Tubular heart valves: A new tissue prosthesis design—Preclinical evaluation of the 3F aortic bioprosthesis

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Background: It was hypothesized that native heart valves function as if they were simple tubes with sides that collapse when external pressure is applied. Because “form follows function,” this hypothesis could theoretically be confirmed by implanting a simple tube into the anatomic position of any native heart valve and documenting that under the same anatomic constraints and physiologic conditions as the native valve, the tube would assume the form of that native valve. If the hypothesis were thus proved, it would follow that a tissue valve based on a tubular design would have superior flow dynamics and stress distribution and would therefore be expected to outlast currently available tissue valves. Such a tubular tissue valve, the 3F Aortic Bioprosthesis (3F Therapeutics, Inc, Lake Forest, Calif) was designed and tested in vitro against a commercially available stentless aortic bioprosthesis.

Methods: With the use of state-of-the-art testing equipment, some of which had to be developed especially to test this truly stentless bioprosthesis in vitro, transvalvular gradients, effective orifice areas, degree of transvalvular laminar flow, finite element analysis of the distribution of leaflet stress, and accelerated wear testing for long-term durability were evaluated for the new 3F Aortic Bioprosthesis in comparison with the St Jude Medical Toronto SPV aortic bioprosthesis (St Jude Medical, Inc, St Paul, Minn).

Results: The valve gradients were lower and the effective orifice areas were greater for the 3F Aortic Bioprosthesis at all valve sizes and under all test conditions, including cardiac outputs ranging from 2.0 to 7.0 L/min, mean perfusion pressures from 40 to 200 mm Hg, and aortic compliances of 4% and 16%. The transvalvular flow across the 3F Aortic Bioprosthesis in vitro was qualitatively smooth, with a minimum of surrounding vortices. Maximum stress occurred in the belly of the leaflets of the 3F Aortic Bioprosthesis, with minimum stress at the commissural posts. The 3F Aortic Bioprosthesis was superior to the Toronto SPV valve in accelerated wear tests.

Conclusions: These in vitro studies show that a tissue aortic valve designed on the basis of the proved engineering principle that form follows function has better hemodynamics, flow dynamics, stress distribution, and durability when compared under identical in vitro conditions with an excellent commercially available tissue aortic valve.

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Historically, tissue valve designs have resulted in transvalvular flow turbulence and improper stress distribution on the valve leaflets, two factors that can limit their long-term durability.¹⁻⁶ Because form is known to follow function, it seemed intuitive that if one could design a bioprosthesis that functioned like a native heart valve, the optimal form of the valve would have to result. Such a bioprosthesis should cause less turbulence and better leaflet stress distribution, thereby improving long-term durability. This hypothesis first demanded, however, that we determine how native heart valves function.

We hypothesized that the native cardiac valves function as if they were simple tubes with sides that collapse when subjected to external pressure. When they are collapsed (closed), their form is dictated by the natural anatomic restraints placed on that tube (ie, “form follows function”). A new tubular aortic bioprosthesis based on this concept was developed and subjected to in vitro testing, the subject of this report.

Methods

Although the tubular design was strictly preserved, some modification was necessary to convert the bioprosthesis into a clinically feasible device. Thus the clinical design evolved from a simple tube to the final product (Figure 1). The valve is constructed of 3 separate leaflets of equine pericardium cut with a specially designed laser. Contiguous wings are left on each leaflet to be interlocked as integral parts of the commissural tabs. This 3F Aortic Bioprosthesis (3F Therapeutics, Inc, Lake Forest, Calif) was then compared in vitro with the St Jude Medical Toronto SPV (St Jude Medical, St Paul, Minn) stentless aortic bioprosthesis as a control valve.

Under specific instructions formulated by the US Food and Drug Administration especially for the testing of this new truly stentless bioprosthesis, synthetic aortas were fabricated from a latex-polyurethane mixture and engineered to have compliances of 4% or 16%. The US Food and Drug Administration–approved protocol dictated that only the synthetic aortas with a compliance within $\pm 1\%$ of the 4% or 16% target compliance (as determined by means of biaxial laser micrometry) could be used in the in vitro tests.

Pulsatile Pressure-Volume Relationships (Gradients) and Effective Orifice Area

A pulsatile pressure-flow loop designed and built at 3F Therapeutics, Inc, was used for the evaluation of both control and test valves at a simulated heart rate of 70 beats/min, with systolic duration set at 35%. When mean cardiac outputs of 2.0, 4.0, 5.5, and 7.0 L/min were obtained, the corresponding driving pressure gradient data were collected at 4 mean aortic pressure ranges: 40 to 80, 80 to 120, 120 to 160, and 160 to 200 mm Hg. Two diameters with orthogonal axes were measured by the biaxial laser micrometer located 5 mm downstream of the commissural plane (sinotubular junction). Static pressure was measured through a catheter positioned in the same plane. Aortic diameter and pressure data were sampled at a rate of 700 Hz. Compliance was calculated for all 4 of the mean aortic pressure ranges. Compliance versus the rate of developed pressure (dP/dT) curves was generated, for a dP/dT span of between 400 and 4000 mm Hg/s. Transmural pressure was calculated as the difference between internal and external pressures measured 5 mm downstream of the sinotubular junction. Ten consecutive cycles of data were acquired and stored for each test condition. The flow and pressure gradient waveforms were analyzed offline by PULSE software (Brüel & Kjaer, Nærum, Denmark) to calculate a range of hemodynamic variables. The PULSE software provides a continuous curve of the pressure differential between the left ventricle and the aorta, ΔP ($P_{LV} - P_{Ao}$), for an entire cycle. Two zero crossings of the ΔP curve and the intervening values are averaged by the software to determine the value of ΔP . The user selects the zero crossings representing the beginning and the end of systolic flow for the same cycle. The

Figure 1. The design of the 3F Aortic Bioprosthesis is based on that of a simple tube. In preparing it to be a commercially viable product, the distal end of the tube was scalloped slightly (*Modified Tube*). The tube was then reconstructed from 3 separate segments of tissue attached by linear suture lines, and commissural tabs were fashioned from the adjacent tissue segments to add strength and to preclude wear at the flexion sites (*Fabricated Tube*). Finally, the proximal end of the tube was scalloped, and a small sewing rim was added.

root-mean-square (Q_{rms}) average of these values is calculated by the software and is defined as follows:

$$Q_{rms} = \sqrt{\frac{\sum_{i=1}^N Q_i^2(t)}{N}},$$

where $Q_i(t)$ are flow data points in milliliters per second, $i=1$ is at the beginning of systole, and $i=N$ is at end-systole. Effective orifice area (EOA) in square centimeters is defined as follows:

$$EOA = \frac{Q_{rms}}{51.6\sqrt{\Delta p}}.$$

All of these variables were imported into Microsoft Excel (Microsoft, Inc, Seattle, Wash), and the data were used to calculate EOA as an average of 10 cycles for a given valve. This result was then averaged with two valves of the same size to give an average for a given valve diameter. Calculated results for the transvalvular pressure gradients and the EOAs of each of the valve sizes were then exported directly from the software into a data file that was further analyzed in a spreadsheet.

Visualization of Transvalvular Flow

The test fluid used to visualize transvalvular flow was a blood analog solution (vol/vol) of glycerin (42%) and distilled water (58%). This mixture has a room temperature viscosity of 4.5 cP and a density of 1.12 g/mL. Five milliliters of cornstarch was added to a 60-mL syringe and then mixed with 40 mL of the test fluid. This mixture was injected into the flow loop to act as an acoustic scattering agent.

Figure 2. Transvalvular gradients across the 3F Aortic Bioprosthesis (3F) were less than gradients across the Toronto SPV valve (SPV). The upper 2 panels show the gradients compared for 29-mm valves in a "normal aorta" (16% compliance) and in a "stiff aorta" (4% compliance) at cardiac outputs ranging from 2.0 to 7.0 L/min. The lower 2 panels show the same comparisons for 19-mm valves. The mean perfusion pressure was 80 to 120 mm Hg in these examples (see Table E1).

Flow visualization across the 3F Aortic Bioprosthesis was accomplished by the pulsatile system described above. The smallest valve (19 mm) was used for these studies so that the analysis would occur at the highest Reynolds number. The effect of aortic compliance on the flow pattern was also determined by visualizing flow in both the 4% and 16% compliant aortic chambers. A YAG-Nd laser source ($\alpha = 532$ nm) was projected through a cylindrical lens through the blood analog test fluid that was seeded with silver-coated glass particles of 40 μ m in average diameter to aid in the visualization process. A video camera and computer were used for image acquisition. Flow through the bioprosthesis was maintained at 5.4 L/min at a heart rate of 70 beats/min and a mean pressure of 95 mm Hg. Two imaging planes 30° apart were recorded through the valve throughout the cardiac cycle. Particle image velocimetry analysis was performed on the acquired images in the Department of Bioengineering at California Institute of Technology to quantify the flow field immediately downstream of the valve.

Finite Element Analysis of Stress Distribution

The characteristics of equine pericardium of specific thickness were incorporated into the finite element model for calculation of stresses and strains. The model was delivered to Structural Research and Analysis Corporation (Los Angeles, Calif) as a Solid-

Works assembly file. The solid model was modified to facilitate the analysis without any changes to the overall dimensions, those of a 29-mm 3F Aortic Bioprosthesis. The modifications included the introduction of split lines to subdivide the leaflets into panels. These panels were necessary to create symmetry models and also, more importantly, to define gap-contact surface pairs during closure. The projected split lines were defined in such a way that they coincided with creases that would form during the valve function. Once these split lines were defined, the entire geometry was exported to GEOSTAR (Structural Research Corp) through COSMOS/Works. In GEOSTAR the panels required for a one-half symmetry model were isolated and meshed by using 3-node shell elements. The average element size was 1 mm for the leaflets and 0.5 mm for the commissural tabs.

Accelerated Wear Testing for Long-Term Durability

There is no standardized method for determining the clinical durability of a new bioprosthesis in vitro. However, it is customary to subject a new bioprosthesis to accelerated cycling at 700 to 900 Hz for a total of 200 million cycles at valve-closing pressures of 100 ± 10 mm Hg at 37°C. Two hundred million cycles in vitro is generally accepted to be equivalent to only 5 years clinically, but experience has shown that if a bioprosthesis is doomed to fail

Figure 3. The effective orifice areas (EOA) of the 3F Aortic Bioprosthesis (3F) were equal to or greater than those for the Toronto SPV valve (SPV). The upper 2 panels show the effective orifice areas compared for 29-mm valves in a "normal aorta" (16% compliance) and in a "stiff aorta" (4% compliance) at cardiac outputs ranging from 2.0 to 7.0 L/min. The lower 2 panels show the same comparisons for 19-mm valves. The mean perfusion pressure was 80 to 120 mm Hg in these examples (see Table E2).

clinically, it will do so before 5 years' equivalence of in vitro accelerated wear testing.^{5,6}

Five 3F Aortic Bioprostheses of a given size and one control valve of the same size were placed in each Dynatek-Delta Heart Valve Durability Testing Device, which was controlled by the Dynatek Delta PC6000 Controller and Data Acquisition System (Dynatek Inc, Columbia, Mo). Six separate testing devices, each holding 5 test valves and one control valve, were used to perform 10 complete (200 million cycles) durability tests, 2 for each valve size (19-, 21-, 23-, 25-, and 27-mm valves). All valves were sutured into the synthetic aortic chambers, with aortic compliance of 4% ± 1% measured as described above. The fluid medium circulating through the accelerated wear testers was normal saline to which 20 ppm Kathon preservative was added to prevent proliferation of bacterial or fungal organisms. External chamber pressure was atmospheric.

Valve opening and closing were observed by strobe light every 10 million cycles. All valves were inspected under 10× magnification and photographed at 0, 60, 80, 100, 120, 140, 160, 180, and 200 million cycles. During the inspection cycle, hydrodynamic performance under pulsatile conditions of both the control and the test valves were measured at 0, 60, 140, and 200 million cycles.

Results

Pulsatile Pressure-Volume Relationships and Effective Orifice Area Comparisons

In all tests under all conditions including aortic compliances of 4% and 16%, at all 4 mean pressure groups, at all recorded cardiac outputs, and at all valve sizes, the pressure gradients across the 3F Aortic Bioprosthesis were less than those across the control valve (Figure 2 and Table E1).

The EOAs of all 3F Aortic Bioprostheses were equal to or greater than those of the control valve under all comparable testing conditions (Figure 3 and Table E2). These data paralleled the pressure-volume relationships for the 3F Aortic Bioprosthesis and the control valve.

Visualization of Flow Across the 3F Aortic Bioprosthesis

Individual velocity vector plots and velocity profiles were recorded for each valve size during systole and diastole in two separate planes of both the 4% and 16% compliant aortic chambers. Because the worst turbulence would be expected to occur during systole in the smallest-sized valves

Figure 4. The velocity field across the 3F Aortic Bioprosthesis during maximum flow in the fully open valve position. *Inset*, Simultaneous recording of the cross-section velocity profile of aortic flow immediately downstream of the valve.

Figure 5. The vorticity field across the 3F Aortic Bioprosthesis during maximum flow in the fully open valve position. Note the lack of turbulence across the valve.

implanted in the stiffest (ie, least compliant) aortas, the examples shown in [Figures 4 and 5](#) are for a 19-mm 3F Aortic Bioprosthesis in a 4% compliant aortic chamber. Note the maintenance of flow integrity ([Figure 4](#)) and the lack of any detectable turbulence ([Figures 4 and 5](#)). This nonturbulent flow was characteristic of the transvalvular flow observed during systole and diastole for all valve sizes in both the 4% and 16% compliant aortic chambers.

Finite Element Analysis of Stress Distribution

The distribution of stress on the leaflets of the 3F Aortic Bioprosthesis shows the greatest degree of stress to be in the belly of the valve leaflets, with less stress at the commissural posts ([Figure 6](#)).

Accelerated Wear Testing for Long-Term Durability

Direct comparisons of the simultaneous performances of the 3F Aortic Bioprosthesis and the control valve documented the superior durability of the 3F Aortic Bioprosthesis under these controlled in vitro conditions ([Figures 7 and 8](#)). In both the 19-mm and the 29-mm valves, evidence of wear in the control valve was apparent by 100 million cycles, whereas there was no evidence of wear at that time in the 3F Aortic Bioprosthesis. At 200 million cycles, this difference became even more obvious, with the control valve near disintegration, whereas the 3F Aortic Bioprosthesis still showed no evidence of wear in most instances. These differences in durability for all valves tested can be quantitated only by noting the number of valves of each type that survived the complete 200-million-cycle program ([Figure 9](#)).

Figure 6. Finite element analysis of the 3F Aortic Bioprosthesis confirms the optimal distribution of stress on the leaflets, with a minimum amount of stress at the commissural posts. This finding should favor enhanced durability of this tissue valve.

Discussion

The primary goal of this project was to develop a tissue bioprosthesis that would overcome the durability problem that has characterized previous tissue valves. Al-

Figure 7. The 19-mm 3F Aortic Bioprosthesis showed superior performance in comparison with the control valve in the accelerated wear tests to determine long-term durability. Note that at 200 million cycles, the 19-mm 3F Aortic Bioprosthesis shows little or no evidence of structural failure. These findings would be expected in a valve with superior flow dynamics (less turbulence) and more optimal stress distribution on its leaflets.

Figure 8. The results of the accelerated wear tests were the same regardless of valve size, as evidenced by this series of photographs showing the superior durability of the 29-mm 3F Aortic Bioprosthesis in comparison with the control valve.

though tissue valve durability problems have long been attributed to such factors as inappropriate tissue type⁷ and the fixation process,⁸ it is worth noting that congenitally bicuspid aortic valves calcify, despite having none of those problems.⁹ The frequent failure of the commercially available bioprostheses by tearing at the commissural posts¹⁰ is consistent with previous experimental studies showing that the greatest points of stress on those valves are at the commissural posts.¹¹ Conversely, the normal human aortic valve does not cause turbulence and has its least level of stress at the commissural posts, the pattern recreated by the tubular design of the 3F Aortic

Bioprosthesis (Figure 9). These factors would seem to be at least as important as the substrate material, the fixation process, or both, in limiting the durability of available bioprostheses. A design based on the principle that form follows function requires the determination of how native cardiac valves function. We hypothesized that native heart valves function as simple collapsible tubes and that the form assumed by the 4 normal heart valves in the collapsed (closed) position is dictated by the constraints that nature places on each end of that tube. If a collapsible tube is inserted into a native valve site and subjected to the same constraints as the native valve, it must take the form of that native valve during closure or else the concept is incorrect.

We first tested this hypothesis in 1991, when we subjected simple computerized tubes to CAD/CAM finite element analysis. The tubes were constrained as if they were in the aortic position, subjected to “diastolic” pressures of 80 mm Hg, and then allowed to deform according to the mathematic formulas governing each finite element in their walls. The resultant shape (form) of the aortic “valve” (Figure 10) strongly suggested that native valves indeed function like collapsible tubes, their final form depending on their anatomic constraints. Most importantly, these early studies showed that the major degree of stress on these “tubular valves” was in the belly of the “leaflets” and that the least stress was at the site of what would be the “commissural posts” if the tubes were in the anatomic aortic valve position.

Figure 9. The percentage of 3F Aortic Bioprostheses that survived the full 200-million-cycle testing process was significantly greater than the percentage of surviving control valves.

Figure 10. These figures were the first to document that a simple tube would take the shape of the normal human aortic valve when subjected to the same anatomic constraints and external pressure of the human aortic valve. **A**, A simple tube made up of finite elements was placed in a CAD/CAM environment and constrained at its proximal end and at 3 equidistant points on its distal end precisely 120° apart. **B**, A constant external pressure of 80 mm Hg was applied to the outside of the tube in panel **A**, and the tube was allowed to deform according to the mathematic formulas guiding the response of each finite element. **C** and **D**, Several hours (this was in 1991) after the external pressure application, the 3 free sides of the tube have collapsed, closing the tube from 3 sides and forming a perfect "aortic valve." Note that the least stress (same scale as in Figure 6) was at the level of what would be the commissural posts, and the greatest stress was in the belly of the "leaflets" of this "aortic valve," mimicking the stress distribution in the normal human aortic valve.

During the ensuing 7 years, autologous tissue grafts of small-intestine submucosa were implanted in the mitral, aortic, and tricuspid positions of dogs and sheep. The hemodynamic performance of the tubular valves was excellent in all 3 positions, and their form at the time of closure was documented to mimic that of the replaced native valve by means of both visual inspection and echocardiography.

The in vitro tests described above document the promise of this new type of aortic bioprosthesis. The gradients measured across the valve are remarkably low and are superior to those of the control valve used in this study. In view of the superb flow characteristics, in combination with the lower gradients

and optimal stress distribution, it came as no surprise that the 3F Aortic Bioprosthesis outperformed the control stentless bioprosthesis in the accelerated wear tests.

Finally, only brief mention has been made in this communication of the type of tissue that is used in the construction of the 3F Aortic Bioprosthesis. That is because in our opinion the critical component of this new bioprosthesis is its design and not the type of tissue used in its construction. Despite that bias and at least one publication questioning the durability of equine pericardium,¹² we selected equine pericardium after intensive in vitro testing of numerous potential tissues because of its decreased thickness, superior flexibility, and increased tensile strength in comparison with other available materials in our studies, including both bovine pericardium and small-intestine submucosa. On the basis of the in vitro studies reported in this communication and of the in vivo performance of the tubular equine pericardial 3F Aortic Bioprosthesis previously reported,¹³ a clinical trial was initiated on October 3, 2001, in Aalst, Belgium, which will be reported in a subsequent communication.

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TABLE E1. Complete data for the valve gradients of all 19-mm and 29-mm 3F Aortic Bioprostheses and Toronto SPV valves analyzed.

29-mm Valve with 16% aortic compliance								
Cardiac output (L/min)	Mean perfusion pressure = 40-80 mm Hg		Mean perfusion pressure = 80-120 mm Hg					
	3F gradient (mm Hg)	SPV gradient (mm Hg)	3F gradient (mm Hg)	SPV gradient (mm Hg)				
2.0	2.52 ± 0.10	3.44 ± 0.05	2.86 ± 0.11	4.03 ± 0.06				
4.0	3.91 ± 0.10	6.42 ± 0.15	4.74 ± 0.1	7.79 ± 0.19				
5.5	4.17 ± 0.07	10.19 ± 0.15	5.85 ± 0.1	10.32 ± 0.27				
7.0	4.92 ± 0.08	11.33 ± 0.24	7.24 ± 0.21	13.57 ± 1.07				
19-mm Valve with 16% aortic compliance								
Cardiac output (L/min)	Mean perfusion pressure = 40-80 mm Hg		Mean perfusion pressure = 80-120 mm Hg					
	3F gradient (mm Hg)	SPV gradient (mm Hg)	3F gradient (mm Hg)	SPV gradient (mm Hg)				
2.0	6.15 ± 0.39	10.77 ± 0.24	7.99 ± 0.23	13.69 ± 0.35				
4.0	10.11 ± 0.32	17.29 ± 0.32	12.79 ± 0.33	19.47 ± 0.35				
5.5	10.83 ± 0.27	17.45 ± 0.39	16.45 ± 0.35	22.37 ± 0.61				
7.0	13.72 ± 0.34	22.74 ± 0.46	21.03 ± 0.67	29.74 ± 0.60				
29-mm Valve with 4% aortic compliance								
Cardiac Output (L/min)	Mean perfusion pressure = 40-80 mm Hg		Mean perfusion pressure = 80-120 mm Hg		Mean Perfusion Pressure 120-160 mmHg		Mean Perfusion Pressure 160-200 mmHg	
	3F gradient (mmHg)	SPV gradient (mm Hg)	3F gradient (mm Hg)	SPV gradient (mm Hg)	3F gradient (mm Hg)	SPV gradient (mm Hg)	3F gradient (mm Hg)	SPV gradient (mm Hg)
2.0	1.30 ± 0.2	2.66 ± 0.07	0.93 ± 0.15	1.69 ± 0.12	1.35 ± 0.12	0.95 ± 0.06	1.64 ± 0.31	0.48 ± 0.1
4.0	2.90 ± 0.13	5.65 ± 0.13	2.07 ± 0.13	5.36 ± 0.23	2.72 ± 0.32*	4.97 ± 0.37	2.31 ± 0.67*	5.00 ± 0.5
5.5	3.93 ± 0.34	7.75 ± 0.29	2.85 ± 0.46	8.80 ± 0.24	2.50 ± 0.20	9.21 ± 0.37	2.82 ± 0.31*	9.16 ± 0.59
7.0	4.41 ± 0.29	10.47 ± 0.24	4.55 ± 0.16	13.98 ± 0.42	3.45 ± 0.24	13.32 ± 0.35	2.79 ± 0.41	13.66 ± 0.52
19-mm Valve with 4% aortic compliance								
Cardiac Output (L/min)	Mean perfusion pressure = 40-80 mm Hg		Mean perfusion pressure = 80-120 mm Hg		Mean perfusion pressure = 120-160 mm Hg		Mean perfusion pressure = 160-200 mm Hg	
	3F gradient (mm Hg)	SPV gradient (mm Hg)	3F gradient (mm Hg)	SPV gradient (mm Hg)	3F gradient (mm Hg)	SPV gradient (mm Hg)	3F gradient (mm Hg)	SPV gradient (mm Hg)
2.0	6.15 ± 0.37	10.60 ± 0.16	5.59 ± 0.19	11.45 ± 0.37	5.42 ± 0.3	12.40 ± 0.33	4.81 ± 0.14	13.91 ± 0.39
4.0	9.71 ± 0.36	24.80 ± 0.41	9.61 ± 0.29	25.90 ± 0.47	10.07 ± 0.58	29.32 ± 0.55	10.76 ± 0.58	31.22 ± 0.57
5.5	10.51 ± 0.17	28.21 ± 0.44	12.87 ± 0.51	38.71 ± 0.85	14.31 ± 0.4	42.36 ± 0.58	14.04 ± 0.53	46.47 ± 0.8
7.0	14.98 ± 0.24	40.78 ± 0.41	16.84 ± 0.63	57.01 ± 1.45	18.38 ± 0.99	64.52 ± 0.76	16.26 ± 0.82	62.15 ± 1.26

Note that the measurements taken at a mean perfusion pressure of 80 to 120 mm Hg are the ones that are shown in Figure 2. The standard deviations of the graphed data were deleted from the figure in the interest of clarity but appear in this table. 3F, 3F Aortic Bioprosthesis; SPV, St Jude Medical Toronto SPV aortic bioprosthesis. *The authors were requested by the editor and reviewers to remove data on several tested prostheses because the calculations involved with gradients across the 3F Aortic Bioprosthesis of less than 1 mm Hg distorted the cumulative result out of proportion to their value.

TABLE E2. Complete data for the effective orifice areas of all 19-mm and 29-mm 3F Aortic Bioprostheses and Toronto SPV valves analyzed.

29-mm Valve with 16% aortic compliance								
Cardiac output (L/min)	Mean perfusion pressure = 40-80 mm Hg				Mean perfusion pressure = 80-120 mm Hg			
	3F EOA		SPV EOA		3F EOA (cm²)		SPV EOA (cm²)	
	(cm²)		(cm²)					
2.0	1.78 ± 0.04		1.37 ± 0.02		1.73 ± 0.04		1.40 ± 0.02	
4.0	2.33 ± 0.04		1.78 ± 0.02		2.22 ± 0.03		1.68 ± 0.03	
5.5	2.33 ± 0.04		1.65 ± 0.03		2.42 ± 0.03		1.77 ± 0.04	
7.0	2.66 ± 0.05		1.81 ± 0.03		2.70 ± 0.05		1.95 ± 0.08	
19-mm Valve with 16% aortic compliance								
Cardiac output (L/min)	Mean perfusion pressure = 40-80 mm Hg				Mean perfusion pressure = 80-120 mm Hg			
	3F EOA		SPV EOA		3F EOA (cm²)		SPV EOA (cm²)	
	(cm²)		(cm²)					
2.0	1.01 ± 0.04		0.89 ± 0.02		0.96 ± 0.02		0.95 ± 0.02	
4.0	1.41 ± 0.04		1.13 ± 0.02		1.28 ± 0.02		1.14 ± 0.02	
5.5	1.53 ± 0.03		1.23 ± 0.04		1.41 ± 0.02		1.26 ± 0.02	
7.0	1.59 ± 0.02		1.29 ± 0.02		1.56 ± 0.03		1.33 ± 0.02	
29-mm Valve with 4% aortic compliance								
Cardiac output (L/min)	Mean perfusion pressure = 40-80 mm Hg		Mean perfusion pressure = 80-120 mm Hg		Mean perfusion pressure = 120-160 mm Hg		Mean perfusion pressure = 160-200 mm Hg	
	3F EOA		SPV EOA		3F EOA		SPV EOA	
	(cm²)		(cm²)		(cm²)		(cm²)	
2.0	2.65 ± 0.13	1.71 ± 0.03	3.80 ± 0.35	2.34 ± 0.09	2.44 ± 0.09	3.35 ± 0.11	3.06 ± 1.45	5.05 ± 0.05
4.0	2.64 ± 0.07	1.91 ± 0.03	3.44 ± 0.15	2.06 ± 0.05	3.16 ± 0.16*	2.22 ± 0.1	3.63 ± 0.51*	2.27 ± 0.12
5.5	2.47 ± 0.12	1.72 ± 0.04	3.67 ± 0.25	1.98 ± 0.05	4.50 ± 0.70	2.02 ± 0.05	4.74 ± 0.49*	2.09 ± 0.07
7.0	2.78 ± 0.11	1.76 ± 0.03	3.57 ± 0.09	1.98 ± 0.03	4.67 ± 0.28	2.06 ± 0.03	5.70 ± 0.81	2.14 ± 0.05
19-mm Valve with 4% aortic compliance								
Cardiac output (L/min)	Mean perfusion pressure = 40-80 mm Hg		Mean perfusion pressure = 80-120 mm Hg		Mean perfusion pressure = 120-160 mm Hg		Mean perfusion pressure = 160-200 mm Hg	
	3F EOA		SPV EOA		3F EOA		SPV EOA	
	(cm²)		(cm²)		(cm²)		(cm²)	
2.0	1.01 ± 0.04	0.69 ± 0.03	1.11 ± 0.03	0.71 ± 0.01	1.17 ± 0.04	0.75 ± 0.02	1.36 ± 0.05	0.75 ± 0.02
4.0	1.36 ± 0.05	0.81 ± 0.02	1.43 ± 0.04	0.82 ± 0.01	1.48 ± 0.07	0.84 ± 0.02	1.57 ± 0.05	0.85 ± 0.01
5.5	1.49 ± 0.03	0.85 ± 0.03	1.58 ± 0.04	0.86 ± 0.02	1.58 ± 0.03	0.86 ± 0.02	1.65 ± 0.04	0.87 ± 0.01
7.0	1.61 ± 0.03	0.90 ± 0.02	1.78 ± 0.05	0.94 ± 0.01	1.76 ± 0.07	0.92 ± 0.02	1.94 ± 0.06	0.96 ± 0.02

Note that the measurements taken at a mean perfusion pressure of 80 to 120 mm Hg are the ones that are shown in [Figure 3](#). The standard deviations of the graphed data were deleted from the figure in the interest of clarity but appear in this table. 3F, 3F Aortic Bioprosthesis; EOA, effective orifice area; SPV, St Jude Medical Toronto SPV aortic bioprosthesis. *The authors were requested by the editor and reviewers to remove data on several tested prostheses because the calculations involved with gradients across the 3F Aortic Bioprosthesis of less than 1 mm Hg distorted the cumulative result out of proportion to their value.