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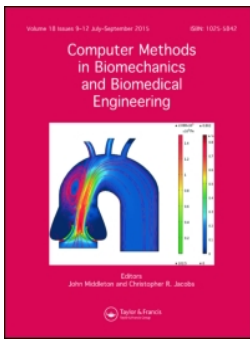
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# Effect of Valve- and Patient- Related Factors on the Effective and Geometric Orifice Areas: An In Vitro Study with the CoreValve

V. Stanová<sup>a</sup>, AS. Zense<sup>a,b</sup>, R. Rieu<sup>a</sup>, L. Kadem<sup>c</sup> and P. Pibarot<sup>b</sup>

<sup>a</sup>Aix Marseille Univ, CNRS, ISM, Inst Movement Sci, GiBoc, Marseille, France; <sup>b</sup>Quebec Heart and Lung Institute, Laval Univ, Quebec, Canada; <sup>c</sup>Department of Mechanical and Industrial Engineering, Concordia Univ, Montreal, QC, Canada

**KEYWORDS** Aortic hemodynamics; aortic flow; effective orifice area; geometric orifice area

## 1. Introduction

Effective orifice area (EOA) is a standard parameter for clinical assessment of the severity of valve stenosis, but it is also used to compare the hydrodynamic performance of various prosthetic heart valves. However, the EOA measured by Doppler echocardiography provides an estimation of the cross-sectional area of the flow jet at the vena contracta. On the other hand, geometric orifice area (GOA) provides an estimation of the area of the valve orifice. Both parameters may be influenced by prosthetic valve-related factors (model and size) as well as patient-related factors (aortic annulus size, level of transvalvular flow).

The objective of this study was to examine, in a pulse duplicator, the impact of flow and different sizes of CoreValve (CV) on valve effective orifice area and geometric orifice area.

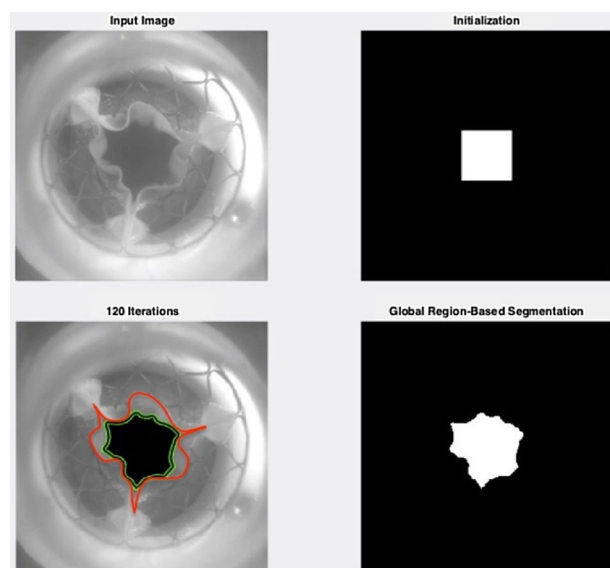
## 2. Methods

Three different sizes of percutaneous aortic valves, CoreValve (Medtronic, Inc.), were tested on a pulse duplicator under the following configurations: CV 23 mm implanted in aortic annuli (AA) ranging from 17 to 20 mm; 2) CV 26 mm implanted in AA ranging from 20 to 23 mm; 3) CV 29 mm implanted in AA ranging from 23 to 26 mm. For each configuration tested, the heart rate was set to 70 bpm, mean aortic pressure to 100 mmHg while the stroke volume (SV) was varied (30, 50, 70, 90 ml). A high-speed camera (Photron, 1000 images/second) was used to acquire images during systole (290 images) and diastole (570 images). In this abstract, we will focus mainly on one size of CV (23 mm).

Doppler EOA was estimated using the standard electro-magnetic flowmeter (Carolina Medical Inc. CME 500 Series) by Doppler velocity-time integral (General Electric

Vivid 7). Determination of GOA was proceeded using program inspired by Chang and Vese (2001). The program was modified by adding the initialization mask that allows to focalize on one precise region in order to determine the valve GOA. This program was optimized for our application by adding the area calculation based on a personalized Matlab application after image calibration (Figure 1).

As the limiting factor in terms of hemodynamic performance is the most restrictive area (Figure 1, 120 iterations: green line), GOA was not measured at the prosthesis free leaflet edge (Figure 1, 120 iterations: red line) as in case of mechanical or surgical bioprostheses, but in the inner area of the valve. Generally, the difference between measured



**Figure 1.** GOA determination using region-based active contour segmentation. The green contour represents the GOA as determined at the base of the leaflets. The red contour represents the GOA as determined at the tip of valve leaflets.

**Table 1.** EOA (cm<sup>2</sup>), GOA (cm<sup>2</sup>) and contraction coefficient for CV 23 mm as a function of AA diameter and SV.

SV (ml)	Aortic valve area (cm <sup>2</sup> ) for CV 23 mm in aortic annuli											
	17 mm			18 mm			19 mm			20 mm		
	EOA	GOA	Cc	EOA	GOA	Cc	EOA	GOA	Cc	EOA	GOA	Cc
30	0.82	1.17	0.69	0.84	1.32	0.64	0.90	1.41	0.64	1.03	1.49	0.69
50	0.95	1.25	0.75	0.99	1.35	0.73	1.12	1.55	0.72	1.24	1.67	0.74
70	0.99	1.30	0.76	1.04	1.36	0.76	1.22	1.57	0.77	1.26	1.69	0.75
90	1.06	1.31	0.81	1.11	1.39	0.80	1.29	1.61	0.80	1.31	1.71	0.77

GOA and GOA on the tip of leaflets was 33%. The ratio of EOA to GOA was termed the contraction coefficient (Cc) and is usually 0.6–0.9 depending on the left ventricular outflow tract geometry and aortic valve morphology.

A Student t-tests was used to test for significant differences (P value < 0.05 was considered statistically significant).

### 3. Results and discussion

For CV 23 mm, the EOA increased significantly with aortic annulus diameter ( $0.96 \pm 0.10$  to  $1.21 \pm 0.12$  cm<sup>2</sup>,  $p < 0.001$ ) and SV (range from  $0.82 \pm 0.01$  to  $1.31 \pm 0.04$  cm<sup>2</sup>,  $p < 0.001$ ). GOA also increased significantly with AA diameter ( $1.25 \pm 0.14$  to  $1.64 \pm 0.10$  cm<sup>2</sup>,  $p < 0.001$ ) and SV (range:  $1.17$  to  $1.71$  cm<sup>2</sup>,  $p = 0.001$ ) for given size and flow conditions (Table 1, Figure 2A, 2B).

EOA ( $0.82 \pm 0.10$  cm<sup>2</sup>) and GOA ( $1.17$  cm<sup>2</sup>) smallest values were obtained in CV 23 mm implanted in aortic annulus of 17 mm with a SV of 30 ml (Table 1) and the largest values ( $1.31 \pm 0.04$  cm<sup>2</sup> and  $1.71$  cm<sup>2</sup> for EOA and GOA respectively) in the CV 23 mm in 20 mm aortic annulus with a stroke volume of 90 ml.

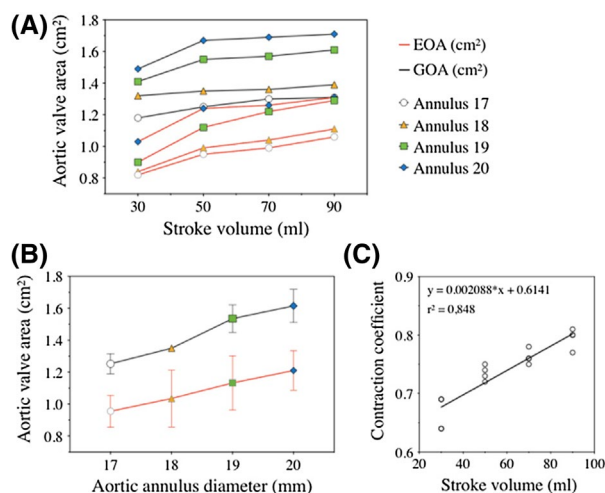
A multiple linear analysis showed that the relationship between EOA and GOA, and therefore the value of Cc, was dependent on the flow ( $p < 0.001$ ,  $r^2 = 0.80$ ), but not on AA diameter ( $p = 0.42$ ). The following relations to predict the contraction coefficient and effective orifice area, in the CV23, were found:

$$Cc = 0.566 + 0.002 \times SV \quad (r = 0.80)$$

$$EOA = -0.186 + 0.674 \times GOA + 0.03 \times SV \quad (r = 0.97)$$

The EOA and hence the Cc (Figure 2C) are both directly related to the stroke volume ( $Cc = 0.74 \pm 0.17$ ,  $p < 0.001$ ). At low flow states, the EOA, and hence the Cc display lower values.

The overall mean difference for CV 23 between the GOA and the EOA was 0.37 cm<sup>2</sup>, representing 30% (mean differences of: 0.45, 0.38, 0.35, 0.31 cm<sup>2</sup> for SV of 30, 50, 70, 90 ml respectively). Thus, the difference between the EOA and the GOA was even higher at lower stroke volumes. Similar results have been observed with two other valves tested: CV 26 (26%) and CV 29 (27%).



**Figure 2.** EOA for CV 23 mm as a function of stroke volume (2A), aortic annulus diameter (2B) and Cc vs. stroke volume (2C).

### 4. Conclusions

The main findings of this study are: firstly, both the EOA and the GOA decrease with the flow (28% and 11% respectively). Hence, the valve opening is incomplete at low flow states. Secondly, the EOA/GOA ratio decreases with the flow (18%) thus indicating that the flow contraction is more pronounced at low flow states. Hence, compared to the GOA, the EOA decreases to a larger extent with decreasing flow. For a given flow, the EOA and the GOA of the CV are essentially determined by the AA size. Furthermore, due to the valvular and vascular determinants of transvalvular gradients, EOA is not constant for a specific GOA. Finally, similar results have been observed with other valves: CV23, CV26 and CV 29 mm.

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