Your August 2015 publication, ‘No-React® Injectable BioPulmonic™ valves re-evaluated’ [7] is part of a great case study on how not all minimally-invasive valves were designed or intended to be used in the same way. The device’s label is for implant in the pulmonic valve without a major operation with CPB [2]. Given the Freiburg-specific aggressive techniques of avoiding opening up the chest further (to assure minimal invasiveness), and retrograde implantation, solid fixation was sacrificed. While this was deemed appropriate for some sick patients in a previous article on those patients [3], it was off-label use. Naturally, as the pulmonary artery (PA) grew with the child, the static valve became tilted (fixation of the stent of the valve with the PA on one side of the stent only, without bilateral fixation, can already allow the valve to tilt in one direction).

Thus the eventual tilt in the valves was possible. Paradigmatically, the turbulence created by the tilt and changes in haemodynamics cause the tissue exact reactions they describe as degenerative. We know from the ubiquitous scourg of distal stenosis in surgical pulmonary conduits that turbulence from overgrowth and undersized valves creates a fibrinous layer which is created by the turbulence and can cause distal stenosis or thicken the cusps of the valve.

The authors mention the very different results from Deorsola and Abbazze [4], but failed to understand why. Deorsola and his group followed labelling and understood two things: that oversized valves are haemodynamically ideal, and that under normal conditions, the No-React® tissue does not incite foreign body reactions. These two concepts were combined in Italy to widen the PA surgically with a patch, oversize the valve (by 2–3 sizes), and thus implant a valve usually reserved for a young adult in a very young child. Most importantly, some of the valves the Italians implanted actually expanded with the child’s PA over time, assuring a fit that only a very biocompatible device could provide. This powerful surgeon-empowered technique is far superior haemodynamically to the cardiologist-focused balloon expansion and valves-in-valves, avoiding 3–4 interventions or surgery as those Italian children grow. Again, the Freiburg group focused on a particular approach, which is not necessarily better for patients.

Cardiologists are an important part of the clinical equation. But as a community of surgeons and cardiologists working together, we need to better understand that each of the minimally-invasive valves were designed differently, and find their best [and impressive] performance when used correctly. If this valve is oversized and fixed on both lateral sides, the clinical results have shown that it goes beyond the nine years experience that Freiburg had with this valve. It is interesting that none of the original authors who have published two papers on this valve and had a positive impression, since they wrote the article several years after they observed the advantages, while the minimally-invasive cardiologist that published this paper, even though most of the valves were used off-label and the patients were children or teenagers that were still growing, they seem to claim that nine years in the child is not enough even though they presented only a few patients in the paper and did not describe all seven cases.

Yes, the results were discouraging for Freiburg, but only for pure interventionists. The cardiac surgeons who employ oversizing to avoid many interventions have been quite satisfied.

Conflict of interest: The author is a heart surgeon and the inventor of this valve.

References