Letters to the Editor

The Editor welcomes submissions for possible publication in the Letters to the Editor section that consist of commentary on an article published in the Journal or other relevant issues. Authors should:

- Include no more than 500 words of text, three authors, and five references
- Type with double-spacing
- See <http://jtcs.ctsnetjournals.org/misc/ifa.html> for detailed submission instructions.
- Submit the letter electronically via jtcvs.editorialmanager.com.

Letters commenting on an article published in the JTCVS will be considered if they are received within 6 weeks of the time the article was published. Authors of the article being commented on will be given an opportunity to offer a timely response (2 weeks) to the letter. Authors of letters will be notified that the letter has been received. Unpublished letters cannot be returned.

The following *Reply to the Editor* refers to an article and a corresponding letter to the editor published in two previous issues of the *Journal*: Cox JL, Ad N, Myers K, Gharib M, Quijano RC. Tubular heart valves: a new tissue prosthesis design—preclinical evaluation of the 3F aortic bioprosthesis. *J Thorac Cardiovasc Surg*. 2005;130:520-7; and Biancucci B. Tubular heart valves. *J Thorac Cardiovasc Surg*. 2006;131:1419.

Tubular heart valves

Reply to the Editor:

We are appreciative of the work that Mr Biancucci performed while he was an employee of 3F Therapeutics, Inc, and we welcome the opportunity to respond to his letter.¹ We regret that Mr Biancucci feels slighted because he was not designated as one of the authors on the article.² It is our practice to limit authorship for articles to those who made significant and/or unique contributions. There is a rather long list of contributors who would have been considered for authorship before Mr Biancucci, some of them extending back to when the initial work on this valve began over 15 years ago.

Mr. Biancucci states: “The text gives the impression that a laser micrometer was used to measure aortic chamber compliance during flow testing. Those measurements were actually made on valveless chambers in a separate test system before flow testing.”

Unlike previous so-called “stentless” tissue valves, there is no supporting structure whatsoever for the 3F Aortic Bioprosthesis (3F Therapeutics, Inc, Lake Forest, Calif). In fact, once implanted, the aortic wall serves as the stent for this artificial valve, much as it does for the native aortic valve. Therefore, it was obvious that the in vitro performance of this valve could be affected by the material used to secure it for testing. Thus, before initiating the in vitro testing on this valve, we met with the Food and Drug Administration (FDA) in Washington, DC, to discuss proposals for

protocols on how to test this truly stentless valve. The FDA Heart Valve Guidance, a set of guidelines that includes stentless valves, was followed precisely throughout the testing procedure. The FDA’s guidelines called for the creation of two sets of aortic compliance chambers, one set engineered to 4% compliance and one set engineered to 16% compliance. These precise specifications were met by confirming compliance of artificial aortic chambers using a laser micrometer, as stated clearly and accurately in the article. The compliance of these testing chambers was documented without implanted valves, as prescribed by the FDA, rather than during flow testing of the bioprosthesis.

Mr Biancucci also objected to our description of the use of a corn starch solution for a portion of the flow visualization studies that he characterized as “nonsensical.” The corn starch scattering agent was used for verification of the applicability of the Bernoulli equation for Doppler flow studies, ultrasound requiring an acoustical scatterer, which perhaps we did not clarify properly in the article. In the next paragraph of the article, however, we clearly described how “silver-coated glass particles of 40- μ m average size” were used during laser flow visualization for particle image velocimetry.

Mr Biancucci also took issue with our use of the term “Hz” to describe the test rate of the valves in the accelerated wear tester. Our use of the term “Hz,” which is commonly used to mean “cycles,” is technically incorrect. The rate should have been stated as “700 to 900 cycles per minute.”

Mr Biancucci implied that we mislead readers in describing the wear testing of the valve when we stated that we had performed 2 tests each on 5 valve sizes for a total of 10 wear tests. We actually performed *three times* that number of tests on the valve, so, in a sense, Mr Biancucci was correct, though his implication was not. The FDA requires 3 valves of the smallest size, 3 valves of medium size, and 3 valves of the largest size to be tested against one

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 ab-

solute 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 ≥ 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 we² 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-