European Journal of Cardio-Thoracic Surgery 2022, 62(4), ezac426
https://doi.org/10.1093/ejcts/ezac426 Advance Access publication 22 August 2022

ORIGINAL ARTICLE

Cite this article as: Sadat N, Scharfschwerdt M, Schaller T, Aboud A, Saisho H, Ensminger S *et al*. Functional performance of 8 small surgical aortic valve bioprostheses: an *in vitro* study. Eur J Cardiothorac Surg 2022; doi:10.1093/ejcts/ezac426.

Functional performance of 8 small surgical aortic valve bioprostheses: an *in vitro* study

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Received 24 February 2022; received in revised form 31 May 2022; accepted 19 August 2022

Key question

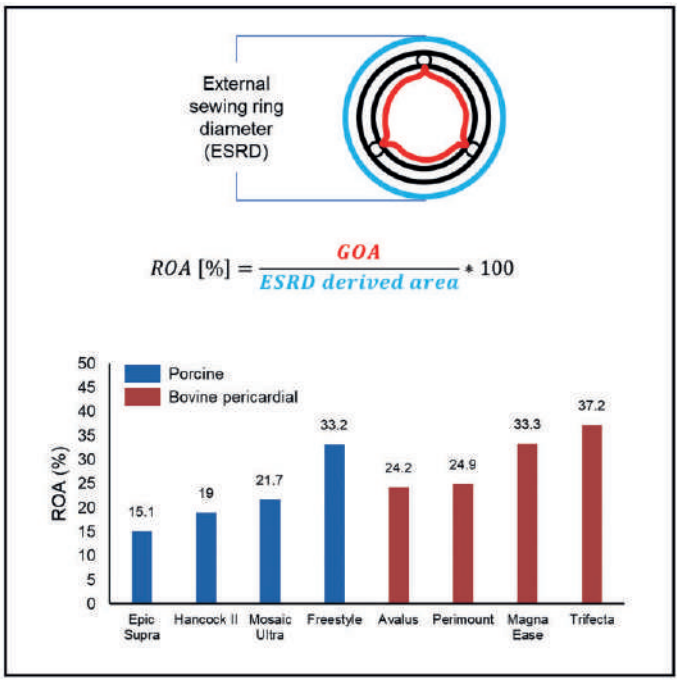
How does the functional performance compare across different aortic valve bioprostheses with the same labelled size?

Key finding(s)

Functional performance differed between valve models despite the same labelled size in our in-vitro study.

Take-home message

Such findings should be taken into account for selection of a valve model to achieve the best possible long-term result.



Abstract

OBJECTIVES: Selection of a surgical aortic valve (SAV) bioprosthesis model for the treatment of aortic valve disease remains controversial. The aim of this study was to characterize the functional performance of 8 SAV models in a standardized *in vitro* setting.

METHODS: The hydrodynamic performance of 8 SAVs with labelled size 21 mm (Avalus™, Hancock® II, Mosaic® Ultra™, Perimount®, Perimount® Magna Ease, Epic™ Supra, Trifecta™ GT; Freestyle®), was investigated in a pulse duplicator. Transvalvular pressure gradients and effective orifice area (EOA) were recorded. The geometrical orifice area and physical dimensions of the valves were determined, and new functional dimensions were introduced.

RESULTS: Mean pressure gradient (MPG) and EOA differed significantly between the analysed SAVs. The Epic presented with the lowest EOA and highest MPG, while the Trifecta showed the highest EOA and the lowest MPG. We introduce a useful way to determine the minimal internal diameter and a new measure termed 'relative orifice area' to characterize a valve's performance.

Presented at the 50th Annual Meeting and Scientific Sessions of the German Society for Thoracic and Cardiovascular Surgery, Wiesbaden, Germany, February 27–28, 2021.

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CONCLUSIONS: SAVs showed significant differences in their hydrodynamic performance despite the same label size. This finding was related to the construction of the valves. We introduce a new measure that characterizes the functional performance of a valve model and size for the treatment of an aortic annulus of a specific size. Our data emphasize that SAV selection should carefully be done using an individual patient approach and that future research is necessary to improve the current generation of SAVs.

Keywords: Aortic valve • Bioprosthesis • Hydrodynamic • Effective orifice area • Pulse duplicator

ABBREVIATIONS

EOA	Effective orifice area
GOA	Geometric orifice area
MID	Minimal internal diameter
MPG	Mean pressure gradient
ROA	Relative orifice area
SAV	Surgical aortic valve
SV	Stroke volume

INTRODUCTION

According to the implantation technique, aortic valve bioprostheses are classified into surgical aortic valve (SAV) bioprostheses, including conventional and rapid deployment (also known as sutureless) prostheses, and transcatheter heart valves [1]. Regarding surgical aortic valve replacement patients, bioprosthetic valves are preferred more and more over mechanical valves to avoid lifelong anticoagulation and the option for transcatheter aortic valve implantation as valve-in-valve implantation in redo procedures [2]. With an anticipated further increase in the use of SAVs, it is important to optimize our understanding of their functional performance [3]. Many SAV models are commercially available for surgical implantation [4]. Numerous clinical studies describe the advantages and disadvantages of specific SAV models [3, 5–8]. However, there is currently no specific recommendation regarding the use of a certain SAV model for a distinct patient. This is in part due to the fact that clinical studies are limited by inhomogeneous study design and patient-related factors, highlighting that more reproducible studies are needed to ensure comparability between different SAV models.

In vitro testing of heart valve prostheses using a mock circulation allows for the investigation of functional performance of heart valves under defined and reproducible conditions [9, 10]. This allows for the adjustment for numerous confounding factors that are inevitably present in clinical studies. However, analysis of valve function with different simulators can cause interlaboratory discrepancies [11]. Therefore, systematical investigation of bioprostheses in 1 simulator system is recommended by the European Association for Cardio-Thoracic Surgery–The Society of Thoracic Surgeons–American Association for Thoracic Surgery Valve Labelling Task Force [12]. At present, no study with a head-to-head comparison of contemporary SAVs regarding their functional performance has been performed. Hence, the aim of this study was to investigate the hydrodynamic performance of 8 commercially available SAVs and characterize their physical dimensions under standardized conditions in an *in vitro* study.

MATERIALS AND METHODS

Ethical statement

Patients and animals were not involved in this *in vitro* study.

Surgical aortic valve bioprostheses

We chose 8 SAV models with labelled size of 21 mm, which are commercially available. We included porcine stented, a porcine stentless and bovine pericardial valves with internally and externally mounted leaflets: Hancock® II, Avalus™, Mosaic® Ultra™, Freestyle® (Medtronic, Minneapolis, Minnesota, USA); Perimount®, Perimount® Magna Ease (Edwards Lifesciences, Irvine, California, USA); and Trifecta™ GT and Epic™ Supra (Abbott, Chicago, Illinois, USA) (Fig. 1). For this study, the Freestyle was implanted in a Dacron prostheses by adapting the Daron-prostheses with continuous suture (Prolene 4–0) from the outside of the Freestyle without changing the size for hydrodynamic measurement.

Physical dimensions of surgical aortic valves

Physical dimensions of the SAVs according to the definition by the European Association for Cardio-Thoracic Surgery–The Society of Thoracic Surgeons–American Association for Thoracic Surgery Valve Labelling Task Force were obtained for all valves [12]. These dimensions included: overall profile height, outflow profile height, minimum internal diameter (MID), internal stent diameter(ISD), external stent diameter(ESD) and external sewing ring diameter (ESRD). In addition, diameters were determined for the 21-mm sizers of these SAVs for supra-annular and annular phantoms. All dimensions, except the MID, were acquired using a calliper gauge (Supplementary Material, Figs. S1 and S2). The MID was calculated from the geometric orifice area (GOA, see below for details). On top of these defined dimensions, we calculated the ratio of the GOA to the prosthesis area, derived from the external sewing ring diameter, to quantify which proportion of the complete area occupied by the prosthesis is functionally available for flow, defined in this study as the 'relative orifice area' (ROA) (Fig. 2):

$$\text{ROA}\ (\%) = \frac{\text{GOA}}{\text{ESRD derived area}} \times 100.$$

Hydrodynamic measurement

The hydrodynamic performance of the 8 SAVs was investigated in the pulse duplicator system of the Department of Cardiac and Thoracic Vascular Surgery at the University Medical Center

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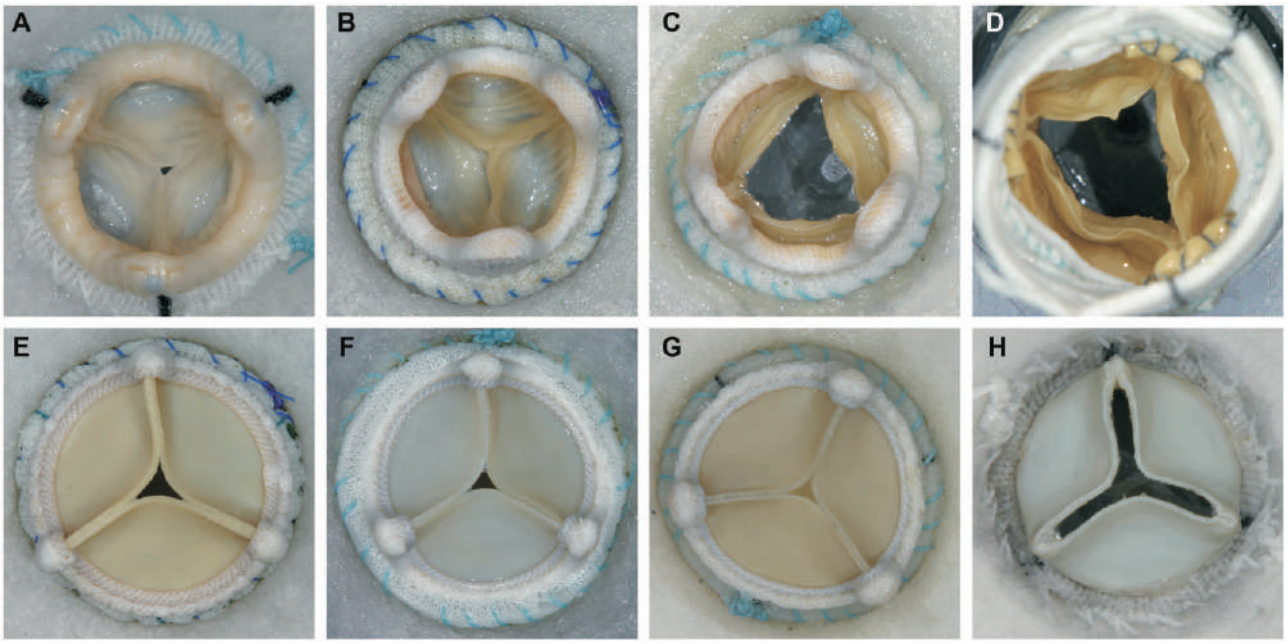

Figure 1: Surgical aortic valve. (**A**) Epic Supra, (**B**) Hancock II, (**C**) Mosaic Ultra, (**D**) Freestyle, (**E**) Avalus, (**F**) Perimount, (**G**) Perimount Magna Ease and (**H**) Trifecta; porcine surgical aortic valve (**A**–**D**) and bovine surgical aortic valve (**E**–**H**).

Schleswig-Holstein (Lübeck, Germany), which was developed by Scharfschwerdt *et al.* [9] and has been described in detail before (Fig. 3). For the investigation of aortic valve performance, flow conditions through the valve at rest and under stress can be simulated and enables the evaluation of functional valve performance in accordance with ISO-5840 requirements [13]. Hydrodynamic testing was performed with a constant heart rate of 64/min and varying stroke volume (SV) to simulate 5 different circulatory conditions (SV = 55, 70, 90, 105 and 120 ml). For each condition, the following values were obtained: mean pressure gradient (MPG) in mmHg, peak pressure gradient in mmHg and effective orifice area (EOA) in cm^2. EOA was calculated using a simplified Bernoulli equation as demanded in the ISO definition [13]:

$$\mathrm{EOA} = \frac{Q_{\mathrm{RMS}}}{51.6\sqrt{\Delta p_{\mathrm{mean}}}},$$

where Q_{RMS} is the forward flow and Δp_{mean} is the MPG.

One measurement comprised the arithmetic mean of 10 consecutive cycles at 1 circulatory condition. Overall, $n = 5$ measurements were obtained per prosthesis per condition.

High-speed camera recording

Cusp dynamics throughout the cardiac cycle were recorded at 500 frames/second using a high-speed video camera (Motionpro Y-1000, Imaging Solutions GmbH, Eningen, Germany) mounted on top of the aortic valve chamber of the pulse duplicator (SV 70 ml and frequency 64/min; Videos 1 and 2). The GOA was determined in cm^2 at each frame by tracing the edges of the opening area (black area in Fig. 5). The MID was calculated using the following formula:

$$\mathrm{MID} = \sqrt{\frac{\mathrm{GOA\ (max)}}{\pi}} \times 2,$$

where GOA (max) refers to the largest GOA during the cardiac cycle. Therefore, MID is a virtual diameter that is derived from the GOA. We chose this approach because if the MID was measured, one can obtain 3 values and it is unclear which one should be deemed representative. Therefore, deriving the diameter from the GOA seems the more sensitive approach.

Statistical analysis

Quantitative data are summarized median (25th–75th percentile) and graphically as box plots. The middle horizontal line represents the median. The lower and upper borders represent the lower and upper quartiles. The lower whisker extends from the 25th percentile to the smallest value above the 25th percentile minus 1.5 × interquartile range and upper whiskers extend from the upper hinge to the largest value within the upper hinge plus 1.5 × interquartile range. For the comparison of groups, the two-sided Wilcoxon rank sum test was performed with the Bonferroni–Holm adjustment for multiple testing if needed. The alpha was set at 0.05. All statistical analyses were performed using R version 4.1.0 (R Core Team. R: A Language and Environment for Statistical computing. R Foundation for Statistical Computing, Vienna, Austria, 2021. https://www.R-project.org/).

RESULTS

Hydrodynamic measurements are reported for circulatory condition using SV of 70 ml throughout the article. Additional

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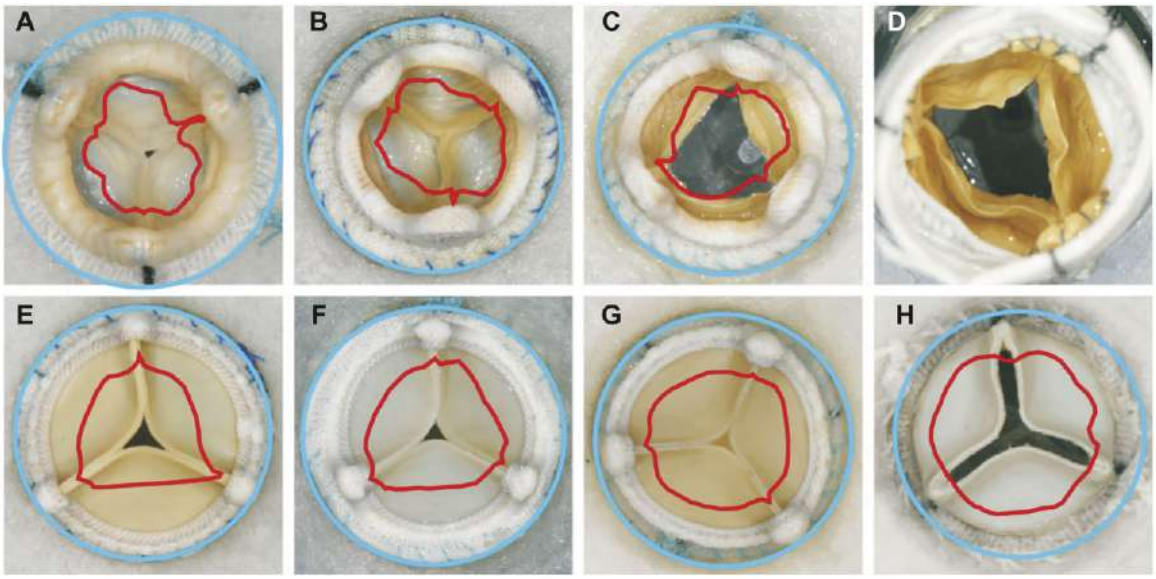

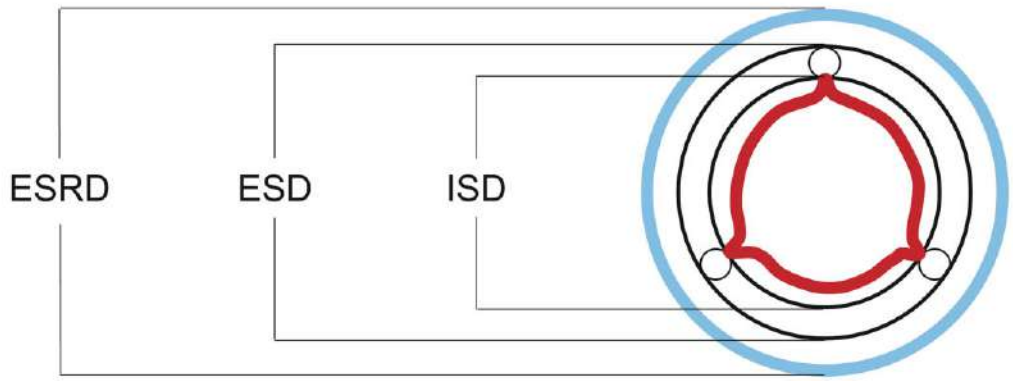

$$ROA\ [\%] = \frac{GOA}{ESRD\ derived\ area} * 100$$

Figure 2: Relative orifice area (ROA) of surgical aortic valve. (**A**) Epic Supra, (**B**) Hancock II, (**C**) Mosaic Ultra, (**D**) Freestyle, (**E**) Avalus, (**F**) Perimount, (**G**) Perimount Magna Ease and (**H**) Trifecta; internal stent diameter (ISD), external stent diameter (ESD), external sewing ring diameter (ESRD), geometric orifice area (GOA). The ROA quantifies the relationship between the ESRD (blue line) and the GOA (red line) in %.

hydrodynamic data for SV of 55, 90, 105 and 120 ml are presented in Supplementary Material, Figs. S3–S5 and Supplementary Material, Tables S2–S14.

Mean pressure gradient and effective orifice area

MPG of investigated valves and adjusted *P*-values for pairwise comparisons are summarized in Table 1. MPG differed significantly in all pairwise comparisons ($P < 0.05$), except Hancock II versus Mosaic Ultra ($P = 0.728$), Hancock II versus Freestyle ($P = 0.903$), Avalus versus Perimount ($P = 0.130$), Avalus versus Magna Ease ($P = 0.115$), Perimount versus Magna Ease ($P = 0.903$), Perimount versus Trifecta ($P = 0.084$) and Magna Ease versus Trifecta ($P = 0.235$) (Table 1 and Fig. 4).

EOA of investigated valves and adjusted *P*-values for pairwise comparisons are summarized in Table 2. EOA was significantly different ($P < 0.05$) in all pairwise comparisons, except Hancock II versus Mosaic Ultra ($P = 0.235$), Freestyle versus Magna Ease ($P = 0.130$), Avalus versus Perimount ($P = 0.130$), Avalus versus Magna Ease ($P = 0.418$), Perimount versus Magna Ease ($P = 0.713$) and Magna Ease versus Trifecta ($P = 0.319$) (Table 2 and Fig. 4).

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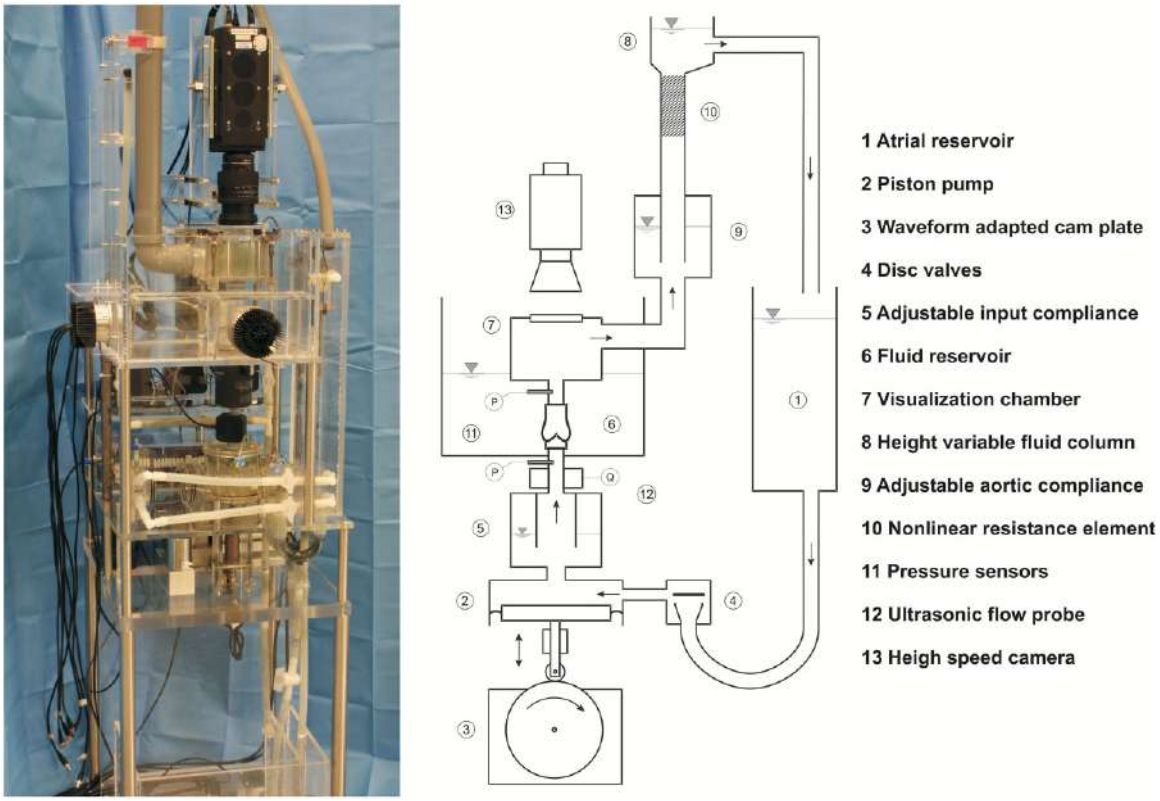
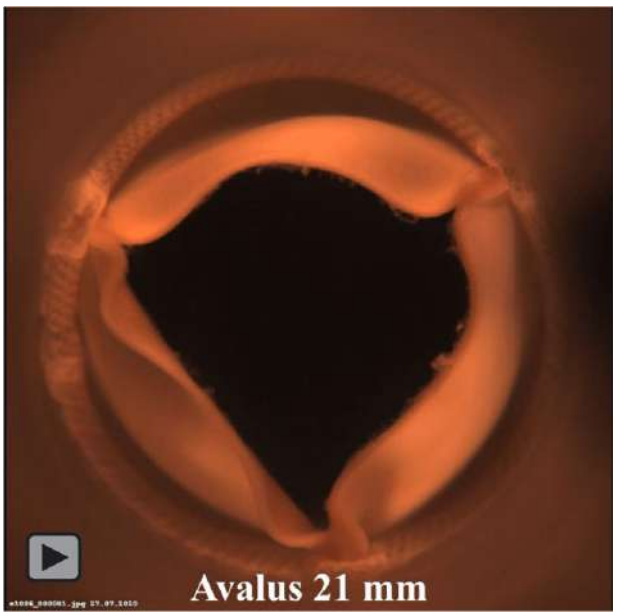


Figure 3: Picture and scheme of the pulse duplicator (modified with permission from Scharfschwerdt *et al.* [9]).



Video 1: Porcine surgical aortic valves inside the pulse duplicator.



Video 2: Bovine surgical aortic valves inside the pulse duplicator.

Taken together, the porcine Epic Supra, Hancock II and Mosaic Ultra prostheses presented with the lowest EOA and highest MPG, while the bovine pericardial Trifecta, Magna Ease and Perimount showed the highest EOA and lowest MPG (Fig. 4). This trend was found under all conditions (SV 50–120 ml; Supplementary Material, Figs. S3 and S4 and Supplementary Material, Tables S2–S9). Moreover, the porcine prostheses had higher peak gradients in comparison to bovine pericardial valves under all conditions (Supplementary Material, Fig. S5 and Supplementary Material, Tables S10–S14).

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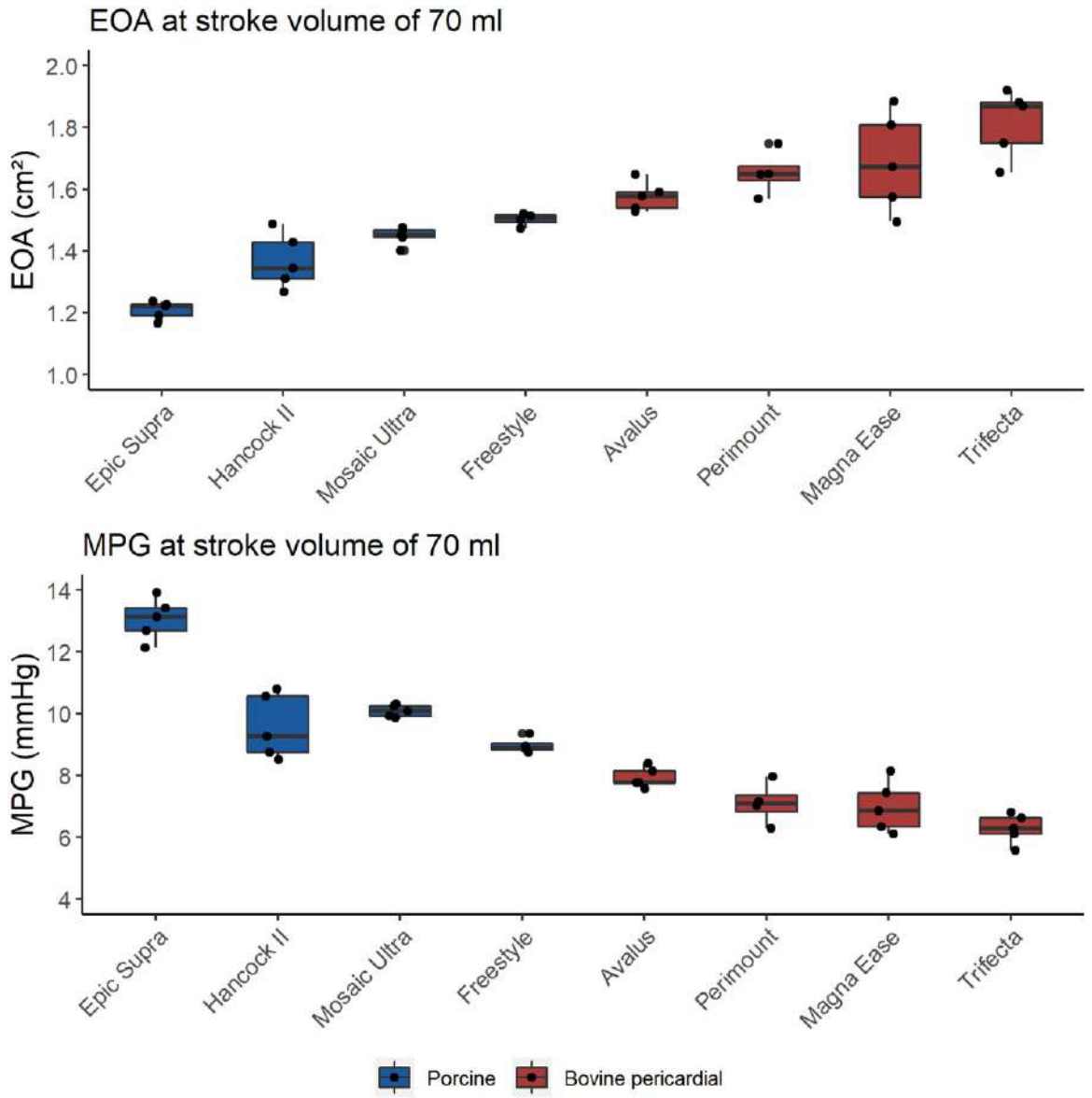

Figure 4: Mean pressure gradient (MPG) and effective orifice area (EOA).

Geometric orifice area

Next, analysis of the GOA as a function of time was performed. The Trifecta presented with the highest maximal GOA and the Epic Supra with the lowest maximal GOA (Fig. 5). The maximal GOA for all investigated models was as follows: Epic Supra: 1 cm^2, Hancock II: 1.09 cm^2, Mosaic Ultra: 1.24 cm^2, Freestyle: 1.5 cm^2, Avalus: 1.39 cm^2, Perimount: 1.53 cm^2, Magna Ease: 1.77 cm^2 and Trifecta: 2.13 cm^2. Still images of each SAV at maximum GOA were obtained (Fig. 5). The shape of the maximum GOA showed differences and was classified into 'wavelike' (Epic Supra, Hancock II, Mosaic Ultra and Freestyle; Fig. 5A–D), 'triangular' (Avalus and Perimount; Fig. 5E and F) and 'round' (Magna Ease and Trifecta; Fig. 5G and H). This classification correlated with the quantitative hydrodynamic performance whereby valves with a wavelike orifice showed the smallest EOA, followed by triangular-shaped GOA, while round-shaped GOA presented the largest EOA (Figs. 4 and 5).

Physical dimensions

Physical dimensions, as defined by the Valve Labelling Task Force [12], for all investigated SAVs, are shown in Table 3. The overall profile height and outflow profile high were 15 mm for all stented prostheses, while the stentless prosthesis presented with 31 mm. The internal stent diameter was smaller for porcine prostheses (15–16 mm) compared to the bovine pericardial valves (17–21 mm). The external stent diameter was similar for all valves (22–25 mm). External sewing ring diameter presented with a range of 26–29 mm, which was lowest for Magna Ease and highest for Epic Supra. Diameters of 21-mm sizers are presented for all 8 SAVs as Supplementary Material, Fig. S2 and Supplementary Material, Table S1. The diameter for annular sizing was 21 mm for all SAV, except for Hancock II (19 mm). The diameter for supra-annular sizing differed regarding SAV model with the highest diameter for Epic Supra (28 mm) and the lowest for Mosaic Ultra (24 mm) (Supplementary Material, Fig. S2 and Supplementary Material, Table S1).

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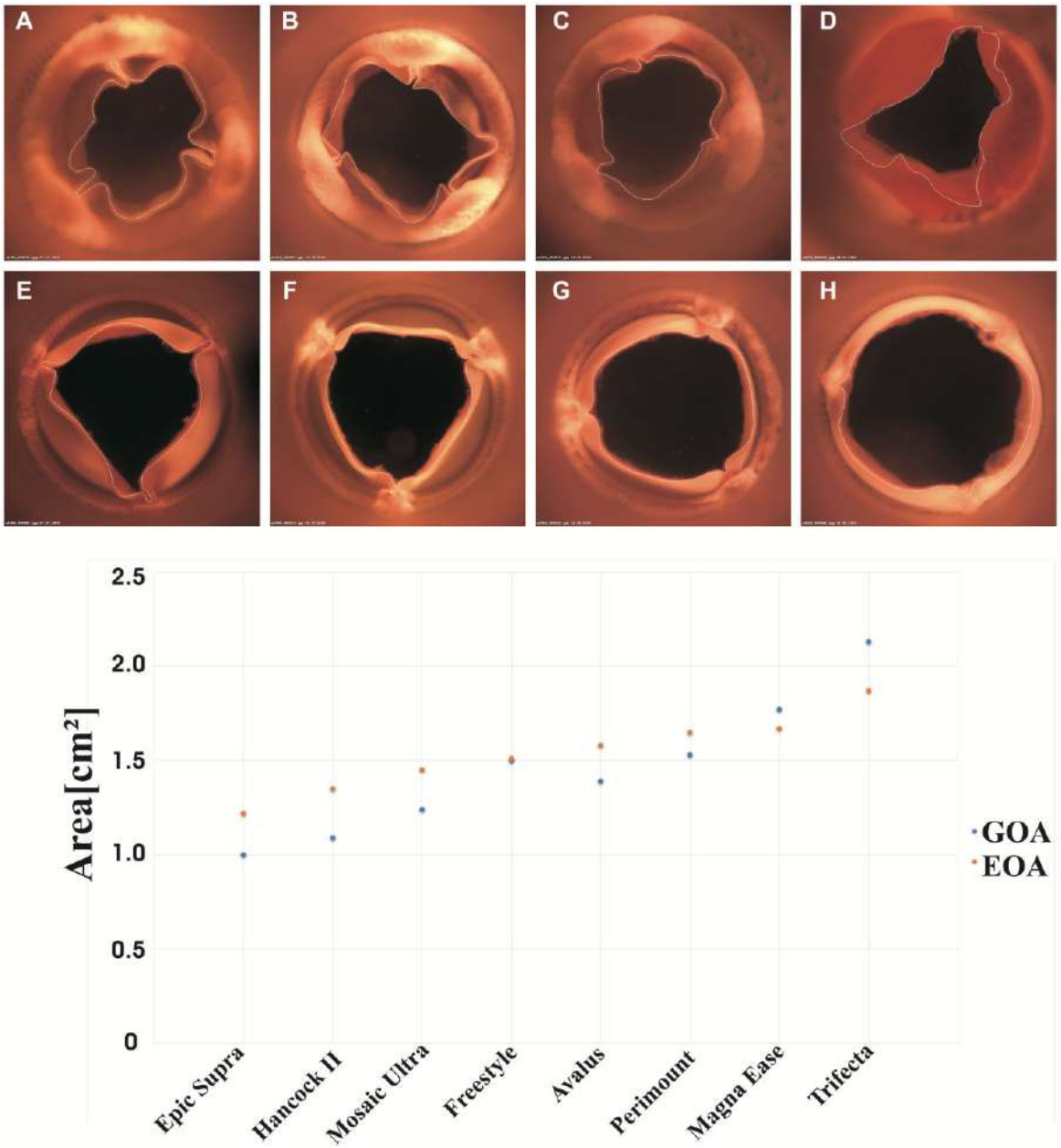

Figure 5: Maximal geometric orifice area (GOA) (black area) of (**A**) Epic Supra, (**B**) Hancock II, (**C**) Mosaic Ultra, (**D**) Freestyle, (**E**) Avalus, (**F**) Perimount, (**G**) Perimount Magna Ease and (**H**) Trifecta; GOA versus effective orifice area (EOA).

Minimal internal diameter and relative orifice area

The MID was lower for porcine stented prostheses (11–13 mm) compared with bovine pericardial prostheses (13–16 mm) and demonstrated the same 'ranking' as the EOA of the valves.

The ROA showed marked differences between the valves. While it was 15–21% for stented porcine valves, it was 24–37% for bovine pericardial valves (Central image, Fig. 2 and Table 3). The ROA of Freestyle was identical to the ROA of the Magna Ease (33.2% vs 33.3%). The lowest ROA was noticed in Epic Supra with 15.1% and the highest in Trifecta with 37.2% (Central image, Fig. 2 and Table 3). ROA ranking of the stented valves (from lowest to highest) was nearly identical with the EOA and GOA order (Central image, Figs. 2 and 4–5 and Table 3).

DISCUSSION

In this study, we investigated the functional performance of 8 contemporary SAVs with the same labelled size (21 mm) in a standardized *in vitro* setup using defined conditions in accordance with ISO-5840 standards [13]. The main findings of this study can be summarized as follows:

1. Bovine pericardial valves showed superiority over porcine valves regarding EOA and MPG, but specific valve models within these groups performed differently.
2. The EOA was influenced by numerous factors related to the construction of the valve (i.e. physical dimensions, shape of the GOA and position of cusp attachment on the stent).

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Table 1: MPG of SAV and adjusted *P*-values for pairwise comparisons

SAV	MPG (mmHg), median (25th–75th percentile)	Pairwise comparisons (*P*-value)						
		Epic Supra	Hancock II	Mosaic Ultra	Freestyle	Avalus	Perimount	Magna Ease
Epic Supra	13.132 (12.694–13.413)							
Hancock II	9.258 (8.748–10.561)	0.028						
Mosaic Ultra	10.092 (9.916–10.243)	0.028	0.728					
Freestyle	8.895 (8.83–9.039)	0.028	0.903	0.028				
Avalus	7.768 (7.764–8.133)	0.028	0.028	0.028	0.028			
Perimount	7.085 (6.829–7.358)	0.028	0.028	0.028	0.041	0.130		
Magna Ease	6.853 (6.336–7.436)	0.028	0.028	0.028	0.028	0.115	0.903	
Trifecta	6.282 (6.115–6.621)	0.028	0.028	0.028	0.028	0.028	0.084	0.235

MPG: mean pressure gradient; SAV: surgical aortic valve.

Table 2: EOA of SAV models and adjusted *P*-values for pairwise comparisons

SAV	EOA (cm^2), median (25th–75th percentile)	Pairwise comparison (*P*-value)						
		Epic Supra	Hancock II	Mosaic Ultra	Freestyle	Avalus	Perimount	Magna Ease
Epic Supra	1.222 (1.191–1.227)							
Hancock II	1.345 (1.311–1.428)	0.028						
Mosaic Ultra	1.452 (1.444–1.468)	0.028	0.235					
Freestyle	1.507 (1.495–1.515)	0.031	0.048	0.048				
Avalus	1.577 (1.538–1.591)	0.028	0.028	0.028	0.031			
Perimount	1.648 (1.628–1.674)	0.031	0.031	0.031	0.045	0.130		
Magna Ease	1.672 (1.574–1.808)	0.028	0.028	0.028	0.130	0.418	0.713	
Trifecta	1.868 (1.749–1.881)	0.028	0.028	0.028	0.031	0.028	0.048	0.319

EOA: effective orifice area; SAV: surgical aortic valve.

Table 3: Physical and functional dimensions of SAV; GOA in cm^2, ROA in % and all other parameters in mm

SAV	Labelled size	Physical dimensions					Functional dimensions		
		Overall profile height	Outflow profile height	Internal stent diameter	External stent diameter	External sewing ring diameter	GOA	minimum internal diameter	ROA
Epic Supra	21	15	15	16	25	29	1	11	15.1
Hancock II	21	15	15	15	22	27	1.09	12	19
Mosaic Ultra	21	15	15	16	22	27	1.24	13	21.7
Freestyle	21	31	31	20	22	24	1.5	14	33.2
Avalus	21	15	15	20	25	27	1.39	13	24.2
Perimount	21	15	15	17	24	28	1.53	14	24.9
Magna Ease	21	15	15	19	24	26	1.77	15	33.3
Trifecta	21	15	15	21	23	27	2.13	16	37.2

GOA: geometric orifice area; ROA: relative orifice area; SAV: surgical aortic valve.

3. We introduce a new dimension named ROA, which characterizes the hydrodynamic performance of a bioprosthetic valve taking into account all above-mentioned factors.

Functional performance of surgical aortic valve models differed significantly

The investigation of functional valve performance in the clinical setting can be highly flawed due to numerous factors such as cardiac function, catecholamine treatment, cardiac rhythm or fluid balance, limited patient numbers and interobserver variability [6]. Furthermore, valve performance is often reported only for entire valve groups (e.g. SAVR versus TAVR or conventional versus rapid deployment prosthesis) instead of specific valve models [14]. Hydrodynamic testing of SAVs in a standardized *in vitro* setting that simulates *in vivo* conditions enables to overcome most of these limitations [9, 11, 14].

Our study demonstrates significant differences between porcine (Epic Supra, Hancock II, Mosaic Ultra and Freestyle) and

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bovine pericardial (Avalus, Perimount, Magna Ease and Trifecta) SAVs with regard to their hydrodynamic performance. Overall, bovine pericardial SAVs showed superior performance over porcine SAVs. The Epic Supra, Hancock II and Mosaic Ultra prostheses presented with the lowest EOA and highest MPG, while the Trifecta, Perimount and Magna Ease showed the highest EOA and lowest MPG. These results are in line with clinical data for the respective valves describing an EOA in the range of 1.2–1.6 cm^2 for porcine and 1.4–1.8 cm^2 for bovine SAVs with a labelled size of 21 mm (Supplementary Material, Table S15) [6, 15–17]. In addition, specific valve models within these groups performed differently despite the same labelled size. This important observation can be explained by numerous factors: The labelling practice of prosthetic heart valves is not standardized as recently highlighted by an expert panel on prosthetic valve labelling [12]. The labelled size refers to the diameter of the annulus to be treated and is often unrelated to dimensions that are more meaningful for the functional performance of a valve.

Physical dimensions of surgical aortic valve models differed significantly

We characterized each valve according to physical dimensions that were defined by the above-mentioned consensus document [12]. Previous studies have shown considerable differences between specific valve models regarding external and internal diameters [16, 18]. In line with these studies, we also found differences among most parameters. However, data regarding the dimension termed 'minimal internal diameter' by the expert document are not systematically available. In fact, the expert panel suggests to find a reproducible way to quantify this dimension. In our view, direct measurement of this distance is not sensible, because our data demonstrated that the orifice area of a particular valve can be very irregularly shaped, especially in porcine valves. Therefore, we propose the GOA-derived diameter to be a more meaningful approach to determine this value as a functional dimension rather than a physical one. As such, the GOA and the MID derived from the GOA showed considerable differences with a range of 1 cm^2 (Epic) to 2.13 cm^2 (Trifecta) for the GOA and 11 mm (Epic Supra) to 16 mm (Trifecta) for MID. These data clearly show that despite an identical labelled size, the remaining MID differs significantly. This finding is related to the different construction design of the valves (Figs. 1 and 2). When looking at a stented bioprosthesis, it becomes obvious that certain parts of the stent do not participate in generating orifice area. Therefore, based on our data, we consider 3 determinants as important for the performance of a bioprosthetic valve:

1. Stented valves require a sewing ring to safely anchor the valve in the annulus as well as a stent frame to attach the cusps to(Fig. 1). The area occupied by these structures varied significantly across valve models and was larger for porcine valves than for bovine pericardial valves (Fig. 1).
2. Cusps can be fixed on the inside or outside of the stent frame. Even though we only investigated 1 valve with externally mounted cusps, this factor obviously contributes to generating a larger EOA.
3. The shape of the GOA differed among valves and correlated with the hydrodynamic performance. This is caused by various factors such as the shape and size of the 'U' between 2 commissures, and its relation to the cusps. In the Avalus and Perimount, this led to largely immobile cusp sections at the base of the 'U' and therefore a triangular-shaped GOA (Fig. 5E and F). In contrast, this was not the case for the Magna Ease as all the cusps can open almost all the way to the inner edge of the stent frame during opening of the valve (Fig. 5G).

Functional performance and surgical aortic valve construction are closely related

These considerations demonstrate that functional valve performance should not be evaluated based on the absolute value of the GOA (or MID), but also considering the 'dead space' the valve components occupy. To this end, we propose a new parameter of prosthetic valves that we termed 'relative orifice area' (ROA). This parameter refers to the area available for flow (e.g. the GOA), in relation to the total area occupied by the valve, which can be calculated from the external sewing ring diameter (Fig. 2). According to this equation, stented porcine valves achieve an ROA of about 20% or less, implying that 80% or more of the area occupied by the valve does not participate in flow, whereas the ROA was 24% or higher for bovine pericardial valves(Central image, Fig. 2 and Table 3). It was lowest for valves with relatively thick stent frame and sewing ring structures. ROA was also lower for bovine pericardial valves with a triangular GOA compared to round-shaped GOA. Finally, ROA was larger for the valve with externally mounted leaflets.

An additional fourth contributing factor is probably the cusp material, i.e. porcine aortic valve cusps or bovine pericardial cusps. As demonstrated in Fig 5A–D, the shape of the GOA was irregularly shaped (such as a 'wavelike' shape) in porcine valves. This is an interesting finding because one would expect a near-perfect result with porcine valves as actual aortic valve cusp tissue is used. However, still images of the valves show that cusp motion seems particularly impaired near the commissures leading to the irregularly shaped GOA, which was evident for all 3 stented porcine valves (Fig. 5A–C). Such impaired cusp motion is not observed in native aortic valves. In native valves, valve opening is a very complex process which, among others, involves annular dilatation and outward movement of commissures during systole. The resulting GOA has been described as triangular or round shaped. However, GOAs with clear borders were not observed in the present study using stented porcine valves. Our findings suggest that fixation of porcine cusps at the stent frame results in disruption of the complex interplay between the cusps and aortic root structures and therefore leads to irregularly shaped GOA. A different way of fixing porcine cusps within a stent frame, a different size ratio between the cusp and the stent or a more flexible stent frame imitating the native anulus may be able to improve results.

Our findings have important clinical implications. ROA is a new single parameter that simply and accurately characterizes the relationship between valve construction and functional performance (Central image and Fig. 2). With current conventional parameters, such as the ones described by the expert panel, this is not possible as interpretation of all those parameters requires consideration of at least 1 additional dimension. For example, the external sewing ring diameter is only useful if information on at least 1 additional dimension, such as the MID, is also provided, and vice versa. In addition, this simple dimension allows for the fast and easy comparison of valve models. As for the functional performance of the investigated valves, which is of paramount

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importance for the treatment of patients with aortic valve disease, our findings are important in multiple aspects. First, in recent years, many studies, including RCTs, that compared outcomes after transcatheter aortic valve replacement (TAVR) and SAVR have been conducted and results have had severe impact on guidelines and clinical practice. These studies mostly report clinical outcomes, including short-term haemodynamic results, based on the procedure (i.e. TAVR versus SAVR) without thoroughly discussing the SAV models [19–21]. Our data demonstrate that functional performance of SAVs differs across models and can become very large in some instances. Therefore, studies reporting the clinical outcomes of SAVR using bioprosthetic valves should always discuss which models and sizes were implanted. Second, valve model selection in clinical practice should also consider these results as valve model selection continues to be poorly standardized. The choice is not solely based on the immediate haemodynamic results but also considers durability, ease of implantation, availability, economic factors and the surgeon's preference. The feasibility of an SAV model for a future transcatheter valve-in-valve procedure has become an important consideration as well. However, to optimize patient care, elaboration of objective and standardized criteria for valve selection is necessary. This may also include durability issues with specific valve models which are also related to valve construction [22]. Finally, our study demonstrates that construction of contemporary bioprosthetic valves has room for improvement and that future research is essential to optimize the results of bioprosthetic SAVR. Particularly, as most elderly patients will be treated with transcatheter aortic valve implantation, SAVR will most likely be used for an increasing group of younger patients. Therefore, future patients requiring SAVR with a bioprosthetic valve may have life expectancies exceeding well over 25–30 years and every effort should be undertaken to offer the perfect heart valve for these patients.

Limitations

We acknowledge some limitations of our study. We utilized a custom-made mock circulation loop, which may differ from other pulse duplicators and we used only 1 valve per bioprostheses model, but the investigated valves have been tested by the manufacturer fulfilling ISO criteria that are required for approval in human use. In addition, we used physiological saline as test fluid which differs from blood regarding viscosity and may have affected results. Nevertheless, our setup was constructed in accordance with ISO regulations, and all our valves were investigated in the same setup therefore our results allow for comparison [11, 23, 24].

CONCLUSIONS

The functional performance of SAVs differed significantly among 8 commercially available models. The construction of the stent, cusp material and position of cusp fixation were related to functional valve performance. The ROA is a new measure that allows for the comparison of SAV models that are intended to treat a given annulus size. These factors should be considered for the elaboration of a standardized way to choose an SAV model for the patient and to improve current generation valves in the future.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *EJCTS* online.

Conflict of interest: none declared.

Funding

This research received no external funding.

Data Availability Statement

All relevant data are within the manuscript and its supporting Information files.

Author contributions

Najla Sadat: Conceptualization; Data curation; Formal analysis; Funding acquisition; Investigation; Methodology; Project administration; Resources; Validation; Visualization; Writing—original draft. **Michael Scharfschwerdt:** Formal analysis; Methodology; Software; Supervision. **Tim Schaller:** Methodology. **Anas Aboud:** Project administration; Supervision. **Hiroyuki Saisho:** Methodology. **Stephan Ensminger:** Formal analysis; Funding acquisition; Supervision; Writing—review & editing. **Buntaro Fujita:** Data curation; Formal analysis; Validation; Writing—review & editing.

Reviewer information

European Journal of Cardio-Thoracic Surgery thanks the anonymous reviewer(s) for their contribution to the peer review process of this article.

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