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In vitro bench testing using patient-specific 3D models for percutaneous pulmonary valve implantation with Venus P-valve

Yu Han[1], Zehua Shao[2], Zirui Sun[1], Yan Han[1], Hongdang Xu[3], Shubo Song[2], Xiangbin Pan[4], Peter P. T. de Jaegere[5], Taibing Fan[2], Gejun Zhang[1,4]

[1]Department of Structure Heart Disease, Central China Fuwai Hospital of Zhengzhou University, Zhengzhou, Henan 451460, China;
[2]Children's Heart Center, Central China Fuwai Hospital of Zhengzhou University, Zhengzhou, Henan 451460, China;
[3]Department of Anesthesiology, Central China Fuwai Hospital of Zhengzhou University, Zhengzhou, Henan 451460, China;
[4]Department of Structure Heart Disease, Fuwai Hospital Chinese Academy of Medical Sciences, Beijing 100037, China;
[5]Department of Cardiology, Erasmus MC, Rotterdam 3015 GD, Netherlands.

Abstract

Background: Due to the wide variety of morphology, size, and dynamics, selecting an optimal valve size and location poses great difficulty in percutaneous pulmonary valve implantation (PPVI). This study aimed to report our experience with *in vitro* bench testing using patient-specific three-dimensional (3D)-printed models for planning PPVI with the Venus P-valve.

Methods: Patient-specific 3D soft models were generated using PolyJet printing with a compliant synthetic material in 15 patients scheduled to undergo PPVI between July 2018 and July 2020 in Central China Fuwai Hospital of Zhengzhou University.

Results: 3D model bench testing altered treatment strategy in all patients (100%). One patient was referred for surgery because testing revealed that even the largest Venus P-valve would not anchor properly. In the remaining 14 patients, valve size and/or implantation location was altered to avoid valve migration and/or compression coronary artery. In four patients, it was decided to change the point anchoring because of inverted cone-shaped right ventricular outflow tract (RVOT) ($n = 2$) or risk of compression coronary artery ($n = 2$). Concerning sizing, we found that an oversize of 2–5 mm suffices. Anchoring of the valve was dictated by the flaring of the in- and outflow portion in the pulmonary artery. PPVI was successful in all 14 patients (absence of valve migration, no coronary compression, and none-to-mild residual pulmonary regurgitation [PR]). The diameter of the Venus P-valve in the 3D simulation group was significantly smaller than that of the conventional planning group (36 [2] *vs.* 32 [4], $Z = -3.77$, $P < 0.001$).

Conclusions: *In vitro* testing indicated no need to oversize the Venus P-valve to the degree recommended by the balloon-sizing technique, as 2–5 mm sufficed.

Keywords: Heart valve prosthesis implantation; Percutaneous pulmonary valve intervention; Pulmonary regurgitation; *In vitro* bench testing; 3D printing; Venus P-valve

Introduction

Percutaneous pulmonary valve implantation (PPVI) is a less-invasive alternative to surgical pulmonary valve replacement. Currently, the commercially available Sapien valve (Edwards lifesciences Inc., USA) is not large enough for patients with dilated or patch-repaired right ventricular outflow tract (RVOT) in China. Harmony (Medtronic, Inc., USA) and Alterra (Edwards lifesciences Inc., USA) pre-stent are available in the U. S., while Pulsta valve (Taewoong Medical Co. Gimpo, South Korea) is available in Asia/Europe. The self-expanding Venus P-valve (Venus Medtech, Hangzhou, China) is specifically designed for patients with dilated RVOT and has been reported to be safe and associated with good early to midterm clinical outcomes.[1–6]

However, size and certain anatomical substrates of the RVOT currently restrict PPVI eligibility to less than one-quarter of patients.[7] Also, sizing remains challenging despite high-quality imaging modalities due to the morphological and functional complexity of the RVOT.[8]

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Yu Han and Zehua Shao contributed equally to this work.

Correspondence to: Gejun Zhang, Department of Structure Heart Disease, Central China Fuwai Hospital of Zhengzhou University, Zhengzhou, Henan 451460, China; Department of Structure Heart Disease, Fuwai Hospital Chinese Academy of Medical Sciences, Beijing 100037, China
E-Mail: gjzhang212@163.com;
Taibing Fan, Children's Heart Center, Central China Fuwai Hospital of Zhengzhou University, Zhengzhou, Henan 451460, China
E-Mail: fantaibing@163.com

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At present, valve size selection and anchoring site are still defined during the procedure through visual interpretation of the anatomy during contrast angiography in combination with the information derived from the inflation of a sizing balloon (expansion and indentation).[9]

An *in vitro* patient-specific three-dimensional (3D) cast or model of the target anatomy offers the operator a direct understanding of the complex anatomy and its relation with surrounding structures. Albeit static, such an approach may also help to improve valve size selection, the selection of optimal anchoring site, and the subsequent risk of valve embolization. This study aimed to describe our experience with *in vitro* bench testing using patient-specific 3D-printed models for the planning of PPVI with the Venus P-valve.

Methods

The population included 15 patients with dilated RVOT and chronic severe pulmonary regurgitation (PR) scheduled to undergo PPVI with the Venus P-valve in Central China Fuwai Hospital of Zhengzhou University between July 2018 and July 2020. All patients underwent surgery for tetralogy of Fallot (TOF) with transannular patching of the RVOT and right heart dilation (indexed right ventricular end-diastolic volume [RVEDVi] exceeding 150 mL/m^2). Also, all patients were in New York Heart Association (NYHA) class ≥II . Pre-procedural clinical assessment included electrocardiogram (ECG), contrast cardiac computed tomography (CT), transthoracic echocardiography (TTE), and magnetic resonance imaging (MRI). This study was approved by the Scientific Research and New Technology, New Business Ethics Committee of Fuwai Central China Cardiovascular Hospital [No. 2017 Ethical Approval [50]). All participants gave informed consent.The research process was adequately monitored, and all regulations were met.

3D-modeling

For each patient, baseline ECG-gated contrast CT of the maximum systolic period of the cardiac cycle was used for patient-specific 3D reconstruction of the target anatomy using the PolyJet™ technique and a compliant synthetic compound (TangoPlus Fullcure, Stratasys Ltd., MN, USA) that was previously described in detail.[10,11] Briefly, the chosen compound (TangoPlus) was loaded in a 3D printer, in which digital instructions were uploaded. A jetting head moved in the *x*, *y*, and *z* direction sprayed small droplets of the compounds layer by layer, followed by ultraviolet light activation. This technique allowed an accurate reconstruction of the patient's anatomy and assessment of its dimensions.

Procedural simulation

A Venus P-valve was inserted in the 3D model of every single patient to assess the morphological characteristics of the stent graft (apposition and degree of deformation), anchoring (risk device migration), and valve function inferred from eventual midsegment deformation of the frame. Based on this assessment, the optimal size and anchoring site were decided. In addition, the narrowest diameter of the waist was measured during the balloon simulation. In addition, the diameter of the frame at the bifurcation, pulmonary artery, and annulus level, especially the compression ratio of flair of the frame (>20%) were measured [Supplementary Figure 1, http://links.lww.com/CM9/B656].

Venus P-valve

The Venus P-valve (Venus Medtech) was a self-expanding percutaneous pulmonary valve with a trileaflet porcine pericardial tissue.[5] It was characterized by a flared design (proximal and distal diameters larger than the one of the middle segments), where the length and diameter of the middle segments varied from 20 mm to 30 mm (in 5 mm increments), and 16–36 mm (in 2 mm increments), respectively [Figure 1].

Valve implantation

All procedures were performed under general anesthesia. The size (convention) of the implanted valve was commonly chosen based on the balloon sizing, which was 2–5 mm larger than the diameter of the balloon

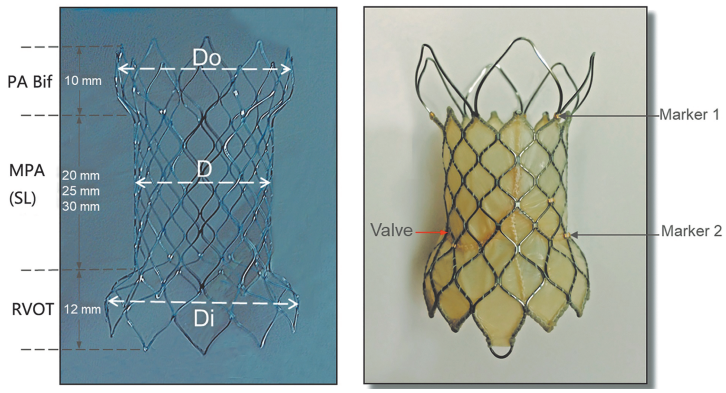

Figure 1: Venus P Stent-graft (Left) and Venus P-valve (Right). D midsegment diameter: 16–36 mm (in 2 mm increments); Di inflow portion: D + 10 mm; Do outflow portion: D + 10 mm; Length proximal flare RVOT: 12 mm; MPA (SL): 20 mm, 25 mm, 30 mm; Length distal flare PA bif: 10 mm; Marker 1: indicating distal flare; Marker 2: indicating proximal flare; Valve position: red arrow. MPA (SL): Straight length main pulmonary artery; PA bif: Pulmonary artery bifurcation; RVOT: Right ventricular outflow tract.

waist. In this study, the balloon sizing only served as a reference, and the implanted valve was selected by the 3D simulation results. Right heart catheterization, RVOT angiography, and balloon sizing were performed. The anteroposterior and lateral projections were used for measuring the diameter of the pulmonary annulus, trunk, and bifurcation, the length of RVOT and main pulmonary artery (MPA) plus the waist of the balloon [Figures 2A, B and 3A, D]. The risk of coronary obstruction was assessed by the location of different valves

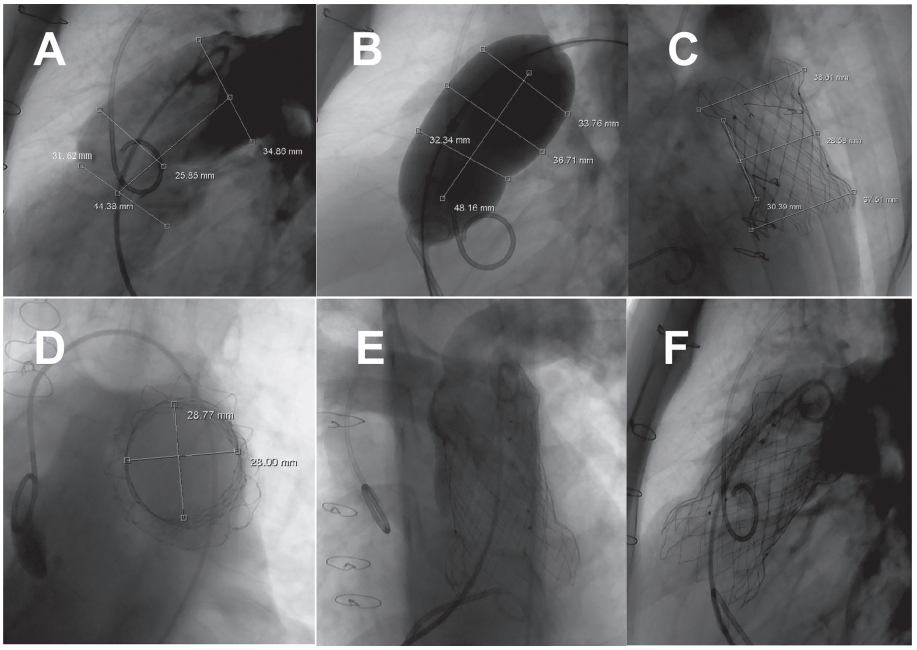

Figure 2: Venus P-valve diameter less than the waist diameter of sizing balloon. Radiography showed that the narrowest diameter at multiple levels was 25.85 mm (A), and the diameter at the level of the waist of the sizing balloon was 32.34 mm (B). According to the results of the preoperative simulation, a Venus P 30–30 mm valve was selected for implantation. The diameter at the level of the waist of the Venus P 30–30 mm valve was 28.58 mm × 28.77 mm (C, D). Anterior and lateral radiography showed that the middle segment of the valve was not constrained by the recipient's anatomy (E, F). The stability and function of the Venus P 30–30 mm valve were good.

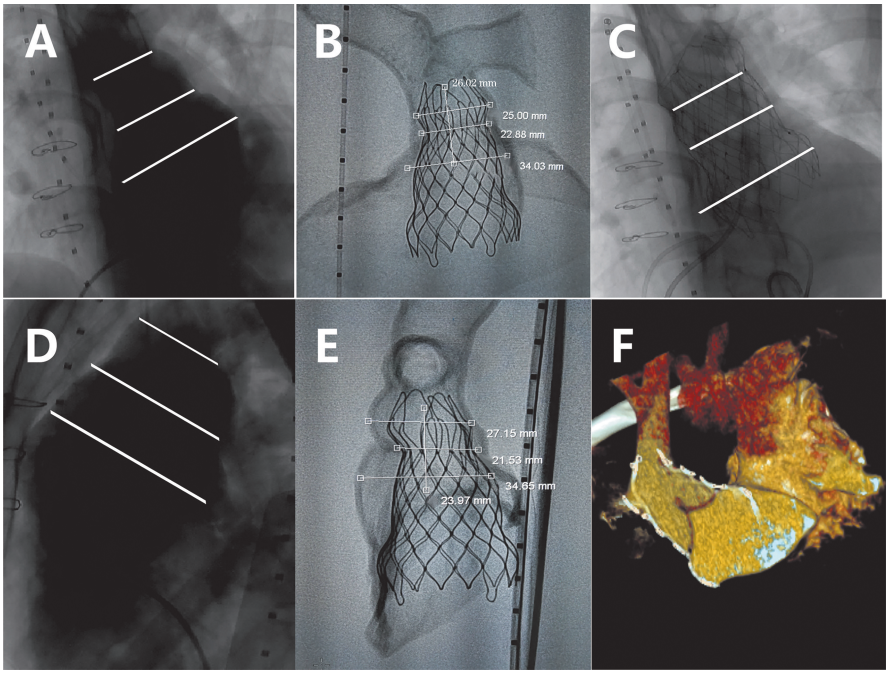

Figure 3: Inverted cone-shaped main pulmonary artery and RVOT. Anterior and lateral radiography showed an inverted cone-shaped main MPA and RVOT (A, D). Multiple levels analysis was performed to simulate the effect of a Venus P stent-graft implantation within the 3D-printed model (B, E). Valve configuration after implantation by radiography and CT (C, F). The bold white line represents the width of the main pulmonary artery. 3D: Three dimensional; CT: Computed tomography; MAP: Main pulmonary artery; RVOT: Right ventricular outflow tract.

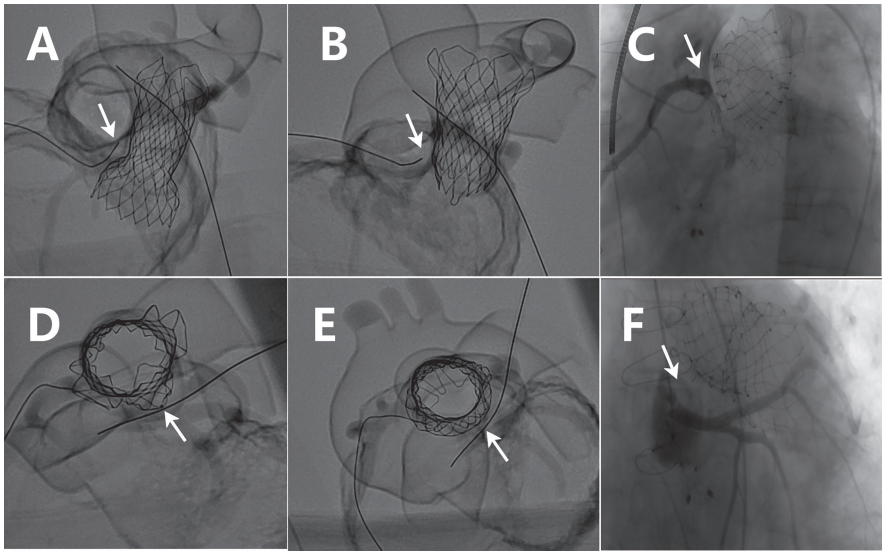

Figure 4: Simulation of coronary arteries compression and results of valve implantation. The black line (white arrow) was placed in the proximal segment of the coronary artery opening. Venus P stent-graft of different sizes was positioned within the 3D model to assess the risk of right and left coronary arteries (panels A, B and D, E). Results of PPVI indicated the absence of compression (C, F). 3D: Three dimensional; PPVI: Percutaneous pulmonary valve implantation.

[Figure 4A, B, D, E]. Aortic root angiography was again performed to assess the risk of coronary compression during pulmonary balloon sizing in the procedure.

Descriptive statistics

SPSS software (version 22.0, SPSS Inc., Chicago, IL, USA) was used for statistical analysis. The quantitative data were first tested for normality (Shapiro–Wilk test, $\alpha = 0.10$), where data with normal distribution were described by mean ± standard deviation (SD), and data with non-normal distribution were described by median (interquartile range [IQR]) (M [IQR]). Classification data were expressed in *n* (%). Two independent samples *t*-test was used for between-group comparisons. The Mann–Whitney *U* test was used for between-group comparisons of quantitative data not conforming to a normal distribution and ordered classification data. The chi-squared test was used for dichotomous data. All tests were two-sided, and $P < 0.05$ represented statistically significance.

Results

A model was successfully constructed in all 15 patients. Patients' baseline characteristics were shown in Table 1. The diameter of preoperative CT and intraoperative balloon measurements and comparison of Venus P-valve size and implantation location by conventional planning (valve picked by balloon sizing) and 3D simulation (valve implanted by 3D print) were shown in Table 2. *In vitro* bench testing (i.e., insertion of the Venus P-valve) affected procedure planning in every patient. In one patient, testing indicated that even the largest Venus P-valve would not anchor properly and migrate into the right ventricle. This patient was referred for surgery. Venus P-valve was successfully implanted in the remaining 14 patients (i.e., absence of valve migration, no coronary compression, residual gradient <15 mmHg, absence of clinically relevant PR). After Venus P-valve implantation, the right ventricular diastolic blood pressure decreased from 12.14 ± 4.00 mmHg to 4.93 ± 1.69 mmHg ($t = 6.22$, $P < 0.001$). The diameter of the Venus P-valve in the 3D simulation group was significantly smaller than that of the conventional planning group (36 [2] *vs.* 32 [4], $Z = -3.77$, $P < 0.001$).

Table 1: Baseline characteristics of all the included patients.

Characteristics	Baseline (*N* = 15)
Age (years)	19 (14)
Weight (kg)	57.73 ± 13.00
Female (*n*)	5/15
Echocardiography	
Severe pulmonary regurgitation (*n*)	15/15
Peak RVOT gradient (mmHg)	0
Left ventricular ejection fraction (%)	64 (12)
CT	
Annulus diameter (mm)	29.40 ± 3.31
Narrowest diameter of MPA (mm)	29.80 ± 4.36
Length of MPA (mm)	37.07 ± 80.10
MRI	
RVEDVi (mL/m^2)	166.50 ± 4.85
ECG	
QRS duration (ms)	155.36 ± 26.58

Data are presented as mean ± standard deviation or median (IQR). CT: Computed tomography; ECG: Electrocardiogram; IQR: Interquartile range; MPA: Main pulmonary artery; MRI: Magnetic resonance imaging; RVEDVi: Indexed right ventricular end-diastolic volume; RVOT: Right ventricular outflow tract.

In vitro testing revealed that the diameter of both the MPA and RVOT had a crucial role in valve size selection. More specifically, we found that the variance with the balloon-sizing technique of 2–5 mm oversizing was sufficient to guarantee proper anchoring of the outflow and inflow portion of the Venus P-valve in the MPA and RVOT, such as the case in Figure 2. Even in cases of an inverted cone-shaped MPA-RVOT, proper anchoring

Table 2: Diameter of preoperative CT, intraoperative balloon-sizing, and comparison of Venus P-valve size and implantation location by conventional planning and 3D simulation.

Case	Annulus* (mm)	Narrowest† (mm)	MPA‡ (mm)	Balloon-sizing§ (mm)	Convention‖,**	3D simulation¶,**
1	28	22	38	32	36–30 annulus-level	30–25 high
2	31	27	44	32	36–30 annulus-level	30–30 annulus-level
3	28	28	36	31	34–30 annulus-level	32–25 annulus-level
4	26	30	28	30	34–25 annulus-level	32–20 high
5	28	28	42	32	36–30 annulus-level	34–30 annulus-level
6	26	26	25	31	34–20 annulus-level	30–20 annulus-level
7	34	30	33	34	36–30 annulus-level	26–25 RPA
8	28	32	27	33	36–25 annulus-level	34–20 high
9	30	34	39	34	36–30 annulus-level	34–25 annulus-level
10	34	34	42	34	36–30 annulus-level	36–25 high
11	28	30	30	32	34–25 annulus-level	30–20 annulus-level
12	30	27	40	30	34–30 annulus-level	30–30 annulus-level
13	26	28	42	32	36–30 annulus-level	32–30 annulus-level
14	27	30	34	30	34–25 annulus-level	32–25 annulus-level
15	37	41	56	–	–	surgery

*Diameter of annulus of pulmonary artery. †Narrowest diameter of main pulmonary artery. ‡The length of main pulmonary artery. §Narrowest diameter of balloon-sizing in the procedure. ‖Venus P-valve size and implantation location (annulus-level or higher) picked by conventional planning. ¶Venus P-valve size and implantation location (annulus-level or higher) implanted by 3D model simulation. **The diameter of Venus P-valve in the 3D simulation group was significantly smaller than that of the conventional planning group (36 [2] *vs.* 32 [4], $Z = -3.77$, $P < 0.001$). 3D: Three dimensional; CT: Computed tomography; MPA: Main pulmonary artery.

and valve function were achieved, such as in Figure 3. The simulation revealed the absence of coronary artery compression, which was confirmed by selective contrast angiography after clinical PPVI, as shown in Figure 4. This was also the case in the presence of a cone-shaped RVOT and single right PA, as shown in Figure 5. In this patient, the valve was deployed in the right pulmonary artery.

All patients were followed up at 1 month, 3 months, 6 months, 12 months, 24 months, and 36 months after PPVI, during which ECG, echocardiography, and chest radiograph were repeated. Cardiac CT and MRI were performed at 6 months or 12 months after PPVI. At 12 months of follow-up, RVEDVi declined from 166.50 ± 4.85 mL/m^2 to 117.36 ± 12.14 mL/m^2 ($t = 14.06$, $P < 0.001$), QRS duration declined from 155.36 ± 26.58 ms to 119.70 ± 14.84 ms ($t = 4.40$, $P < 0.001$). None-to-mild PR was found in all patients except for one with a progressive PR increase found during follow-up. This patient suffered from a 22q11.2 micro-deletion, characterized by recurrent infections due to immune system deficiency. This patient had intermittent fever after PPVI, for which a long-acting penicillin was administered; however, his blood cultures were negative. None of the patients had a paravalvular leak or pulmonary artery thrombosis. There was no valve migration and absence of frame fracture.

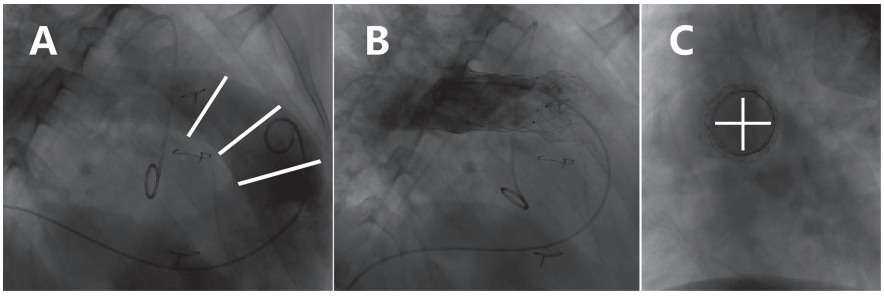

Figure 5: Cone-shaped RVOT with single right pulmonary artery. Radiography showed a cone-shaped RVOT with a single right pulmonary artery (A). Venus P-valve implantation was shown in panel (B) with good stability and function (C). The bold white line represents the width of the main pulmonary artery. RVOT: Right ventricular outflow tract.

Discussion

In the present study, we described our experience with patient-specific *in vitro* bench testing to assess the feasibility and Venus P-valve size selection in 15 patients with severe PR and dilated RVOT. All patients previously underwent surgical correction for Tetralogy of Fallot with transannular patching of the RVOT. Baseline CT was used to construct a patient-specific 3D cast of the target anatomy using the PolyJet technique and a rubber-like material (TangoPlus Fullcure). Our preoperative *in vitro* bench testing revealed that the flared in- and outflow portion of the valve dictate the anchoring of the valve and that—at variance with standard balloon-sizing recommendations–there was no need to oversize the valve, as 2–5 mm oversizing was enough.

Based upon the *in vitro* testing, one patient was rejected for PPVI and referred for surgery as testing revealed no safe anchoring. The remaining 14 patients successfully underwent PPVI. No valve migration or coronary obstruction was found. All patients had a postoperative gradient <15 mmHg and none or mild residual PR. Except for one patient with 22q11.2 deletion, none suffered any adverse event. Also, there was no evidence of valve failure during the follow-up period.

Treatment planning and especially valve size selection in patients with the herein-reported pathology posed a clinical problem.[5,6] Despite the use of CT or cardiac magnetic resonance (CMR) and contrast angiography, it remained a challenge to understand and accurately measure and interpret the dimensions of the RVOT-pulmonary tract. Accordingly, balloon-sizing was used in clinical practice to select the valve size.[12,13] However, recommendations tend to vary and range from a valve with a diameter that exceeds the balloon-sizing findings by 2–4 mm, or 3–5 mm or 5–10 mm.[2,5,6,14] This is particularly intriguing if we consider that the difference between the contrast angiographic and the balloon-sizing derived dimension vary substantially and may even exceed 10 mm.[2,6]

Accordingly, the advanced planning using 3D-printed models had a vital role in elucidating the anatomy (geometry, dimensions) and its relationship with other structures such as the coronary arteries.[12] Our results showed the valve anchors well when a distal and proximal flare of the valve anchors in the distal MPA and RVOT, respectively. The diameter of the valve did not need to be larger than 2–5 mm than the diameter of the balloon waist. Interestingly, this corresponded with the manufacturer's recommendations of valve sizing and experimental data recommending a reduction of approximately 20% of the original diameter of the distal and proximal flares of the Venus P-valve in bilateral view.[11,15] Thus, there was no need for anchoring the cylindrical central body of the Venus P-valve. Consequently, the central portion that held the bioprosthetic leaflets and was eventually exposed to the muscle contraction of the RVOT might be spared from unneeded stress and deformation, thereby safeguarding frame integrity and less risk of frame fracture during follow-up. Consequently, patients with large RVOT and MPA could benefit from PPVI. While Zhou *et al*[5] reported that the inverted cone-shaped RVOT and MPA might not be suitable for Venus P-valve implantation, we found it feasible for two patients. It was also suitable for patients at risk of coronary artery compression that occurs in about 5% of patients, and has been associated with death and/or need for coronary artery bypass grafting.[16,17]

Our findings needed to be interpreted in the context of the observational and single-center nature of this study, which did not allow making conclusions on the added clinical value of the herein-used *in vitro* bench testing technique. Accordingly, appropriately designed randomized clinical studies were needed, as they could promote PPVI decision-making in terms of feasibility and valve size, which at the moment were randomly defined by either a physician or the bench testing-driven approach. However, the prevalence of patients with PR and RVOT dilatation was relatively infrequent, rendering such RCT's less probable. Greater insight into the clinical value of the *in vitro* testing technique might be achieved by extending the herein reported observations via prospectively designed (inter) national registries with predefined objectives and, consequently, outcome measurers plus methods of (independent) analysis, monitoring, and rapportage.

Herein, we used *in vitro* bench testing pioneered by Biglino *et al*[10], while *in vivo* patient-specific computer simulation might be more suitable.[11,12] At variance with *in vitro* bench testing, patient-specific *in vivo*-simulation entails assessing the interaction of the device and the host based upon the incorporation into the computer model of the geometric details plus mechanical characteristics of both the device and host.[18] At present, *in vivo* patient-specific computer simulation for PPVI was not yet available, except for TAVR in patients with aortic stenosis, for whom it had been validated and clinically evaluated in various studies and multicenter observational registries.[19–24]

In vitro bench testing implied imaging-derived representations of the patient's anatomy using a synthetic compound.[10,11] By definition, the latter differs from the mechanical properties of the patient's anatomy. Also, the compliance and distensibility of the cast depend on its wall thickness.[10,11] As such, *in vitro*-bench testing offers insight into the geometric match between the device and host but did not inform how the device and host truly interact.[10,11,18] Biglino *et al*[11] reported a case study on a patient with PR and dilated RVOT. They found a good agreement between the *in vitro* (bench) testing and computational (*in silico*) modeling of PPVI using a stent-graft with a similar symmetrical hourglass configuration. A mock circulatory circuit with pulsatile flow, and fluoroscopy was used to assess valve frame anchoring, frame deformation, and radial displacement. The computational (virtual) model correlated well with the *in vitro* model and fluoroscopy images. In addition, at variance with our study, the valve only consisted of a frame (stent-graft) devoid of the bioprosthetic leaflets, and the agreement between *in vitro* testing and computational

modeling decreased with the increasing complexity of the testing mode and model.[10,11]

In conclusion, *in vitro* testing indicated that there is no need to oversize the bioprosthetic Venus P-valve to the degree recommended by the balloon-sizing technique since anchoring is dictated by the apposition of the in-outflow portion of the valve into the RVOT and MPA. Two to 5 mm suffices. Consequently, the mid portion of the valve containing the bioprosthetic leaflets is minimally or not deformed at all. The reported findings, the clinical benefit, and its effect on frame integrity during follow-up must be further confirmed by larger series and ideally through direct comparisons with standard treatment planning techniques.

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Conflicts of interest

None.

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