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Operationalizing low-cost three-dimensional printing in planning for complex congenital cardiac interventions

Ayman Abdelkarim*, Abbie Hageman, Daniel S. Levi, Jamil Aboulhosn

David Geffen School of Medicine at UCLA, Ahmanson/UCLA Adult Congenital Heart Disease Center, 100 UCLA Medical Plaza #630, Los Angeles, CA 90024, United States

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ABSTRACT

Objectives: This study aims to evaluate the feasibility and efficacy of commercially available 3-D printing technology for anatomical modeling.
Background: Additive manufacturing has been widely talked about in the context of personalized medical care and interventional and surgical planning for the past decade. Early studies have shown reduction in procedure time and optimization of device deployment by improving anticipation of potential obstacles by bench testing reconstructed models. However, commercially printed 3-D models are costly, ranging between $ 1,500–$ 3500 per model. Our goal is to produce heart models of acceptable quality for as low as $ 1–$ 20 and to demonstrate their utility in planning and carrying out complex congenital heart interventions.
Methods: Low-and mid-tier fused deposition modeling (FDM) printers able to utilize flexible filament along with a sophisticated modeling software were used in our practice to create congenital heart models for bench testing. For cases that required softer and more stretchable material than the available flexible filaments offered, molding and casting with dissolvable filament and silicone was carried out.
Results: 15 models were constructed and 13 were bench tested (8 commercial models), preliminary data gathered by questionnaires completed by treating physicians before and after obtaining the 3D models show equal improvement in pre-procedure planning and increased confidence about the procedure with both model types.
Conclusions: The use of commercially available reasonably priced 3–D printing technology is feasible for printing complex congenital heart disease models in a cost-effective manner. These models were not deemed to be inferior to commercially printed models that are up to 100 times more expensive.

1. Introduction

Medical and surgical services have recently begun to utilize additive manufacturing for interventional and surgical planning. Adaption of this technology has shown reduction in procedure time and optimization of device deployment by improving anticipation of potential obstacles by bench testing reconstructed models [1–8].

Despite promising early studies, access to anatomical reconstruction remains costly with prices ranging between $1500-$3500 per model. Given lack of health insurance coverage and reimbursement most physicians are deterred from using this technology in their practices.

Therefore our goal is to produce models of acceptable quality for as low as a few dollars and to demonstrate their utility in planning surgical procedures.

2. Methods

Our study will focus on producing heart models with congenital heart defects to help carry out complex interventions. Nonetheless our methodology may be applied and adapted across all surgical sub-specialties for use in pre-surgical planning.

After a comprehensive and comparative analysis of low- and mid-tier fused deposition modeling (FDM) printers our practice purchased and operated two FDM printers meeting three primary requirements – low cost (less than $3000), a large print platform (minimum 250 mm × 200 mm × 160 mm), and ability to utilize flexible filament.

Sophisticated 3-D rendering software was used for model reconstruction. DICOM formatted chest Computerized Tomography Angiography (CTA) and Magnetic Resonance Angiography (MRA) images were imported into Materialise Mimics (Materialise NV, Leuven, Belgium) for heart segmentation using proprietary algorithms and

* Corresponding author.
E-mail addresses: Aabdelkarim@mednet.ucla.edu (A. Abdelkarim), Abbiehageman@mednet.ucla.edu (A. Hageman), Dlevi@mednet.ucla.edu (D.S. Levi), Jaboulhosn@mednet.ucla.edu (J. Aboulhosn).

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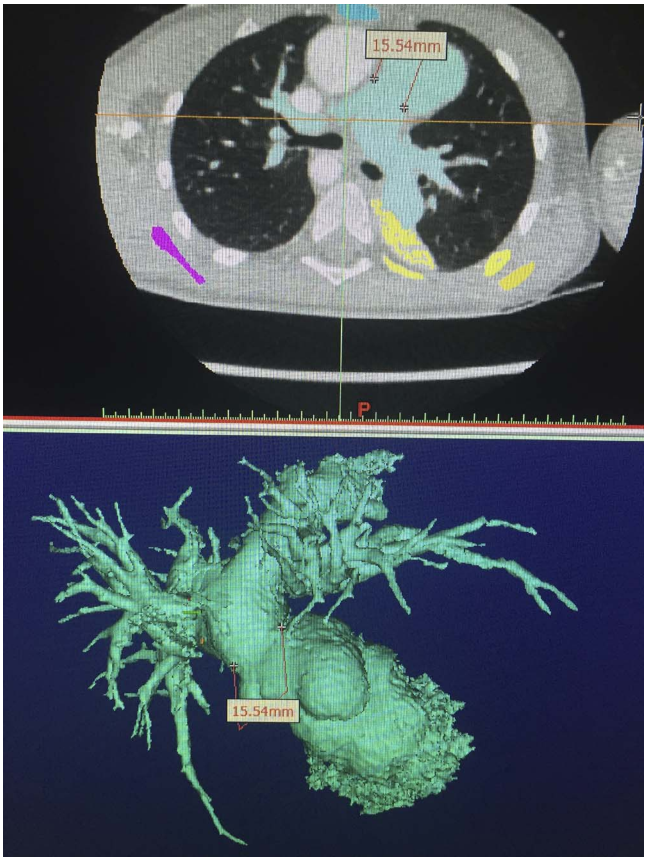

Fig. 1. Segmented Computed Tomography (CT) imaging dataset with 3-dimensional rendering of model.

various thresholding techniques. Contrast filled heart cavities helped delineate heart structures by demonstrating blood as bright (high Hounsfield unit or HU) and myocardium as dark (low HU). The reconstructed model was computed and exported as a Stereolithography or .stl file once the anomaly was visualized (Fig. 1).

Fig. 2. Commercial models sitting beside FDM printed TPE models (right).

Thereafter the 3-D slicer program Cura (Ultimaker, Geldermalsen, Netherlands) compiled the 3-D files to GCode for the 3-D printer to execute. Commercially available thermoplastic elastomer/polyurethane (TPE/TPU) filament (NinjaFlex by NinjaTek) was used for all FDM models. For cases that required softer and more stretchable material than the available flexible filaments offered, molding and casting with water dissolvable polyvinyl alcohol (PVA) filament and silicone was carried out.

Questionnaires completed by interventionalists before and after obtaining 3-D models were used to determine changes in pre-procedural planning and to evaluate confidence with both model types. Some of these models were bench tested in the operating room to test appropriate device sizing and implantation.

3. Results

15 models were reconstructed including 8 commercial models and 7 FDM models. 10 were bench tested (8 commercial and 2 FDM models), 3 were visualized (all FDM models), and 2 were neither bench tested or visualized due to deferment of intervention prior to seeing the model. Each model along with type and completed questionnaire are shown in Table 1.

Table 1
Physician Questionnaire.

Patient #	Imaging Type	Model Type	Bench Tested	How confident do you/did you feel about the planned procedure BEFORE using the 3D model? (1 = not confident, 10 = very confident)	Did your procedural plan change after bench testing or visualizing the 3D model?	Did your bench testing or using the 3D model confirm your pre-model interventional plan?	If plan to proceed with catheterized intervention after bench testing, how confident did you feel about the planned procedure AFTER using the 3D model? (1 = not confident, 10 = very confident)	Change in Confidence?	How critical were these changes in order to prevent any patient harm or complications? (1 = not critical, 10 = very critical)
1	CTA	Commercial	Yes	3	No	Yes	10	70%	8
2	CTA	Commercial	Yes	2	Yes	No	N/A aborted	N/A	10
3	CTA	Commercial	Yes	2	Yes	No	N/A aborted	N/A	10
4	CTA	Commercial	Yes	2	Yes	No	N/A aborted	N/A	10
5	CTA	Commercial	Yes	2	Yes	No	N/A aborted	N/A	10
6	CTA	Commercial	Yes	4	Yes	Yes	10	60%	8
7	CTA	Commercial	Yes	3	No	Yes	7	40%	9
8	CTA	Commercial	Yes	4	Yes	Yes	N/A surgical	N/A	9
9	MRA	FDM	Visualized	9	Yes	Yes	10	10%	8
10	CTA	FDM	Visualized	8	Yes	No	N/A aborted	N/A	10
11	CTA	FDM	Visualized	8	Yes	No	N/A aborted	N/A	9
12	MRA	FDM	Yes	4	Yes	No	N/A aborted	N/A	9
13	MRA	FDM	Yes	10	No	Yes	10	0%	6
14	CTA	FDM	Deferred	N/A	N/A	N/A	N/A	N/A	N/A
15	CTA	FDM	Deferred	N/A	N/A	N/A	N/A	N/A	N/A

Abbreviations: CTA: computed tomography angiography; MRA: magnetic resonance angiography; FDM: fused deposition modeling.