

Three-dimensional-printed cardiac prototypes in complex congenital cardiac defects: New technology with exciting possibilities

Three-dimensional (3D) printing has been an exciting and fast growing technology which primarily fills the void of customization and results in democratization of design and manufacturing. There are different methods used in 3D printing, but the complexity depends on the material used and the product that is being printed. Rapid prototyping which is creating models has long been used in engineering since 1980s but recently extended to medicine a decade later. There has been a significant effort toward adapting the technology to the clinical and teaching arenas. Although it has been applied in many specialties of medicine such as orthopedics, craniofacial surgeries, oncology, and radiology, in the early 1990s, the application in cardiovascular medicine was first reported in the context of surgery and transcatheter intervention of aortic aneurysms in 2001.^[1] One of the early reports by Schievano *et al.* concluded about its use in appropriate patient selection for transcatheter pulmonary valve implantation procedure.^[2]

Due to the biological variation of spatial relationships in congenital cardiac disorders, 3D rapid prototyping appears to be a better tool to comprehend their anatomical nuances. The cardiac substrate that is either congenitally malformed or iatrogenically altered is replicated into a 3D model that is thought to better clinical management. Kappanayil *et al.* in their early experience have affirmed this potential of rapid prototyping in a small cohort of five cases with complex cardiac anatomies.^[3] Hence, pediatric cardiologists and cardiothoracic surgeons are excited about this technology, which promises to be an individualized personal fabricator of heart models, in turn improving the understanding of structural issues before any intervention.

The primary requirement of rapid prototyping is a good 3D image data set which is now available through computed tomography (CT) scans, magnetic resonance imaging (MRI), and echocardiography although currently CT or magnetic resonance data sets are preferred. Second, a robust software is needed to perform cardiac segmentation that highlights the area of interest which is easier said than done when complex spatial relationships are defined. A versatile 3D printer which can utilize varying materials such as acrylic or plastic for rigid models in case of learners and parents or thermoelastic resin for softer models, typically useful for hands on formats, becomes the centerpiece of this modeling technology.^[4] However, it is important to note that many

of these tools may be inaccessible or may be unmet in a typical resource-constrained environment.

The adage “more information means better outcomes” may be a clear advantage in favor of 3D-printed cardiac prototypes. Importantly, the complexity of the heart that we as cardiac caregivers deal with encompasses and results in significant variations in the understanding of cardiac anatomy. Although the current 2D imaging does the job, it requires prolonged learning and conversion of 2D information to 3D spatial relationships in the caregivers’ brain. Hence, the belief is that a 3D cardiac prototype helps better communicate this understanding to caregivers. In addition, the cardiac prototypes would definitely help in surgical/interventional planning as a surgeon/cardiologist visualizes how the surgical changes may affect the patient, with a unique cardiac anatomy. Intuitively, a better understanding or the lack thereof will have an impact on procedural outcomes. Some surgeons and cardiologists would argue that testing the anatomical alterations proposed before performing the intervention on a live subject may make this technology many times worthwhile, although a seasoned cardiologist or a cardiothoracic surgeon would agree that this need occurs in only a few patients. In the article about rapid prototyping in a resource-limited environment, Kappanayil *et al.* have demonstrated how the right choice of palliative or definitive surgeries can be made “within minutes” using a 3D model. In three patients, it resulted in a biventricular repair while a one and a half ventricular repair was chosen in another. In one patient, they decided to defer a full repair in favor of a Aortoplasty with pulmonary artery banding.^[3] Obviously, it could mean a dramatic change in the patient’s life if the surgical options change from a palliative procedure to a definitive procedure.

As of date, 3D-printed prototypes utilize long processing times and its availability is limited by geography. For advanced nations with immediate access, it could take 5–7 days to 3D print a prototype. More recently, researchers in a Japanese university have produced fabricating materials that can be printed using an inkjet printer that shorten the processing times by half. It has also been touted to be more similar to the native tissue and, hence, may provide a dimension of realism to the handlers of biological tissues. Still, it could take as long as 4–5 days. Clearly, the ease of production and the time

taken to produce the prototype is very important as it could preclude its use in urgent situations. Currently, its utility is relegated only to elective procedures.

Other perceived advantages are in the area of teaching medical learners and caregivers. There is a concerted effort in maintaining open source 3D data sets such as the National Institutes of Health 3D print exchange or private repositories such as Thingiverse which can be used for public consumption, thereby reducing production costs. Fabrication laboratories are also being considered in public spaces such as libraries to facilitate rapid prototyping for eager learners. However, the above mentioned are less convincing reasons to create a 3D cardiac prototype in resource-poor countries. There are other competing technologies such as holographic projections and augmented- and virtual-reality (AR and VR) that could be more cost-effective for teaching and learning purpose.^[4] The clear advantage of these virtual imagery is the absence of physical model. However, it is flexible in allowing the user to alter and slice the image to note the data set according to their needs. Clearly, the surgeon's needs are different from an interventional cardiologist's need versus that of a learner of cardiac anatomy and physiology.

When adopting any new technology, it is important to understand what incremental value the technology brings and at what cost. It is not enough if a void is filled, but whether this would actually help in improving the care and if so, what type of patients would benefit from it? In places where the monetary constraints are high, it is important to give adequate weightage to resource utilization. The cost of having a model made will include not only the model and the type of material used but also the cost of MRI/CT from which the 3D images are derived which is typically borne by the patient. The cost of owning a 3D printer may make sense in certain environments, but it would not be cost-efficient unless it is available for a whole organization where other medical/surgical specialties could benefit from the same. The average cost of making the cardiac prototype commercially ranges from Rs. 10,000 to Rs. 30,000 for material and along with the segmentation and cleaning costs could make up to Rs. 70,000–80,000.^[5] However, the production costs tend to decrease over time.

While the 3D printing technology is here to stay and may very well become the future of congenital cardiac disease management for procedural planning, the incremental value it provides currently could only be balanced by cost-effectiveness through its wider use. The normal technology rule, where “more market penetration means higher product volumes and hence lower cost of production” is a contrarian argument with regard to medical technologies. In their article

on 3D rapid prototyping, the authors recognize the cost factor and have rightly suggested development of in-house infrastructure to reduce production costs.^[3] While this could be one option depending on the volume of production for that organization, in a typical resource-limited country, where there are more stand-alone, private, health-care institutions, this technology does not make much sense at this time unless the cost is borne by third parties such as insurance payers or the state itself. However, like all other technologies, 3D printers may even become a household item, but until then, the cost of ownership will be a barrier. One option would be to consider regional centralized 3D design and printing centers which can spread the production cost by volume from various medical specialties.

Despite the current limitations, the future of this technology holds great promise in the area of personalized medicine with the advent of biological tissue printing which is tissue engineering married to 3D printing. Although printing whole-complex biological organs may still be far from reality, some say another 20 years, this technology is being studied in the context of cardiac valves through seeding of the vascular cells into a 3D-printed tissue scaffold. Similar success has been obtained in prototyping blood vessels such as aorta. The real strength of owning and using 3D printing lies in this area which requires further development.

Taking a leaf out of cell phone adoption and penetration in developing countries, biological and 3D model printing could be leapfrogged through useful research and development in tissue and organ engineering while channeling resources to building and adopting other cost-effective yet robust 3D modeling tools such as AR and VR systems and/or holography for procedural planning and learning.

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