Utilizing 3D Printing to Assist Planning of Percutaneous/Endovascular Procedures in Interventional Radiology

By

Lucas Richards
B.Sc., Kansas State University, 2018

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Committee Chair: Won Choi, PhD, MPH

Aaron Rohr, MD, MS

Sharon Fitzgerald-Wolff, MPH

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The thesis committee for Lucas Richards certifies that this is
the approved version of the following thesis:

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Chair: Won Choi, PhD, MPH

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Graduate Director: Won Choi, PhD, MPH

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Abstract

Purpose

3D printing has been incorporated by the surgical community for a variety of different applications including the creation of anatomic models for use in preoperative planning. The purpose of this study is to assess the impact on procedure time ionizing radiation exposure, intravascular contrast dosage, fluoroscopy time, and provider confidence in use of a 3D printed anatomic models in pre-procedure planning in interventional radiology.

Materials and Methods

Patients who underwent transjugular intrahepatic portosystemic shunt placement, endovascular stent repair, or prostate artery embolism were included. A quasi-experimental design was used. For the control group, retrospective data was collected on patients who received the procedures prior to Oct 1, 2020. For the experimental group, a model was created for every patient that received one of the procedures of interest between Oct 1, 2020 and April 15, 2021. Data was collected on patient demographics and procedure details. The interventionalist was surveyed on their confidence level and model usage following each procedure.

Results

3D prints were created for six TIPS and one PAE patient. In the TIPS group, mean ionizing radiation exposure was 808.8 mGy in the group with a model compared to 1731.7 mGy without (p= 0.09). Twelve survey responses were received and 91.7% reported either “increased” or “significantly increased” confidence after reviewing the 3D model.

Conclusion

Including 3D printed models in the planning of endovascular procedures may provide improved patient care while potentially optimizing procedural efficiency. Study including more patients is needed and currently in process to better measure this. Initial preliminary procedural data demonstrates increased value, while secondary findings of operator satisfaction and overall benefit to trainees is also promising.

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Chapter 1: Introduction

3D printing is a manufacturing process that has recently been incorporated by the surgical community in a variety of different applications. Among these applications is the creation of patient specific anatomic models for use in preoperative planning and as an intraoperative reference [1-13]. The use of these anatomic models during the planning of surgical procedures has been shown to consistently lead to changing of operative plans and increasing confidence in clinical decisions [3-6]. We propose that this will be particularly useful in planning of procedures in interventional radiology.

Interventional radiology is a medical specialty where physicians use imaging techniques to guide minimally invasive procedures. Procedures in interventional radiology are performed percutaneously with the option of endovascular platforms using catheters and wires. These wires can be used to navigate through the patient’s vascular system while using a live x-ray imaging technique called fluoroscopy to direct the process. Some of the negative impacts that an interventional radiology procedure can have on the patient are ionizing radiation exposure, long procedure time resulting in prolonged sedation, and risks associated with intravascular contrast administration. Many of these risks are due to excess fluoroscopic use in difficult anatomy.

Creation of a 3D printed model from images collected in a pre-procedure setting allows for the optimization of diagnostic information, which helps the interventionist better understand the patient’s anatomy and may reduce the amount of imaging that has to be collected during the procedure. As a result, ionizing radiation exposure, procedure time, and contrast dosage may be reduced, minimizing the impact that the procedure has on the patient. In some cases, 3D printing has also allowed for the selection and testing of specific wires and catheters before entering the procedure room [7-9], reducing material waste and cost. This improves patient safety, as the exchange of wires and/or catheters always introduces a new risk.

The integration of 3D printed models in procedure planning has been the subject of publications in multiple different specialties including urology, cardiology, and cardiothoracic surgery. Several examples claim that the integration of 3D printed models into procedure planning successfully facilitated better surgical outcomes [3-13]. Itagaki utilized a 3D printed model of a patient's splenic artery to plan an endovascular approach and treatment of splenic artery aneurysms. In this case, the splenic artery had unique anatomy that was difficult to visualize on 2D imaging and the creation of the 3D model allowed for better understanding of anatomy and also facilitated preoperative selection and testing of catheter equipment, which led to the success of the procedure [8]. In the Winter 2020 edition of IR Quarterly, Dr. Oklu at The Mayo Clinic explains how he used a 3D printed model to aid in the planning of a procedure to embolize arteriovenous malformations. He further states that the use of the model increased the number of vessels he was able to access and theoretically helped him reduce contrast and radiation dosage [14].

These are a few examples showing the promise of using 3D printed models to plan procedures in interventional radiology, but there is no current literature that quantifies the impact of this technique using a measurable procedural outcome. Moreover, there is not sufficient clinical assessment of its efficacy via physician input (i.e. surveys). We believe that the application of this technology will have an over-arching impact on the outcomes of interventional radiology procedures, and there is a clear need for more studies to demonstrate and quantify its value so it may potentially become a reimbursable part of endovascular intervention. [3, 7] The purpose of this study is to assess the impact that the inclusion of a 3D printed anatomic model in procedure planning has on procedure time, ionizing radiation exposure, intravascular contrast dosage, fluoroscopy time, and provider confidence.

Chapter 2: Materials and Methods

2.1 Study Design

This pilot study utilizes a quasi-experimental study design with retrospective control and prospective experimental groups from three different procedures in interventional radiology. The three procedures that this study focused on are transjugular intrahepatic portosystemic shunt placement (TIPS), endovascular stent repair (EVAR), and prostate artery embolism (PAE). Each of these procedures comprises their own study arm with an independent retrospective control group and prospective experimental group. The patients in the control groups all had procedures that were planned and performed in the conventional way before 3D printed models were integrated as a part of procedure planning. The patients in the experimental group all had procedures that included a 3D printed model that was successfully created and included in the procedure planning process.

2.2 Participants and Setting:

Retrospective data was collected from patients that received either a TIPS, EVAR, or PAE at a single institution from October 1, 2017 to October 1, 2020. Every patient that underwent one of the procedures of interest from October 1, 2020 to April 15, 2021 at the same institution prompted an attempt to create a 3D printed model. Factors including inadequate imaging quality and short lead time (in emergent situations) limited the ability to create a model for every case that was performed in the prospective period. Only the patients in which a model was successfully made and given to the interventionist prior to the procedure were included in the experimental group. Study procedures were approved by the Institutional Review Board (IRB) at the study institution. Written informed consent was obtained from patients in the experimental group.

2.3 Inclusion/Exclusion Criteria

Patients for the experimental group had to meet the following inclusion/exclusion criteria.

Inclusion criteria:

- Underwent a TIPS, EVAR, or PAE procedure at the study institution between October 1, 2020 and April 15, 2021
- Had a CT or MRI a maximum of a year prior to the scheduled procedure date that was of sufficient quality to create a meaningful 3D printed model
- Had a minimum of 48 hours of lead time prior to the procedure start time to facilitate the creation of a 3D printed model

Exclusion criteria:

- Under the age of 18 years

2.4 Model Creation

Patient-specific 3D printed models were created starting with CT or MRI imaging that was collected as a conventional part of patient care. The anatomy to be modelled was determined by the interventionist scheduled to perform the procedure and communicated to the study team. This communication was done in person while both parties were looking at the imaging to ensure accurate goals and expectations. Imaging studies were burned to deidentified discs. 3D segmentation of the desired anatomy was performed in 3D Slicer by study team members that were trained in this technique. In Figure 1 an image of 3D Slicer is shown towards the end of the segmentation process.

Three different views of the CT are shown with colors overlaid showing what is being selected to create the 3D model.

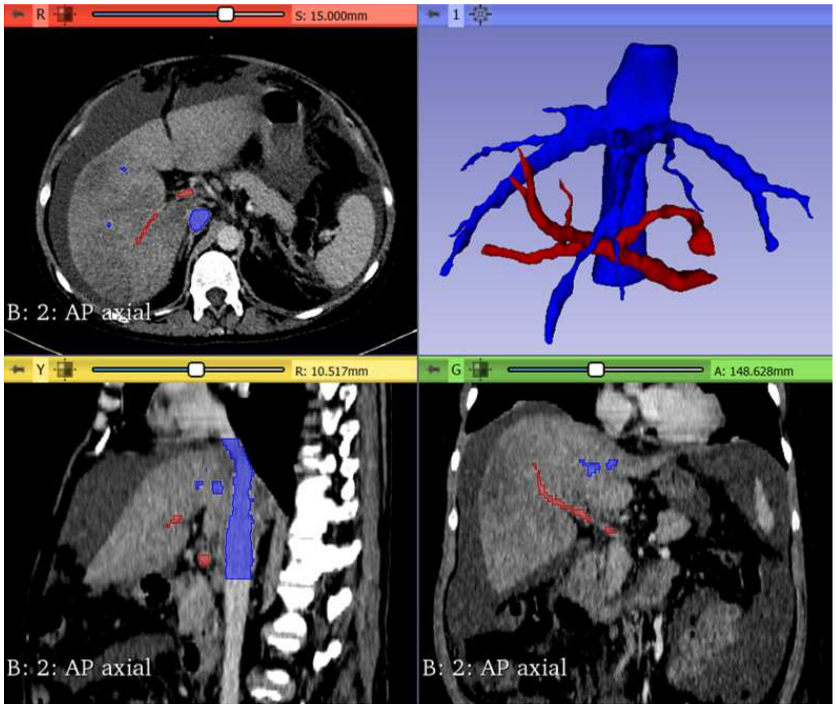

Figure 1. Segmentation Process
A screen capture of the segmentation software 3D Slicer while a model is being created to aid in the preparation of a TIPS procedure. On the top left and the bottom right and left, different views of the patient's CT are displayed with bright colors displaying the anatomy that has been selected from the background. On the top right the resulting 3D geometry is displayed.

The procedures of interest in this study were all endovascular and as a result, the target structures for this study were blood vessels. The models that were created using the segmentation software were representations of the vessel lumens due to picking up the radiopaque intravascular contrast. However, the goal of the models was to deliver a representation of the patient's anatomy so further processing was required. Using Meshmixer, the surface of the .STL files were extruded from and then made hollow in order to create 1.2mm wall thickness tubular structures that had the inner geometry matching the 3D model that was exported from the segmentation software. The 1.2mm figure was chosen for our study as it allowed for a balance between strength and translucency in the resulting model and this was communicated to the interventionists to avoid false assumptions being made about true vessel wall thickness. In Figure 2A, a model is displayed after the vessel walls have been extruded from the lumen. A base has also been created to allow the model to stand in anatomical orientation on a flat surface creating the final geometry that will be printed. The final print file was created in PreForm using a layer thickness of 0.1mm, touchpoint size of 0.4mm, and density support setting of 0.8. Printing was done using a FormLabs Form2 stereolithography printer with FormLabs Standard Clear resin. A model following print completion is shown in Figure 2B. The model is adhered to the build platform from above and is left in this position to allow excess resin to drip before post-processing. The models were post-processed by washing with 99% isopropyl alcohol and curing with a FormLabs Form Cure. 3D printed models of the patient's anatomy of interest were given to the scheduled provider at least 24 hours prior to the procedure start time. Interventionists were free to use the model as they saw fit. A model after all post-processing and delivery to the scheduled interventionist is shown in Figure 2C.

Figure 2. Printing Process.
A. A 3D rendering of a model displayed in Meshmixer. This is the final geometry that will be sent to the printer. **B**. A 3D model on the build platform after print completion. The model is adhered to the build platform from above and is left in this position for an hour to allow dripping of excess resin. **C**. A 3D model in the hands of the interventionist, now ready to be used in the procedure planning process.

2.5 Data Collection and Measures

Measures collected in this study include:

- Procedure time to completion
- Fluoroscopy time
- Ionizing radiation exposure
- Intravascular contrast dosage
- Demographics
  - Age
  - Gender
  - Race
  - Ethnicity

All measures are captured as a normal part of procedure documentation which was collected from the procedure notes in the electronic medical record (EMR) in both the control and experimental groups. A patient was only included in the control group if all of the measures of interest were available. “Procedural time to completion” was calculated as a difference between “Procedure Start” and “Procedure Finish” as recorded in the EMR during the procedure.

A short survey was sent immediately following each prospective procedure to the interventionists. The survey questions inquired about model usage, altering procedural plans, role in teaching trainees, and confidence levels in the context of the models being used. The survey as it appeared when accessed by the interventionists is shown in Figure 3.

Please answer the questions below	
My confidence level ________ after reviewing the 3D model. (select best fit)	◯ Significantly decreased ◯ Decreased ◯ Did not change ◯ Increased ◯ Significantly increased
Did your procedure plan change after reviewing the patient's 3D model?	◯ Yes ◯ No
In your opinion, do you think including a 3D model in procedure planning would be a helpful tool for training fellows, residents, and medical students?	◯ Yes ◯ No
How did you use the model in your procedure planning process? (select all that apply)	☐ As a visual aid ☐ Directly with wires and catheters ☐ To make measurements ☐ As a teaching tool ☐ As a reference during the procedure ☐ Did not use the model ☐ Other
If selected "other" in use question, please briefly describe.	______________________________

Figure 3. Survey Questions

2.6 Data Analysis

All data was stored securely in a REDCap database and deidentified when exported for analysis [15]. Analysis was carried out in SAS v9.4. Descriptive statistics were used to examine population demographics. T-tests and chi-squared were used to make comparisons between the experimental and control groups.

Chapter 3: Results

Table 1: Demographics

		TIPS		PAE		EVAR	
		Control n=20	Experimental n=6	Control n=15	Experimental n=1	Control n=15	Experimental n=0
Age	Mean(SD)	63.1 (10.4)	58.5 (13)	68.7 (5.4)	70 (-)	71.5 (7.7)	-
Gender							
	Female n(%)	8 (35)	3 (50)	0 (0)	0 (0)	4 (26.7)	-
	Male n(%)	14 (65)	3 (50)	15 (100)	1 (100)	11 (73.3)	-
Race							
	White n(%)	19 (90)	6 (100)	11 (73.3)	1 (100)	15 (100)	-
	Other n(%)	3 (10)	0 (0)	4 (26.7)	0 (0)	0 (0)	-
Ethnicity							
	Hispanic n(%)	2 (5)	0 (0)	2 (13.3)	0 (0)	0 (0)	-
	Non-hispanic n(%)	20 (95)	6 (100)	13 (86.7)	1 (100)	15 (100)	-

3.1 TIPS

Control data for the TIPS study arm was collected via retrospective chart review including the 20 most recent cases prior to Oct 1, 2020. Experimental data for the TIPS arm included 6 cases starting on Nov 12, 2020 and ending on March 6, 2021. The average age in the TIPS experimental group was 58.5 (SD 13) compared to 63.1 (SD 10.4) in the control group. In the experimental group 3 (50%) were male compared to 65% in the controls, 6 (100%) were white compared to 90% in the controls, and 6 (100%) were non-Hispanic compared to 95% in the controls. Mean procedure time was 81.2 min (SD 24), compared to 82.5 min (SD 38.1) in the control group (p-value 0.93). Mean ionizing radiation exposure was 880.8 mGy (SD 616.5), compared to 1731.7mGy (SD 1133.9) in the control group (p-value 0.09). Mean intravascular contrast dosage was 135.8 ml (SD 65.9), compared to 143.8 min (SD 49.3) in the control group (p-value 0.75). Mean fluoroscopy time was 19.2 min (SD 6.6), compared to 25.7 min (SD 13.4) in the control group (p-value 0.26).

Table 2: TIPS

	Control n=20	Experimental n=6	p-value
Procedure time (min)	82.5 (38.1)	81.2 (24)	0.93
Radiation (mGy)	1731.7 (1133.9)	880.8 (616.5)	0.09
Contrast (ml)	143.8 (49.3)	135.8 (65.9)	0.75
Fluoroscopy time (min)	25.7 (13.4)	19.2 (6.6)	0.26
Values given as mean(SD), p-value reported from t-test			

3.2 EVAR and PAE

Control data included the 15 most recent cases prior to Oct 1, 2020 for both the EVAR and PAE study arms. Experimental data for the PAE arm included 1 case. Experimental data for the EVAR arm did not include any cases. Due to low numbers of cases in the experimental groups for both study arms, statistical comparisons were not made between the groups.

Table 3. EVAR and PAE

	PAE Control n=15	PAE Experimental n=1	EVAR Control n=15	EVAR Experimental n=0
Procedure time (min)	107.7 (39.1)	63 (-)	118.4 (29.5)	-
Radiation (mGy)	5070 (3194.3)	714 (-)	2396.3 (1571.9)	-
Contrast (ml)	148 (42.8)	75 (-)	107.6 (35.1)	-
Fluoroscopy time (min)	35.5 (15.2)	23 (-)	19.2 (7.9)	-
Values given as mean(SD)				

3.3 Survey Data

Over the seven prospective cases, 14 surveys were sent, and 12 responses were received. When asked to examine how the 3D model affected their confidence level, 11 (91.7%) responded that their confidence either “increased” or “significantly increased”. A graph displaying all responses to this question is shown in Figure 4.

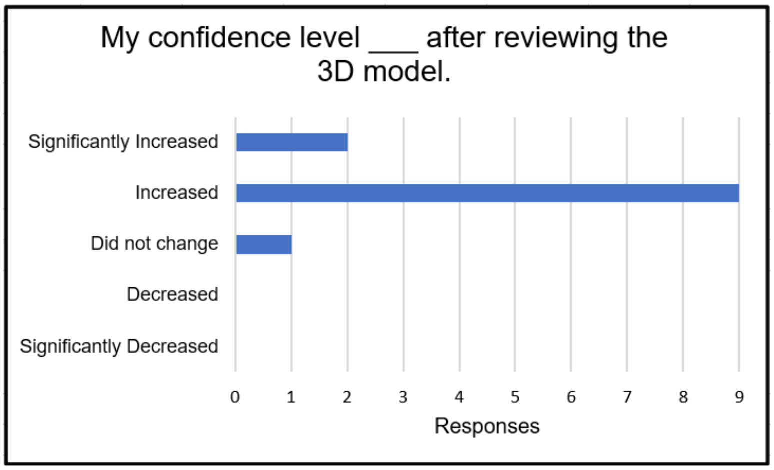

Figure 4. Confidence Level.

To the question “Did your procedure plan change after reviewing the patient’s 3D model?”, 5 (41.7%) responded “Yes”. To the question “In your opinion, do you think including a 3D model in procedure planning would be a helpful tool for training fellows, residents, and medical students?”, 12 (100%) responded “Yes”. To the question, “How did you use the model in your procedure planning process?”, the most popular response was “As a visual aid” with 12 (100%) responses followed by “As a teaching tool” with 9 (75%) responses. A graph displaying all responses to this question is shown in Figure 5.

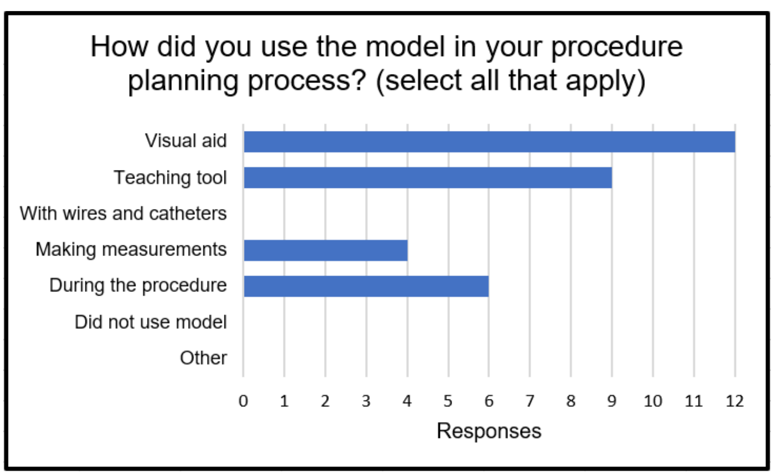

Figure 5. Model Use.

Chapter 4: Discussion

The only arm of the study that comparisons can be made from is the TIPS arm. With only 6 patients in the prospective section, the changes in procedure time and intravascular contrast dosage are minimal and no statistical conclusions can be drawn responsibly. The mean fluoroscopy time in the experimental group showed a 25% reduction when including a model, but with a p-value of 0.26, conclusions must be made carefully as the possibility of chance cannot be ruled out. Ionizing radiation exposure in the experimental group showed a 49% reduction from the control group with a p-value of 0.09. Compared to the intended alpha of 0.05, this still doesn't allow strong conclusions to be drawn but with such a small prospective group, this shows promise. In the PAE study arm, the procedure that was in the prospective group had reduced procedure time, ionizing radiation exposure, intravascular contrast dose, and fluoroscopy time when compared to the means in the control group. This is only one case, not allowing for statistical comparisons, but every outcome showed improvement.

Responses to post-procedure surveys from the interventionists were positive. Over 90% of the responses reported that confidence was either increased or significantly increased which was expected. Being able to look at and hold a 3D model of the anatomy prior to the procedure seems to reduce some of the guess work involved in planning of minimally invasive procedures and allow for more confidence in the surgical plan. The value of these models doesn't stop at just planning procedures. Every interventionist surveyed responded that a 3D model would be a helpful tool for training fellows, residents, and medical students. This is also not a surprise and supports the thinking that a 3D representation helps understand the anatomy of interest and think through the procedure. This holds even more truth in less experienced care providers.

While the data captured in this study doesn't allow for definite conclusions to be drawn, promise has been demonstrated. It is not a surprise that a small study like this cannot adequately measure the impact of including a 3D printed model in procedure planning on procedural measures. This is especially true with the intrinsically high variance that measures like procedure time and radiation exposure will have, even when only focusing on one type of procedure. What has been demonstrated is that most of the time it is possible to use imaging that is already available in the procedure planning process to make models that are useful to interventionists planning endovascular procedures. In our experience these models can be created in a little as 48 hours and had an average material cost of around $10 USD per model. At such a low cost, a resource that consistently increases the confidence of interventionist and is a helpful teaching tool clearly has value. A more strongly powered study is currently being conducted with the goal of more adequately measuring the impact that the inclusion of a model has on procedural measures.

4.1 At the Mercy of the Imaging

The method used for segmentation utilized imaging that is collected as a routine part of procedure planning. A major advantage of this is the lack of any additional time required of the patient as well as minimal to no health risk incurred by the patient due to the inclusion of a 3D model in their care. A disadvantage of this method is related to the variability of imaging quality that is used to plan procedures.

The segmentation software relies on either manual input from the user or pixel value differences to interpret structures by grouping pixels that belong together. If you cannot see the target vessel visually, the software won't be able to differentiate it either. This limits segmenting anatomy from imaging with low contrast, artifact, or a grainy appearance. This is not a problem when trying to segment out arterial or even large venous structures when starting with a series that includes a well-timed contrast bolus. In this case, the high contrast between the fluid in the vessel lumen and the surrounding tissue allows the anatomy to be easily selected. In Figure 6A, there is great contrast between vessels and the surrounding tissue, making vessel segmentation easy. This was the case for all PAE and EVAR cases attempted. The segmentation process in these cases was straightforward and relied primarily on clear communication between the scheduled interventionist and the person doing the segmentation to ensure the anatomy of interest was focused on.

Poor opacification of the portal and hepatic venous systems made for a greater challenge when making models for TIPS procedures. This was mostly due to imaging acquisition from outside facilities when utilized for 3D model printing. Faint vascular structures surrounded by noisy liver parenchyma often required manual “painting” of structures on each slice of imaging to adequately capture the anatomy. In Figure 6B, the vessels show enough contrast compared to the surrounding tissues to be selected, but the vessels in Figure 6C have no opacification compared to the liver parenchyma, making selection impossible. In four of the 11 attempted TIPS cases, the imaging of the liver vessels was not of sufficient quality to facilitate model creation. In our study this meant that we were unable to include every patient that consented to be a part of the study. More importantly this shows a limitation of this technology. Segmentation can be an augmentation to conventional imaging techniques but in the end, it is only redisplaying the information that is already available. If the image acquisition is subpar, segmentation cannot help.

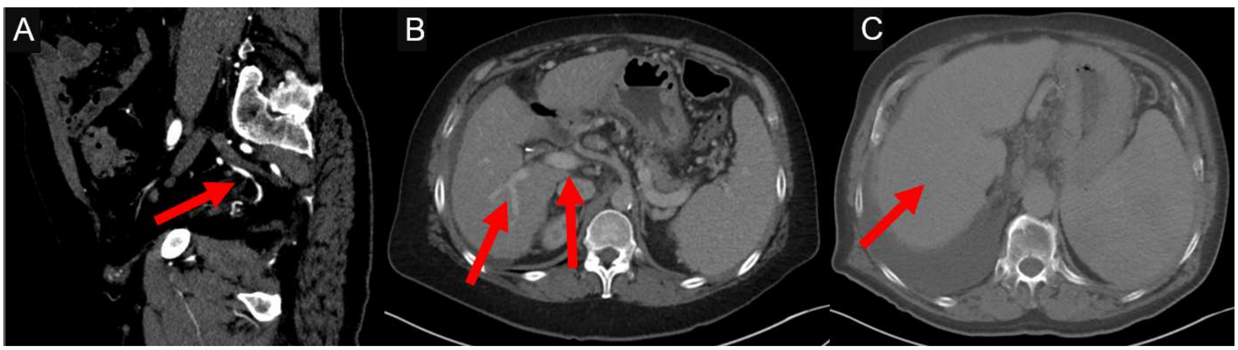

Figure 6. Opacification of Vessels
A. A contrast enhanced CT in the arterial phase displayed in the sagittal plane shows strong opacification in the prostate artery, making segmentation straight forward. **B**. A contrast enhanced CT in the venous phase displayed in the axial plane shows weak but present opacification of the liver vessels making segmentation possible but more of a challenge compared to segmenting arteries. **C**. A contrast enhanced CT in the venous phase displayed in the axial plane showing very poor opacification of the liver vessels making segmentation and model creation of hepatic vessels impossible.

4.2 Experience with Desktop SLA Printing

The printer used for the models in this study was a Formlabs Form2 stereolithography (SLA) printer. Compared to other printers used for medical applications, the Form2 is very affordable and user friendly. This was initially thought to be a limitation of this study brought about by budget constraints but using this printer was less of a compromise than expected.

SLA printing creates plastic models with high resolution starting with a liquid resin. The build platform is lowered into a tank of resin and a laser converges on multiple spots, hardening the resin to the platform to create the first layer of the print. After a layer has been cured by the laser, the elevator lifts the build platform and cured resin out of the resin tank and then lowers it back into the resin for the next layer of the print which can be seen in Figure 7. This process of printing allows for models that don't have the classic layered look of fused deposition modeling (FDM). This allows for smooth models that have a layer height of 0.1mm in the case of the Formlabs Form2.

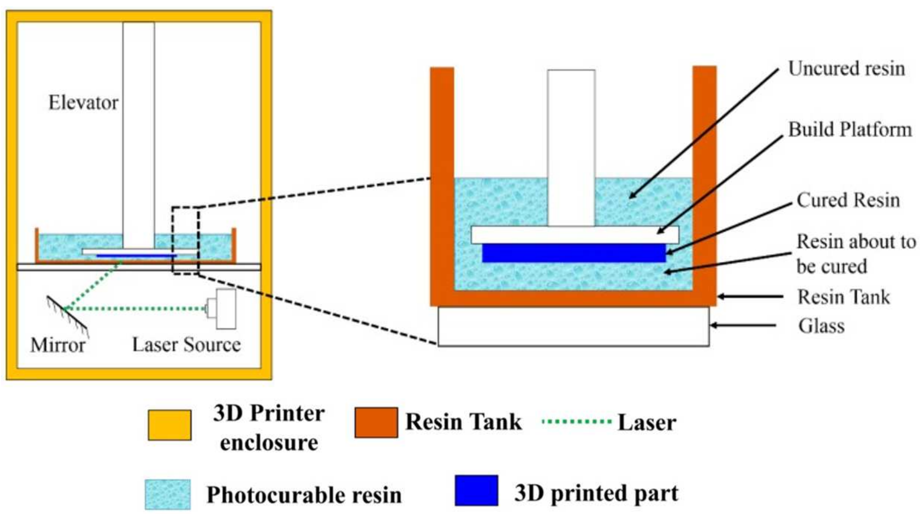

Figure 7. Bottom-Up SLA Printing.
This figure has been adapted and modified from Kundu et. al. [16]
A diagram of the Bottom-Up SLA printing process is shown. A build platform is lowered into a resin tank and a laser source is directed with a mirror from below, hardening uncured resin to the previous layer of the print. Following each print layer, the elevator lifts the print platform out of the resin tank and then lowers it back into the uncured resin so that the laser can be used to add the next layer. This process is continued until every layer of the print has been hardened to the build platform and the resulting model hangs below.

After the print has finished, the models require a wash in a solvent such as isopropyl alcohol and curing by ultraviolet (UV) light before they can be handled. One possible limitation of SLA printing is the curing process. When the model comes off of the build platform, it cannot be handled without gloves because it is soft and has uncured resin on its surface. A model before curing is seen in Figure 8A. The models are then cured with heat and UV light as shown in Figure 8B in order to harden the uncured resin. The result is a model that is less transparent but hard and ready to handle, shown in Figure 8C. The curing process can cause shrinkage and if the supports are removed before this curing is complete, the model can droop, ultimately changing the geometry. The magnitude of this change in our application is not known and relatively small but is a common occurrence with SLA printing techniques. For this reason, it was communicated to the interventionists involved that exact measurements could not be made from the models. Further study would be required to be able to know what tolerance the dimensions of the models were within the actual anatomy.

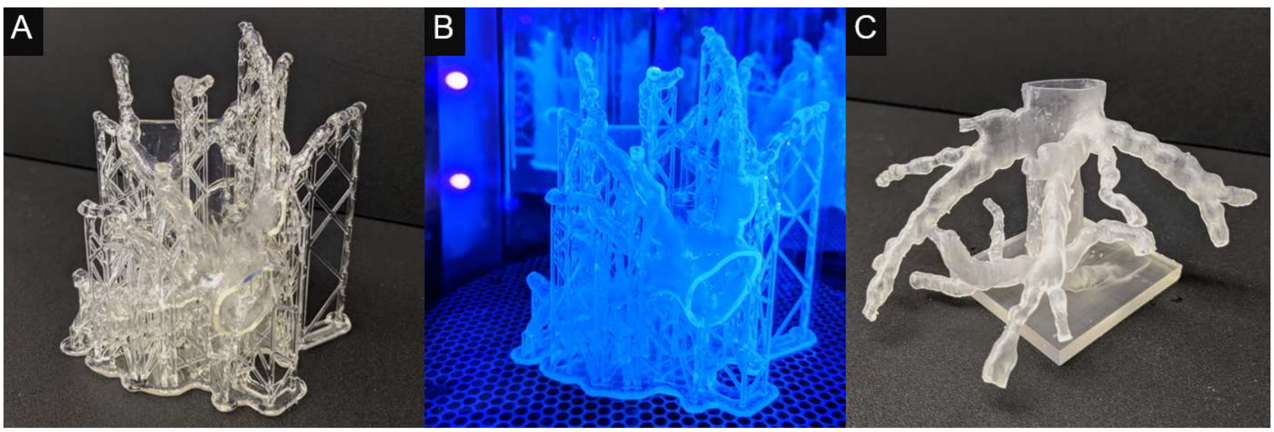

Figure 8. Model Curing Process
A. A model immediately after print completion, before curing. At this point the model is soft and cannot be handled without gloves. **B**. A model during the curing process. The model is heated and exposed to UV light for 20 to 40 minutes to harden the resin. **C**. The model after being cured and having the supports removed. At this point the model is finished and ready for handling by interventionists.

Clear resin was used to create prints to facilitate the use of wires and catheters on the models prior to the procedure while directly visualizing the vessel lumen. A small layer height paired with the smooth finish that SLA printing offers allowed for great transparency compared to other clear printing options. Our experiences did not include any print failures.

4.3 Personalized Patient Education

Several patients enrolled in the study were enthusiastic to be involved and asked to take their models home with them. Our study was focused on procedural measures and the reactions of interventionists, but more attention should have been paid to the impact this had on the patients involved other than just their procedural measures. In several cases, the models were used to educate the patient about the procedure they were about to undergo, and these patients expressed increased understanding after seeing the model. These stories are anecdotal because this study was not prepared to capture this, but future study will undoubtedly include patient education and understanding as a part of the aims. Great potential to increase patient understanding and reduce anxiety was observed and should be explored.

4.4 Limitations

The most obvious limitation of this study is the lack of a sufficient number of patients in the experimental groups. This can be accounted for primarily by the short prospective period which spanned just over six months. To properly measure the impact of 3D printed models on endovascular procedures in IR, a study including more cases is needed. The over-arching goal of this study will be to expand upon this initial data and potentially extrapolate to additional procedure types. The measures that were chosen for the study, while very relevant to patient outcome, have high variance. It may be difficult to properly power a study in the future using measures with such high variance.

The non-concurrent method of data collection utilized was also an unfortunate necessity due to time and resource constraints. This introduces several important variables that could not be controlled for including but not limited to operating physicians, interventionist experience, and possible changes in hardware used for endovascular access and imaging. Given more time and resources, a study design that included randomizing patients into the control or experimental groups, collecting data concurrently, may help mitigate these possible confounding factors.

A source of bias that will be present using 3D printed models for surgical planning in the foreseeable future is the time that is required to make a model. While the turn-around time of 48 hours for a model is impressive, this limits its applications in emergent situations.

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