

Mitral Paravalvular Leak 3D Printing from 3D-Transesophageal Echocardiography

ABSTRACT

Background: Paravalvular leaks can be detected in almost 15% of patients after mitral valve prosthesis implantation. This complication can result in congestive heart failure and hemolysis. Despite advancements in non-invasive imaging, percutaneous closure of paravalvular leaks is not always successful. Therefore, efforts are made to improve treatment outcomes by using 3D-printed models of defects as pre-procedural support for interventional cardiologists.

Methods: Retrospectively, 3D-transesophageal echocardiography recordings of 8 patients with clinically significant mitral paravalvular leaks were analyzed. Qlab Software was used to export DICOM images of each paravalvular leak channel, including surrounding tissue. Image segmentation was performed in 3D Slicer, a free, open-source software package used for imaging research. Models were printed to actual size with the poly jet Stratasy's Objet 30 printer with a transparent, rigid material.

Results: Duration of model preparation and printing, as well as the total cost, was calculated. Mean total time of model preparation was 430.5 ± 196 minutes.

Conclusion: 3D-printing from 3D-transesophageal echocardiography is technically feasible. Both shape and location of paravalvular leaks are preserved during model preparation and printing. It remains to be tested if 3D-printing would improve outcomes of percutaneous paravalvular leaks closure.

Keywords: Paravalvular leak, 3D-printing, echocardiography

INTRODUCTION

Studies in which routine transesophageal echocardiography (TEE) was used to examine patients who underwent surgical valve replacement procedures revealed that paravalvular leaks (PVL) can be detected in approximately 10% of subjects who received an aortic prosthetic valve and in 15% of patients with a mitral prosthesis 6 months after surgery.¹

Despite the fact that most PVLs are asymptomatic and are accidentally detected during echocardiographic examinations, 1%-5% of patients may have serious symptoms that require treatment.² Patients with clinically significant PVLs often present with signs and symptoms of congestive heart failure (90% of cases)³ that may be accompanied by hemolysis in 33%-75% of cases.⁴ Paravalvular leaks are also considered to be a risk factor for infective endocarditis due to the turbulent pattern of blood flow through these intracardiac channels. Paravalvular leaks closure may alleviate symptoms and contribute to a better quality of life.⁵

Historically, surgical intervention was the only procedure available for treatment of clinically significant PVLs. Nowadays, due to progress in interventional cardiology techniques, surgery is primarily reserved for cases that cannot be treated percutaneously (rocking valves, PVLs in active endocarditis), because surgical intervention is associated with high mortality.⁶ Percutaneous treatment of aortic and mitral PVLs is a complex procedure that requires careful pre-procedural planning and good peri-procedural cooperation between an operator and echocardiographer. There is no gold standard for either the interventional techniques

ORIGINAL INVESTIGATION

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or the ideal imaging modalities that should be used to ensure the highest success rates.

Both 2D- and 3D-transesophageal echocardiography (2D-TEE and 3D-TEE) are most commonly used for the diagnosis and peri-procedural management of patients with PVLs.⁷ Prior to the procedure, these modalities are used to detect both the number and location of PVLs as well as the graded severity of regurgitation. During the procedure, TEE (especially 3D-TEE)⁸ is critical in the assessment of PVL size and shape as correct measurements warrant the selection of a proper closure device.⁹

The challenges associated with PVL visualization in TTE or cardiac computed tomography (CCT)¹⁰ are related to the type of prosthesis (biological or mechanical), position of prosthesis, and location of PVLs. The most important limitations of TEE are color artifacts, acoustic shadowing, and reverberations. Under CCT imaging, the PVLs are often poorly visualized due to artifacts from prostheses, dense sutures, or calcifications. Despite advancements in echocardiographic equipment and excellent quality of images, it may not be possible to predict the final result of intervention after closure devices have been placed in the PVL channel. This phenomenon can have several reasons. The closure device may shift after being released from the delivery shaft. It is also possible to improperly select a closure device based on echocardiographical measurements alone, because this imaging modality may not adequately visualize the course and angulation of the PVL channel—in such case, the device has to be removed and exchanged for a different one which makes the procedure longer and more costly. An incomplete seal of the PVL channel worsens patient's prognosis and increases the chances of post-procedural hemolysis. Studies are underway to better understand how various properties of PVL channels can influence the likelihood of hemolysis.¹¹ The success of those complex structural procedures may depend on efficient multimodality imaging, which includes not only echocardiography and CCT but also novel imaging technologies such as 3D printing.¹²⁻¹⁴

Therefore, we decided to perform a feasibility study that would assess if 3D-TEE can be used as source data to prepare

HIGHLIGHTS

- Study shows for the first time that 3D models of mitral prosthetic valve paravalvular leaks can be prepared from echocardiographic data.
- Preparation of 3D models from 3D-transesophageal echocardiography if performed in a stepwise manner and involves data acquisition, data transfer, segmentation, and printing.
- 3D printing is not a costly procedure. Free open-source software can be used for segmentation and the printing itself can be outsourced to lower the initial cost.
- Further studies are required to determine if 3D printing will improve procedural outcomes in subjects with paravalvular leaks.

3D models of various PVLs. 3D printing is often employed to visualize complex anatomy to plan medical procedures. However, the preparation of 3D models from echocardiographic data is more challenging than from CT or MRI due to lack of full compatibility between echocardiographic DICOM format and the software used to prepare stereolithography models. The 3D printing allows the operator to interact with the physical model of the defect and surrounding structures prior to the procedure in order to better appreciate the anatomy. The aim of our study was to create a simple and repeatable method that would lead from 3D-TEE to the printing of a 3D PVL model comparable with initial 3D-TEE datasets.

METHOD

Ethics Approval and Consent to Participate

The need for ethical approval and for informed consent was waived by the ethics committee because of the retrospective nature of the study (Decision number: PCN/0022/KB1/82/20/21).

Study Design

We retrospectively analyzed 3D-TEE of 8 patients with mitral PVLs, acquired prior to percutaneous PVL closure procedures, who were admitted to our unit between 2015 and 2020. We included subjects with at least 1 mitral PVL who had a good quality 3D-TEE recording of the whole mitral prosthesis. This study was performed in line with the principles of the Declaration of Helsinki.¹⁵

3D-Transesophageal Echocardiography Image Acquisition

3D-transesophageal echocardiography imaging was performed with an iE33 or EPIQ7C ultrasound system (Philips Medical Systems, Andover, MA, USA) with a fully sampled matrix transducer (X7-2t). All examinations were performed according to recommendations of the European Association of Cardiovascular Imaging (EACVI) under conscious sedation with diazepam administered intravenously.

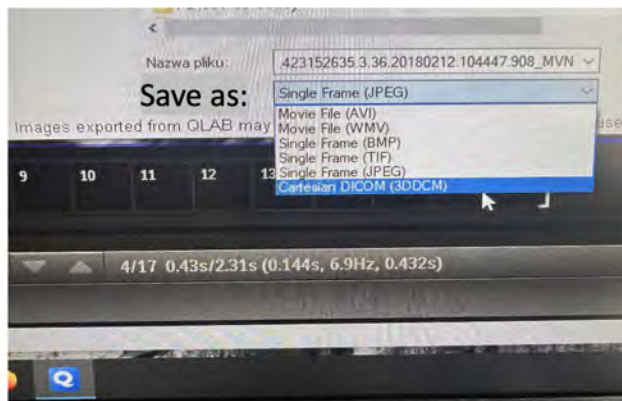
At least 3 sets of the following 3D datasets were acquired: (1) ECG-gated, zoomed, full volume 4-beat recording of the whole mitral prosthesis during breath hold; (2) ECG-gated, zoomed, full volume 4-beat recording of the whole mitral prosthesis during breath hold with color doppler; (3) ECG-gated, zoomed, single-beat recording of the whole mitral valve in High Volume Rate (HVR) mode; and (4) ECG-gated, zoomed, single-beat recording of the whole mitral valve in HVR mode with color doppler. Sector size was carefully chosen to achieve the highest possible frame rate. Images with significant stitching artifacts were excluded.

Image Transfer and Segmentation

Images were transferred to the workstation and uploaded to QLab station ver 3.8.5. The quality of images was assessed and recordings with the best quality were identified. Selected non-color 3D volumes were exported in Cartesian DICOM (3DDCM) format. Next, the Cartesian DICOM files were uploaded into Slicer,¹⁶ which is a free, open-source software package used for imaging research. To convert Cartesian DICOM to a standard DICOM format, Philips DICOM Patcher module in Slicer was used (this step requires



Step 1.



Qlab

Step 2



Step 3



Slicer 3D

Step 4

Figure 1. Four steps to transfer data from Qlab to Slicer Patcher. Steps 1 and 2 in Qlab. Steps 3 and 4 in Slicer 3D.

that the SlicerHeart and Sequences extensions are installed) (Figure 1).

Figure 2 shows DICOM data during various steps of processing. Semi-automatic segmentation of volumetric data was performed using thresholding with subsequent manual correction. Diastolic frames were selected for the best PVL channel visualization. The created model was cropped to remove expandable and excessive parts in order to lower the cost of printing and improve the visibility of the region of interest. Built-in smoothing algorithms were applied. The final result was exported as a .stl file which was ready for 3D printing.

3D Printing

Stl files were imported into the 3D printer software. All models were printed to actual size with the polyjet Stratasys Objet 30 printer. Rigid printing (IORA Model) and support (IORA Support) materials, produced by Isquared, were used. Printing accuracy of the Stratasys Objet 30 printer, provided by the manufacturer, for models printed with rigid materials, is based on the actual size of the model and is reported as maximal size deviation from the original size of the model—for model dimensions under 100 mm maximal deviation is ±100 µm and above 100 mm the deviation is ±200 µm

or ±0.06%, whichever is greater. Material usage and printing time were determined automatically. After printing was complete, support material was separated from the model with a high-pressure water jet.

We calculated how much time was spent on each of the following steps: (1) conducting a TEE examination and data transfer from the echocardiographic machine to Q-Station software; (2) Cartesian DICOM patching, segmentation, and model preparation in 3D Slicer; and (3) printing of a 3D model. In addition, the amount of material used to prepare each model was established based on data reported by the printer software. For better visualization, red and blue paint was used to highlight the structures of interest: mitral prostheses were painted blue and the tissue surrounding the PVL channel was painted red.

Statistical Analysis

Continuous variables are expressed as mean and SD or median and range depending on the distribution of variables. Shapiro–Wilk test was used to check for normal distribution of variables.

RESULTS

Model preparation times for each model are presented in Table 1. Mean time of TEE recording and data transfer was

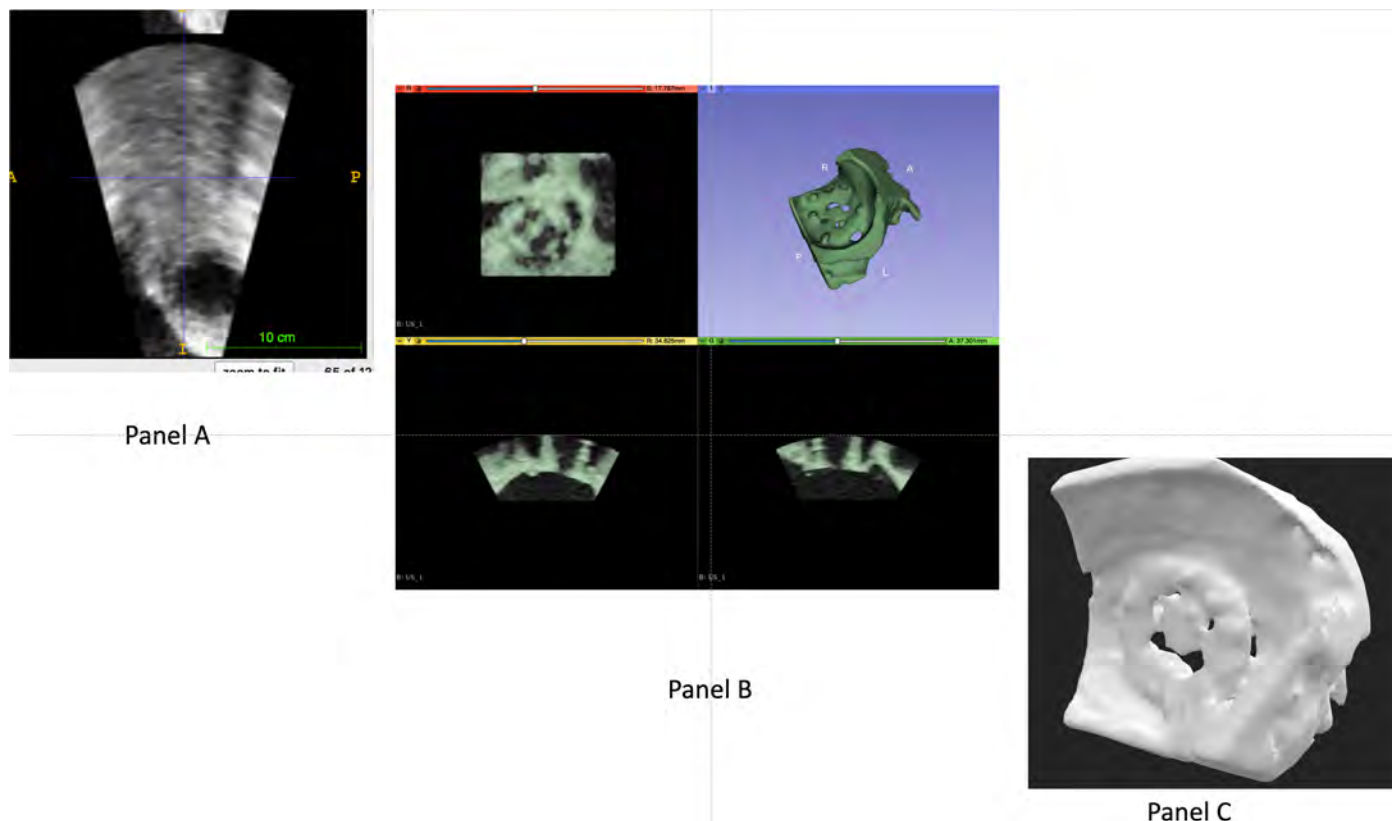


Figure 2. Panel A shows initial, uncorrected Cartesian DICOM data prior to conversion with the SlicerHeart extension. Panel B displays corrected version of DICOM data during segmentation. Panel C shows the final STL file after segmentation.

42.25 ± 6 minutes. Mean time of segmentation was 60.62 ± 12 minutes. Median time of printing was 284 (range 492) minutes. Mean total time of model preparation was 430.5 ± 196 minutes. Figure 3 shows the correlation in TEE, standard triangle language (STL) object, and printed model, and Figure 4 shows photos of all printed models shot from an angle that provided the best visualization of the PVL.

DISCUSSION

In our work, we demonstrated that printing mitral PVL models based on data obtained from 3D transesophageal echocardiography is technically feasible. Paravalvular leaks of various sizes and locations around the mitral annulus were selected, in each case, a model was created and then successfully printed. Models were compared with original 3D datasets with and without color Doppler. Both location and shapes of PVLs were preserved.

Up to date, there is no established methodology for the printing of mitral PVLs from echocardiographic data.

3D model preparation of PVLs begins with good-quality 3D-TEEs. Contrary to 3D-TTEs, it is rare to encounter difficulties in obtaining satisfactory images when performing TEEs. Possible problems during this step include lack of adequate experience of the echocardiographer, excessive motion of the structure of interest during the respiratory cycle and poor tolerance of the TEE by the subject. All of these can be improved by applying specific measures such as additional training of clinical staff in centers experienced in 3D TEE, performing 3D acquisition during a breath hold or in HVR mode and properly sedating the patient.

The key step in 3D model preparation is known as segmentation. During this process, the structure of interest within acquired data is selected and labeled, which can be done in an automatic, semi-automatic, or manual manner. The international standard to store, transmit, process, and display medical data is DICOM. In contrast to other imaging modalities, commonly used for medical purposes, such as CCT or MRI, the ultrasound data in the DICOM object is encrypted in vendor-specific formats. Therefore DICOM

Table 1. 3D Paravalvular Leaks Models Preparation Time (in Minutes)

	Model a	Model b	Model c	Model d	Model e	Model f	Model g	Model h
Recording and Transfer	41	45	40	47	50	38	35	42
Segmentation	75	55	60	45	80	50	55	65
Printing	340	183	278	193	675	534	191	290
Total	456	283	378	285	805	622	281	397

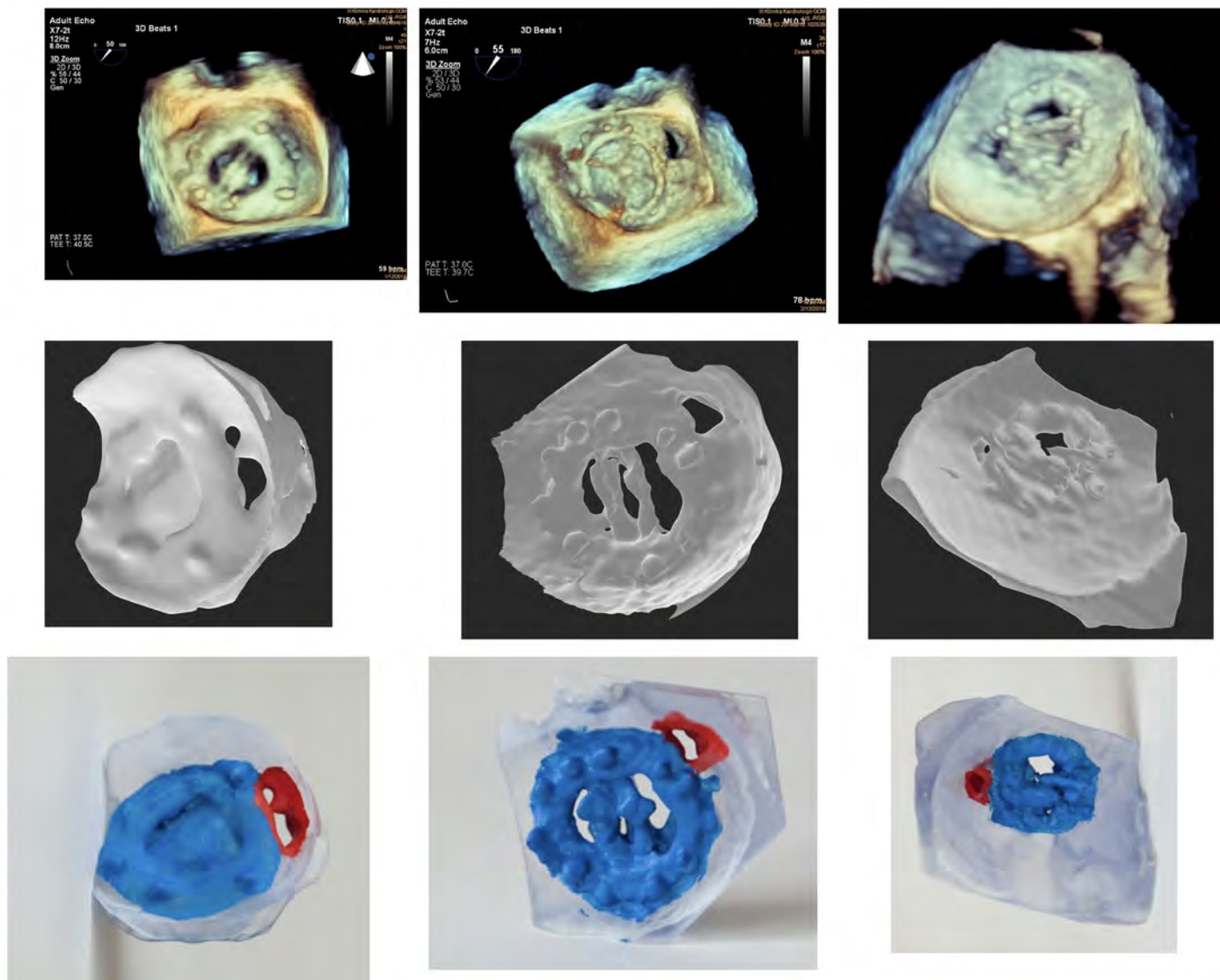


Figure 3. Presentations of pictures from TEE, STL, and printed model for 3 cases. TEE, transesophageal echocardiography.

data acquired during echocardiographic examinations cannot be directly used as source data for segmentation and requires specific conversion. Nowadays, only Philips Q-Station software allows converting DICOM data to a format that can be used for segmentation. This is done in 2 steps. First, DICOM data is exported from the Q-Station software in a proprietary Philips Cartesian DICOM format. During this step anisotropic, frustum-shaped voxels, of which the raw 3D ultrasound data is composed of, are resampled into uniform, cube-shaped voxels. Second, Cartesian DICOM files are loaded into the 3DSlicer and are converted again with the SlicerHeart extension to be appropriate for the actual segmentation. Cartesian DICOM data prior to conversion with the SlicerHeart extension is presented in Figure 1. Segmentation of 3D-TEE images is in our opinion more difficult than using CT data for the same purpose. The first and most obvious reason is the necessity to access the proprietary Philips software since other vendors don't provide Cartesian DICOM export options. In addition, as mentioned earlier, further post-processing is required in 3DSlicer

so a requirement to familiarize oneself with new software can be challenging for novice users. Correct and reliable segmentation mandates good echocardiographic experience and knowledge of heart anatomy.

We measured the time required to complete each step of a 3D model preparation. The initial step is to perform TEE and then transfer all images to the Q-Station software. This step did not take longer than 50 minutes and is probably the easiest one, especially in centers with extensive experience in PVL treatment and 3D-TEE. Next cartesian DICOM files were loaded into 3D Slicer software, converted, and then underwent semi-automatic segmentation with subsequent manual correction. This method of segmentation provides a good balance between the quality of the created model and the time required to complete the process, since the initial step that involves separating blood from tissue is conducted automatically and manual correction is only applied for the region of interest, which in our case was the PVL. The duration of this step is based on user experience, in our case the

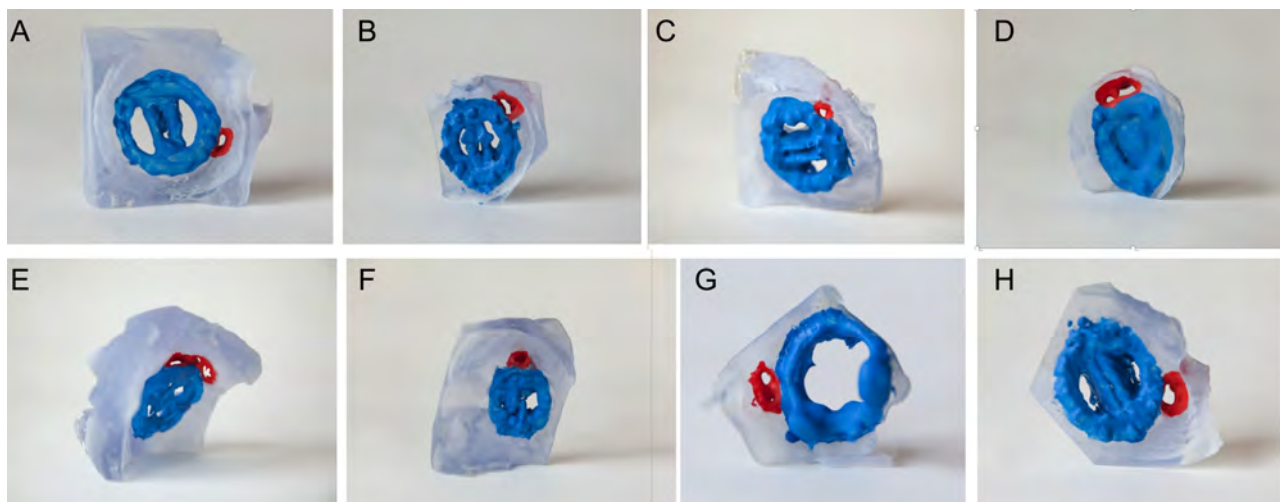


Figure 4. Printed models. Images a to h represent models 1-8, respectively. Photos were shot at an angle that allowed the best visualization of the PVL. Blue paint was used to highlight the mitral prosthesis and red paint to show the tissues surrounding the PVL channel. PVL, paravalvular leak.

mean time was 60.62 ± 12 minutes and longer times should be expected for novice users. The longest part of PVL model preparation is printing which is influenced by parameters such as the size of the model or its orientation on the printer tray. Although a significant reduction in printing times could be achieved by printing several models at once, we did not attempt this approach in order to allow for credible comparison of printing times between each model. In our opinion, the greatest challenge in this final step is the cost of purchasing a 3D printing machine. This, however, can be simply overcome by outsourcing the process of printing to a specialized company. This is an affordable option that allows to experiment with 3D printing without investing a significant amount of money upfront.

In all published articles CCT with contrast was used as source data for model preparation with good results.¹⁶ The advantage of CCT is that its DICOM data does not require any additional conversion and can be directly used for segmentation purposes. However, it is not possible to perform CCT of adequate quality in every patient with a PVL due to a lack of cooperation, atrial fibrillation, or artifacts from mechanical prostheses. In addition, CCT may be contraindicated in this population due to chronic renal disease. It should also be mentioned that analysis of CCT data is performed after the scan is completed, therefore no corrective measures can be applied if the scan is of unacceptable quality. TEE, on the other hand, delivers excellent temporal and spatial resolution with real-time analysis of acquired data performed by an experienced echocardiographer. Therefore, utilizing 3D echocardiography for PVL model preparation may be a preferable option in pre-procedural planning of percutaneous PVL closure. Of note, 3D-TEE is a low-cost procedure with few absolute contraindications that are readily available in units that treat patients with PVLs.

It remains to be tested if pre-procedural printing of mitral PVLs would facilitate the procedure and improve technical success rates. Importantly, a recent work in which

LAA closure was performed with device sizing based on 3D models prepared from 3D-TEE datasets showed superior outcomes in subjects in whom device selection was in agreement with 3D model sizes.¹⁷ Nevertheless, despite significant technological advancements, echocardiography is not perfect in predicting procedural outcomes in percutaneous PVL closure. Paravalvular leak channels are often angulated (C-shaped or S-shaped) and this can result in unexpected behavior of closure devices once these are placed in the PVL channel. Our clinical experience shows that even when a PVL channel is properly sized with echocardiography, a shift in device position can occur once the device is released from the delivery cable. Thus, being able to test several devices on a 3D model prior to the procedure may lead to fewer peri-procedural complications (such as device embolization), improve success rates, and lower the total cost of the procedure since improperly sized devices have to be removed from the patient and discarded. Due to the retrospective nature of the study, no conclusions can be made regarding the potential clinical utility of TEE-based 3D models of PVLs on procedural success and clinical outcomes. Our further research would concentrate on designing a randomized clinical trial in which procedural success rates and outcomes would be tested between the contemporary percutaneous PVL closure approach and a 3D model-guided one.

CONCLUSIONS

3D printing of mitral PVL models from 3D-TEE is technically feasible. Echocardiographic studies, routinely performed for diagnostic purposes, can serve as source data for model creation. Open-source software can be used for image segmentation and model preparation. 3D printing can also be outsourced and therefore it is not necessary to commit to 3D printing from the get-go by making a significant investment in a 3D printer. It remains to be tested in a randomized clinical trial whether 3D printing can improve procedural success rates and outcomes.

Data Availability Statement: The datasets generated and/or analyzed during the current study are not publicly available due to national policy but are available from the corresponding author upon reasonable request.

Ethics Committee Approval: The need for ethical approval was waived by the Ethics Committee (because of the retrospective nature of the study, decision number: PCN/0022/KB1/82/20/21).

Informed Consent: Anonymous imaging data was used for this study therefore consent was not required.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – M.J., M.K.; Design – M.J., M.K.; Supervision – W.W., G.S.; Resources – M.J., M.K., T.J.; Materials – M.J., M.K.; Data Collection and/or Processing – M.J., M.K.; Analysis and/or Interpretation – T.J., W.W., G.S.; Literature Search – M.J., M.K., T.J.; Writing – M.J., M.K., T.J.; Critical Review – W.W., G.S.; Funding acquisition – W.W., G.S.; Software – M.J., M.K., E.P.P.; Validation, M.J., M.K., P.P.

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Declaration of Interests: The authors have no conflict of interest to declare.

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