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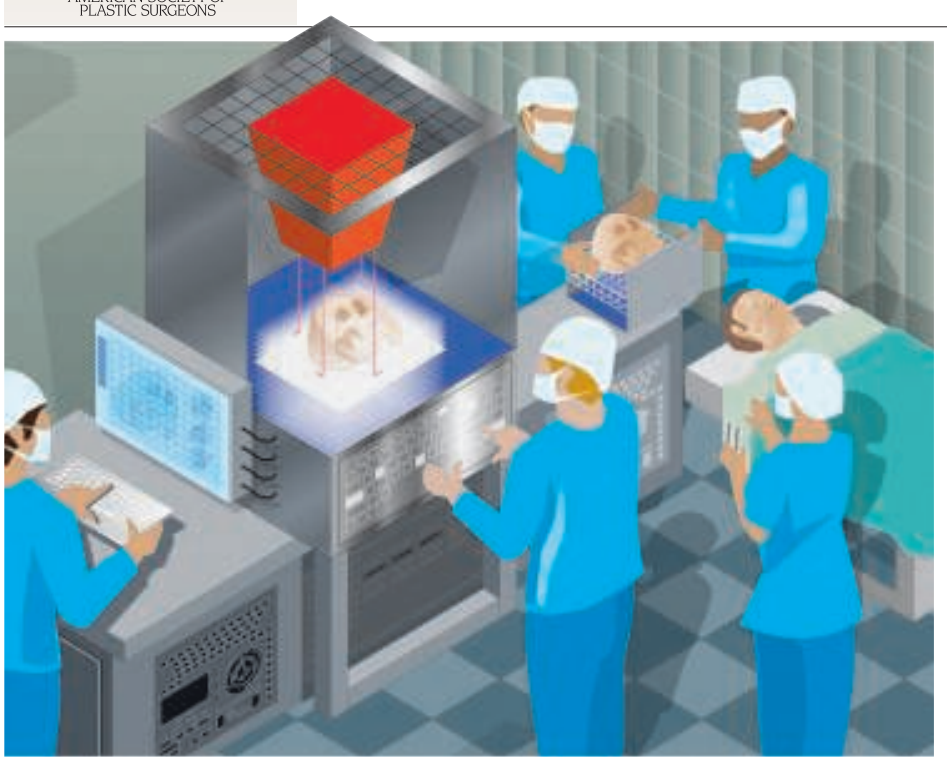

Rise of 3-D printing stretches the limits of plastic surgery's potential

BY KEITH LORIA

Plastic surgeons do not like surprises. They are known for meticulously planning surgical procedures, and a growing number are embracing 3-D printing as a viable

tool to further eliminate variables in the O.R. Though the technology has existed since the 1980s, 3-D printing's embrace by the medical community has accelerated in recent years – and ASPS members are using it to extend the limits of treatment possibilities.

Also known as "additive manufacturing" or "rapid prototyping" (or "one layer at a time"), the process works by creating objects through sequential layering of plastic, resin, metal, paper or other material – including biomaterial – based on a three-dimensional digital scan or model. The $2 billion 3-D printing industry – which is projected to expand into a $6 billion industry by 2017 – represents a rapidly evolving technology that is currently being used by surgeons to create physical objects from digital renderings to plan complex surgical procedures. Future application hold even greater promise, from "printing" patient-specific surgical tools to implants imbued with living cells to regenerate human tissue.

3-D printed organs and body parts, and computer-aided tissue engineering, all may one day result from this relatively nascent technology.

"We use 3-D printing as an educational and planning tool, where we can 'cut out' a patient's anatomy and learn what it is before going into surgery," says ASPS member Samuel Lin, MD, Boston, associate professor of surgery at Beth Israel Deaconess Medical Center. "The precise and cost-effective prefabricated model ascertained from computed tomographic data have the ability to yield pre-contoured plates that can help surgeons plan for potential bone-graft harvest geometry before the procedure."

The 3-D printing process begins with entering geometric data into a computer, which forms it into graphics in a process that has been likened to digital sculpting. The

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Plastic surgeons join RAND panel on ALCL

Extending efforts to better understand and eradicate breast implant-associated anaplastic large-cell lymphoma (BIA-ALCL), the RAND Corp. on March 26-27 convened an advisory panel on the rare condition. ASPS members Mark Clemens, MD, and V. Leroy Young, MD, joined experts from other specialties involved with the diagnosis and treatment of the rare condition for the rigorous, two-day session, in which they were asked to provide plastic surgery's perspective and information gleaned from their experience with ALCL and implants. The panel summary is expected this summer. **Page 8**

ASPS unveils ambitious national ad campaign

ASPS public education efforts are about to arrive in prime time. The Society is launching an eight-week, national marketing campaign aimed squarely at promoting ASPS member practices while informing prospective patients of the importance of choosing ABPS-certified plastic surgeons – who represent the gold standard in patient care and patient safety. The campaign includes TV, the Internet and movie theater ad placements, as well as a new call center dedicated to routing public inquiries to member practices. **Page 7**

Regen Med Task Force offers 'Stem Cells 101'

The marriage between plastic surgery and stem cell technology is all but assured; the only question that remains is "when." Federal regulation combined with a nascent – but rapidly growing – body of research are causing the use of stem cells in medicine in general to move at a crawl. However, with breakthroughs and regulatory approval inevitable, ASPS Regenerative Medicine Task Force members are providing Society members with a basic primer on this burgeoning field. **Page 22**

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computer then scans the "sculpture" and forms the 3-D model of the digitally created piece. Digital models can created from standard CT images in 30-120 minutes, with the physical 3-D printed models created in one day.

"The primary advantage of this technique is its ability to create almost any shape or geometric feature, which can then be used to assist in a plastic surgeon's procedure," says Kevin Lewis, corporate strategy director for Xerox, one of the 3-D printing brands fighting for U.S. dominance in this groundbreaking and rapidly developing field.

"3-D printing can allow surgeons to quickly, cost-effectively and accurately print accurate physical models related to a patient's case," adds Conor MacCormack, CEO and co-founder of 3-D printer developer Mcor Technologies, Dunleer, Ireland. "These models can serve as a surgical guide in the O.R., where time is critical. When a patient can be quickly closed up and begin recovery, chances are greater for a healthy recovery."

Early adopters

A handful of plastic surgeons became early adopters of 3-D printing to plan for rare and groundbreaking cases. In October 2003, Egyptian conjoined twins Mohamed and Ibrahim were separated in a 34-hour operation headed by ASPS Life member Kenneth Salyer, MD, founder of the World Craniofacial Foundation. Though less-refined by today's standards, 3-D printing technology was considered revolutionary at the time. The first technique, known as "stereolithography," employed a laser-curing liquid plastic to create its models – and it likely saved the lives of the 2-year-old craniopagus twins, Dr. Salyer says.

Using CT scans and MRI technology, Medical Modeling LLC (now part of 3D Systems Corp.) fabricated accurate plastic models that allowed Dr. Salyer and his team to visualize the bone along with colorized, differentiated vascular structures – which proved crucial to the separation procedure, as the boys shared significant vasculature. Dr. Salyer is convinced that, without this 3-D printed model, the separation would not have come close to the success of its eventual outcome.

"This is speculative, but if that technology hadn't existed, I doubt very much whether the twins could have been successfully separated," he says. The history of the separation of twins to that point had been extremely dismal; death of one or both – and for the survivors, more than half experienced significant neurological deficits limiting function, notes Dr. Salyer.

"The models gave us something that we could hold in our hands, to turn over and around, to use as a guide – which is exactly what we did during that 34-hour separation process," he says.

Because most if not all operative procedures have a tactile component that can't be replicated, the 3-D models gave the team an unprecedented tool to work with: the actual skull prior to entering the O.R.

"This gave us skeletal portions, which helped direct cutting processes quite effectively – where to place the saw tip and how far in to go, for instance. It provided a great deal of confidence and support," Dr. Salyer says. "What we were given was quite revolutionary. We were really way ahead of the curve with the boys."

A decade later, the boys are healthy, happy and thriving in Egypt, Dr. Salyer tells *PSN*.

Bohdan Pomahac, MD, Boston, director of plastic surgery transplantation at the Brigham & Women's Hospital, where he led the first full face transplant in the United States in March 2011, says he began using 3-D printing in preparation for that procedure.

"We have used skeletal 3D printing for modeling of cranial deformities and specifically in face transplant patients to visualize their defects," says Dr. Pomahac. "We've also used it to evaluate the actual territories of the face transplant recipients, visualizing in 3-D the relationships between bones, vessels and soft tissues so that we minimize the unknowns at the start of the operation. The recipient is the primary target for this information given their relatively changed anatomy due to multiple reasons, including previous trauma, previous surgical reconstructive procedures, depletion of vessels and so forth.

"It's been a little more than five years ago since we got the first 3-D printed model for skeletal planning of osteotomy in our face transplant patient," he says. "It's been a long time – but we're now discovering more exciting applications and seeing more widespread use, so we're looking at 3-D printing a little differently than we did back then."

Assistance to the max

Oren Tepper, MD, Bronx, N.Y., attending surgeon in the Division of Reconstructive and Plastic Surgery at Montefiore Medical Center, says 3-D printing of maxillofacial models that can be deployed in the O.R. are becoming the standard of care for some facets of head and neck reconstruction.

He believes that using this technology to map the anatomy of a patient with craniofacial injuries and post-traumatic deformities, and to develop a surgical plan prior to arriving at the O.R., eliminates surprises, minimizes complications and improves the precision of surgery.

"For complex reconstruction in kids, I've been printing these models and guides to help me position and perform the reconstruction," he says.

Dr. Tepper notes that 3-D really got off the ground with simple printings of the skull – which surgeons found quite useful. "Then it became printing an idealized skull of what you were trying to achieve, and now it's made its way into not just printing something you can look at as a reference, but actually printing something you can use to guide where you make the cuts, how you put the bones together and how you do the reconstruction," he says.

Dr. Tepper published a case study in the *International Journal of Pediatric Otorhinolaryngology* about a 3-week-old girl who had difficulty breathing due to a small lower jaw. By using virtual planning technology, he created 3-D computer

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models of the infant's jaw and used them as a guide intraoperatively to successfully lengthen her lower jaw and open her airway. The child's breathing reportedly has vastly improved and her jaw is developing normally, thanks to the surgery.

Earlier this year, ASPS member Elliot Duboys, MD, associate professor of surgery at Stony Brook University School of Medicine, and Michael Egnor, MD, director of pediatric neurosurgery at Stony Brook Children's Hospital, collaborated with Colorado-based Medical Modeling Inc., to plan the virtual surgery of a 6-month-old infant who had unilateral coronal synostosis.

Using 3-D printing technology, the modeling company created before-and-after models of the young boy's skull, simulating the symmetry and dimensions it should have, so the surgeons could accurately predict how the results of the operation would look.

Dr. Duboys says they had accurate cutting templates to follow – so they simply traced where the cuts should be on the skull like a stencil.

Going soft

While 3-D printing for bone is gaining popularity, Dr. Tepper believes that it won't be too long until the technology proves useful in soft-tissue reconstructive procedures.

"I think we will see 3-D printing in the O.R. for soft tissue in the next couple of years. This is the next big area of reconstruction surgery," he says. "It's a lot easier when planning on bone to see where cuts are made, how you can print a guide to help and print a solid structure."

"There are plans for the future to have actual printed models that would allow us to peel off the soft-tissues and look at the vessels in relationship to the soft tissues as well as to the bone," adds Dr. Pomahac. "That's where the future is in terms of medical modeling and 3-D printing applications in plastic surgery."

Dr. Tepper, who specializes in ear reconstruction, says he looks forward to the day when he can use the 3-D technology for otoplastic procedures.

"I'm actually collaborating with some 3-D colleagues who work in automation and aerospace, and incorporating some of that technology," he says. "We're starting to come up with ways we can print 3-D constructs that we can use as a reference – guides we can use in the O.R. A lot of what happens with ear reconstruction is postoperative, with the dressing and getting things to heal in the way you want them to."

The ability to create patient-specific orthoses and splints custom-designed to fit the patient in the position needed for optimal postoperative results – without the need for an occupational therapist to redesign or fine-tune the device postoperatively – is also a real possibility, say Drs. Tepper and Pomahac.

"You could even print, perhaps, instruments that you could use in the O.R. rather than selecting from hundreds of instruments in a kit," says Dr. Pomahac. "The ability to immediately substitute things that you need – or to make patient-specific products – would result in greater efficiency in the O.R."

'Customizable' implants

Dr. Lin co-authored a February 2014 *PRS* article on 3-D printing, "A Plastic Surgery Application in Evolution: Three-Dimensional Printing," which notes how hand surgery could benefit from this technology, as it one day might form prosthetic portions of the upper extremity adapted specifically to individual patients' functional needs and anatomy, in addition to customized implants for both large and small joints.

He also tells *PSN* that 3-D printing could have revolutionary aesthetic applications, as well. Breast implants, for instance, theoretically could be designed in an office setting by the plastic surgeon, who would input a patient's measurements and desires to generate a 3-D model – with the result being a customized implant that would originate in a printer, he says.

"This technique has the potential to produce improved aesthetic outcomes as a result of individual fitting, and to complement individual anatomical needs," says Dr. Lin.

"In the future, there might be a way to print-out customized implants for a patient. I think over time the material will get better and the speed at which implants can be made and implantable will increase."

Dr. Salyer agrees: "This technology may one day be used in breast repair or enhancement, to provide a customized breast for each patient."

The 3-D printing principle also could be applied to facial aesthetics as well, Dr. Lin adds.

Using mandible reconstruction as an example, Dima Elissa, CEO of ProofX, a Chicago-based prototype and short-run fabrication company, says that 3-D printing can reach a plastic surgeon's objective of obtaining a true rendering of the lower jaw that's accurately sized and contoured. This rendering can allow the surgeon to properly form the titanium reinforcement, for example, to be screwed into the patient's jaw, to act as a lifetime support structure as a whole and for the bone graft that would be concurrently performed.

"The advantage to this process is that it reduces the amount of time the patient has to be in the O.R. by 15-20 minutes and allows the surgeon to do the physically hard labor of bending the titanium in advance – rather than immediately just before complex microsurgery is about to start," Elissa says.

"One ancillary benefit is the reduction of hand fatigue for the surgeon at a critical time in the procedure," she adds. "In addition, it can reduce overall operative time and improve outcomes, both through a better fit of the titanium reinforcement and the lessened risks associated with shorter surgical times, and reduce the number of stitches."

If adopted as a standard, Elissa says it will eliminate the need to purchase the tin plate typically used in mandible reconstruction to create a template of the lower jaw after it's exposed.

A journey begins

An anatomical part begins its 3-D journey when the geometric data is uploaded through a computer design model or scanned in.

MacCormack explains that all 3-D printing starts with a 3-D data file, with stereolithography (STL) being the universal industry standard file format for 3-D product designs. Also widely utilized are "object files (.obj)" and "virtual reality modeling language (.vrml)."

"All mainstream 3-D computer-aided design (CAD) software products, including free programs such as SketchUp, produce STL files," he says. "Completed designs offered for download are typically presented in STL, as are files produced by scanning a physical object."

Price of advancement

The costs associated with 3-D printing are still significant, but experts agree that more competition and the increasing production of the materials needed for this new technology together should help bring down prices.

The price of 3-D printers can range from $500 to upwards of $10,000, but the cost of materials is where the expenditures become truly significant. While there are some cheap plastics that come in big spools, materials such as metal and titanium can run tens of thousands of dollars.

"In the case of a facial reconstruction, printing a mandible for maxillofacial surgery, you can expect a price in the range of $2,500-$3,200 for a custom-printed plastic-form jaw," says Elissa. "Those costs include every step after the initial scan, CT or MRI digital source, pre-flight to printout."

Most plastic surgeons are using a third-party house for their printing needs, saving them the trouble and expense of buying a machine. But that may soon change, Dr. Tepper says.

"What I think you are going to see in the upcoming years is that 3-D printers will become more accessible and more affordable, and things will move in-house," he maintains. "In my mind, there's no question that people will see the value of it, insurance companies will see value in it and I think it will become routine for plastic surgeons."

Currently, however, costs associated with medical 3-D printing processes are generally not covered by insurers.

Dr. Tepper estimates that a small percentage of plastic surgeons are currently using 3-D printing now – mostly limited due to cost, unfamiliarity and intimidation by the technology. Still, there's not a reconstructive procedure that he performs which does not involve 3-D planning or 3-D printing on some level.

"In order to print in 3-D, you need a 3-D picture," he says. "3-D cameras have been sold to plastic surgeons for a while now, but for the most part, those are mostly marketing tools. However, what's emerging is pictures that have a lot more capability than just showing patients what they may or may not look like. Things are becoming so user-friendly that we are going to see more and more of this."

Dr. Salyer predicts that says the technology will continue to evolve in unexpected ways, and that it holds so much promise that he refuses to predict its end point.

"This has unlimited application in the medical field," he says. "3-D will have a fairly significant expansion and refinement – it's absolutely important and significant, and no one can predict where it will go. I'd never have predicted that I would be using a cell phone or a computer. This will be fun to watch." PSN

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