Dr Eleftheriades is a co-founder of CoolSpine; a consultant for Cryolife; and is on the Data/Safety Monitoring Board for Terumo and Jarvik Heart. Dr Ziganshin has nothing to disclose with regard to commercial support.

REPLY: EFFECTIVE ORIFICE AREA OF PROSTHETIC HEART VALVES—NOT PERFECT, BUT STILL VALUABLE

Reply to the Editor:

We thank Dr Doenst for his kind comments¹ regarding the European Association for Cardio-Thoracic Surgery/Society

of Thoracic Surgeons/American Association for Thoracic Surgery document on prosthetic valve size labeling.²

After applauding the work of the Committee, Dr Doenst focuses the remainder of his letter on the nature of effective orifice area (EOA), pointing out that EOA is patient specific—so that “the same prosthesis in 2 anatomically different patients will result in 2 different EOAs despite the same geometric orifice area of the prosthesis.” He concludes by arguing that, for this reason, EOA should not be used to judge the “hemodynamic quality of the implant or the presence of patient–prosthesis mismatch.” Dr Doenst properly points out that the anatomy of an individual patient's left ventricular outflow tract affects calculations of EOA.

Although EOA is patient dependent, it still remains a useful parameter for valve selection and postoperative assessment.

I. in vitro performance of a BILEAFLET 25 mm reference valve in centers A-F

II. in vitro performance of a TISSUE 25 mm reference valve in centers A-F

FIGURE 1. In vitro round-robin testing results. (I) EOA and regurgitant fraction results of a 25-mm bileaflet mechanical reference valve (St Jude Medical, St Paul, Minn), determined by in vitro pulsatile testing in 6 different centers (A-F) coded from light to dark shades of green. (II) EOA and regurgitant fraction results of a 25-mm tissue reference valve (Edwards Lifesciences, Irvine, Calif), determined by in vitro pulsatile testing at 6 different centers (A-F) coded from light to dark shades of green. *Minimum performance requirements as defined in the International Organization for Standardization 5840:2005 standard. EOA, Effective orifice area; RF, regurgitant fraction. Data from Retta SM, Kepner J, Marquez S, Herman BA, S Shu MC, Grossman LW. In-vitro pulsatile flow measurement in prosthetic heart valves: an inter-laboratory comparison. *J Heart Valve Dis.* 2017;26:72-80. Reproduced with permission from Durko and colleagues.²

FIGURE 2. A, Difference between geometric orifice area and EOA in bileaflet mechanical valves. The convergence of flow lines in both aortic and mitral positions determines the effectiveness (ie, performance) of the prosthesis. More pronounced flow contraction in the prosthesis results in less effective use of the geometric orifice area. B, Plot for the St Jude Medical mechanical mitral valve prostheses by valve size of EOA. Note the considerable variation in EOA among different individuals. *EOA CON*, Effective orifice area calculated by the continuity equation. A, Reprinted with permission from Bertrand PB, Pettinari M, De Cannière H, et al. Effective orifice area during exercise in bileaflet mechanical valve prostheses. *J Am Soc Echocardiogr.* 2017;30:404-13. B, Reprinted with permission from Blauwet LA, Malouf JF, Connolly HM, et al. Comprehensive hemodynamic assessment of 368 normal St Jude Medical mechanical mitral valve prostheses based on early postimplantation echocardiographic studies. *J Am Soc Echocardiogr.* 2013;26:381-9.

1. EOA can be assessed in vitro in engineering laboratories. Figure 5 in the European Association for Cardio-Thoracic Surgery/Society of Thoracic Surgeons/American Association for Thoracic Surgery document² (reprinted in part in Figure 1) shows that in vitro EOA calculations in 6 different laboratories provide comparable and consistent results.
2. EOA can be assessed in vivo in large groups of patients. This has been done on many occasions. Such in vivo studies permit both assessment of the adequacy of function of 1 particular valve in 1 patient and establishment of expected ranges of EOA for specific types and sizes of valves (Figure 2). Of course, individual patient EOA measurements in these studies vary around a mean, as do most physiologic parameters. So, EOA values can be meaningful in decisions regarding valve selection. Reference ranges have been established for different model valves and different sizes within a given model. Table 1 shows such reference ranges developed via assimilation of data from relevant articles in the literature.³

We thank Dr Doenst¹ for focusing attention on the important topic of the patient-specific character of EOA measurements. His comments are on the mark and helpful in placing the corresponding section of the European Association for Cardio-Thoracic Surgery/Society of Thoracic Surgeons/American Association for Thoracic Surgery document² in proper perspective.

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TABLE 1. Reference values for effective orifice area for prosthetic heart valves, determined from articles published in the literature, reproduced with permission from Lancellotti and colleagues³

Prosthetic valve size (mm)	19	21	23	25	27	29
Stented bioprosthetic valves						
Mosaic (Medtronic, Minneapolis, Minn)	1.1 ± 0.2	1.2 ± 0.3	1.4 ± 0.3	1.7 ± 0.4	1.8 ± 0.4	2.0 ± 0.4
Hancock II (Medtronic)	–	1.2 ± 0.2	1.3 ± 0.2	1.5 ± 0.2	1.6 ± 0.2	1.6 ± 0.2
Carpentier-Edwards Perimount (Edwards Lifesciences, Irvine, Calif)	1.1 ± 0.3	1.3 ± 0.4	1.5 ± 0.4	1.8 ± 0.4	2.1 ± 0.4	2.2 ± 0.4
Carpentier-Edwards Magna (Edwards Lifesciences)	1.3 ± 0.3	1.5 ± 0.3	1.8 ± 0.4	2.1 ± 0.5	–	–
Biocor (Epic) (St Jude Medical, St Paul, Minn)	1.0 ± 0.3	1.3 ± 0.5	1.4 ± 0.5	1.9 ± 0.7	–	–
Mitroflow (Sorin Group, Arvada, Colo)	1.1 ± 0.2	1.2 ± 0.3	1.4 ± 0.3	1.6 ± 0.3	1.8 ± 0.3	–
Trifecta (St Jude Medical)	1.4	1.6	1.8	2.0	2.2	2.4
Stentless bioprosthetic valves						
Medtronic Freestyle	1.2 ± 0.2	1.4 ± 0.2	1.5 ± 0.3	2.0 ± 0.4	2.3 ± 0.5	–
St Jude Medical Toronto SPV (St Jude Medical, St Paul, Minn)	–	1.3 ± 0.3	1.5 ± 0.5	1.7 ± 0.8	2.1 ± 0.7	2.7 ± 1.0
Prima Edwards (Edwards Lifesciences)	–	1.3 ± 0.3	1.6 ± 0.3	1.9 ± 0.4	–	–
Mechanical valves						
Medtronic-Hall	1.2 ± 0.2	1.3 ± 0.2	–	–	–	–
St Jude Medical Standard	1.0 ± 0.2	1.4 ± 0.2	1.5 ± 0.5	2.1 ± 0.4	2.7 ± 0.6	3.2 ± 0.3
St Jude Medical Regent	1.6 ± 0.4	2.0 ± 0.7	2.2 ± 0.9	2.5 ± 0.9	3.6 ± 1.3	4.4 ± 0.6
MCRI On-X (CryoLife, Kennesaw, Ga)	1.5 ± 0.2	1.7 ± 0.4	2.0 ± 0.6	2.4 ± 0.8	3.2 ± 0.6	3.2 ± 0.6
Carbomedics Standard and Top Hat (Austin, Tex)	1.0 ± 0.4	1.5 ± 0.3	1.7 ± 0.3	2.0 ± 0.4	2.5 ± 0.4	2.6 ± 0.4
ATS Medical (Minneapolis, Minn)*	1.1 ± 0.3	1.6 ± 0.4	1.8 ± 0.5	1.9 ± 0.3	2.3 ± 0.8	–

*For the ATS medical valve, the label valve sizes are 18, 20, 22, 24, and 26 mm. High velocities are common in size 19 or 21 prostheses.

REPLY FROM THE AUTHORS: ON THE VALUE OF IN VIVO EFFECTIVE ORIFICE AREAS

Reply to the Editor:

We thank Dr Doenst for discussing the role of the in vivo effective orifice area (EOA) in judging the performance of surgical heart valves (SHVs) in relation to the Position Statement of the European Association for Cardio-Thoracic Surgery Society of Thoracic Surgeons American Association for Thoracic Surgery Valve Labelling Task Force.¹

In his letter,² Dr Doenst points out the fact that in vivo EOAs are influenced by patient-related factors and claims that “in vivo EOA (...) should not allow judging the hemodynamic performance of the implant or the presence of prosthesis–patient mismatch (PPM).” We disagree with this statement and provide below further clarification.

When discussing the role of in vivo EOAs in characterizing SHV performance, a clear distinction should be made between measured (actual) and reference EOA values. In vivo reference EOAs are determined in patient populations receiving the same model of SHV and are reported for each SHV model and size.^{3,4} They provide the hemodynamic fingerprint of a given model and size of the SHV and are useful in predicting the risk of prosthesis–patient mismatch before aortic valve replacement. In fact, in vivo reference EOAs are the most

important benchmarks when predicting or assessing SHV hemodynamic performance in patients undergoing valve replacement.^{5,6}

The actual EOA of an SHV, measured in the patient after SHV implantation, is indeed dependent on the patient's hemodynamic status and may be different from the EOA predicted before valve replacement using the mean reference EOA. For example, an SHV with a nominal mean reference EOA of 1.7 cm² may have a smaller measured EOA of 1.2 cm² because the patient is in a low-flow state. In such a patient, one may erroneously conclude that the patient has prosthesis–patient mismatch, whereas in fact the reduction of EOA is pseudo-severe (ie, valve leaflet not completely opened) because of low flow. On the other hand, the reference EOA of the implanted SHV is independent of the hemodynamics of the individual patient and thus provides an accurate assessment of the presence and severity of prosthesis–patient mismatch, regardless of the hemodynamic status of the patient. Nevertheless, considering that in vivo reference EOAs are determined in a population of patients, in vivo reference EOA values should always be considered as a value distribution (described with a mean and its standard deviation), and not only as a single mean value.

Taking these into account are necessary when using in vivo EOAs for evaluating the hemodynamic performance of SHVs preoperatively or postoperatively, or when assessing the risk of prosthesis–patient mismatch. We thank Dr Doenst for raising awareness of this important issue.