size 31-mm *stented* control valve. We actually tested *10* valves in each category of small (19 mm), medium (25 mm) and large (29 mm) sizes for a total of 30 wear tests. Furthermore, to provide a more rigorous trial for the valve, we tested it against the SJM Toronto SPV (St Jude Medical, Inc, St Paul, Minn), a *stentless* valve approved by the FDA for commercial distribution in the United States. We note that Mr Biancucci did not challenge the accuracy of the data that we reported for accelerated wear testing in the article.

We agree with Mr Biancucci that the paragraph titled "Visualization of Flow Across the 3F Aortic Bioprosthesis" that appears in the Results section of the paper is technically incorrect in that it states that we performed flow visualization studies in valves other than the 19-mm valve size. However, the unintentional and harmless nature of this error is verified by the fact that in that same paragraph we stated that we used the smallest size valve (19 mm) in the stiffest aortic testing chamber (4% compliance) to illustrate the lack of turbulence shown in Figures 4 and 5. In fact, the FDA-sanctioned protocol, to which we were meticulously adhering, called for the testing of 19-mm valves *only,* because of their predictably higher Reynolds numbers and the scientifically acceptable practice of extrapolating the lack of turbulence observed in our small 19-mm valve to its larger sizes without having to test the larger sizes individually. Thus, the information reported in the article relating to the lack of turbulence associated with the 3F Aortic Bioprosthesis is scientifically accurate and conforms precisely to the FDA testing protocol.

Again, rather than challenging the fundamental truth, accuracy, and/or interpretations of the finite element analysis studies, Mr Biancucci chose to attack the technical aspects of the manuscript. The original studies were performed in 1991 to validate or refute the concept of the tubular prosthesis and, as clearly shown in Figure 10, confirmed that the greatest degree of stress on a simple tube, subjected to the same anatomic constraints as the native aortic valve, occurs in the belly of the resultant tubular "valve" and the least degree of stress occurs where the commissural posts of that tubular "valve" would be. The absolute levels of stress on that hypothetical tubular valve were far greater than the absolute levels of stress that occur with the actual 3F Aortic Bioprosthesis in its final tubular design (Figure 6).

The relative stress scale shown beside the valve leaflet in Figure 6 clearly shows at the right side of the figure that the commissural region from the bottom to the top is virtually stress free with only minor stress along the leading edge of the leaflet that disappears as it nears the region of the commissural tab. It is possible that Mr Biancucci is referring to the minor stress on the left side of the figure that appears to be in the commissural attachment area but is only so due to the orientation of the view. Perhaps a quick review of the magnitude and distribution of stress on currently available artificial tissue valves would enlighten Mr Biancucci to the potential of the 3F Aortic Bioprosthesis to extend the life of artificial tissue valves.

Finally, in none of his comments, with the possible exception of those directed at the finite element studies, did Mr Biancucci challenge the accuracy of the reported data or of our interpretations of the data. Mr Biancucci states in his closing paragraph that his criticisms "are not intended to be petty or esoteric." There is little wonder that he felt it necessary to add that disclaimer. Mr Biancucci may not be enamored with the concept that underlies this valve or with its tubular geometry, but the objective observations described in our article would seem to trump his subjective opinion. Furthermore, we question his qualifications to lecture us, and by implication the editors and reviewers of the *Journal of Thoracic and Cardiovascular Surgery*, on the importance of producing "intellectually and scientifically rigorous" papers. One of the criteria of intellectual honesty is to reserve authorship on scientific papers to those contributors who have earned it, a criterion that we are confident was satisfied with the publication of this article.

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## Improved prosthesis–annulus interaction and postoperative hemodynamic performance of new-generation aortic bioprosthesis

***To the Editor:***

We read with extreme interest the article, "Small Aortic Annulus: The Hydrodynamic Performances of 5 Commercially Available Tissue Valves," published in the May 2006 issue of the *Journal*.[1] We would like to congratulate Gerosa and coauthors for the well-designed study, but we would also add some brief comments. The authors evaluated in vitro performances of 5 bioprosthesis designed for supra-annular implantation and showed improved performances of the Mitroflow valve compared with the CE Perimount Magna (for cardiac output $\geq$ 5 L/min). Inasmuch as the nominal size is not uniform for different prosthesis, they compared the size of each type fitting a 21-mm mounting ring (mimicking a 21-mm aortic annulus). The concept of supra-annular design is, however, different for the different prosthesis used in the study. As we[2] recently showed, the CE Perimount Magna, the new generation of CE Perimount characterized by a new sewing cuff, allows the implantation of a bigger size prosthesis than does the standard CE Perimount valve in almost 50% of patients. This is due to the improved interaction between the new sewing cuff and the aortic surgical annulus, which is not a flat plane. This improved annulus-prosthesis interaction could also explain the improved in vivo performance of the CE Perimount Magna when compared with the standard CE Perimount valve of the same size, even though the valve itself (housing and leaflets) is not changed.

The supra-annular concept of the Mitroflow valve is different inasmuch as the sewing ring is on a flat plane. The mounting ring used in the study from Gerosa and coauthors is also on a flat plane, and this may have influenced the results of the study. In vitro hemodynamic performances of the CE Perimount Magna valve reported in this study, in fact, do not reflect in vivo hemo-

dynamic performances that we reported in our study and that were also confirmed by other authors.[3] This is quite unusual because, as the authors also state in their article, the in vitro effective orifice areas usually tend to overestimate the in vivo effective orifice areas. Furthermore, hemodynamic performances reported by Gerosa and coauthors do not reflect the in vitro hemodynamic performances reported for the CE Perimount standard valve by Marquez, Hon, and Yoganathan,[4] even though, as we already stressed, the valve itself is not changed.

In conclusion we agree with the authors that in vivo hemodynamic behavior of a valve might differ from our idealized assumption. However, we do believe that in the case of prostheses with a supra-annular design, such as the CE Perimount Magna, in vivo performances could be improved owing to the improved annulus-prosthesis interaction. In vitro tests, like those reported in this study, are extremely useful in evaluating opening mechanism as well as descriptive parameters for each prosthesis. However, a real comparison of hemodynamic performances of two valves with such a different design as the Mitroflow and CE Perimount Magna can be made only in a randomized study evaluating cumulative mean postoperative effective orifice areas for two groups.

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***Reply to the Editor:***

We appreciate the comments of Drs Totaro and Argano on our recent article reporting in vitro performances of 5 different aortic tissue valves designed for supra-annular implantation.[1] To our minds, Drs Totaro and Argano raised more questions than comments, and we will discuss them in this reply.

***Supra-annular concept.*** During aortic valve surgery, one of the main end points should logically be to relieve as much stenosis as possible by ensuring that the indexed effective orifice area (EOA) after the operation is above 0.85 to 0.90 $cm^2/m^2$.[2] Hence, it seems logical to implant supra-annular valves that are placed on top of the aortic annulus.[3] The Medtronic Mosaic, Carpentier-Edwards Magna, Sorin Soprano, SJM-Biocor-Epic-Supra, and Mitroflow valves all belong to this category of prostheses. The concept of supra-annular design is exclusively related to the placement of a specifically designed prosthesis, whether mechanical or biological, on the top of the aortic annulus. The patient annulus-prosthesis stent interaction may explain why different valves are more easily implanted than others, such as the Sorin Soprano[4] and the Mitroflow valves, which have a flat profile. However, it cannot explain differential hydraulic performances. Unfortunately, at present, the hypothetical differential hydraulic behavior between different prosthetic heart valves has not yet been sufficiently and comprehensively revealed.

***The mounting ring of the pulse duplicator may have influenced the results.*** We tested production quality bioprostheses including the sewing ring cuffs secured in between the 2 O-rings of the pulse duplicator holder. To allow a meaningful comparison regardless industry-labeled valve size, we tested the supra-annular tissue valves with a tissue annulus diameter that could be fit in a 21-mm pulse duplicator ring. Owing to the supra-annular configuration, the opposite ring to fix the valve measured a size larger than the first (23 mm), therefore mimicking patient annulus-prosthesis interaction. The valves and the holder were sealed before testing. We agree with Drs Totaro and Argano that the pulse duplicator holder has a flat profile. Nevertheless, we selected a relatively homogeneous group of valves by using those with the largest tissue annulus diameter that could be superimposed in a definite pulse duplicator ring, without forcing the insertion, to avoid stent modification. We are fully aware that the distortion of the normal planar geometry of the pericardial prosthesis, induced by fixation with a second inadequate ring, may result in failure of adequate central leaflet coaptation. This was not the case in our study. Unfortunately, Totaro and Argano failed to constructively and fully explain how the mounting ring of the pulse duplicator may influence the comparison of different tissue valves analyzed under identical conditions.

***Our in vitro hydrodynamic performances do not reflect the in vivo results reported by Totaro and associates.***[5] The EOA, the most commonly used parameter for prosthetic heart valve comparison, is usually calculated by dividing the flow measured in the left ventricular outflow tract by transvalvular velocity. Meanwhile, whereas the EOA was initially believed to be a flow-independent parameter, Kadem and coauthors[6] recently suggested that it is actually a flow-related parameter. Therefore, the predominance of unsteady effects at low flow rates may be further considered in measuring prosthetic EOA.[6] Moreover, as recommended by the American Society of Echocardiography,[7] measurements should be made over 3 cycles in sinus rhythm or over 6 cycles in atrial fibrillation. It is further suggested that regurgitant jets also be calculated. These should be localized and then graded by a combination of the diameter of the base of the jet and the density and slope of the aortic regurgitant signal. Additionally, focusing on prosthetic heart valve comparison, the in vivo values should ideally be measured 1 year after the operation, because the latter may change during the first postoperative year.[2] Concerning the pressure recovery phenomenon, it has been shown that mild stenosis, such as in a patient with a prosthesis, and a small aortic root may lead to confounding echocardiographic results.[8] Pibarot and Dumesnil[2] also observed that the impact of a mismatch may be overestimated in these patients; thus, under the same indexed EOA, patients with a smaller aorta will have less energy loss and less burden on their left ventricle than those with a larger aorta.

To summarize, unfortunately, in vivo studies are not only limited by echocardiographic technical pitfalls, but also different clinical setting may intervene, leading to