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Patterns of Normal Transvalvular Regurgitation in Mechanical Valve Prostheses

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The magnitude and spatial distribution of normal leakage through mechanical prosthetic valves were studied in an in vitro model of mitral regurgitation. The effective regurgitant orifice was calculated from regurgitant rate at different transvalvular pressure differences and flow velocities. This effective orifice area was 0.6 to 2 mm^2 for three tilting disc prostheses (Medtronic-Hall sizes 21, 25 and 29) and 0.2 to 1.1 mm^2 for three bileaflet valves (St. Jude Medical sizes 21, 25 and 33).

In the single disc valves, Doppler color flow examination disclosed a prominent central regurgitant jet around the central hole for the strut, accompanied by minor leakage along the rim of the disc (central to peripheral jet area ratio 3.3 ± 1.2). The bileaflet prostheses showed a peculiar complex pattern: in planes parallel to the two disc axes, convergent peripherally arising jets were visualized, whereas in orthogonal planes several diverging jets were seen.

Mounting the disc and bileaflet valves on a water-filled tube allowed reproduction and interpretation of this pattern: for the bileaflet valve, the jets originated predominantly from valve ring protrusions that contained the axis hinge points and created a converging V pattern in planes parallel to the leaflets and a diverging V pattern in orthogonal planes.

Similar patterns were observed during transesophageal echocardiography in 20 patients with a normally functioning St. Jude prosthesis. In 10 patients with a Medtronic-Hall valve, a dominant central jet was observed with one or more smaller peripheral jets. The median central to peripheral jet area ratio was 5 to 1.

In summary, in two types of mechanical valve prostheses, effective leakage orifice areas are reported and criteria proposed for the differentiation of "physiologic" and pathologic regurgitation based on the spatial configuration of the jets.

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Since the introduction of the tilting disc valve in 1969 (Björk-Shiley) and the bileaflet valve in 1977 (St. Jude Medical), mechanical prostheses of these types have become the most frequently implanted artificial heart valves. In vitro examinations (1–3) and Doppler echocardiography (4–7) have shown that transvalvular regurgitation is invariably present in these prostheses. Transvalvular regurgitation can be divided into *closure backflow*, the regurgitant flow resulting from the closing movement of the occluding device (such as the tilting disc), and *leakage backflow*, the regurgitant flow occurring after the valve is fully closed (Fig. 1) (8). However, the magnitude of this "physiologic" or normal regurgitation and the characteristics that distinguish it from pathologic regurgitation are not fully understood.

Doppler color flow mapping allows the in vivo visualization of intracardiac blood flow and, when combined with transesophageal imaging, yields high resolution images of regurgitant jets issuing from mitral prostheses into the left atrium (9–11). These jets may be multiple with significant overall size and thus may prompt concern for prosthetic valve dysfunction, leading to inappropriate invasive assessment or surgical intervention. Therefore, the need for criteria to characterize "normal" prosthetic valve regurgitation, especially the spatial distribution of the regurgitant jets, encouraged us to pursue this question in an in vitro model and a series of clinical patients. Specifically, we investigated 1) the effective regurgitant orifice area, and 2) the spatial patterns of regurgitant leakage in normal mechanical valve prostheses.

Methods

Mechanical valve prostheses (Table 1). New prostheses, quality tested for clinical use, were provided by the manufacturers (Medtronic and St. Jude Medical).

Calculation of regurgitant orifice. We used a constant flow model in which a constant pressure gradient is generated by gravity (Fig. 2). The model was operated with water at 20°C; cornstarch was added to provide ultrasonic backscatter. The constancy of the fluid levels in both the high and

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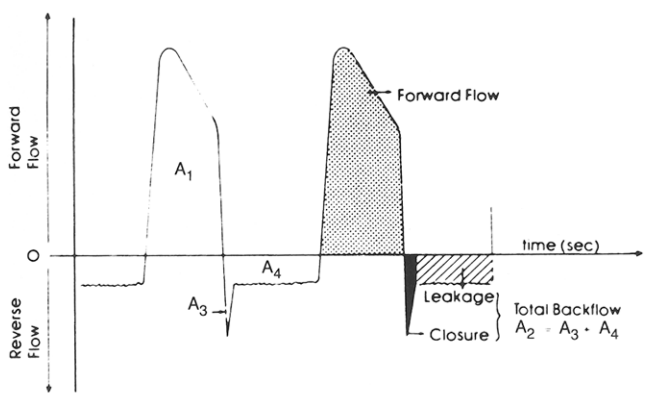

Figure 1. Schematic plot of transvalvular flow against time in a mechanical prosthesis during pulsatile flow. Two cardiac cycles are shown. A_1 = forward flow, A_3 = closure backflow and A_4 = leakage backflow. Reprinted from Dellsperger et al. (8) with permission of the author and the *American Journal of Cardiology*.

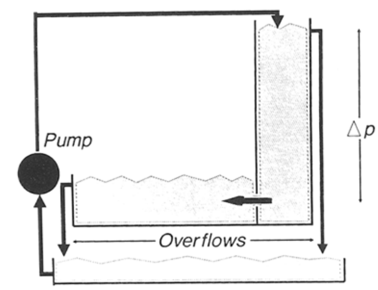

Figure 2. Constant flow model. The height of the fluid column is held constant by two overflows; energy to maintain the pressure gradient is provided by a pump; the valve is mounted in the reverse orientation between the high pressure (**right**) and low pressure (**left**) chamber. See text for details. Δp = pressure difference across the valve.

low pressure chamber was achieved by two overflows into a common reservoir from which a mechanical pump forced the fluid into the upper chamber. Therefore, the pressure gradient did not depend on the pump setting, but only on the height difference of the two overflows, which could be freely varied. The mechanical prostheses were mounted with the distal surface of the valve facing the high pressure chamber, so that they were kept shut by the pressure gradient. The dimensions of the low pressure chamber are 100 cm long by 30 cm wide by 30 cm high.

The regurgitant flow rate (q) through the valve depends on the pressure difference (Δp) across the valve and the effective regurgitant orifice area (A) in the following way: $q = Av$ and $\Delta p = \frac{1}{2}\rho v^2$, where v is flow velocity and ρ is fluid density. The first equation is the continuity equation for constant flow rate and the second is the "simplified" Bernoulli equation applicable to restrictive orifices with negligible velocities upstream from the orifice (12). Effective orifice area therefore can be calculated if the pressure gradient and the flow rate are known:

$$A = \frac{q}{\sqrt{2\Delta p/\rho}}, \qquad [1]$$

which corresponds to the Gorlin equation but without a correction factor for the coefficient of discharge. The pressure difference was calculated as the height of the fluid column times the density of the fluid times the gravitational constant; the flow rate was measured with a beaker and a stopwatch. Pressure differences of 23, 63 and 92 mm Hg were used. Five flow measurements were made with each valve and each pressure gradient, totaling 90 flow rate measurements. The effective regurgitant areas were then calculated according to equation 1.

For each valve, average values of regurgitant orifice area at each of the three pressure gradients were expressed as a percent of regurgitant orifice area at a pressure gradient of 92 mm Hg. Linear correlation of the 18 resulting percentage areas with the three pressure gradients was performed to test for the influence of the pressure gradient on the geometry of the closed valve and, thus, effective regurgitant area.

Doppler color flow examination. Doppler color flow imaging was performed with a commercially available machine (Hewlett-Packard 77090) equipped with a 3.5 MHz transducer that was immersed in the low pressure reservoir at a distance of 8 to 10 cm from the valve and oriented colinear with the central valve axis. Recordings were made with the imaging plane rotated incrementally around this central axis. Machine gain was adjusted to maximize jet area while avoiding color in regions without flow. A pressure gradient of 92 mm Hg was uniformly used for the Doppler color flow studies.

To characterize the normal pattern of regurgitation in Medtronic-Hall valves, color jets arising from the center and from the periphery of the valve were measured by planimetry and their ratio was calculated. This procedure was followed in 10 frames with good visualization of central and peripheral jets.

To directly visualize the spatial pattern of the regurgitant jets, the size 25 bileaflet valve and the size 25 tilting disc

Table 1. Effective Regurgitant Orifice Area*

Valve Type	Effective Regurgitant Orifice Area (mm^2)
Bileaflet valve (St. Jude Medical)†	
21M–101	0.2
25M–101	1.1
33M–101	0.7
Tilting disc (Medtronic-Hall)†	
21AHK	0.6
25AHK	1.0
29AHK	2.0

*Mean of 15 measurements. †The first two digits of the specification of each valve indicate the ring diameter.

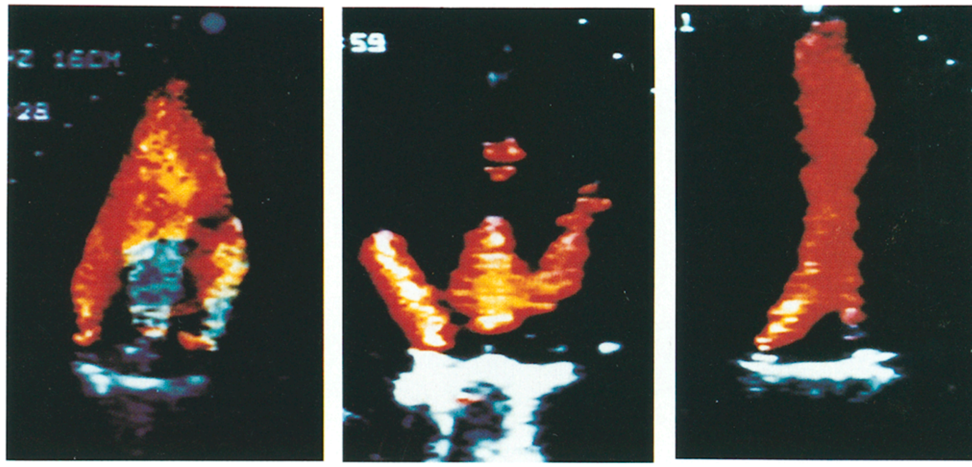

Figure 3. In vitro visualization of regurgitant jets. **Left,** Medtronic-Hall tilting disc valve. A marked central jet and two peripheral jets are seen. **Center,** St. Jude Medical bileaflet valve. The central leaflet closure line is perpendicular to the imaging plane; a central jet and two diverging peripheral jets are seen. **Right,** St. Jude Medical bileaflet valve. The central leaflet closure line lies in the imaging plane and runs horizontally. Two peripherally arising converging jets are seen.

valve were mounted in reverse orientation on a 2.5 cm diameter plastic tube; the tube was filled with water to a column height of 100 cm, providing an initial pressure gradient of 74 mm Hg. The emerging regurgitant jets were photographed in close-up views at different angles.

Clinical examples. To assess the patterns of regurgitation seen clinically, we reviewed the transesophageal echocardiograms of 20 patients with a St. Jude prosthesis and 10 with a Medtronic-Hall prosthesis. All examinations were performed with a 5 MHz transducer with use of either a single scanning plane, two orthogonal planes or a rotationally steerable single plane. Studies were performed either immediately after implantation or to determine a source of embolus or the possible presence of endocarditis. All valves were ultimately considered to be functioning normally on the basis of a combination of (variously) direct hemodynamic assessment (in the operating room), cardiac catheterization, physical examination, chest X-ray study, absence of hemolytic anemia, serial echocardiographic studies and long-term clinical follow-up. Gain settings were adjusted as usual to maximize jet size while avoiding random color signals in areas of little or no flow. For fixed monoplane and biplane examinations, the transducer was initially placed with the central beam coaxial with the central valve axis (thus showing maximal valve diameter). Through a combination of torque and angulation, the entire valve surface and periphery were interrogated. For the steerable transducers, the imaging plane was rotated in stepwise increments around the central axis to cover the full perimeter of the valve. For the Medtronic-Hall valves, the ratio between the central and the peripheral jet area was calculated as in the in vitro model.

Results

Regurgitant flow rates and orifices. The regurgitant orifice areas (representing a mean of 15 measurements, 5 for each

Figure 4. Clinical example of mechanical prostheses in the mitral position imaged immediately postoperatively by transesophageal echocardiography and oriented as in Figures 3, 5 and 6. **Left,** Tilting disc prosthesis. The predominant central regurgitant jet and smaller peripheral jets are seen. **Center,** Bileaflet prosthesis, imaged in a plane perpendicular to the closure line. Divergent jets are seen. **Right,** Bileaflet prosthesis, imaged in a plane parallel to the closure line. A pair of converging jets is seen. LA = left atrium.

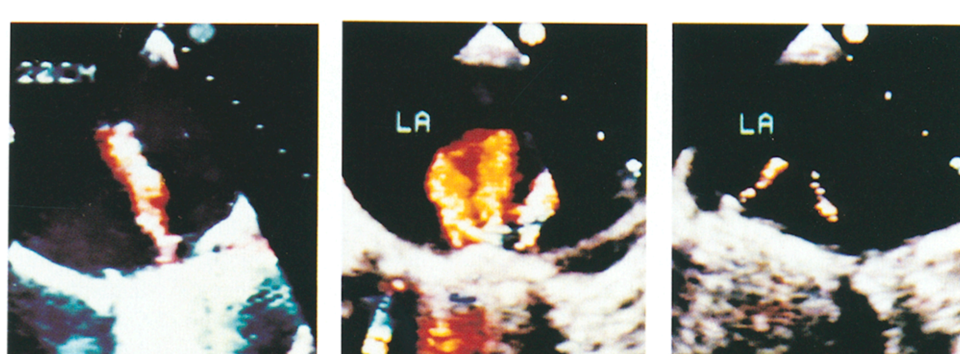

Figure 5. Closeup photographs of prosthetic valves mounted on a water-filled tube in the reverse position; a seal was obtained with silicone rubber. The retrograde perfusion pressure was 74 mm Hg; the orientation is as in Figures 3, 4 and 6. **Left,** Tilting disc prosthesis. A central jet issuing from the central hole in the disc is surrounded by smaller jets emerging from the disc circumference. **Center,** Bileaflet prosthesis. The closure line of the leaflets runs into the plane of the picture; multiple jets emerge from the leaflet hinge points and appear predominantly to diverge from this perspective. There is also minor regurgitation at the circumference of the leaflets and from the central closure line. **Right,** Bileaflet prosthesis. The closure line of the leaflets runs horizontally in the plane of the figure. Viewed from this vantage, the many jets emerging from the leaflet hinge points appear predominantly to converge.

pressure gradient) for the six valves studied are shown in Table 1. The regurgitant orifice area was small (≤ 2 mm^2 in all cases), with the bileaflet valves having slightly less regurgitation than the tilting disc prostheses ($p < 0.05$). There was no correlation between regurgitant orifice area and pressure gradient for either valve type, indicating that the closure geometry did not change significantly with pressure.

Doppler color flow examination in vitro. The following regurgitant patterns were visualized:

1. *In the tilting disc prostheses,* a prominent central regurgitant jet issued from the central orifice around the strut and there was peripheral regurgitation along the border of the disc (Fig. 3, left). Hence, in each plane containing the valve center and transecting the sewing ring, the central jet and two peripheral smaller jets were seen. This pattern was observed in all three Medtronic-Hall valves. The central jet was consistently larger than the peripheral jet, with a central to peripheral jet area ratio of 3.3 ± 1.2 (mean ± SD) in 10 measurements at a pressure gradient of 92 mm Hg.

2. *The bileaflet prostheses* showed a complex arrangement of regurgitant jets with distinctly different patterns demonstrated, depending on the orientation of the viewing plane. In the plane *parallel to the leaflet axes,* converging jets arising in the valve periphery were seen (inverted V shape; the mean angle between the jets in 15 measurements was 44°); in addition, a small amount of regurgitation issuing from the center was present. In the plane *orthogonal to the leaflet axes,* the peripheral jets diverged in a V shape with an angle of 24° from the central valve axis (mean of 15 measurements); again, minor central regurgitation was seen (Fig. 3, center and left).

Clinical findings. The patterns of regurgitant jets found in vitro in the two mechanical valve types are closely matched by the clinical examples. Figure 4 (left) shows the central regurgitant jet of a tilting disc valve, and the plane-dependent patterns of bileaflet valve regurgitation are recognizable in the center and right panels. Overall, multiple jets were visualized in all patients with a St. Jude prosthesis when the full valve surface was interrogated. Both diverging and converging patterns were routinely observed. With the steerable scanning plane, dominant diverging and converging patterns were observed at 90° rotations from each other. In all patients with a Medtronic-Hall valve, a dominant central jet was observed with an area of 2.77 ± 1.14 cm^2 (mean ± SD). In addition, one (seven patients) or two (three patients) small jets were observed at the disc margins with an area of 0.6 ± 0.43 cm^2. The ratio of the central to the peripheral jet area ranged from 2.4:1 to 16.1:1 (median 5:1).

Direct visualization of regurgitant jets. Photographs of valve regurgitation into air provided additional insight into the three-dimensional orientation of the jets (Fig. 5). The complex pattern of the bileaflet valve with its V and inverted V shape is clearly discerned (center and right), as well as the dominant central and lesser peripheral regurgitation through the tilting disc prosthesis (left).

Discussion

Normal versus pathologic regurgitation. Transvalvular regurgitation through a closed mechanical valve prosthesis is a recognized feature in tilting and bileaflet valves; safeguard against sudden irreversible occlusion has been stated as the main reason for designing these valves with a small amount of leakage. The increasingly powerful echocardiographic techniques allow detection of even small degrees of regurgitation; hence, they have raised the problem of how to distinguish "normal" regurgitation from the pathologic regurgitation that is due to paravalvular leakage or valvular malfunction. Although valvular malfunction with severe transvalvular regurgitation is a relatively rare incident in mechanical valve prostheses, paravalvular leakage is frequent and can vary from minimal to torrential regurgitation in valve ring dehiscence. However, as shown in this study, even normal valves can have a large regurgitant jet when imaged by transesophageal echocardiography, a finding that might lead to inappropriate invasive testing or operative intervention. Our data indicate that the magnitude of backflow leakage is normally quite small and suggest Doppler color flow criteria that may be helpful in recognizing normal regurgitation in mechanical prostheses in the mitral position.

Magnitude of normal leakage. Our measurements indicate that the effective regurgitant orifice area ranges between 0.2 and 2 mm^2 in these mechanical prostheses. Other in vitro studies (1,8), although not reporting regurgitant orifice areas, have reported leakage backflow values in prosthetic valves compatible with our data. This effective area corresponds to the sum of the areas of all orifices with leakage in a given valve multiplied by their respective discharge coefficients. Because these discharge coefficients differ according to the geometric features of these orifices, the exact magnitude of the total "true" geometric regurgitant orifice area is difficult to estimate, although it must be larger than the effective area (13). However, in assessing the hemodynamic impact of valve leakage, the effective regurgitant area seems to be the most relevant quantity. In our study there was little correlation between effective regurgitant area and sewing ring size, which may reflect minimal variations in the manufacturing process.

We emphasize that a 1 mm^2 effective regurgitant area would result in a clinically insignificant amount of leakage backflow. For example, such a regurgitant area in the setting of a systole of 300 ms duration and a mean transmitral systolic pressure gradient of 120 mm Hg would yield a regurgitant volume of only 1.7 cm^3/beat. That all of the jets in each panel of Figure 4 may represent only 5 cm^3/s in blood flow is testimony to the extreme sensitivity of Doppler flow mapping to small degrees of regurgitation.

Leakage backflow is only one part of total backflow; the other is closure backflow. A previous in vitro study (8) using a pulsatile model found, in the setting of high heart rates and low cardiac output, substantial regurgitant fractions in mechanical prostheses due to a relatively high contribution of closure backflow. The purpose of the current study was to assess the magnitude of leakage backflow and, in particular, to examine the spatial pattern of normal regurgitant jets.

Spatial Jet Patterns

Our findings indicate that the following criteria may help to distinguish "normal" or "physiologic" regurgitation from paravalvular leakage:

1. Tilting disc valves. In these prostheses most "normal" regurgitation occurs around the central strut; the area of the central jet clearly exceeds the area of each peripheral jet. The peripheral jets in the tilting disc valves in vitro are tilted slightly outward as in Figure 6A. Hence, a peripherally arising jet of the same or a larger area than that of the central jet should suggest the possibility of paravalvular leakage, provided that the maximal central jet size has been sought and imaged. Conversely, peripheral jets clearly smaller than the central jet are likely to be "normal." Because of the circular design of the valve occluder, peripheral jets will frequently issue from both opposing borders, leading to a symmetric appearance (Fig. 3, left). However, because leakage need not be present around the whole circumference, no, one or two peripheral jets may be imaged in any

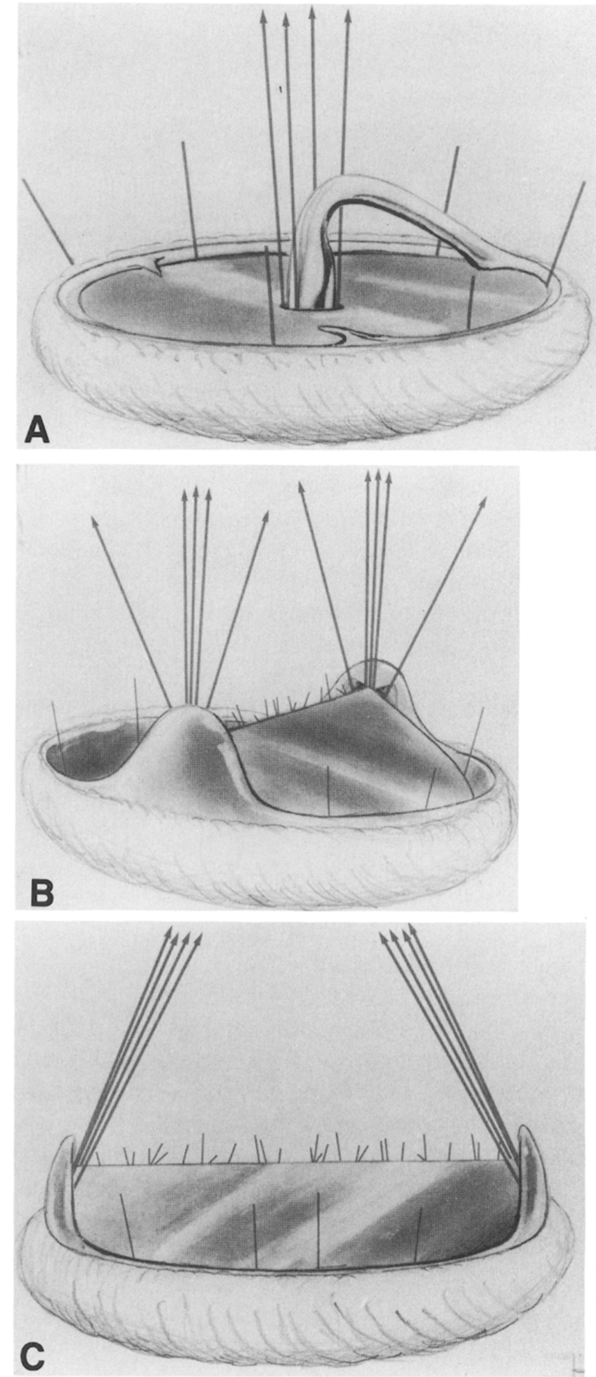

Figure 6. Schematic drawing of the orientation of regurgitant jets through the tilting disc prosthesis (**A**) and through the bileaflet prosthesis viewed from two perspectives (**B** and **C**), respectively corresponding to the center and right panels in Figures 3, 4 and 5. See text for further details.

given scanning plane (Fig. 4, left). Plane orientation may fool the observer by not including the central orifice or by failing to display the true maximal extent of central or peripheral jets. Careful scanning in as many planes as possible is therefore necessary to define the pattern of regurgitation to avoid a falsely positive or negative diagnosis of pathologic leakage.

2. Bileaflet valves. In the bileaflet valves, central regurgitation along the central closure line of the discs is less than that occurring from the hinge points of the leaflets, as represented schematically in Figure 6, B and C. Depending on the orientation of the plane, either these jets arise peripherally and converge (inverted V in the plane parallel to the leaflet axes, Fig. 6C) or their origin is projected on the center of the valve and they exhibit a diverging V pattern (in the plane perpendicular to the leaflet axes, Fig. 6B). Intermediate plane orientations produce corresponding intermediate jet patterns, as seen by rotating the schematic representation in Figure 6B by 90° into that seen in Figure 6C. The observation of a pattern significantly different from this, such as a large, dominant peripheral jet, should suggest the possibility of pathologic regurgitation.

Conclusions. In this study we used a model of mitral regurgitation to analyze the magnitude and spatial patterns of normal leakage backflow in two commonly implanted mechanical prostheses and compared these with observations in clinical echocardiographic examinations of normally functioning prostheses.

Effective regurgitant orifice areas ranged from 0.2 to 2 mm^2, predicting a leakage volume in the range of only a few milliliters per beat. In tilting disc valves, a predominant central jet and minor, often symmetric, peripheral regurgitant jets characterize normal regurgitation. In bileaflet valves the typical normal pattern features multiple jets arising from the leaflet hinge points, which generate a converging pattern when viewed in planes parallel to the leaflet axes; in the plane orthogonal to the leaflets axes, these normal jets appear to diverge.

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