Testing errors in measuring the effective orifice diameter as a new sizing parameter of surgical valve prostheses

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We are very thankful to Wu and the rest of the International Organization for Standardization (ISO) Cardiac Valves Working Group (the Working Group) for their efforts to increase transparency and better inform surgeons about the orifice sizes of prosthetic heart valves with their 2024 paper entitled "Effective orifice diameter: a new sizing parameter of surgical valve prostheses to inform valve selection" (1). However, the paper contains essential errors in the chosen test methodology. These errors cause published effective orifice area's (EOA's) to be too small in the smaller sizes of the tested prosthetic valves in this paper.

The purpose of the study was to determine whether the effective orifice diameter (ID-effective) could be derived from the EOA measured under steady flow conditions in a repeatable and reproducible manner as described in the ISO Publicly Available Specification (PAS) 7020:2023 (2). In their paper (1), Wu *et al.* concluded that this test method provided a repeatable and reproducible characterization and the results of the steady flow round-robin study were reported, naming the manufacturers, brands and sizes.

However, we noticed in the test set-up description, that an outlet tube of 35 mm internal diameter was used for all sizes of prosthetic valves, which is in violence of the stipulations of the ISO PAS (2). The PAS describes, that for valves with an inflow orifice diameter of 20.0 mm or less a 25 mm outlet tube should be used. Using the same sized outlet tube for all sizes of inflow orifice diameters results in an underestimation of the effective orifice diameter in the smaller sizes of prosthetic valves. Furthermore, in itself this dichotomy in two sizes of outlet tubes is a regrettable simplification, as ideally each internal diameter should be matched to the appropriate outlet tube.

Regrettable also is the fact that the results were published without warning the reader about their flawed nature and without any explanation why the Working Group departed from their own published stipulations in the ISO PAS (2). Anonymisation of the various individual valvar prostheses could have avoided any misperception about the published, but only partly correct EOA's.

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We strongly suggest that this study should be repeated whilst adhering to the PAS 7020 and a revision of the study should be published. If not, we request the published EOA's to be retracted, since it consists of flawed results, by which results of a partially flawed test-up only adds to the already confusing information in valve sizing.

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Footnote

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