Assessment of effective orifice area of prosthetic aortic valves with Doppler echocardiography: An in vivo and in vitro study

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Objectives: We sought to evaluate the Doppler assessment of effective orifice area in aortic prosthetic valves. The effective orifice area is a less flow-dependent parameter than Doppler gradients that is used to assess prosthetic valve function. However, in vivo reference values show a pronounced spread of effective orifice area and smaller orifices than expected compared with the geometric area.

Methods: Using Doppler echocardiography, we studied patients who received a bileaflet St Jude Medical valve (n = 75; St Jude Medical, Inc, St Paul, Minn) or a tilting disc Omniscarbon valve (n = 46; MedicalCV, Incorporated, Inver Grove Heights, Minn). The prosthetic valves were also investigated in vitro in a steady-flow model with Doppler and catheter measurements in the different orifices. The effective orifice area was calculated according to the continuity equation.

Results: In vivo, there was a wide distribution with the coefficient of variation (SD/mean × 100%) for different valve sizes ranging from 21% to 39% in the St Jude Medical valve and from 25% to 33% in the Omniscarbon valve. The differences between geometric orifice area and effective orifice area in vitro were 1.26 ± 0.41 cm² for St Jude Medical and 1.17 ± 0.38 cm² for Omniscarbon valves. The overall effective orifice areas and peak catheter gradients were similar: 1.35 ± 0.37 cm² and 25.9 ± 16.1 mm Hg for St Jude Medical and 1.46 ± 0.49 cm² and 24.6 ± 17.7 mm Hg for Omniscarbon. However, in St Jude Medical valves, more pressure was recovered downstream, 11.6 ± 6.3 mm Hg versus 3.4 ± 1.6 mm Hg in Omniscarbon valves ($P = .0001$).

Conclusions: In the patients, we found a pronounced spread of effective orifice areas, which can be explained by measurement errors or true biologic variations. The in vitro effective orifice area was small compared with the geometric orifice area, and we suspect that nonuniformity in the spatial velocity profile causes underestimation. The St Jude Medical and Omniscarbon valves showed similar peak catheter gradients and effective orifice areas in vitro, but more pressure was recovered in the St Jude Medical valve. The effective orifice area can therefore be misleading in the assessment of prosthetic valve performance when bileaflet and tilting disc valves are compared.

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Doppler echocardiographic investigation is now frequently used as part of the follow-up for patients with prosthetic heart valves. Studies of long-term survival in patients undergoing aortic valve replacement reveal excess mortality when these patients are compared with the background population.^{1,2} Prosthetic valve function is one of the important determinants for the outcome of aor-

P₁₋₂: Peak catheter gradient

P₃₋₂: Pressure recovery

P₁₋₃: Net catheter gradient

Figure 1. Schematic representation of a pullback pressure recording in the central orifice of a St Jude Medical prosthetic valve from the ventricular chamber (1) to the aorta (3). Calculations of peak catheter gradients, pressure recovery, and the net pressure gradient are illustrated.

tic valve replacement. In mechanical prosthetic valves, tissue ingrowth or thrombus formation might cause obstruction. Furthermore, in some patients with a large body size relative to the aortic root or in physically active individuals, a normally functioning prosthetic valve can cause an obstruction of hemodynamic importance.³

In prosthetic aortic valves, the detection of prosthesis dysfunction and the assessment of hemodynamic performance are complicated by the flow dependence of Doppler gradients. The occurrence of local high velocities and pressure recovery, especially in bileaflet valves, further limits the usefulness of Doppler gradients.^{4,5} In mechanical prosthetic valves, the effective orifice area (EOA) of the valve can be assumed to be independent of flow,⁶ and the use of the EOA in prosthetic valve function assessment is recommended.⁷ When blood accelerates through a prosthesis, the bloodstream contracts; the EOA, which corresponds to the

vena contracta, can therefore be expected to be a fraction less than the geometric orifice itself.⁸ However, in vivo Doppler echocardiographic reference values for prosthetic valves show a pronounced spread of EOA within the same valve size group, and the EOA tends to be smaller than expected compared with the geometric orifice area.⁹⁻¹¹

We hypothesized that the previously observed pronounced spread of EOA in vivo was caused by measurement errors. We therefore performed an in vitro study in which these errors were minimized. The aims of the study were to evaluate the Doppler echocardiographic assessment of EOA. Further, we evaluated the relationship between valve EOA, design, and hemodynamic performance.

Methods

Valve Design

The St Jude Medical (SJM) standard valve (St Jude Medical, Inc, St Paul, Minn) is a bileaflet pyrolytic carbon valve with an 85° leaflet angle in the open position. The two-leaflet occluder design divides the area available for forward flow into three regions, one central and two side orifices. The tilting disc Omnicarbon (OMNI) valve (MedicalCV, Incorporated, Inver Grove Heights, Minn) consists of pyrolytic carbon with a maximum opening angle of 80°. The area available for forward flow is divided into a major and a minor orifice.

The Proportion of the Forward Flow Entering Different Orifices

To estimate the proportion of forward flow entering different orifices, we calculated the orifice areas separately. The full orifice areas and the separate areas were determined by planimetry using NIH Image 1.62 software (National Institutes of Health, Bethesda, Md). The proportion of the forward flow entering different orifices was assumed to correspond to the area proportion.

In Vitro Study

Model. Prosthetic valves were mounted in an in vitro flow model described previously,⁵ producing a continuous flow of between 178 and 395 mL/s. The model consisted of a circular ventricular chamber (78 × 46 mm) with a conically shaped outflow tract and a circular aortic chamber (93 × 36 mm). Flow entered the ventricular chamber by gravity from an upper reservoir, and different flow levels were obtained by changing the reservoir model height. The model was designed with the largest resistance at the entrance to the ventricular chamber, thereby promoting uniformity of flow. Corn starch was added to the fluid to facilitate Doppler measurements (water 70% and glycerol 30%, temperature 21°C, and viscosity 3×10^{-3} ns/m², ie, similar to whole blood).

Flow was measured with an ultrasonic flowmeter (HT 109; Transonic Systems, Inc, Ithaca, NY). The validity of the system was tested by series of timed collections. The flowmeter accurately predicted the flow (y) rates calculated from timed collections ($y = 1.018x + 5.7$; $r = 0.99$, $P = .0001$).

Test protocol. Five sizes (19, 21, 23, 25, and 27 mm) of SJM and OMNI prostheses were tested at 7 different flow rates. The flow rates were increased with increasing valve size to mimic

Figure 2. Distribution of EOA grouped by prosthesis size of the St Jude Medical (left) and Omnicarbon (right) valves. Results are shown for the in vivo (●) and in vitro (○) studies. Bars indicate mean ± SD. Boxes show the geometric orifice area.

physiologic conditions. At each flow level, 3 catheter pullback maneuvers were performed with the aim of identifying the maximum pressure decrease in the central and side orifices of the SJM valve and the major and minor orifices of the OMNI valve. A continuous wave Doppler investigation of the different orifices was performed twice at each flow rate.

Pressure measurements. Aortic and ventricular pressures were recorded with fluid-filled stainless steel catheters (outer diameter 1.50 mm and inner diameter 1.00 mm) connected to electronic pressure transducers (PRCR 75 S/D 889; Druck Ltd, Leicester, United Kingdom) and a pressure recorder system (Gould WindoGraf; Gould Instrument Systems, Valley View, Ohio). The catheter had a side-hole orifice 3 mm from the catheter tip. This design of the catheter eliminates the dynamic pressure component. It was pulled back manually from a ventricular position approximately 10 mm from the plane of the first structure in the prosthesis (0-level) to a position approximately 65 mm from the 0-level on the aortic side. The pressure gradients were measured between the start position on the ventricular side and at different locations in the prosthesis and aorta during pullback. Figure 1 shows a schematic representation of a pullback pressure recording in the central orifice of the SJM valve.

Doppler echocardiography. Doppler velocity measurements were obtained with a Vingmed System 5 (Vingmed Sound AS, Horten, Norway) with a 3.5-MHz ultrasound transducer. The transducer was positioned on the ventricular chamber side of the model at a distance of 78 mm from the prostheses. To facilitate the separation of the maximum velocities in the different orifices, we improved the lateral resolution by changes in the software of the ultrasound machine.

Doppler measurements. The Doppler tracings were stored on S-VHS videotapes and compact disks and analyzed off-line in the

Echopac computer program (Vingmed Sound AS). The spectral display from pulsed and continuous wave Doppler recordings was digitized along its outer border, giving the velocity time integral (VTI).

In Vivo Study

The present study presents data from 121 patients who participated in a study that has previously been described in detail.¹⁰ The patients were investigated after aortic valve replacement (median 5 days postoperatively, range 2-35 days). The bileaflet SJM valve was inserted in 75 patients, and the tilting disc OMNI valve was used in 46 patients. Informed consent was obtained from all patients, and the study was approved by the human ethics committee at Sahlgrenska University Hospital.

Two-dimensional echocardiography. Echocardiography was performed with an Acuson 128 or 128 XP Computed Sonograph (Acuson, Mountain View, Calif). From a parasternal long-axis position, we obtained a digital cine loop of an enlarged view of the left ventricular outflow tract (LVOT). Using electronic calipers, we measured the diameter just below the aortic valve from the trailing edge of the anterior echo to the leading edge of the posterior echo.¹²

Doppler measurements. Blood flow velocity in the LVOT (V_{LVOT}) was estimated by pulsed wave Doppler echocardiography from an apical window (sample axial volume size of 5 mm). Continuous wave Doppler signals were recorded by a 2-MHz non-imaging probe. Continuous wave Doppler recordings of the jet velocity through the prosthetic valve were obtained only from an apical window for practical reasons (difficulty changing the position of the patients, bandages). The velocity profiles were recorded on paper and traced along the outer border of the spectral display by means of a digitizing table (Summagraphics

TABLE 1. In vitro EOAs and discharge coefficients calculated according to the continuity equation

	Size (mm)				
	19	21	23	25	27
<i>SJM</i>					
Geometric orifice area	1.6	2.1	2.6	3.1	3.7
EOA _{Peak}	0.83 ± 0.06	1.08 ± 0.05	1.39 ± 0.06	1.63 ± 0.02	1.80 ± 0.04
EOA _{Separate}	0.87 ± 0.08	1.16 ± 0.04	1.57 ± 0.06	1.78 ± 0.08	2.02 ± 0.04
<i>P</i> value	.056	.0002	.0001	.015	.0001
Discharge _{Peak}	0.52 ± 0.04	0.51 ± 0.03	0.53 ± 0.02	0.53 ± 0.01	0.49 ± 0.01
Discharge _{Separate}	0.54 ± 0.05	0.56 ± 0.02	0.61 ± 0.02	0.58 ± 0.03	0.55 ± 0.01
<i>OMNI</i>					
Geometric orifice area	1.6	2	2.5	3.1	3.8
EOA _{Peak}	0.83 ± 0.04	1.13 ± 0.02	1.39 ± 0.06	1.68 ± 0.07	2.16 ± 0.06
EOA _{Separate}	0.83 ± 0.03	1.13 ± 0.01	1.40 ± 0.05	1.67 ± 0.07	2.15 ± 0.06
<i>P</i> value	.10	.47	.70	.28	.81
Discharge _{Peak}	0.55 ± 0.03	0.57 ± 0.01	0.56 ± 0.02	0.54 ± 0.02	0.57 ± 0.02
Discharge _{Separate}	0.55 ± 0.02	0.56 ± 0.01	0.56 ± 0.02	0.54 ± 0.02	0.57 ± 0.02

Five valve sizes were tested at 7 different flow rates. Mean ± SD. EOA, Effective orifice area; Discharge, discharge coefficient. *P* value for comparison between EOA_{Peak} and EOA_{Separate}.

TABLE 2. Catheter pressure gradients in the SJM and OMNI valves

	SJM	OMNI	<i>P</i> value
Peak catheter gradient (mm Hg)	25.9 ± 16.1	24.6 ± 17.7	.74
Net catheter gradient (mm Hg)	14.4 ± 10.8	21.2 ± 16.5	.05
Recovered pressure (mm Hg)	11.6 ± 6.3	3.4 ± 1.6	.0001
Percent recovered pressure	48.1 ± 12.2	17.6 ± 7.2	.0001

Mean ± SD. SJM, St Jude Medical; OMNI, Omnicarbon.

ID-2CTR-TAB17; GTCO CalComp, Inc, Columbia, Md), a micro-computer (Professional-380; Digital Equipment Corp, Maynard, Mass), and a specially designed computer program. The VTI of the pulsed wave Doppler recordings from the LVOT (VTI_{LVOT}) and the VTI of continuous wave Doppler recordings of highest transprosthetic velocity (VTI_{Peak}) were computed. The stroke volume was calculated as the product of the cross-sectional area of the LVOT and VTI_{LVOT}.

Calculations

Areas were calculated by means of either the peak velocity (VTI_{Peak}) across the valve (EOA_{Peak}) or separately for different orifices (EOA_{Separate}).

1. In vivo: EOA_{Peak} = Stroke volume/VTI_{Peak}
2. In vitro: EOA_{Peak} = Flow/VTI_{Peak}/s
3. EOA_{Separate} = Fraction of flow/VTI_{Separate}
4. Discharge coefficient = EOA/geometric orifice area

Statistics

The results are expressed as the mean ± SD. The mean of 3 Doppler measurements was used in patients with sinus rhythm and

the mean of 10 measurements was used for patients in atrial fibrillation. The spread of data was expressed in percent as the coefficient of variation (SD/mean × 100%). The differences between the central and side orifices in the SJM valve and the major and minor orifices in the OMNI valve were tested with the use of a paired Student *t* test. The difference between SJM and OMNI valves was tested by means of an unpaired Student *t* test. The relationship between variables was assessed by linear regression.

Results

The Proportion of the Forward Flow Entering Different Orifices

In the SJM valve, the central orifice constitutes 25% of the full orifice area. In the OMNI valve, the minor orifice is 20% of the full orifice area.

EOA in Vivo and in Vitro

Figure 2 shows the relationship between prosthetic valve size and EOA in vivo and in vitro. In vivo, valve size could explain 31% and 37% (*R*²) of the variability in calculated EOA in the SJM and OMNI valves, respectively. A wide distribution was present, with the coefficient of variation (SD/mean × 100%) ranging from 21% to 39% for the SJM valve and from 25% to 33% for the OMNI valve. In vitro, valve size could explain 97% of the variability in EOA in both the SJM and OMNI valves. We observed a very narrow distribution, with coefficients of variation ranging from 1% to 7% in the SJM valve and from 1% to 5% in the OMNI valve. The discrepancies between geometric orifice valve areas and EOA_{Peak} were 0.96 ± 0.49 cm² for SJM versus 0.87 ± 0.59 cm² for OMNI valves in vivo and 1.26 ± 0.41 cm² for SJM versus 1.17 ± 0.38 cm² for OMNI valves in vitro.

Figure 3. Peak catheter gradients versus net catheter gradients in the St Jude Medical (*SJM*) and Omniscarbon (*OMNI*) valves. Mean difference between peak catheter gradient and net catheter gradient is 11.6 ± 6.3 mm Hg in St Jude Medical and 3.4 ± 1.5 mm Hg in Omniscarbon valves.

EOA and Discharge Coefficients Calculated Separately in Different Orifices

In the *SJM* valve (Table 1), the separate calculation of the EOA for different orifices increased the area significantly ($P = .0001$) because of higher central orifice velocity compared with the side orifice velocity (2.4 ± 0.7 m/s vs 2.2 ± 0.7 m/s; $P = .0001$). The mean difference between the two methods was 0.14 ± 0.09 cm² (95% confidence interval 0.10-0.17 cm²). The overall increase in EOA was $9.6\% \pm 5.0\%$. In the *OMNI* valve, calculating the major and minor effective orifices separately did not change the total EOA. The mean difference between the two methods was 0.01 ± 0.01 cm². In the *SJM* valve, the side orifice had the highest discharge coefficient ($P = .0001$), with an overall difference of 0.049 ± 0.025 between the side and central orifices. In the *OMNI* valve, the difference between the major and minor orifices was small, 0.002 ± 0.005 ($P = .03$).

EOA and Discharge Coefficients in *SJM* Versus *OMNI* Valves

The overall volume flow was similar for *SJM* and *OMNI* valves (304 mL/s vs 305 mL/s; $P = .96$). The overall EOA_{Peak} was 1.35 ± 0.37 cm² and 1.45 ± 0.49 cm² for the *SJM* and *OMNI* valves, respectively ($P = .41$). Calculating the orifice areas in the *SJM* valve separately increased the

Figure 4. Relationship between peak EOA_{Separate} and net catheter gradients. The St Jude Medical (*SJM*) ($y = -20.7x + 44.7$, $R^2 = 0.69$, $P = .0001$) and Omniscarbon (*OMNI*) ($y = -28.3x + 61.9$, $R^2 = 0.65$, $P = .0001$) valves had a comparable effective orifice area (EOA), but the Omniscarbon valve had higher net catheter gradients than the St Jude Medical valve.

EOA to 1.49 ± 0.45 cm² in the *SJM* valve. The overall discharge coefficient using peak velocity for calculation was significantly lower in the *SJM* valve than in the *OMNI* valve (0.52 ± 0.03 vs 0.56 ± 0.022 ; $P = .0001$). When the EOA was calculated separately, the *SJM* discharge coefficient increased to 0.57 ± 0.038 .

Catheter Gradients Versus Doppler Areas

The *SJM* and *OMNI* valves had similar peak catheter gradients (Table 2). However, pressure recovery was more pronounced in the *SJM* valve than in the *OMNI* valve. Figure 3 shows the relationship between peak and net catheter pressure gradients. The *SJM* and *OMNI* valves had comparable EOAs, but the *OMNI* valve had higher net catheter gradients than the *SJM* valve (Figure 4).

Location of Peak Pressure in Different Orifices

Table 3 shows the position of the peak catheter pressure gradient in relation to the prosthetic design and size. In the *SJM* valve, the peak pressure gradient was obtained at the entrance of the central orifice with pronounced pressure recovery within the central tunnel (Figure 5). In the side orifice, the pressure decreased less abruptly and the peak gradient was situated around the tip of the prosthetic leaflet. In the *OMNI* valve, the peak gradient was located near the

TABLE 3. The position of peak catheter gradient in relation to prosthetic valve profile

	Size (mm)				
	19	21	23	25	27
			<i>SJM</i>		
Central orifice (mm)	3.3 ± 5.7	3.3 ± 0.6	2.1 ± 0.7	3.4 ± 0.4	2.5 ± 0.5
Side orifice (mm)	7.9 ± 1.1	8.0 ± 1.1	8.1 ± 0.9	9.4 ± 1.7	9.6 ± 0.8
			<i>OMNI</i>		
Major orifice	18.2 ± 3.6	17.1 ± 2.6	11.2 ± 5.4	13.1 ± 2.8	15.5 ± 3.1
Minor orifice	4.8 ± 1.0	4.7 ± 0.5	5.1 ± 1.3	6.1 ± 0.9	9.1 ± 0.9

Mean ± SD. *SJM*, St Jude Medical; *OMNI*, Omnicarbon. The catheter position is defined relative to the first structure in the prosthesis on the ventricular side.

entrance of the minor orifice and around the tip of the leaflet in the major orifice.

Discussion

The Doppler echocardiographic investigation of patients with prosthetic valves provides information relevant to the assessment of prosthetic valve function. The clinically most important question is whether or not the prosthetic valve is obstructed. With different valve designs (tilting disc, bileaflet, biologic), the extent to which the Doppler echocardiographic information can be used to describe hemodynamic performance and to compare one design with another is also important. The flow dependence of peak velocities and Bernoulli gradients limits their use. The EOA, calculated according to the continuity equation, is less flow dependent and therefore recommended in the assessment of prosthetic function.⁷ However, its usefulness rests with the freedom from, or existence of, other measurement errors, which we studied in the current investigation.

Sources of Variation in EOA

The EOA might vary in patients with the same prosthesis size because of true biologic variation, measurement errors, or underestimations or overestimations imposed when the prerequisites of the continuity principle are not fulfilled (Table 4).

The effect of subvalvular geometry on the size of the vena contracta has previously been described.¹³ A gradual narrowing favors a larger vena contracta compared with a more abrupt narrowing. Theoretically, therefore, some of the variation in EOA observed in vivo could be explained by the influence of the geometry of the LVOT.

Anatomic variation regarding the orientation of the annular ring and the surgeon's efforts to use the largest prosthetic valve might result in an oblique position of the valve relative to flow direction. This will reduce the EOA and could explain part of the variation observed in vivo. Further, in tilting disc valves, the orientation of the major and minor orifices might influence the relationship between leaflet and flow, and thereby the EOA, in an important manner.^{14,15}

According to Table 4, measurement errors in the assessment of EOA are principally due to errors in the determination of LVOT area or angulation errors during the Doppler registration. In the in vitro study, we minimized both these errors, which may explain the very narrow spread in observed values for EOA.

According to the continuity principle, the velocity profile in both the subvalvular position and the prosthetic valve position must be uniform or flat. The subvalvular velocity profile has been investigated in patients with aortic stenosis^{16,17} and prosthetic valves.¹⁷ In prosthetic valves, the clinically obtained velocity with pulsed wave Doppler echocardiography was representative of the velocity profile in LVOT.¹⁷ However, there were individual differences, and these can explain cases of both overestimation and underestimation of EOA in our in vivo study. The velocity profile in prosthetic valves has been investigated by Yoganathan and associates¹⁸ using laser Doppler methods, which permits a detailed description of the spatial distribution of velocities. In bileaflet and tilting disc valves, they found relatively similar peak velocities in different orifices. However, these flow measurements were performed 8 to 11 mm downstream of the valve. The presence of higher velocities in the central orifice of the bileaflet valve has been documented previously by means of continuous wave Doppler recordings in the *SJM* valve.¹⁹ We were able to confirm this in the *SJM* valve, but in the *OMNI* valve we found similar velocities in the minor and major orifices.⁵ A possible effect of the nonuniformity of calculated EOA in the *SJM* valve has been postulated,⁶ but the magnitude has not been previously described. In the present study, we calculated the EOA for different orifices to evaluate the magnitude of error and found that, in overall terms, the total area increased by approximately 10%.

In the in vitro study, we found for both the *SJM* and *OMNI* valves that a relatively small part of the geometric orifice area was used for forward flow with discharge coefficients ranging from 0.54 to 0.61. The contraction of a jet through a constriction is dependent on orifice and LVOT geometry.^{20,21} In the model, the LVOT was conically shaped

Figure 5. Pressure profiles obtained from catheter pullback in the central and side orifices of the St Jude Medical valve (size 23, *left*) and in the major and minor orifices of the Omniscarbon valve (size 21, *right*). Arrows indicate the distal part of the prosthesis. In the St Jude Medical valve the pressure drop is most pronounced in the proximal portion of the central orifice, with marked pressure recovery within the central tunnel.

to allow the fluid to enter the prosthesis smoothly, and we expected to find higher discharge coefficients. Using laser Doppler echocardiography, Shandas, Kwon, and Valdes-Cruz²² found the vena contracta area in the side orifice of the SJM valve, which corresponds to the discharge coefficient, to be 0.94. We therefore suspect that the calculated EOA and discharge coefficients, even after corrections for higher central velocities in the SJM valve, underestimate the actual EOA. Underestimation of flow and overestimation of peak velocity are possible sources of a systematic underestimation of the EOA in the *in vitro* study. The flow measurements (Transonic Systems, Inc) were calibrated with timed collections as a reference, with a strong linear relationship. The spatial velocity profile has been described downstream in the aorta with laser Doppler echocardiography^{18,23} but, to our knowledge, not within the prosthetic valves. It is conceivable that the velocity profile in the different orifices is not laminar or flat. Therefore, the most likely source of error is that the peak velocity overestimates the spatial velocity profile.

Hemodynamic Performance

Today, Doppler gradients and EOAs are frequently used to describe the hemodynamic performance of prosthetic valves and to compare one design with another. The limitations of Doppler gradients in the assessment of prosthesis performance have previously been demonstrated.^{4,5,24} The degree of pressure recovery varies and depends on valve design,^{5,24}

size,⁵ and aortic root dimensions.¹⁹ It is generally accepted that the net gradient is the gradient of interest in describing the hemodynamic performance of a prosthetic valve.²⁵ In the present study, we found that the EOA in the SJM and OMNI valves was similar, but the SJM valve had more pronounced pressure recovery and lower net gradients than the OMNI valve. This finding therefore indicates that the EOA is also of limited value in the assessment of prosthetic hemodynamic performance.

Location of the Vena Contracta

In the present study, we determined the position of the peak pressure gradient within the different orifices. These gradients correspond to the location of the vena contracta. In the SJM valve, the smallest flow area lies a few millimeters from the proximal tip of the valve, with marked pressure recovery, and we can assume an increase in flow area within the central tunnel. In a recent report by Shandas, Kwon, and Valdes-Cruz,²² the EOA in the SJM valve was determined with laser Doppler echocardiography in the distal vicinity of the prosthesis. The authors propose that these measurements can be used as reference data. However, our data indicate that this method overestimates the central area of the prosthesis.

Study limitations

Recent knowledge shows that, in tilting disc valves like the OMNI valve, the surgeon should try to orient the leaflet in the

TABLE 4. Principal causes of the variation in EOA within the same valve size according to the continuity principle

Cause for variation	Result
True biologic variation in EOA within the same valve size group	
Subvalvular geometry might influence the size of the vena contracta	Decrease in EOA
Tilting of the prosthesis	Decrease in EOA
Orientation of the monoleaflet	Decrease in EOA
Errors in measurement	
Incorrect LVOT area	Overestimation or underestimation of EOA
Angulation error in V_{LVOT}	Underestimation of EOA
Angulation error in V_{Peak}	Overestimation of EOA
Prerequisites of the continuity principle not fulfilled	
Nonuniformity in subvalvular velocity profile	Overestimation or underestimation of EOA
Nonuniformity in prosthetic velocity profile	Underestimation of EOA

EOA, Effective orifice area; LVOT, left ventricular outflow tract; V_{LVOT} , blood velocity in the left ventricular outflow tract; V_{Peak} , peak velocity.

flow direction to minimize the flow disturbance and energy loss.^{14,15} This usually means that the major orifice is oriented to the right and, dependent on the flow direction, the disc does not necessarily open completely. In the in vitro model, the prosthetic valves were mounted with the sewing ring perpendicular to the flow direction. In the period 1991 to 1993, when the study patients were operated on, the importance of valve orientation was not recognized. Therefore, in both the in vivo and in vitro studies, the position of the OMNI valve might be suboptimal, and this may have increased the flow velocities and reduced the calculated EOA.

We used a steady-flow model, and the possible effects of differences in prosthetic leakage cannot be evaluated. It is therefore impossible to compare the SJM and OMNI valves from our data and to draw any conclusions about which is the better prosthesis.

Although it was not verified that the SD was proportional to the measured area, the coefficient of variation was used to elucidate the large variation in valve areas within each valve size group.

Clinical Implications

With Doppler echocardiography, prosthetic valve function can be assessed semiquantitatively. Using reference values specified for valve design and size and, if available, comparing the observed values with a previous investigation provide an instrument for detecting prosthetic dysfunction.¹⁰ However, Doppler echocardiographic data, both flow dependent and flow independent, can be misleading in the assessment of prosthetic performance when bileaflet and tilting disc valves are compared.

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