

Impact of Three-Dimensional Printing on the Study and Treatment of Congenital Heart Disease

Matthew Bramlet, Laura Olivieri, Kanwal Farooqi, Beth Ripley, Meghan Coakley

Three-dimensional (3D) printing technology allows for the translation of a 2-dimensional medical imaging study into a physical replica of a patient's individual anatomy. 3D printed models can facilitate a deeper understanding of complex patient anatomy and can aid in presurgical decision-making.¹ Although there are 3D printing case reports in almost every subspecialty of medicine to date, the rate of adoption in the field of congenital heart disease (CHD) is particularly advanced.^{2,3} This is due, in no small part, to the fact that the heart is a hollow organ, which makes it a perfect substrate for 3D printing. More importantly, medical decision-making in CHD is informed by assessment of the anatomic morphology of the heart because cardiac pathology is a direct manifestation of the underlying 3D structure.

Reports on the application of 3D printing in the study and treatment of CHD are accumulating rapidly; these studies cover uses, including advanced visualization, surgical planning, and education.⁴ Individual case reports and small studies indicate the potential to improve patient outcomes using patient-specific 3D models. There is a growing body of literature that demonstrates the value of 3D models in decision-making,⁵ procedural

planning,⁵⁻⁷ and postoperative care simulation.^{8,9} Two specific cases are illustrated for the reader's interest in Figures 1 and 2.

Identifying and Overcoming Barriers to Adoption

Although initial reports describing the benefits of 3D printing in treating CHD are promising, the practice is not yet mainstream. Barriers to adoption for most programs include one or more of the following: start-up costs for 3D modeling software and 3D printing equipment; lack of expertise in medical image segmentation, 3D modeling, 3D printing methods, and 3D printer operation; and lack of incentives for administrators to introduce a 3D printing program.

Start-Up Costs

The price of 3D printers and materials range from several thousands to hundreds of thousands of dollars. Licenses for 3D segmentation software continue to evolve but can be expensive. While open-source options exist, they have a steep learning curve. Factors that mitigate start-up costs include innovations from the open-source community and the fact that the Food and Drug Administration does not provide oversight for the production or use of patient-specific models when used as a visual aid.¹⁰

Lack of Expertise

The translation of medical imaging data into 3D printed models requires knowledge of anatomy, pathology, imaging physics, and engineering concepts related to 3D printing. There is seldom 1 person who embodies all this knowledge. Therefore, models are most likely to be created by a team approach, with expertise in imaging and anatomic pathology on one end of the spectrum and experience with creation and manipulation of computer-aided design files and 3D printing on the other end of the spectrum. As with any handoff in medicine, there needs to be extreme care taken that essential information is not lost at some point in the process. Additionally, we cannot ignore the critical need to ensure the accuracy and quality of 3D models, both digital and physical, when used in the health-care setting. For this reason, high-level expertise and training will be essential, along with standards and metrics against which 3D models should be measured.

The opinions expressed in this article are not necessarily those of the editors or of the American Heart Association.

From the Pediatric Cardiology, University of Illinois College of Medicine at Peoria (M.B.); Advanced Imaging and Modeling Initiative, Jump Trading Simulation and Education Center, Peoria, IL (M.B.); Division of Cardiology, Children's National Medical Center, Northwest, Washington, DC (L.O.); Rutgers, Division of Pediatric Cardiology, Department of Pediatrics, New Jersey Medical School, Newark (K.F.); Division of Pediatric Cardiology, Department of Pediatrics, Icahn School of Medicine at Mount Sinai, New York, NY (K.F.); Radiology, VA Puget Sound Health Care System and University of Washington Medical School, Seattle (B.R.); and Bioinformatics and Computational Biosciences Branch, Office of Cyber Infrastructure and Computational Biology, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD (M.C.).

Correspondence to Matthew Bramlet, MD, Pediatric Cardiology, University of Illinois College of Medicine at Peoria; and Advanced Imaging and Modeling Initiative, Jump Trading Simulation and Education Center, 1306 N Berkeley Ave, Peoria, IL 61603. E-mail Matthew.T.Bramlet@osfhealthcare.org

(*Circ Res.* 2017;120:904-907.)

DOI: 10.1161/CIRCRESAHA.116.310546.

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Circulation Research is available at <http://circres.ahajournals.org>

DOI: 10.1161/CIRCRESAHA.116.310546

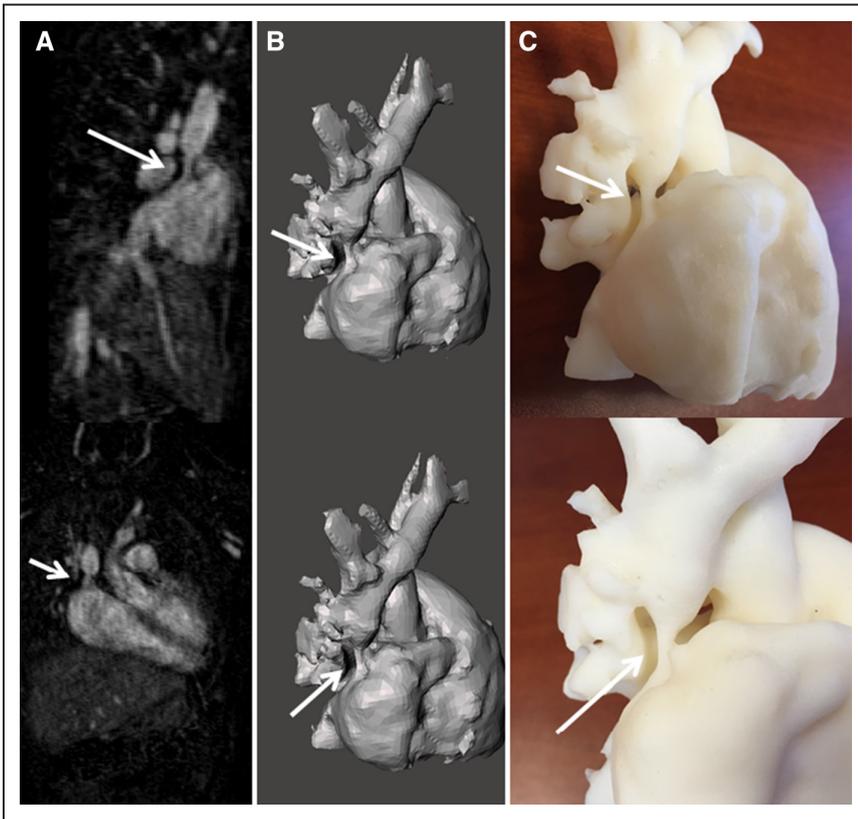


Figure 1. After surgical repair of a superior sinus venosus defect and anomalous pulmonary venous drainage, a 4-year-old girl was found to have a long-segment stenosis of the superior vena cava (SVC) as it entered the right atrium, anterior to the right upper pulmonary venous baffle. A 3-dimensional (3D) printed model created from the magnetic resonance imaging (MRI) data more clearly demonstrated the relationship of the SVC stenosis to the right upper pulmonary vein baffle, giving operators the confidence to proceed with balloon angioplasty of the SVC. **A**, Magnetic resonance image. **B**, 3D virtual. **C**, 3D printed models.

Lack of Incentive for Administrators to Introduce a Program

A commitment from administrators to integrate advanced 3D printing capabilities into a healthcare system depends, in large part, on financial reimbursement from health insurance providers, who are reluctant to support 3D printing without quantitative proof of improved patient outcomes and cost savings. Thus, establishment of 3D printing programs is impeded by the lack of evidence needed to justify such initiatives. There will need to be initial pilot studies, funded by the research community, to obtain this necessary data.

The 3D Heart Library: A Community-Driven Initiative to Advance 3D Printing for CHD

The 3D Heart Library is a digital, open-access collection of peer-reviewed 3D-printable models of healthy and diseased hearts created from patient imaging data, with a focus on

CHD. In establishing the Heart Library, we hope to preserve important anatomic data, as well as democratize access to CHD pathology, improving the knowledge base of our physicians. Further, as we carry out this project, we are working toward 3 primary objectives that will help to meet the broader goals of the 3D printing community: (1) develop standardized criteria and metrics for assessing quality of 3D heart models; (2) create a repository of 3D heart models validated against these criteria in a peer review process; and (3) provide scholarly incentive for clinicians to share their models with the community.

To discuss these objectives and formulate strategies to meet them, the authors gathered with other subject matter experts for a workshop held on October 12, 2016, in Chicago, Illinois. The event was part of the American Heart Association’s Cor Nexus Series, organized in partnership with OSF (Order of St. Francis) Healthcare. In this viewpoint, we

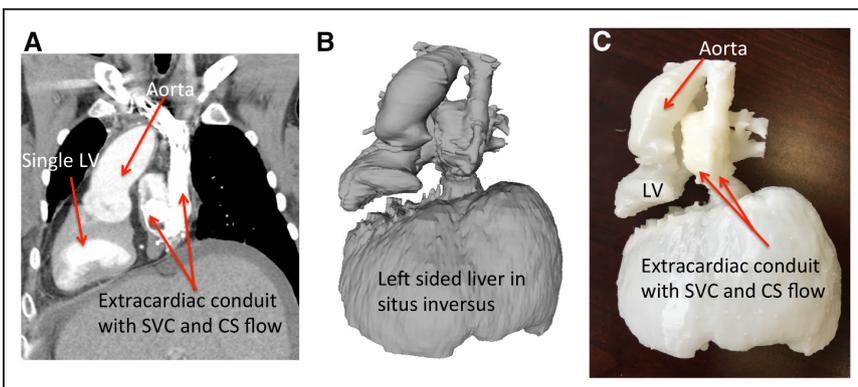


Figure 2. A 3-dimensional (3D) printed heart and liver of a 31-year-old patient with situs inversus totalis, tricuspid atresia, pulmonary atresia, and complex Fontan palliation provided for improved understanding of potential surgical anastomoses relationships prior to en bloc heart and liver transplant. The coronal computed tomographic (CT) scan image (A), 3D virtual (B), and 3D printed model (C) are shown. LV indicates left ventricle; CS indicates coronary sinus; SVC, superior vena cava.

summarize some of the consensus opinions reached during that meeting.

Standardized Metrics and Quality Criteria

It is our hope that 3D-printed models from the Heart Library will act as anatomically accurate replicas of a specific individual's anatomy (as cadaveric specimens do now), and therefore, it is essential that we define and institute quality metrics. To understand what these metrics will entail, it is first important to review the workflow from imaging data to model.

The workflow begins with image segmentation, during which a mask is layered over the desired anatomic details on each 2-dimensional slice of a 3D image data set. The masked data set is then converted into a meshed surface file, composed of edge-to-edge triangles or polygons. This file can then be imported into software for viewing via a virtual or augmented reality device or can be sent to a 3D printer to be rendered in physical form.

3D printers can create quality, high-resolution prints. However, a 3D print is only as accurate as the digital model from which it is derived. Accuracy of the digital model is dependent on the segmentation steps and any editing of the meshed file that may occur. We think that the digital model deserves the most critical evaluation from a quality standpoint because it is entirely dependent on the file creator's interpretation of complex anatomy. Because of the manual translation of image to model, we think that a standardized peer review process of 3D models is needed. This process will establish a mechanism by which to gather and refine metrics and information pertaining to quality and methods of cardiac image segmentation.

Grading submissions against a quality goal will allow for a deeper understanding of the current standard and will accelerate new research discoveries and technology. The mere establishment of a defined quality goal will drive the anatomic surrogate upwards toward exact replication of the actual anatomy.

A Centralized, Open-Access Repository for 3D Models

The 3D Heart Library will disseminate validated 3D models through an open-access platform as a peer-reviewed subset of content on the National Institutes of Health 3D Print Exchange (<https://3dprint.nih.gov>), an online portal dedicated to bioscientific and medical 3D printing and visualization.¹¹ The Exchange has been structured to include an open-access database of user-contributed 3D models along with models generated from free web tools hosted on the site. The broad range of 3D content includes custom-designed hardware for laboratory research; 3D-printable prostheses and assistive devices; and 3D models derived directly from raw molecular structure, microscopy, and medical imaging data. The 3D Heart Library is the first Library devoted to a specific subset of anatomic disease, cardiac pathology. It was created in response to the growing use of 3D heart models within cardiology and radiology to depict congenital and structural heart disease, and we expect to see it grow as these technologies become more widespread.

The National Institutes of Health 3D Print Exchange is an initiative from the National Institute of Allergy and Infectious Diseases, part of the US National Institutes of Health. Through this project, National Institute of Allergy and Infectious Diseases aims to facilitate and increase adoption of 3D printing in basic and clinical research and practice, both within and beyond the field of infectious disease research and treatment. National Institute of Allergy and Infectious Diseases supports the 3D Heart Library as a part of this goal to serve the global scientific and medical communities.

Incentivizing Contributions

Given the work and review process needed for successful submission of a model, we think that the sharing of a 3D model with an accompanying description and knowledge points should be counted toward the author's scholarly output. The 3D Heart Library peer review process is led by an independent, external group of clinicians and subject matter experts in pediatric cardiology, cardiac imaging, and medical 3D printing; the process is analogous to manuscript peer review. In addition, 3D models that are supplements to a published article can be submitted for review to be included in the heart library for more rigorous assessment of the 3D model, independent of peer review of the article itself. The 3D model review process brings added value and credibility to a contributor's 3D content, adding a higher level of trust for clinicians, educators, and patients alike. We hope that Academia will see the benefit of adopting these contributions as scholarly currency to incentivize physicians to devote their time and expertise to creating and sharing complex models.

Outcomes

The body of what is known about human variation and human pathology is expanding every day. Clinicians must keep up with the enormous amount of information that is constantly added to their field, which takes a serious commitment of time. One advantage that learning with 3D models confers to the lifelong clinician and clinical educator is the conservation of time. It eliminates variations in visual spatial understanding.¹²⁻¹⁴ 3D models can display complex anatomies, which can be digested and retained in much less time than it would take to deduce complex anatomy from a series of 2-dimensional images or pictures.¹⁵

We do not deny that the experience of cadaver dissection is vital to understanding human anatomy whether one plans a career in surgery, psychiatry, radiology, or pediatric cardiology. However, with the advent of new tools granting access to 3D models, one is able to use life-like anatomic models (digital and printed) to demonstrate any number of anatomic variants.^{8,9,16}

This resource will serve to further physician and patient education. Most importantly, it will provide a centralized location in which to gather models to amass evidence for utility of cardiac 3D models.

Conclusion

The value 3D anatomic models play in the improved understanding of congenital heart lesions is being increasingly

recognized. We think that the congenital heart community should look to a future where 3D printing will be incorporated in the medical decision-making process as a standard practice of care. To that aim, we are advocating for standards and recognition of scholarly contribution to build a database of 3D heart models complete with quality metrics for inclusion, a transparent process for validation of a model, and academic credit for contributions to the 3D Heart Library, which meet these standards. We hope that readers will consider submitting their own contributions, and we look forward to an ever-growing, enduring collection of accurate CHD anatomy.

Acknowledgments

The AHA Cor Nexus: The Cor Nexus Series is an initiative of the American Heart Association (AHA) created to make a tangible difference in the fight against cardiovascular disease by (1) Providing a platform for idea sharing and collaboration; (2) Educating the health-care community on critical areas of need in heart and stroke care; (3) Leveraging the AHA's community of subject-matter experts to reduce barriers to the development of disruptive and potentially lifesaving technology. We acknowledge the work of the National Institutes of Health (NIH) 3D Print Exchange team and Darrell Hurt and Michael Tartakovsky for continued support of the resource.

Sources of Funding

The National Institutes of Health (NIH) 3D Print Exchange is operated by the Office of Cyber Infrastructure and Computational Biology, National Institute of Allergy and Infectious Diseases, National Institutes of Health. Resources are provided in part through BCBB Support Services Contract [GS35F0373X], funded by the National Institutes of Allergy and Infectious Diseases. Initial funding for the 3D Print Exchange was supplemented by the US Department of Health and Human Services through the HHS Ignite and HHS Ventures programs.

Disclosures

None.

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KEY WORDS: 3D printing ■ cardiac models ■ congenital heart disease ■ database ■ peer review ■ segmentation

Circulation Research

JOURNAL OF THE AMERICAN HEART ASSOCIATION



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Circ Res. 2017;120:904-907

doi: 10.1161/CIRCRESAHA.116.310546

Circulation Research is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

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Print ISSN: 0009-7330. Online ISSN: 1524-4571

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