

3D printing from transesophageal echocardiography for planning mitral paravalvular leak closure – feasibility study

Marek Jędrzejek¹, Ewa Peszek-Przybyła¹, Tomasz Jadczyk¹, Jakub Zemik², Paulina Piprek³, Piotr Pysz¹, Michał Kozłowski¹, Wojciech Wojakowski¹, Grzegorz Smolka¹

¹Department of Cardiology and Structural Heart Diseases, Medical University of Silesia, Katowice, Poland

²Faculty of Sciences and Technology, University of Silesia, Katowice, Poland

³Doctoral School, Medical University of Silesia, Katowice, Poland

Adv Interv Cardiol 2023; 19, 3 (73): 270–276
DOI: <https://doi.org/10.5114/aic.2023.131481>

Abstract

Introduction: Transcatheter closure of paravalvular leak (PVL) is still a demanding procedure due to the complex anatomy of PVL channels and risk of interference between the implanted occluder and surrounding structures. Efforts are made to improve procedural outcomes in transcatheter structural heart interventions by establishing treatment strategy in advance with the use of 3D-printed physical models based on data obtained from cardiac computed tomography (CT) studies.

Aim: In this feasibility study 3D printing of PVL models based on data recorded during transesophageal echocardiography (TEE) examinations was evaluated.

Material and methods: 3D-TEE data of patients with significant PVL around mitral valve prostheses were used to prepare 3D models. QLab software was used to export DICOM images in Cartesian DICOM format of each PVL with the surrounding tissue. Image segmentation was performed in Slicer, a free, open-source software package used for imaging research. Models were printed to actual size with the Polyjet printer with a transparent, rigid material. We measured dimensions of PVLs both in TEE recordings and printed 3D models. The results were correlated with sizes of occluding devices used to close the defects.

Results: In 7 out of 8 patients, there was concordance between procedurally implanted occluders and pre-procedurally matched closing devices based on 3D-printed models.

Conclusions: 3D-printing from 3D-TEE is technically feasible. Both shape and location of PVLs are preserved during model preparation and printing. It remains to be tested whether 3D printing would improve outcomes of percutaneous PVL closure.

Key words: paravalvular leak, 3D printing, echocardiography, mitral valve, slicer.

Summary

This study explores the feasibility of using 3D printing technology to create physical models of paravalvular leaks (PVL) based on data obtained from transesophageal echocardiography (TEE) examinations. PVL closure through transcatheter procedures presents challenges due to complex anatomy and potential interference between implanted occluders and nearby structures. The research aims to enhance procedural planning for structural heart interventions by generating 3D-printed models from TEE data.

Introduction

The increasing number of valve replacement procedures (both transcatheter and surgical) results in a rising number of paravalvular leaks (PVL). The exact incidence rate of PVLs remains unknown, but it is estimated at about 10% of patients after aortic valve surgery and, according to the literature, can even be as high as 15%

after mitral valve replacement [1]. Between one and five percent of patients with a PVL are symptomatic and may require invasive treatment [2]. The main signs and symptoms arise from congestive heart failure (90%) and may also be accompanied by hemolysis, occurring in nearly 33–75% of cases [3, 4]. Moreover, PVLs are considered a risk factor for infective endocarditis due to the tur-

Corresponding author:

Marek Jędrzejek, Department of Cardiology and Structural Heart Diseases, Medical University of Silesia, Katowice, Poland,
e-mail: marek.jedrzejek@poczta.fm

Received: 13.08.2023, **accepted:** 18.08.2023.

bulent pattern of blood flow through these intracardiac channels [5, 6]. Therefore, PVL presence may influence the patient's quality of life and, in some cases, treatment is life-saving.

Nowadays interventional procedures are being used to close PVLs with percutaneous or transapical access, with the latter approach reserved for more challenging cases [7].

The surgical approach is associated with a higher mortality rate and is reserved for treatment of PVLs with valve dehiscence (rocking valves) or those that accompany active endocarditis [8, 9].

From a procedural point of view, planning and imaging are crucial steps that significantly impact clinical outcomes [10]. The most common modality used for diagnosis and peri-procedural management of patients with PVLs is two- and three-dimensional transesophageal echocardiography (2D-TEE and 3D-TEE) [11]. Prior to the intervention, it is used to identify both the anatomical location and number of PVLs as well as to grade severity of regurgitation in all patients [8]. During the procedure, TEE (especially 3D-TEE) is critical in assessment of PVL size and shape and accurate measurements are essential for selection of the appropriate closure device [12].

Another useful tool for PVL imaging is electrocardiography-gated cardiac computed tomography (CT) with three-dimensional or four-dimensional reconstruction. However, the benefits of high temporal and spatial resolution are limited by artifacts from dense structures or high heart rate, risks associated with the use of contrast and (especially in younger patients) radiation.

The challenges with TEE or CT-based visualization of PVLs are related to the type of prosthesis (biological or mechanical), position of the prosthesis and location of the PVL and are similar between the two imaging modalities. Despite advancements in imaging techniques, it may not be possible to predict the final result of intervention prior to closure device placement in the PVL channel. The main reason for this is the lack of ability to adequately determine the shape and position of the occluder in the PVL channel after deployment and the risk of interference between the occluder and surrounding structures. The latter is especially relevant in patients with mechanical valve prostheses.

An incomplete seal of the PVL channel worsens the patient's prognosis and increases the risk of post-procedural hemolysis. Failing to identify subjects in whom these complications may occur can lead to procedural failure [3]. Unpredicted interactions of the occluder with surrounding structures may lead to serious consequences, including blockage of the mechanical prosthesis or high risk of erosion.

To overcome these limitations 3D printing (until now based mostly on CT scanning) was proposed for planning of structural interventions [13]. It provides the unique

possibility to visualize interactions between prosthetic discs, surrounding tissues and occluders used for PVL closure.

As the use of real-time 3D color Doppler imaging enables exact localization of the PVL it seems reasonable to use TEE data for 3D printed models. There are reports of using TEE-based 3D printings for cardiac interventional procedures [14, 15]. However, the preparation of 3D models from echocardiographic data is more challenging in comparison to CT due to lack of compatibility between echocardiographic (non-Cartesian) DICOM data and software used for stereolithography model preparation [16–19].

The feasibility of TEE-based 3D printing for planning and implanting PVL occluders is still unknown.

Aim

We aimed to test whether TEE-based 3D printed models could allow for the appropriate choice of an occluder for transcatheter PVL closure.

Material and methods

Study design

The data of all patients who underwent percutaneous mitral PVL closure around mitral valve prosthesis in the last year were reviewed. Eight consecutive cases with satisfactory quality of pre-procedural 3D-TEE recordings were chosen for the study. Based on TEE data, 3D models of each valve prosthesis and surrounding structures, including the PVL channel, were printed. In the next step, an investigator blinded to the results of transcatheter PVL closures tested different occluders on the 3D model following the rules used during the real procedures. Two types of closure devices were used: Paravalvular Leak Device (PLD; Occlutech) and Amplatzer Valvular Plug III (AVP III; Abbott), both of which are commonly used in our center during percutaneous PVL closure procedures. For larger PVLs with a short channel (< 5 mm) the Occlutech PLD was the first choice, whereas the tortuous course of the channel or length > 5 mm were indications for AVP III. In the case of larger PVLs, when a single device was not likely to completely close the leak, multiple plugs (up to 3 devices) were allowed [11].

In addition, results were correlated with actual occluders implanted *in vivo*.

This study was performed according to the principles of the Declaration of Helsinki and did not require the consent of an Ethics Committee. All steps from image acquisition to printing are shown in Figure 1.

3D-TEE image acquisition

3D-TEE imaging was performed with the EPIQ7C ultrasound system (Philips Medical Systems, Andover, MA) with a fully sampled matrix transducer (X7-2t) according

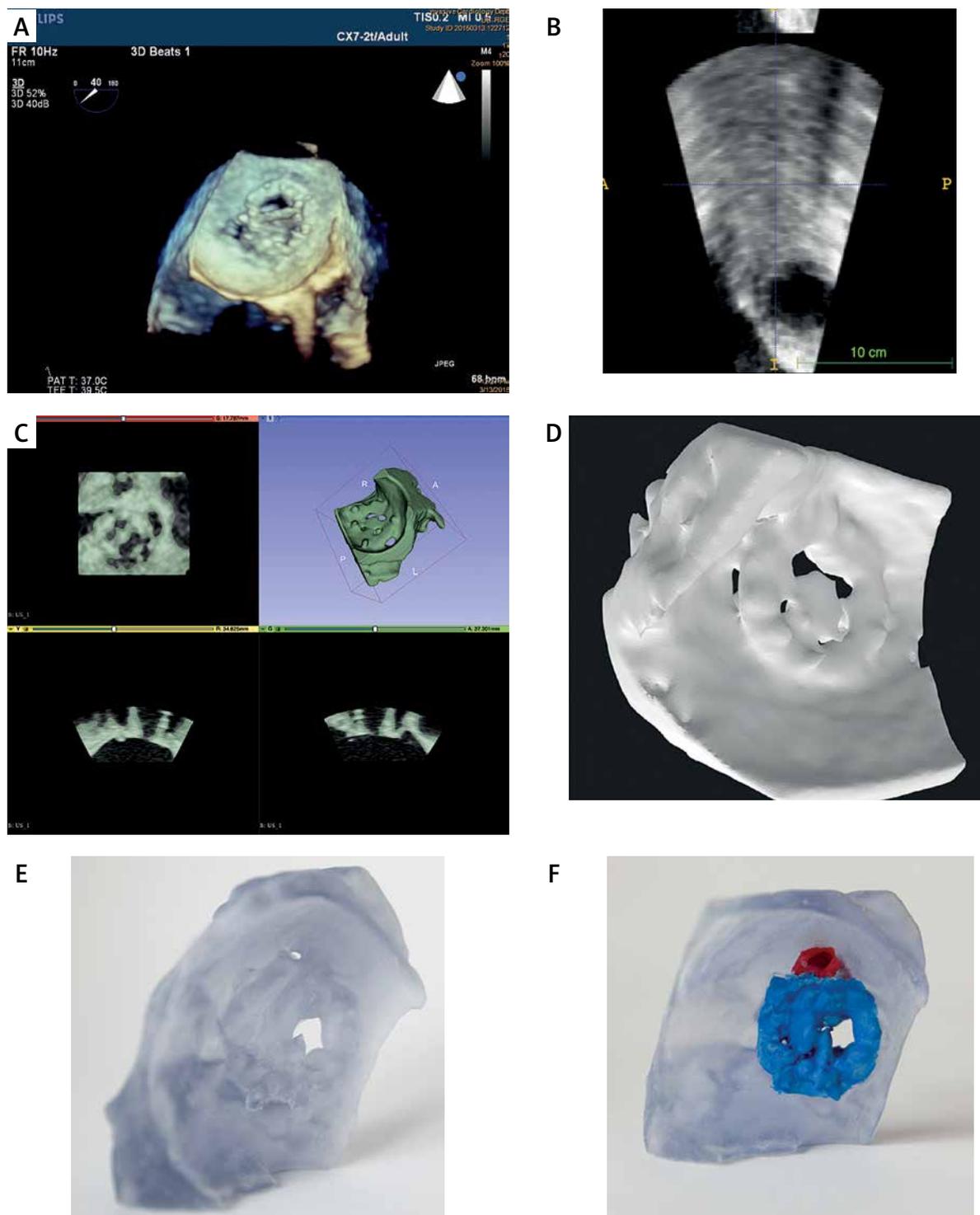


Figure 1. Steps of 3D model preparation. **A** – transesophageal echocardiography, **B** – image before patching in Slicer, **C** – segmentation, **D** – 3D STL data, **E** – printed 3D model, **F** – 3D model colored to represent the PVL (red) and valve (blue)

to a local protocol. All examinations were performed by 2 operators in accordance with the European Association of Cardiovascular Imaging (EACVI) recommendations under conscious sedation with diazepam administered intravenously [20].

Image transfer and segmentation

Images were transferred to the workstation and uploaded to a QLab station (Philips Medical Systems, Andover, MA, ver 3.8.5). Quality of images was assessed and recordings with satisfactory quality were identified. Se-

lected non-color 3D volumes were exported in Cartesian DICOM (3DDCM) format. Next, the Cartesian DICOM files were uploaded into Slicer (Freeware software, v. 5.2.2 r31382/fb46bd1) [13], which is a free, open-source software package used for imaging research. To convert Cartesian DICOM to standard DICOM, the Philips DICOM Patcher module in Slicer was used (this step requires installation of the SlicerHeart and Sequences extensions). Semi-automatic segmentation of volumetric data was performed using thresholding with subsequent manual correction. Diastolic frames were selected for the best PVL channel visualization.

3D printing

All .stl files were imported into the 3D printer software. Afterwards the models were printed to actual size with the Polyjet printer (Stratasys, Commerce Way, Eden Prairie, MN, Objet 30 v.3). Rigid printing (IORA Model) and support (IORA Support) materials (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 $\pm 100 \mu\text{m}$ [17].

Results

We retrospectively evaluated pre-procedural 3D echo scans of patients with mitral PVLs who underwent transcatheter closure. From this population, 8 patients' data were selected for assessment and printing. Characteristics of printed PVLs are presented in Table I.

The occluder implanted during the actual procedure corresponded well to the 1 suggested in 7 patients (87.5% of the study group). In 1 case, during the invasive procedure, the PLD occluder was initially selected, but due to significant deformation it was replaced with two AVPIII occluders, which aligned well with the benchmark study.

Table II presents procedural and pre-procedural data. Figure 2 shows corresponding 3D-TEE images (2A), Slicer models (2B), 3D-printed models (2C) and 3D-printed models with occluders (2D). Figure 3 illustrates 3D-printed models of PVLs, matched with different types of tested occluders.

Table I. Types of valves, position of PVLs and model preparation time

Variable	1	2	3	4	5	6	7	8
Type of valve	Hancock II 29	Sorin Bicarbon 27	STJM 29	ATS 29	SJM 29	STJM 27	SJM 31	Medtronic 29
Mechanical mitral valve	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Location of the PVL	Anterior	Medial	Lateral	Medial	Lateral	Medial	Lateral	Anterior
Time of data preparation for 3D printing [min]	116	100	100	92	130	88	90	107
Time of 3D printing [min]	340	283	378	285	805	622	281	397

Table II. Comparison of the benchmark testing and real-life data

Variable	1	2	3	4	5	6	7	8
Type of implanted occluder	PLD-W	PLD-W	AVP III	PLD-W	PLD-W	PLD-W	AVP III	PLDW
Size of implanted occluder	12x5	12x5	8x4 and 6x3**	6x3	4x2	12x5	10x5	6x3
Number of implanted occluders	1	1	2	1	1	1	1	1
Occluder(s) proposed in benchmark testing	PLD-W 12 × 5 or AVP III 14 × 5 or 3 × AVPIII 6 × 3	PLD-W 12 × 5	2 × AVPIII 8 × 4	AVP III 8 × 4	PLD-W 4 × 2 or AVP III 6 × 3	PLD-W 12 × 5	AVP III 10 × 5 or 3 × AVPIII 6 × 3	PLD-W 6 × 3
Residual leak <i>in vivo</i>	No	No	Yes	Yes	No	No	No	No
Interaction with valve <i>in vivo</i>	No	No	No	No	No	No	No	No
One year survival after implantation	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

*Bold size occluder is preferred one. **PLD-W – W 8 × 4 removed – dog bone formation.

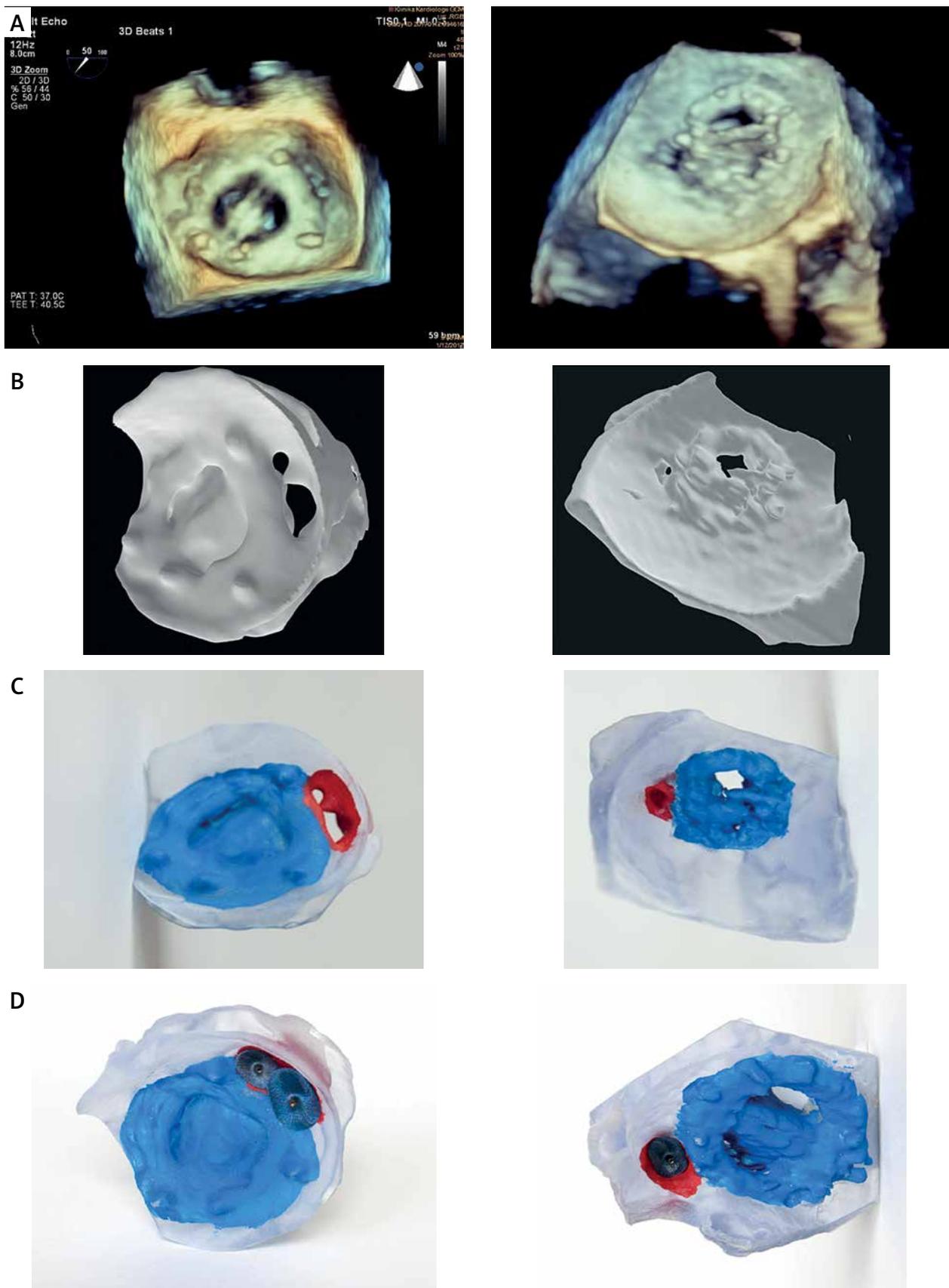


Figure 2. Results of occluder matching in printed models. 3D-TEE images (A), Slicer models (B), 3D-printed models (C) and 3D-printed models with occluders (D)



Figure 3. Printed PVL models with tested occluders

Discussion

In our study, we confirmed the feasibility of using 3D-printed mitral valve models to simulate PVL closure procedures, relying on data obtained from 3D-TEE imaging. Up until now, the literature has primarily focused on discussing the potential of CT images for 3D model preparation and transcatheter PVL closure [15, 21–24]. Our study adds to the existing knowledge by showing the practical application and benefits of 3D-printed mitral valve models in simulating PVL closure procedures, providing valuable insights for further advancements in this field.

The wide variety of occluders used for PVL closure posed a challenge in including the entire spectrum within the scope of this study. Therefore, two types of occluders, most commonly used in our center, were employed. This approach is consistent with common practice and, as demonstrated in the article by Hascoët *et al.*, these two occluders (AVPIII – 56%, PLD – 14%) are also the most frequently utilized ones [25].

In our series of patients the empirical measurements corresponded well with sizes of implanted devices, but the study is only a demonstration of technical feasibility. The choice of a strategy is based on many variables and is beyond the scope of this article. One of the significant limitations is the small number of patients included in the study.

The PVL 3D model preparation is usually a time-consuming and complex process, due to the necessity of data re-formatting, manual segmentation of the images, the printing process and postprocessing [17]. Automation of these processes through dedicated software would significantly increase the potential usefulness of this method. In the literature there are examples where more sophisticated software is applied to prepare 3D models (Mimics 19.0, Materialise, Leuven, Belgium), which significantly reduces the model preparation time [26–28]. Unfortunately, license cost precludes everyday use of such software.

Another limitation of the study may be the type of the material used for printing. We decided to use rigid

printing materials as they properly depict not only the location, size and complexity of the PVL, but also accurately represent the mechanical properties of the prosthetic valve and correspond well to the calcified structure of the aortic bulb. Rigid materials also properly depict the relationship between the prosthesis and surrounding tissues, but may unfortunately fail to accurately represent interactions between compliant tissues, as may occur in the case of mitral PVLs. Therefore some reports advise the use of multi-material 3D printing [29], and this may indicate the direction for further research.

Nowadays diverse models of virtual implantation of different intracardiac occluders are suggested. They allow one to partially predict the efficacy of occluder implantation and its interaction with surrounding tissues (FEops), but currently there is no virtual modeling available for assessing the performance of an occluder significantly deformed by a PVL channel [30].

Conclusions

Imaging data acquired during 3D-TEE can be used to prepare accurate 3D printed models of PVL.

3D-printed models of mitral PVLs allow the operator to simulate interactions with the defect before the procedure. It facilitates detection of interactions between the occluder, valvular prosthesis and surrounding tissues. Additionally, the model offers valuable insights to guide the operator in selecting the optimal type and size of the occluder.

The data processing methods used in the study are very time-consuming, and only automation of this process could increase the likelihood of practical application of TEE-based 3D models in everyday practice.

This is a hypothesis-generating study, and to draw stronger conclusions, a prospective study is necessary, followed by a study utilizing 3D modeling to guide the operator towards the optimal occluder selection.

Acknowledgments

This work was co-financed by the National Center for Research and Development as part of the strategic pro-

gram “Prevention and treatment of civilization diseases” Strategmed II Project.

Conflict of interest

The authors declare no conflict of interest.

References

1. Ionescu A, Fraser AG, Butchart EG. Prevalence and clinical significance of incidental paraprosthetic valvar regurgitation: a prospective study using transoesophageal echocardiography. *Heart* 2003; 89: 1316-21.
2. Kozłowski M, Malczewska M, Pysz P, et al. Quality of life after percutaneous paravalvular leak closure – a prospective registry. *Adv Interv Cardiol* 2022; 18: 261-8.
3. Smolka G, Pysz P, Ochała A, et al. Transcatheter paravalvular leak closure and hemolysis – a prospective registry. *Arch Med Sci* 2017; 13: 575-84.
4. Ruiz CE, Jelnin V, Kronzon I, et al. Clinical outcomes in patients undergoing percutaneous closure of periprosthetic paravalvular leaks. *J Am Coll Cardiol* 2011; 58: 2210-7.
5. Gil KE, Jellis C, Krishnaswamy A. Challenging mitral paravalvular leak and recurrent infective endocarditis. *Kardiologia Pol* 2021; 79: 885-6.
6. Cahill TJ, Baddour LM, Habib G, et al. Challenges in infective endocarditis. *J Am Coll Cardiol* 2017; 69: 325-44.
7. Cruz-Gonzalez I, Rama-Merchan JC, Rodríguez-Collado J, et al. Transcatheter closure of paravalvular leaks: state of the art. *Netherlands Hear J* 2017; 25: 116-24.
8. Ruiz CE, Hahn RT, Berrebi A, et al. Clinical trial principles and endpoint definitions for paravalvular leaks in surgical prosthesis: an expert statement. *J Am Coll Cardiol* 2017; 69: 2067-87.
9. Alkhouli M, Rihal CS, Zack CJ, et al. Transcatheter and surgical management of mitral paravalvular leak: long-term outcomes. *JACC Cardiovasc Interv* 2017; 10: 1946-56.
10. Eleid MF, Cabalka AK, Malouf JF, et al. Techniques and outcomes for the treatment of paravalvular leak. *Circ Cardiovasc Interv* 2015; 8: e001945.
11. Pysz P, Wojakowski W, Smolka G. Paravalvular leak echo imaging before and during the percutaneous procedure. *J Clin Med* 2022; 11: 3155.
12. Smolka G, Wojakowski W, Tendera M. Transcatheter paravalvular leak closure. In: *Transcatheter Paravalvular Leak Closure*. Smolka G, Wojakowski W, Tendera M (eds.). Springer, Singapore 2017; 1-182.
13. Hosny A, Dilley JD, Kelil T, et al. Pre-procedural fit-testing of TAVR valves using parametric modeling and 3D printing. *J Cardiovasc Comput Tomogr* 2019; 13: 21-30.
14. Fan Y, Yang F, Cheung GSH, et al. Device sizing guided by echocardiography-based three-dimensional printing is associated with superior outcome after percutaneous left atrial appendage occlusion. *J Am Soc Echocardiogr* 2019; 32: 708-19.
15. Ciobotaru V, Tadros VX, Batistella M, et al. 3D-printing to plan complex transcatheter paravalvular leaks closure. *J Clin Med* 2022; 11: 4758.
16. Jędrzejek M, Garczyk-Mundala Z, Peszek-Przybyła E, et al. Multimodality imaging (3D Echocardiography, 3D printing and confocal microscopy) for paravalvular leak visualization. *Eur Hear J Cardiovasc Imaging* 2023; 24 (Suppl 1): 335-6.
17. Jędrzejek M, Kozłowski M, Peszek-Przybyła E, et al. Mitral paravalvular leak 3D printing from 3D-transesophageal echocardiography. *Anatol J Cardiol* 2023 Jun 7 [Epub ahead of print]; doi: 10.14744/AnatolJCardiol.2023.3008.
18. Jędrzejek M, Kozłowski M, Pysz P, et al. Mitral paravalvular leak 3D printing from 3D-transesophageal echocardiography – proof of concept. *Eur Hear J Cardiovasc Imaging* 2022; 23 (Suppl 1): 502-3.
19. Hosny A, Shen T, Kuo AS, et al. Unlocking vendor-specific tags: three-dimensional printing of echocardiographic data sets. *J Thorac Cardiovasc Surg* 2018; 155: 143-5.
20. Faletra FF, Agricola E, Flachskampf FA, et al. Three-dimensional transoesophageal echocardiography: how to use and when to use – a clinical consensus statement from the European Association of Cardiovascular Imaging of the European Society of Cardiology. *Eur Hear J Cardiovasc Imaging* 2023; 24: e119-97.
21. Wang C, Zhang L, Qin T, et al. 3D printing in adult cardiovascular surgery and interventions: a systematic review. *J Thorac Dis* 2020; 12: 3227-37.
22. Wang DD, Qian Z, Vukicevic M, et al. 3D printing, computational modeling, and artificial intelligence for structural heart disease. *JACC Cardiovasc Imaging* 2021; 14: 41-60.
23. Motwani M, Burley O, Luckie M, et al. 3D-printing assisted closure of paravalvular leak. *J Cardiovasc Comput Tomogr* 2020; 14: e66-8.
24. Cruz-González I, Barreiro-Pérez M, Valverde I. 3D-printing in preprocedural planning of paravalvular leak closure: feasibility/proof-of-concept. *Rev Esp Cardiol* 2019; 72: 342.
25. Hascoët S, Smolka G, Kilic T, I et al. Procedural tools and technics for transcatheter paravalvular leak closure: lessons from a decade of experience. *J Clin Med* 2022; 12: 119.
26. Fan Y, Yang F, Cheung GS, et al. Device sizing guided by echocardiography-based three-dimensional printing is associated with superior outcome after percutaneous left atrial appendage occlusion. *J Am Soc Echocardiogr* 2019; 32: 708-19.
27. Song H, Zhou Q, Zhang L, et al. Evaluating the morphology of the left atrial appendage by a transesophageal echocardiographic 3-dimensional printed model. *Medicine (United States)* 2017; 96: e7865.
28. Zhu Y, Liu J, Wang L, et al. Preliminary study of the application of transthoracic echocardiography-guided three-dimensional printing for the assessment of structural heart disease. *Echocardiography* 2017; 34: 1903-8.
29. Smith ML, Jones JFX. Dual-extrusion 3D printing of anatomical models for education. *Anat Sci Educ* 2018; 11: 65-72.
30. Bochenek T, Lelek M, Gruchlik B, et al. Use of FEops artificial intelligence enabled technology for preprocedural planning of left atrial appendage occlusion with Amulet Amplatzer device. *Adv Interv Cardiol* 2022; 18: 296-9.