Ultrasonic assessment of the St. Jude prosthetic valve: M mode, two-dimensional, and Doppler echocardiography*

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ABSTRACT To determine whether the flow characteristics of aortic and mitral St. Jude Medical valves could be defined noninvasively, we analyzed Doppler transprosthetic flow velocity spectra in 23 relatively asymptomatic patients. Results were interpreted in the framework of M mode and two-dimensional echocardiographic data and were compared with Doppler transvalvular flow velocity spectra from native valves of healthy subjects. Although the morphologic characteristics of Doppler spectra were similar, peak and mean transprosthetic mitral flow velocities were higher than values obtained across native valves (1.38 ± 0.3 m/sec and 0.73 ± 0.1 m/sec vs 0.78 ± 0.1 m/sec and 0.35 ± 0.06 m/sec, respectively; p < .001). However, calculated pressure half-times were not different (61.2 ± 16.9 msec vs 57.2 ± 13.2 msec; p > .05) and calculated transprosthetic mitral gradients were small (2.3 ± 0.9 mm Hg). Similarly, the morphologic characteristics of aortic Doppler flow spectra in St. Jude and native valves were analogous. However, prosthetic valves exhibited higher peak and mean velocities (p < .01) and slightly prolonged time-to-peak flow (p = .02). M mode and two-dimensional studies did not show useful quantitative measures of prosthetic function and did not demonstrate evidence of paravalvular leaks, which were detected in four cases by Doppler techniques. Thus Doppler echocardiography provides quantitative information about transprosthetic flow characteristics in patients with implanted St. Jude valves and is useful in identifying patients with prosthetic dysfunction.

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CINERADIOGRAPHY,1 combined echophonocardiography2 (with M mode techniques), and two-dimensional echocardiography3 have been used to detect and characterize prosthetic valve dysfunction objectively. However, their sensitivity and specificity have not been substantiated. This reflects, in part, the modest populations in individual studies, difficulties encountered in defining parameters of normal prosthetic valves, and the lack of quantitative information suitable for comparison of individual patients. The addition of Doppler techniques to conventional echocardiography presents a promising approach for noninvasive evaluation of transvalvular flow patterns.5,6 However, little information is available concerning their application to patients with prosthetic heart valves.7-10

The St. Jude Medical valve is a low-profile, bileaflet mechanical prosthesis, recently approved for clinical use in the United States. Among the mechanical prostheses, dynamic studies performed in vitro have demonstrated that the St. Jude valve permits flow through the center of the prosthesis in contrast to the tilting disc and ball-in-cage valves that exhibit semicentral or peripheral flow, respectively.11,12 As a result, the St. Jude valve presumably has excellent hemodynamic performance in the mitral or aortic position.

This investigation was designed to determine whether the central flow provided by the St. Jude valve can be characterized noninvasively by Doppler echocardiography in order to provide baseline quantitative data that should be useful subsequently in identifying patients with prosthetic valve dysfunction. Doppler echocardiography is best suited to characterization of flow when the flow occurs nearly parallel to the ultra-
sonic interrogating beam. M mode and two-dimensional echocardiography were performed in the same patients to compare their potential utility to Doppler methods for the functional assessment of the prostheses.

Materials and methods

Patients. Twenty-three unselected patients from the Barnes Hospital St. Jude Medical valve registry comprised the study group. The patients ranged in age from 20 to 76 years and consisted of 13 patients with mitral prostheses and 10 with aortic prostheses. They were examined with particular attention to evidence of prosthetic valve dysfunction and were categorized according to New York Heart Association (NYHA) functional class. Valve replacement had been performed from 15 to 900 days before the study. A control group comprising 10 normal men, 25 to 32 years of age, was studied identically.

Instrumentation. Ultrasonic studies were performed with an Irex System III-B that interfaces Doppler with two-dimensional echocardiography (Irex Medical Systems, Ramsey, NJ). This system uses a phased-array transducer with a center frequency of 2.5 MHz that permits simultaneous recording of two-dimensional and M mode echocardiograms or simultaneous recording of two-dimensional echocardiograms and Doppler echocardiographic information.

Echocardiography

Two-dimensional and M mode. Two-dimensional echocardiograms were obtained with patients in the supine or left lateral decubitus position, with 20 degree elevation of the head for conventional parasternal and apical views. Recordings were made on 1/2 inch videotape. M mode echocardiograms were derived from the real-time two-dimensional image by locating a cursor across the regions of interest. Images were derived from both the long- and short-axis views, with particular attention to native and prosthetic valve motion. Recordings were made on the Irex strip chart recorder at 25 mm/sec.

Doppler. The theoretical basis of Doppler echocardiography has been previously described.\(^6\)\(^8\)\(^1\)\(^2\) Once the velocity of blood flow across a given area of interest is determined, application of a modification of the Bernoulli equation permits calculation of a pressure drop (mm Hg)

\[
\Delta P = 4V^2
\]

where \(\Delta P\) = pressure gradient and \(V\) = maximal velocity in meters per second. The assumptions involved in the derivation of the equation and its application and validation in cardiac valves have been previously described.\(^1\)\(^2\)\)\(^3\)\(^4\)\(^5\) Doppler echocardiography was performed with the PCD-1 Doppler module of the Irex System III-B. This unit uses a transmit frequency of 2.0 MHz and can be operated in either a pulsed or continuous-wave mode. The Doppler module operations are integrated with the two-dimensional scanning functions by means of a time-sharing relay, with the path of the Doppler sampling beam indicated by a cursor in the two-dimensional image display. In the pulsed mode the sample volume consists of a \(7 \times 7 \times 7\) mm volume, which can be located at various depths between 0 and 13.5 cm by range gating. The exact location of the sample volume in the cross-sectional display is indicated by a box along the Doppler cursor. The pulse repetition frequency is 8.62 kHz for sampling at depths of 0 to 8 cm and 5.74 kHz for depths between 8 and 13.5 cm. Thus for a blood flow vector parallel to the Doppler beam (\(\cos \theta = 1\) or \(-1\)), velocities to 1.7 m/sec at depths of less than 8 cm and to 1.1 m/sec between 8 and 13.5 cm are measurable in the pulsed mode. A baseline offset in the spectrometer analyzer allows the operator to display the Nyquist range asymmetrically, permitting the recording of velocities of 3.4 and 2.2 m/sec at the high- and low-pulse repetition frequencies, respectively. By switching to continuous-wave Doppler, the system permits detection of maximum velocities of 6.0 m/sec; however, range resolution is eliminated as Doppler shifts are detected along the entire Doppler beam. The added capability of continuous-wave Doppler is of critical importance in assessing frequency shifts exceeding the Nyquist range when their analysis is obscured by signal aliasing. Thus the use of continuous-wave Doppler permits detection of high velocities without ambiguity, permitting confirmation of the peak velocities seen with pulsed mode that are near the limits of the Nyquist range. Analysis of the Doppler shift spectrum is accomplished on-line by Chirp-Z transform. The graphic display presents the frequency spectrum with a variable scale (m/sec) based on the COS of the angle \(\theta\) between the Doppler beam and the vector of blood flow as approximated with a small cursor in the two-dimensional image. In this study, the vector of blood flow is assumed to be perpendicular to the plane of the prosthetic valve ring. In addition, the graphic display depicts mean and maximum velocity estimators, signal amplitude, and electrocardiogram. An audio output is of primary importance in locating the Doppler sample volume in the desired cardiac region while the two-dimensional image is viewed.

Mitrail valve examination. Transmitral velocity profiles were examined by placing the transducer in the apical position. The plane of the valve anulus, or ring in the case of prosthetic valves, was located perpendicular to the Doppler transmit beam. Initial positioning of the sample volume was made with the two-dimensional image. The audio output guided final positioning until an optimal audio signal was obtained. After data were obtained in the pulsed mode, the equipment was switched to continuous-wave Doppler to confirm that maximum velocities had been detected. After evaluation of the left ventricular inflow had been completed, the left atrium was examined in patients with prosthetic valves from the parasternal and apical views to detect transvalvular or paravalvular leaks. Because the valves are strong echo-reflectors, only examinations of the para- valvular areas were possible from the apical position.

Aortic valve examination. Evaluation of native and prosthetic aortic valves was performed by systematically examining the patients with the transducer in the apical, left parasternal, suprasternal, and right parasternal positions. The apical position proved to be the most productive. In the case of prosthetic valves, it was possible to "thread" the sample volume through the valve from the left ventricular outflow tract to the ascending aorta. Again, an attempt was made to locate the valve plane perpendicular to the transmit beam. Pulsed- and continuous-wave modes were used as described for the mitral valve. After aortic outflow had been examined, the subvalvular region was inspected for transvalvular or paravalvular leaks.

Calculations. M mode measurements of ring diameter and leaflet separation in prosthetic valves were performed in a manner similar to that described by Tri et al.\(^9\) Peak flow velocity was derived from visual inspection of the Doppler spectrum analysis plot, which was calibrated in meters per second. Mean velocity was calculated after planimetry of the area of the velocity spectrum depicted in the analysis plot. Pressure half-time, time-to-peak flow, and time-to-peak flow/ventricular ejection time were calculated as described elsewhere.\(^10\)\(^11\) All calculations were the average of four cardiac cycles for patients in sinus rhythm and eight cardiac cycles for patients in atrial fibrillation. These computations are schematically depicted in figure 1. Mean transprosthetic pressure gradients were calculated for the mitral St. Jude valves from the measured velocities with the use of the Bernoulli equation.
PATHOPHYSIOLOGY AND NATURAL HISTORY—PROSTHETIC VALVES

Statistics. Comparison of Doppler echocardiographic indexes of valve performance between native valves in healthy subjects and patients’ prosthetic valves were performed with the use of Students' t test for unpaired samples.

Results

Native valves. Healthy subjects had normal M mode and two-dimensional echocardiographic studies. The Doppler velocity spectra of mitral valves typically exhibited a narrow band that described an M-shaped pattern, corresponding to an early and late diastolic increase in inflow velocity (figure 2, top). The velocity spectra of aortic valves rose rapidly to a sharp peak and then had a more gradual return to baseline (figure 3, top). The velocities in the aortic valve spectra were also distributed in a narrow band. Maximum velocities across mitral and aortic valves were less than 1.00 and 1.64 m/sec, respectively, as shown in table 1.

Prosthetic valves

Mitral position. Among the 13 patients with St. Jude mitral prostheses, seven had a 29 mm valve and six had a 31 mm prosthesis implanted. Nine patients were in NYHA functional class I and four patients were in class II. All patients were free of congestive failure as evidenced by a lack of pedal edema, pulmonary rales, jugular venous distention, or a third heart sound. Opening and closing prosthetic valve sounds were present during cardiac auscultation in all patients. The closing sound was louder and higher pitched with a more “metallic” quality than the opening sound.

M mode echocardiography. Considerable variability in both the orifice ring diameter and the valve leaflet separation was found with diameter values ranging from 1.5 to 2.3 cm and leaflet separation from 0.25 to 0.5 cm. These results bore little relationship to the true geometric values of the valves (St. Jude Medical Valve specifications, St. Paul, MN). In addition, the leaflets exhibited marked variation of their location within the ring during diastole, ranging from a central position where both leaflets were well visualized with similar excursions, to an eccentric position with the leaflet adjacent to the ring echoes. In most cases, the leaflets were located at various positions between these two extremes (figure 4). There was no relationship between the extent of leaflet separation and the degree of eccentricity of the leaflets within the valve ring.

Two-dimensional echocardiography. Good-quality two-dimensional images were obtained for all 13 patients, with valve motion clearly observed in all views obtained. Characteristically, the valve leaflets appeared as two bright, parallel lines with the onset of diastole (figure 5, A and B). The central cleft between the prosthetic leaflets was oriented close to perpendicular to the anteroposterior axis in every patient. None of the valves examined showed evidence of ex-

![FIGURE 1. Schematic representation of typical Doppler flow velocity spectra of mitral (A) and aortic valves (B) showing the calculated and estimated parameters of flow.](http://circ.ahajournals.org/content/68/5/899)
cessive valve motion, limitation of leaflet motion, or thrombus formation. Although a paravalvular leak was suspected by physical examination in one patient, both the M mode and two-dimensional echocardiograms were unremarkable.

**Doppler Echocardiography.** Excellent recording of Doppler shifts across mitral prostheses was obtained in each patient. Flow parallel to the interrogating beam was achieved in every mitral prosthesis from the apical position, making the use of a correction angle unnecessary. Spectral analysis demonstrated the velocity spectrum associated with diastolic left ventricular inflow through the prostheses (figure 2). For patients in sinus rhythm the velocity spectrum exhibited an M-shaped pattern with early and late diastolic peaks of flow velocity similar to those seen in native valves of healthy subjects. Patients with atrial fibrillation had only an early diastolic peak. In all cases the velocities were distributed in a narrow band within the spectral display. Peak flow velocity averaged \(1.35 \pm 0.33\) m/sec (SD) and mean flow velocity averaged \(0.73 \pm 0.16\) m/sec. Calculated pressure half-time averaged \(61.2 \pm 16.9\) msec and extrapolated transprosthetic mean pressure gradient averaged \(2.3 \pm 0.9\) mm Hg. Comparison of peak velocity, mean velocity, and pressure half-time between patients with a 29 mm prosthesis and those with a 31 mm prosthesis did not reveal significant differences. A paravalvular leak, suspected by physical examination in one patient, was confirmed by the detection of velocity signals during systole while sampling in the left atrium from the parasternal position. Normally, velocity signals are not detectable within the left atrium during systole, as was the case with our healthy subjects (figure 6, A). Comparison of the quantitative flow parameters between the St. Jude and native valves of healthy subjects demonstrated statistically significant differences of both mean velocity and maximum velocity (table 1). The two groups were clearly separated with the use of a mean velocity of 0.47 m/sec as a cutoff point. Pressure half-time was not significantly different between the two groups.

**Aortic Position.** Ten patients with St. Jude Medical valves implanted in the aortic position had valves of various sizes, including 21 mm (two patients), 23 mm (three patients), 27 mm (three patients), and 29 mm valves (two patients). Eight patients were in NYHA functional class I and two were in class II. No patient demonstrated evidence of congestive failure. Aortic prosthetic sounds were similar to those of mitral valves, with a higher pitched more metallic sound present during valve closure.

**M-Mode Echocardiography.** In contrast to the mitral valves, aortic prostheses frequently yielded unsatisfactory M mode tracings of both leaflets, and measure-

**FIGURE 2.** Representative Doppler spectra of trans-mitral flow from a native valve of a healthy subject (top left) and a patient's St. Jude valve (bottom left). Corresponding two-dimensional echocardiographic images are shown on the right, with the sample volume indicating the region from which the spectra were recorded.
ment of leaflet separation was possible in only three cases. In most instances the leaflets were markedly eccentric within the ring orifice, making it difficult to differentiate the leaflet structures from the ring.

**Two-dimensional echocardiography.** These studies provided insight into the difficulties encountered with M mode echocardiography. Valve leaflets were detected in all but one patient and were best seen in the short-axis view. In most cases the leaflets were visualized at the lower edge of the valve ring (figure 5, C and D). In every patient the central cleft was located perpendicular to the anteroposterior axis and the leaflets appeared in systole and disappeared in diastole. Prosthetic valve dysfunction was not suspected in any patient.

**Doppler echocardiography.** In seven patients (five examined from the apical position and one examined from both the suprasternal and right parasternal positions), Doppler echocardiography provided data suitable for analysis (figure 3). Adequate Doppler flow velocities could not be obtained in three patients with aortic prostheses. This was presumably due to a large body habitus preventing insonification of the area of interest. Visualization of the prostheses from the apical position with the simultaneous two-dimensional image allowed orientation of a correction angle cursor. The apical position rarely resulted in an angle-to-presumed aortic outflow that was less than 20 degrees. The cosines of these angles ranged from 0.67 to 0.98 (mean 0.84), with resulting calculated changes in velocities between 1.9% and 49.4% (mean 18.4%). The pattern of the Doppler velocity spectra were similar to those of native aortic valves with rapid peaking after the onset

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**TABLE 1**

Comparison of velocities for St. Jude valves and native valves

<table>
<thead>
<tr>
<th></th>
<th>St. Jude valve</th>
<th>Native valves</th>
<th>Mitral</th>
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<td></td>
<td>Aortic</td>
<td></td>
<td>Mitral</td>
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<tr>
<td></td>
<td>n</td>
<td>V (m/sec)</td>
<td>Vmax (m/sec)</td>
</tr>
<tr>
<td>St. Jude</td>
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<td>1.23±0.25</td>
<td>1.97±0.52</td>
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<tr>
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<td>1.22±0.19</td>
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T<sub>p50</sub> = pressure half-time; TTP = time-to-peak velocity; V = mean velocity; Vmax = maximum velocity.

Values are reported as ± SD.
of systole, a more gradual decline to baseline, and velocities that distributed in a narrow band. Time-to-peak flow averaged 82.7 msec. Comparison between the flow characteristics of prosthetic valves with those of native valves in healthy subjects revealed significant differences in maximum and mean velocity (table 1). Time-to-peak flow corrected by left ventricular ejection time was less than 0.5 in all patients. Although the number of patients with each size valve was too small to allow a comparison between valve sizes, larger valves tended to generate smaller mean and peak flow velocities.

The relationship of prosthetic geometric orifice area vs mean and peak flow velocity is depicted in figure 7. Paraprosthetic leaks were detected in three patients, one of whom had a diastolic murmur on physical examination attributed to pulmonic insufficiency from correction of tetralogy of Fallot (figure 6). In the other two patients paravalvular leaks were unsuspected. Of particular interest was our ability to "thread" the St. Jude valve in the aortic position. By gradually advancing the sample volume to the valve ring from the left ventricle, a gradual increase in flow velocity in the aortic outflow tract was appreciated. However, a sudden marked increase in flow velocity was noted when the sample volume crossed the plane of the valve.

Discussion

Our results demonstrate that Doppler echocardiography provides a functional assessment of the St. Jude

FIGURE 4. M mode echocardiograms obtained in a patient with a centrally localized St. Jude mitral valve (left) and a patient with an eccentrically positioned mitral prosthesis (right).

FIGURE 5. Two-dimensional echocardiographic images of mitral (A and B) and aortic (C and D) St. Jude prostheses. VS = ventricular septum; RV = right ventricle; LVOT = left ventricular outflow tract; PL = prosthetic leaflet; RA = right atrium; LA = left atrium; RS = ring shadow of prosthetic anulus.
value, complementing information obtained by M mode and two-dimensional echocardiography. Results differ quantitatively from those obtained with native valves in healthy subjects. Although flow velocity spectra of mitral prostheses were morphologically similar to those of native valves, mean and peak flow velocities were significantly greater with prosthetic valves, which is in consonance with the known reduction of orifice with all prostheses in comparison with native valves.

**FIGURE 6.** Paravalvular leaks in patients with mitral (A) and aortic prostheses (B). Detection of mitral paravalvular leak is indicated by recording flow velocity above and below the baseline in systole, with the sample volume located in the left atrium and the transducer oriented from a parasternal position. Recognition of aortic prosthetic leak is based on recording flow during diastole in the left ventricular outflow tract as interrogated from the apex.

**FIGURE 7.** Relationship between geometric orifice area of St. Jude aortic prosthesis (St. Jude Medical valve specifications, St. Paul, MN) and Doppler echocardiographic mean (left) and maximum transprosthetic flow velocities (right). Higher velocities were obtained in smaller valves with smaller orifices. Corresponding valves and orifices were as follows: 29 mm = 4.41 cm², 27 mm = 3.67 cm², 23 mm = 2.55 cm², 21 mm = 2.06 cm².
Pressure half-time, a parameter previously described as an index of mitral orifice size that is less dependent on flow, was not significantly different between prosthetic and native mitral valves. Although this finding may reflect lack of sensitivity of the parameter for large orifice sizes, it may indicate a lack of applicability to prosthetic valves. However, the latter is unlikely in view of the similarity of flow spectra between prosthetic and native valves. The lack of significant differences between patients with 31 and 29 mm prostheses with respect to velocities and pressure half-times may be related to variations in resting cardiac output and consequent transvalvular flow, resulting in overlap of the data.

Previous studies with Doppler echocardiography and simultaneously obtained hemodynamic data have demonstrated a close correlation for the two in assessment of transvalvular gradients in patients with Bjork-Shiley, Lillehei-Kaster, and Beall valves in the mitral position.7,8 Our patients were categorized as NYHA class I or II; many of them had returned to full-time employment at the time of study and were not candidates for repeat cardiac catheterization. Nevertheless, extrapolation of peak flow velocity to pressure gradients via the assumptions inherent in the Bernoulli equation provided a measure for comparison between our results and those previously reported for the St. Jude valve.

Hemodynamic data acquired by Chaux et al.18 in patients studied early after surgery demonstrated a mean diastolic gradient of 1.8 ± 0.8 mm Hg (SD) in 16 patients with 29 mm prostheses and a gradient of 1.6 ± 0.4 mm Hg in three patients with 31 mm prostheses. Horstkotte et al.19 reported results from 22 patients with mitral prostheses studied at a mean of 10.2 months after surgery, an interval similar to that in our patients. Their results showed mean mitral gradients of 2.5 ± 0.9 mm Hg for the entire group and 2.2 ± 0.8 mm Hg for 17 patients with 29 mm prostheses, values similar to those in our study.

Doppler echocardiography yielded adequate information for analysis in most patients, confirming the complementary aspects of the approaches used. In general, two-dimensional and M mode echocardiography provide the most useful information concerning valvular orifice from the parasternal transducer position. On the other hand, the most reliable quantitative information by Doppler is obtained with the beam parallel to the direction of blood flow, i.e., from the apical position for mitral valves and the apical or suprasternal notch for aortic valves. We have observed patients in whom examination from the parasternal position provided a poor image as compared with the apical view and vice versa. Hence, the use of Doppler and two-dimensional echocardiography viewing windows that are orthogonal, in addition to providing functional vs anatomic information, enhances the complementary nature of the techniques in the assessment of native and prosthetic valve function.

The importance of adequate two-dimensional images is stressed by our results. The direction of presumed aortic flow differed from the direction of the Doppler beam by an average of 32 degrees, resulting in an average velocity correction of 18%. Since this angle between directions was derived from a two-dimensional image of a three-dimensional structure, it may be an underestimation given the assumption that flow is perpendicular to the valve ring in the immediate postvalvular region.

Paraprosthetic leaks were discovered in three patients with aortic prostheses and one with a mitral prosthesis. Although the mitral valve dysfunction was presumed on the basis of clinical examination, paraprosthetic aortic insufficiency was not suspected before Doppler studies in two of the patients. In addition, none of these patients demonstrated two-dimensional or M mode echocardiographic signs of aortic insufficiency. Such results are not surprising in view of recent studies,9,21,22 documenting the sensitivity of Doppler echocardiography in detecting valvular insufficiency. Esper21 demonstrated the lack of sensitivity of both auscultation and fluttering of the mitral valve in angiographically documented aortic insufficiency. In that report, the conditions of all patients were detected with Doppler echocardiography and the discrepancy was most evident in mild cases. Similar sensitivity with prosthetic valves9 has been shown and is consistent with our findings.

A theoretical advantage was noted with respect to Doppler echocardiographic examination in patients with aortic St. Jude valves as compared with other tilting-disc valves. By placing the transducer in the apical position we were able to “thread” the valve. The unique design features of the St. Jude valve, which provide leaflet opening of 85 degrees with respect to the ring, most likely permit this maneuver. Although this design presumably results in minimal obstruction to aortic outflow, it also presents a minimum profile to the Doppler beam, thus avoiding disruption of the postvalvular tracings with highly reflective surfaces.

Continuous-wave Doppler echocardiography proved to be a necessary and valuable tool in the present study. In spite of the use of a baseline offset, several of the
aortic velocity spectra approached the maximum size that could be displayed in the pulsed mode. Hence, when the Doppler shift approached the limits of the Nyquist range, it was advantageous to switch to continuous-wave mode to confirm that maximum velocities were not obscured by signal aliasing.

We chose healthy subjects as a comparison group rather than an age-matched population to minimize the possibility of including individuals with minimal valvular or myocardial disease. The flow velocity parameters of an age-matched comparison group are expected to be lower than those in the healthy group we studied. Therefore, if an older age group had been used for comparison, the observed differences from flow velocities in prosthetic valves would have been greater.

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**PATHOPHYSIOLOGY AND NATURAL HISTORY—PROSTHETIC VALVES**

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