plastics to make models from CT and MRI images, has established a niche in medicine. Meanwhile, bioprinting, a cousin to 3-D printing, is starting to emerge with mind-blowing possibilities. With bioprinting, a printer is used to print out cells within a supportive biomatrix or scaffolding with a dash of stem cells. Then, the material is placed into an incubator and nurtured until a tissue or organ is ready for transplant.

Bioprinting sounds like science fiction, but it's already happening.

3-D printing has been used to print replacement parts, such as for a bike. Bioprinting has been used to grow tubular structures, such as blood vessels, urethras or windpipes, and hollow organs, such as the bladder and stomach. On the horizon are solid organs such as hearts, kidneys and livers.

Last year, for example, researchers at Weill Cornell Medical College in New York, reported that they had bioprinted and grown a replacement ear that could be used for reconstructive surgery on children born with malformed outer ears. In Ann Arbor, researchers at the University of Michigan's C.S. Mott Children's Hospital reported last year that in a medical first they had used a 3-D printer to produce a splint to treat the trachea and bronchus of a child with tracheobronchomalacia, which causes deadly breathing problems.

Darryl D'Lima, MD, a bioengineer and orthopedic surgeon at the Scripps Research Institute in La Jolla, Calif., said that skin and cartilage are the low-hanging fruit for bioprinting. "The technical challenges for the most part have been solved. The hurdles, in my opinion, are just regulatory," he said of his work on artificial cartilage to be used in knee surgery. However, printing complex organs is still some way off. "Bioprinted livers and kidneys may actually save lives, but technically it is so challenging that the technology may be 10–20 years away," he said.

The problem with solid organs is they are complex, involving growing multiple types of tissue. Dr. D'Lima said, "If you're printing a kidney, you have to hook it up not only to the blood supply, but also to the plumbing for the urinary system. If you're printing the heart, you have to print not only the tissue, but also the electrical conducting portions of the heart."

The ultimate goal for bioengineering—and now bioprinting—is to make whole solid organs from scratch, but this still is not feasible. Yet, many researchers think that tissue patches and partial replacements may be enough to restore organ function. For instance, bioengineer and urologist Anthony Atala, MD, director of the Wake Forest Institute for Regenerative Medicine in Winston-Salem, NC, is exploring a strategy of "cassette replacement" as an intermediary and alternative to growing whole organs.

After all, most organs do not have to work at full steam all the time. Failures typically do not affect the body until about 90% of function is lost. "You don't even need one kidney," Dr. Atala said. "So if you have above one finger [of kidney tissue] rolled up, you get yourself out of dialysis. We're creating these cartridges or cassettes that we can implant and that can boost your organ functionality."

Dima Elissa is CEO and co-founder of Chicago-based ProofX, which uses CT and MRI imaging to print out 3-D models to guide surgeons. But her eye ultimately is on bioprinting, what she refers to as the "endgame" for her start-up. "We'd like to believe what we're doing today—learning about how to print unique use cases and edge cases and the very difficult cases. We're able to use these tools in the higher- risk scenarios. We're going to see a tremendous benefit. We can learn from them to the extent that we optimize how to print tissue, how to print bone with anomalies. It's going to give us the lenses we need to understand bioprinting.

"I think the real advancements we're going to bring forward have to do with printing soft tissue and printing it better than anybody. I think the more important point for ProofX and what we're doing today is that these 3-D models are giving us the pathway to be ready for bioprinting."

3-D printers are part of bioprinting

patient's anatomy.

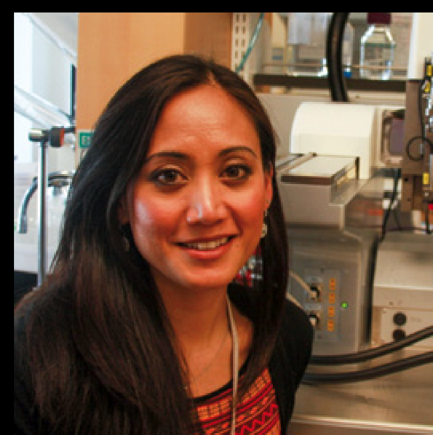
"Using the model, the surgeon can bend the plate prior to surgery, saving maybe 20 minutes of time in the OR, while reducing the amount of time patients are under anesthesia and reducing the cost of the procedure," said Dr. Pittman, an assistant professor at the Stritch School of Medicine.

She said it is possible to print the bar, also known as a plate, from titanium, sparing the surgeon from bending the plate. "It's something we can do, and I've done it once this past year, but I think it is an expensive technology right now, too. It's useful in certain situations, where you have to reconstruct the entire segment of the mandible or jawbone. In that situation, it might be worth the cost. For some of the more straightforward cases, it's harder to justify spending the money when you don't need to," she said.

Models as Educational Tools

3-D models may cost anywhere from several hundred to several thousand dollars to make. Parsad said NorthShore has recently determined how reimbursement will work for 3-D printing: "We actually are having the surgical billing department look at this right now. There are many different ways you can bring innovative instruments into surgical practice. This is a lot like visualization. Every surgeon loves it. But you still have to pay for it. I think the insurance code for 3-D visualization is $150. Is that really going to cover the cost of doing this procedure? Who knows? But one of the things they're doing right now is looking at all the possible ways because surgery involves innovation."

Pravin Patel, MD, chief of pediatric plastic surgery and director of the craniofacial surgery service at the University of Illinois at Chicago College of Medicine, said, "Today the 3-D printers



FROM LEFT TO RIGHT: Orthopedic surgeon Dr. Nirav Shah calls 3-D printing the new frontier; Dima Elissa, CEO of ProofX, finds bioprinting to be the "endgame" for her start-up company; researcher Ramille Shah is developing new material links that can be used for 3-D printing of functional tissues and organs.

systems. Another key component is the matrices used to cultivate growth of tissues and eventually organs to treat patients.

Researcher Ramille Shah, PhD, assistant professor, Department of Materials Science and Engineering, and assistant professor, Department of Surgery (Transplant Division), focuses on this work at the Tissue Engineering and Additive Manufacturing (TEAM) Lab at the Simpson Querrey Institute for BioNanotechnology on Northwestern University's medical campus downtown.

In essence, she is developing new material "inks" that can be used for 3-D printing functional tissues and organs. One particularly promising ink is a material slurry with the consistency of Elmer's Glue that when 3-D printed can provide a supportive bone-like ceramic matrix for cells. The ceramic particle within the ink is hydroxyapatite, the main mineral found in natural bone.

"We are taking what is found naturally in human tissue, putting it into a 3-D printable ink, and fabricating optimal biomimetic templates to induce tissue regeneration," said Dr. Shah. Her ink is made from synthetic hydroxyapatite.

Dr. Shah said despite containing ceramic material, this unique 3-D printed hydroxyapatite scaffold is the first with "hyper-elastic-like" properties, making it more flexible and malleable compared with traditional ceramics that are very brittle. This flexibility allows for its application in a variety of different orthopedic and dental applications. It's called "hyper-elastic bone," and it is the first product that she, her husband Nirav Shah, MD, some members of her lab and others plan to launch out of a start-up. Other inks in development in the Shah lab include ones specific for soft tissue and organ engineering.

Nirav Shah, MD, an orthopedic surgeon who practices in the city and southwest suburbs is upbeat about the future of 3-D bioprinting: "This is the frontier. 3-D printing and new materials discovered through 3-D printing can potentially enhance the function of implants that may get patients back to normal sooner with less therapy. This will lower the cost to society of patients missing work or needing more medical care or therapy. I think it will not only revolutionize medicine, it will also revolutionize each patient's outcome."

LEFT: Research scientist Nigel Parsad has created 3-D anatomical models, including one of the spine, for surgical innovation. RIGHT: Dr. Amy Pittman, an otolaryngologist, said CT scans are printed out to both plan surgery and to make bars into which fibula bone from the lower leg is transplanted to fill the gap in the jawbone.

have enormous capabilities printing internal anatomy in varying materials and hues to give the surgeon a road map not only of the skeleton but also the vascular anatomy."

3-D printing not only has found a place in the OR, but is also helping in the development of models that serve as multi-purpose educational tools. "There is an educational component. 3-D models help show the parents and child what a defect looks like and how the surgeon can reconstruct complex facial clefts and skull deformities," Dr. Patel said.

"For residents, we now have the ability to give a relevant homework problem. We ask them how they would reconstruct a deformity and discuss the pros and cons. For the resident surgeon, it becomes a video game. As an attending surgeon, I can say, 'Yes, this is going to work. Or no, this isn't going to work."

Katherine Barsness, MD, assistant professor of surgery at the Feinberg School of Medicine at Northwestern University and at the Center for Education in Medicine, is using 3-D printing to fill a gap in medical education—the lack of pediatric surgery simulators to repair rare congenital defects in newborns. "You want to be sure when you're teaching students and they're practicing, it's not on a real patient. We have developed a series of pediatric surgery simulators to train fellows at Lurie Children's Hospital as well as surgeons from all over the country and the world to perform minimally invasive surgeries on our 3-D printed models," she said.

Lauren Davis, formerly a designer in the Innovations Lab at Northwestern, developed a simulated infant-sized ribcage that could be produced on a 3-D printer. Dr. Barsness said the goal was to come up with a way to teach surgeons how to place a drainage tube in an infant's chest. Based on this work, Dr. Barsness and her team have developed a series of simulators to teach students to repair congenital defects.

She said the only simulators on the market were adult sized: "For a pediatric surgeon, every operation we do on a newborn infant takes place inside the space of an egg. Working on a large abdominal or large chest of an adult is not very relevant to our trainees. We had an education gap."

"Every operation we do on a newborn takes place inside the space of an egg. Working on a large abdominal or large chest of an adult is not very relevant to our trainees."

The Road Ahead

The original models made in 2011 on a 3-D printer snapped. But through trial and error with plastics, researchers developed a simulated ribcage that was 3-D printed from a rubber-like material that is flexible—just like an infant's ribcage. Dr. Barsness said Northwestern filed for a patent with the United States Patent and Trademark Office in May and hopes to commercialize the simulator.

The simulators are covered with silicone "skin" draped over a printed ribcage, and fetal bovine tissue is used to imitate human tissue for simulated surgery. But Dr. Barsness hopes to take 3-D printing to the next level, moving from 3-D printed ribcages to 3-D bioprinted tissue of actual defects. "Straight from the CT scan, we would 3-D print the actual anatomy," she said. "This is really personalized medicine."

"Imagine that a child is born with a TEF (tracheoesophageal fistula). We would come to the simulation lab the night before the operation. The trainee and the surgeon would evaluate the whole anatomy, make some of the more difficult decisions ahead of time, and better educate the families as to what to expect based on our findings from the imaging and from the 3-D printed operation. This means we would literally have done just-in-time training specific to the child's exact anatomy. That is ultimately where we're going."

Howard Wolinsky is the former medical and technology reporter for the Chicago Sun-Times. He previously worked as a staff writer for American Medical News and as an instructor at Northwestern University's Medill School of Journalism.