THE EFFECT OF SIZING ON THE IN VITRO HYDRODYNAMIC CHARACTERISTICS AND LEAFLET MOTION OF THE TORONTO SPV* STENTLESS VALVE

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Objectives: We established an in vitro model to investigate the effects of valve sizing on the hemodynamic characteristics and leaflet motion of the Toronto SPV valve (St Jude Medical, Inc, St Paul, Minn). **Methods:** Nine valves were first implanted in fresh porcine aortic roots and then retested in glutaraldehyde-treated porcine aortic roots. Three valves were 1- to 2-mm oversized, 3 were 1- to 2-mm undersized, and there were 3 size-for-size implantations. The elasticities of the aortic roots and the composite roots were measured in the pressure range between 0 and 120 mm Hg, and the composite roots were then tested in a pulsatile flow simulator. The transvalvular gradient and regurgitation were measured and the effective orifice area and performance index were calculated for each root. Leaflet motion was recorded on videotape. **Results:** The external diameter of the fresh root increased by 35% as the hydrostatic pressure rose from 0 to 120 mm Hg, as compared with 11% for the glutaraldehyde-treated root. Valve implantation in the fresh root reduced the distensibility to 22% but did not change distensibility in the glutaraldehyde-treated root. The effective orifice area was dependent on the valve size, with the transvalvular gradient decreasing as the valve size increased. For the same size of valve the hydrodynamic parameters were slightly better if the valve was undersized by 1 mm. A significant difference in favor of the undersized valves was found in open-leaflet bending deformation. **Conclusion:** Leaflet motion of the stentless porcine aortic valve in vitro is improved if the valve is slightly undersized, and this may be beneficial to the long-term durability of the prosthesis. (J Thorac Cardiovasc Surg 1999;117:92-8)

Since 1961, when aortic valve replacement was first performed, continual efforts have been made to develop the ideal heart valve substitute. Valve repair has not generally been successful in the aortic position. The pulmonary autograft is potentially the best aortic valve

substitute, but the pulmonary root still needs homograft replacement.¹ The frame-mounted bioprostheses, despite changes in the fixation technique, still have limited durability.² Furthermore, the rigid stent immobilizes the host aortic anulus and sinuses and, most important, is obstructive, especially in small sizes.³ Homograft valve durability and hemodynamic performance are better, but availability is limited.⁴ To overcome these problems there has been increasing interest in a new generation of bioprosthesis, the stentless porcine valve. Its availability is unlimited, the hemodynamic characteristics are better than those of the frame-mounted valve, and potentially the durability is longer because of increased flexibility and reduced leaflet deformation.⁵ Although the number of valves implanted is increasing, debate continues regarding the best sizing protocol and implantation technique, and long-term durability still remains to be demonstrated. In an attempt to answer some of these questions, we established an in vitro model to investigate the effect of siz-

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ing on the hydrodynamic characteristics and leaflet deformation of the Toronto SPV stentless bioprosthesis (St Jude Medical, Inc, St Paul, Minn).

Materials and methods

Three 19-mm, three 21-mm, and three 23-mm standard Toronto SPV valves were tested in our series. The valves were implanted in fresh porcine aortic roots and glutaraldehyde-treated porcine aortic roots. These 2 types of root were selected because they represent the extremes of the compliance range, as recommended by the Food and Drug Administration for valve testing.

Aortic roots. Aortic roots were dissected out from fresh pig hearts, stored at 4°C in normal saline solution, and used within 24 hours or fixed in 0.5% glutaraldehyde solution for 48 hours. The right and left coronary arteries were ligated. The annular size was measured by passing an obturator through the annulus from the ventricular side. The external diameters of the aortic roots were measured at the sinotubular junction at hydrostatic pressures of 0, 60, 80, 100, and 120 mm Hg by means of digital vernier calipers.

Technique of valve insertion. The lower rim of the valve was sewn to the host annulus with 4-0 continuous polypropylene suture from the ventricular side in such a way that the valve was sitting on the annulus. A 5-0 polypropylene commissural suspending mattress suture was placed at the top of each commissure, passing through the host aortic wall in alignment with the host's commissural attachment. The upper row of subcoronary continuous sutures was placed through the scalloped upper margin of the valve and through the half-thickness of the host aortic wall with 5-0 polypropylene suture in such a way that the coronary ostia remained clear. Then the external diameters of the composite roots were measured at the sinotubular junction at hydrostatic pressures of 0, 60, 80, 100, and 120 mm Hg.

Hydrodynamic testing. The composite roots were tested in a pulsatile flow simulator, details of which have been described previously elsewhere.⁶ The flow simulator consisted of 2 rigid cylindric test sections for each of the mitral and aortic valves, a compliance chamber, peripheral resistance, and an atrial reservoir. The system was driven by a servo-controlled piston pump. The composite roots were mounted in place of the rigid aortic valve section (Fig 1) and tested at a rate of 72 cycles/min with a stroke volume of 70 mL for a systemic pressure of 120/80 mm Hg. The pressure difference across the root was measured directly by a differential transducer, and the flow was measured with an electromagnetic flowmeter positioned downstream from the valve. Pressure, flow, pump displacement, and velocity signals were collected digitally for 10 seconds at a sampling frequency of 200 Hz and stored on disk for analysis with an IBM PS/2 computer (International Business Machines Corp, White Plains, NY).

The data were ensemble averaged to create 1 cycle, and valve function was analyzed with respect to this averaged waveform. The effective orifice area (EOA) was calculated according to the following formula: $EOA = Q/51.6 \cdot \sqrt{\Delta p}$

Fig 1. Porcine aortic root mounted in the aortic valve section of the pulsatile flow simulator, attached to appropriately sized inflow and outflow spigots.

(where Q is the root mean square forward flow in milliliters per second and Δp is the mean pressure drop during forward flow in millimeters of mercury). The performance index (PI) of the valve was derived from the following formula: $PI = EOA/\text{Theoretic orifice area}$ (where the theoretic orifice area was πr^2 , with r the radius of the valve annulus). Valve leaflet movements were recorded with a video camera positioned axially to the flow through the aorta to determine the configuration of the open valve leaflets. A spigot of the same diameter as that of the aorta in its distended state allowed a video recording of the leaflet motions of the entire valve, including the commissural area. The open-leaflet bending deformations were determined from the still image of the fully open position in midsystole by means of an image-analysis system. The open-leaflet deformation at the commissures was quantified by taking 3 points along the leaflet edge in the region of maximum deformation (Fig 2). The spatial deviation of the center point (BD) from the straight line formed by joining the 2 endpoints (AC) was used as a measure of leaflet deformation.⁷ The ratio BD/BC was used as a leaflet-bending deformation index (BDI). The BDI was quantified at all 3 commissures, and the average of these data was given as a characteristic of the valve. The mean and standard deviation of the data were calculated. Statistical analysis was performed by Student t test.

Results

The distensibilities of the roots are shown in Fig 3. The fresh aortic roots were extremely elastic, with the external diameters of the roots at the sinotubular junction dilating $35\% \pm 7.8\%$ as the pressure increased from 0 to 120 mm Hg. In the physiologic range between 80 and 120 mm Hg, there was a $10\% \pm 3.5\%$ change in external diameter. After implantation of the Toronto SPV valve the elasticity decreased significantly;

Fig 2. The fold in the leaflet (ABC) was converted into a triangle to quantify the bending in the leaflet. If BD/BC was closer to zero, the leaflet was said to be more in a straight line, whereas if it was nearing 1, the folding was considered greater.

Fig 3. The mean percentages of dilatation for native aortic root, glutaraldehyde-treated aortic root, native composite root, and glutaraldehyde-treated composite root in the pressure range between 0 and 120 mm Hg.

the dilatation from 0 to 120 mm Hg was only $22\% \pm 3.9\%$, and in the physiologic range it dropped to $5\% \pm 1.7\%$ ($P = .0001$). Glutaraldehyde treatment made the native roots a lot stiffer. We found only a change of

$11\% \pm 2.8\%$ in external diameter between 0 and 120 mm Hg pressures. Valve implantation did not reduce the distensibility of the glutaraldehyde-treated roots significantly ($P = .2$).

Table I. Transvalvular gradients measured for Toronto SPV valves implanted in different sizes of fresh and glutaraldehyde-treated porcine aortic roots

	Fresh	Glutaraldehyde-treated	P*
19 mm			.002
Oversized	7.4	11.5	
Size for size	7.1	11.9	
Undersized	6.2	10.1	
21 mm			.20
Oversized	4.7	5.9	
Size for size	5.0	5.7	
Undersized	3.4	3.9	
23 mm			.50
Oversized	7.6†	5.5	
Size for size	2.6	3.9	
Undersized	1.8‡	2.6	

All gradient values are in millimeters of mercury.

*By *t* test.

†Valve oversized by 2 mm.

‡Valve undersized by more than 2 mm.

The transvalvular gradients measured for the composite roots are listed in Table I. Obviously, the bigger valves had lower gradients in both groups. The gradients measured for the glutaraldehyde-treated composite roots were slightly greater than for the fresh composite roots, but the difference was significant only for the 19-mm valves ($P = .002$). For each valve size the measurements showed a slightly smaller gradient when the valve was undersized, but a major difference was found only when the valve was severely oversized or undersized (Table I).

Table II shows the calculated EOAs for the 2 groups of composite roots. Again, the bigger valves had larger orifice areas in both groups. It was also demonstrated that the EOA was slightly bigger in the case of undersized valves. The orifice area was significantly less for the glutaraldehyde-treated composite roots only at the 19-mm valve size ($P = .01$).

The closing volumes were similar in all valves. Regurgitation was detected only in 1 valve, which was undersized by more than 2 mm. This valve had a central coaptation defect in the diastolic phase as a result of overstretching of the valve leaflets (Fig 4). All the other valves were competent.

Table III summarizes the PIs and the BDIs of the implanted stentless valves. The sizing protocol did not have any effect on the PI for either the fresh or the glutaraldehyde-treated roots, but the PI was significantly higher in the fresh composite roots than in the glutaraldehyde-treated roots ($P = .03$). A significant difference between the oversized and undersized valves was also found in the BDI; this difference was in favor of

Table II. EOAs calculated for Toronto SPV valves implanted in different sizes of fresh and glutaraldehyde-treated porcine aortic roots

	Fresh	Glutaraldehyde-treated	P*
19 mm			.01
Oversized	1.77	1.44	
Size for size	1.83	1.54	
Undersized	1.97	1.66	
21 mm			.20
Oversized	2.22	2.01	
Size for size	2.20	2.06	
Undersized	2.66	2.47	
23 mm			.40
Oversized	1.66†	2.11	
Size for size	2.97	2.49	
Undersized	3.24‡	2.85	

All EOA values are in square centimeters.

*By *t* test.

†Valve oversized by 2 mm.

‡Valve undersized by more than 2 mm.

Table III. PIs and BDIs of the Toronto SPV valves implanted in different sizes of fresh and glutaraldehyde-treated porcine aortic roots

	Fresh	Glutaraldehyde-treated	P*
PI			.03
Oversized	60 ± 11.6	59 ± 4.4	
Size for size	66 ± 3.8	58 ± 3.5	
Undersized	66 ± 3.5	60 ± 6.4	
BDI			.20
Oversized	0.41 ± 0.10	0.44 ± 0.06	
Size for size	0.26 ± 0.07	0.36 ± 0.09	
Undersized	0.14 ± 0.06	0.27 ± 0.04	

*By *t* test.

undersizing ($P = .009$ for the fresh roots, $P = .007$ for the glutaraldehyde-treated roots). The 2-mm oversized valve in a fresh root produced a BDI of 0.55 (Fig 5). The BDI of the 1-mm oversized valves averaged 0.35 ± 0.02 (Fig 6), whereas the 1-mm undersized valves showed the best BDI of 0.17 ± 0.01 and the valves still remained competent (Fig 7). The glutaraldehyde-treated group showed a similar trend.

Discussion

The first heterologous aortic valve implantations were performed in 1964 by Binet and Duran.⁸ The early results were promising in terms of hemodynamic performance, but inadequate tissue preservation allowed early structural deterioration. The durability of bioprosthetic valves was much improved with the introduction of glutaraldehyde tissue preservation.⁹

Fig 4. Toronto SPV valve undersized by more than 2 mm. The overstretched leaflets were unable to close in diastole.

Fig 6. Toronto SPV valve oversized by 1 mm in its fully opened position.

Fig 5. Toronto SPV valve oversized by 2 mm. There was a lot of leaflet deformation in its fully open position.

Fig 7. Toronto SPV valve undersized by 1 mm. This valve showed minimal leaflet deformation in its fully opened position and was still competent.

Because of the favorable midterm results and easy implantation technique, the frame-mounted porcine valve became the bioprosthesis of choice in most cardiac centers in the 1970s and 1980s. As time passed, however, it became clear that long-term results were not ideal. Late structural deterioration has been attributed to the bending strains at the commissures caused by the rigid frame. To overcome this problem a new generation of bioprosthesis, the glutaraldehyde-fixed stentless porcine valve, was developed. In 1990 David and coworkers¹⁰ reported superior hemodynamic results in 22 freehand-implanted stentless xenografts compared with the same number of frame-mounted xenografts. Theoretically, if the durability of the valve depends on leaflet deformation and bending strains,

stentless valves should last longer than the stented valves. In this in vitro study we investigated whether the sizing of the valve has any effect on the hemodynamic performance and the leaflet deformation.

The porcine aortic roots, which were comparable in size to the human aorta, were harvested from piglets. Two major differences from the human aorta were found: the porcine aortic wall was a lot thicker, and also probably much more elastic, than elderly human calcified aortic anulus and root would be. In an attempt to reduce elasticity, a second set of porcine roots was treated with glutaraldehyde. This made the aortic wall even thicker, rubbery and stiff, which again did not show great similarity to human tissues. Implanting the valves in these 2 types of roots provid-

ed a range of compliances, however, as recommended by the Food and Drug Administration for testing free-sewn valves. Implanting a Toronto SPV valve into a fresh aortic root reduced the root's distensibility significantly. Our previous study showed that suturing fresh or glutaraldehyde-treated scalloped aortic valves into fresh aortic roots did not change the distensibility of the host root.¹¹ It is probable that the thin polyethylene terephthalate (Dacron) cloth that covered the muscle shelf and the commissures was responsible for the reduced elasticity. These types of observations are only possible when using a tissue host root model and correct surgical procedure for in vitro testing of free-sewn valves.

Our results support the previous findings of other investigators that the hemodynamic performance of the stentless valves is better than that of the frame-mounted valves, especially in small sizes.^{10,12-14} The size of the host aortic root was measured at the level of the anulus. Most of the aortic roots' internal diameters were 1 to 2 mm larger at the sinotubular junction than at the anulus. Furthermore, the aortic wall at the sinotubular junction was more distensible than the fibrous anulus, and this plays an important role in normal aortic valve function.¹⁵ We found it easier and more accurate to size the root at the anulus than at the sinotubular junction. Oversizing by 1 to 2 mm according to the anulus diameter was thus equivalent to size-for-size implantation at the sinotubular junction. The current recommendation for sizing stentless valves is that if the sinotubular junction diameter is larger than the anulus, then the larger size is used as the valve size to avoid regurgitation, as long as it is not different by more than 2 sizes. Our measurements did not show regurgitation on the undersized valves, however, even if they were implanted in extremely elastic fresh aortic roots. The single valve that was incompetent was implanted in a fresh aortic root with an internal diameter that was more than 2 mm bigger than the valve size. That particular root's internal diameter was a lot bigger at the sinotubular junction than at the anulus. On testing we found very little open leaflet bending deformation and nearly normal triangular orifice (Fig 8), but the over-stretched leaflets were unable to close in diastole (Fig 4). On the other hand, in both groups we found a slightly larger orifice area and lower transvalvular gradient on the Toronto SPV valve if it was undersized by 1 mm than in the case of either size-for-size implantation or oversizing, although the differences were not significant. Most important, the sizing had a marked effect on the open-leaflet bending deformation. In both groups the BDI was significantly lower when the valve was 1-

Fig 8. Toronto SPV valve undersized by more than 2 mm in its fully opened position. The orifice was ideally triangular, but the valve became regurgitant in diastole.

mm undersized on the anulus than if the matching size valve or an oversized valve was used.

Our in vitro measurements suggest that, in small aortic roots, 1-mm undersizing of the stentless valve results in better hemodynamic performance without the hazard of regurgitation. The reduced open-leaflet bending deformation may have an important effect on long-term durability. In dilated aortic roots with great discrepancy between the size of the sinotubular junction and the anulus (eg, poststenotic dilatation), however, the implantation of a stentless bioprosthesis is not recommended.¹⁶

Conclusion. In our series we found slightly better hemodynamic performance and significantly less open-leaflet bending deformation for the Toronto SPV stentless valve when it was implanted in a 1-mm larger fresh or glutaraldehyde-treated porcine aortic root. In those roots in which the internal diameters of the aortic root were similar at the anulus and at the sinotubular junction, the valve undersizing did not result in regurgitation. Moreover the reduced open-leaflet bending deformation could be an important determinant of long-term durability.

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