Small aortic annulus: The hydrodynamic performances of 5 commercially available tissue valves

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Background: In vivo comparison of the performance of heart valve prostheses is confounded by several factors, such as different nominal size, patients’ characteristics and hemodynamics, surgical techniques, and study design. The aim of this study was to compare the in vitro hydrodynamic performances of 5 different tissue valves that would fit a 21-mm-diameter valve holder of the Sheffield pulse duplicator.

Methods: Three samples of 5 supra-annular production-quality tissue valves, including the sewing ring cuffs, were tested in the aortic chamber of the Sheffield pulse duplicator. The prostheses fitting a 21-mm valve holder, which is comparable with a 21-mm aortic annulus, were as follows: 20-mm Sorin Soprano, 21-mm Carpentier-Edwards Magna, 21-mm SJM-Biocor-Epic-Supra, 21-mm Medtronic Mosaic, and 23-mm Mitroflow. The tests were carried out at a fixed pulse rate (70 beats/min) and at increasing cardiac outputs of 2, 4, 5, and 7 L/min. Each valve was tested 10 times for each different cardiac output. This resulted in a total of 40 tests for each valve and 120 tests for each valve model. Forward flow pressure decrease, effective orifice area, stroke work loss, and total regurgitant, closing, and leakage volumes were recorded while the valve operated under each cardiac output.

Results: Pericardial valves showed significantly lower transvalvular gradients than porcine valves, unlike the SJM-Biocor-Epic-Supra valve at 2 L/min of cardiac output. Although the Carpentier-Edwards Magna valve provided the best performance at 2 and 4 L/min, the Mitroflow valve exhibited the lowest mean and peak gradients at 5 to 7 L/min. Total regurgitant and leakage volumes were higher for the Carpentier-Edwards Magna valve and lower for the SJM-Biocor-Epic-Supra and Mitroflow valves. Between 2 and 4 L/min, the calculated effective orifice area and stroke work loss were better for the Carpentier-Edwards Magna valve, whereas between 5 and 7 L/min, they were significantly superior with the Mitroflow prosthesis. Among the porcine bioprostheses, the SJM-Biocor-Epic-Supra valve showed significantly better results when compared with the Medtronic Mosaic valve at each cardiac output.

Conclusion: Assuming that the valve holder is comparable with a defined aortic annulus of 21 mm in which a spread of supra-annular tissue valves could be fitted, this hydrodynamic evaluation model allows comparison of the efficiency of currently available bioprostheses with a definite tissue annulus diameter. Pericardial valves exhibited the best performances, and the Mitroflow valve showed the lowest gradients and stroke work loss at increasing cardiac output.

The task of aortic valve surgery is to eliminate left ventricular outflow tract obstruction, allowing regression of left ventricular hypertrophy. According to these principles, it is crucial to select the optimal stented valve substitute with the lowest residual gradients. Additional options are the use of stentless valves or annulus enlargement. However, in these cases the increased operative risk must be weighed against the hemodynamic benefits. Stentless valve
implantation and annulus-enlarging procedures are more demanding techniques.\(^5,7\) Hence it seems logical to implant supra-annular tissue valves, which are placed on top of the aortic annulus and can guarantee the advantages of the stented valve (easier and less time-consuming implantation).\(^8\) Medtronic Mosaic (MM), Carpentier-Edwards Magna (CEM), Sorin Soprano (SS), SJM-Biocor-Epic-Supra (SJME), and Mitroflow (MF) valves belong to this latter category of prostheses. Nevertheless, for these prostheses, the nominal valve size is not uniform, and therefore the hemodynamic comparison is somehow misleading.\(^9\) Moreover, the in vivo studies are further penalized by patients’ differences, selection biases, and variability in suturing techniques.\(^10\) After our previous study with mechanical prostheses, we compared the hydrodynamic performances of these 5 different models of supra-annular pericardial and porcine bioprostheses, selecting for each model the tissue annulus diameter that could fit a 21-mm-diameter valve holder of a Sheffield pulse duplicator (SPD), regardless of the industry-labeled valve size.

### Materials and Methods

The SPD is a system designed to perform pulsatile hydrodynamic testing of prosthetic heart valves by means of continuous measurement of flow and transvalvular pressure gradients. The system has been previously described in detail.\(^11,12\)

Production-quality bioprostheses, including the sewing ring cuffs, were tested in the aortic chamber of the SPD. The pulse duplicator holder is composed of 2 O-rings, and the prosthesis is secured between these rings (Figure 1).

To allow a meaningful comparison regardless of industry-labeled valve size, we tested the supra-annular tissue valves with a tissue annulus diameter that could be fitted in a 21-mm pulse duplicator ring. Because of the supra-annular configuration, the opposite ring to fix the valve measured 23 mm. Measured dimensions and labeling sizes of the tested valves are reported in Table 1. The valves and the holder were sealed before testing. The sizes of the tested valves were as follows: 20 mm for the SS valve; 21 mm for the SJME, CEM, and MM valves; and 23 mm for the MF valve. The valves were tested according to standard protocols previously reported.\(^12-14\)

Three production-quality samples of each tissue valve were tested. The tests were carried out at a single pulse rate (70 beats/min), with a cardiac output (CO) of 2, 4, 5, and 7 L/min according to ISO5840\(^15\) and the US Food and Drug Administration “Replacement heart valve guidance” protocol.\(^16\) For the aortic tests, the transducers are located 30 mm from the prosthesis (upstream) and 100 mm from the valve (downstream), with the tip of the

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**Abbreviations and Acronyms**

- CEM = Carpentier-Edwards Magna
- CO = cardiac output
- EOA = effective orifice area
- MF = Mitroflow
- MM = Medtronic Mosaic
- SPD = Sheffield pulse duplicator
- SJME = SJM-Biocor-Epic-Supra
- SS = Sorin Soprano

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**Figure 1.** The supra-annular tissue valve is placed on top of the aortic annulus, with pledgets usually placed in a subannular fashion. In our model we considered the top of the aortic annulus to be the top of the first mounting ring. We compared the prostheses with the larger tissue annulus diameters that could be superimposed to the first mounting ring (21 mm). No larger label size of each valve could be used because in each case a valve with a greater size would have had a greater encumbrance (sewing ring >28 mm), limiting their use in a hypothetical small aortic annulus. With the tissue annulus diameter and the sewing ring diameter larger than the internal diameter, to fix the valve at the top of the first mounting ring as it occurs in the supra-aortic position, we used a second thinner mounting ring larger than the first one (23 mm), allowing the slipping through the ring of commissural posts and of the collar of the sewing cuff, without applying any force and without deforming the stent, as it should be in vivo when the valve is sutured with subannular pledgeted sutures inside the sinus portion of the ascending aorta. Therefore the results of this study are not confounded by the suture technique.
TABLE 1. Geometrics of the tested valves

<table>
<thead>
<tr>
<th>Model</th>
<th>Label size (mm)</th>
<th>Internal diameter (mm)</th>
<th>Tissue-annulus diameter (mm)</th>
<th>Sewing ring diameter (mm)</th>
<th>Height (mm)</th>
<th>Aortic protrusion (mm)</th>
<th>Coronary-sinus protrusion (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sorin Soprano</td>
<td>20</td>
<td>19 ± 0.3 (19.8)</td>
<td>23 ± 0.4 (23)</td>
<td>28 ± 0.5</td>
<td>14.5 ± 0.5</td>
<td>14.5 ± 0.5</td>
<td>0.6 ± 0.1</td>
</tr>
<tr>
<td>Carpentier-Edwards Magna</td>
<td>21</td>
<td>19 ± 0.4 (20)</td>
<td>22 ± 0.4 (21)</td>
<td>26.5 ± 0.5 (26)</td>
<td>15 ± 0.3 (15)</td>
<td>13 ± 0.4</td>
<td>0.4 ± 0.1</td>
</tr>
<tr>
<td>Mitroflow</td>
<td>23</td>
<td>19 ± 0.3 (19)</td>
<td>22.5 ± 0.4 (22.6)</td>
<td>26 ± 0.5 (26.2)</td>
<td>15 ± 0.3 (13.7)</td>
<td>15 ± 0.3</td>
<td>0.4 ± 0.1</td>
</tr>
<tr>
<td>SJM-Biocor-Epic-Supra</td>
<td>21</td>
<td>18 ± 0.5 (20.8)</td>
<td>22 ± 0.4 (21)</td>
<td>27.5 ± 0.3</td>
<td>14 ± 0.4 (13)</td>
<td>11 ± 0.4 (11)</td>
<td>0.5 ± 0.1</td>
</tr>
<tr>
<td>Medtronic Mosaic</td>
<td>21</td>
<td>17 ± 0.3 (18.5)</td>
<td>21 ± 0.2 (21)</td>
<td>26 ± 0.3 (27)</td>
<td>15 ± 0.4 (15)</td>
<td>12.5 ± 0.4 (12)</td>
<td>0.5 ± 0.1</td>
</tr>
</tbody>
</table>

Manufacturers’ values are shown in parentheses.

transducer adjusted to lie flush with the inner wall of the flow chamber. Each valve was tested 10 times at each different CO. This resulted in a total of 40 tests for each valve and 120 tests for each valve model. All the tests and the acquisition of data (mean and standard deviations) were performed as previously described.12 The following parameters were determined for each cardiac cycle: (1) forward flow pressure decrease (ΔP); (2) closing volume (in milliliters); (3) leakage volume (in milliliters); (4) total regurgitant volume (in milliliters); (5) effective orifice area (EOA; in square centimeters; EOA = RMS systolic flow rate[mL/s]/[51.6-Root square {Mean systolic pressure difference/1.0085}]); and (6) stroke work loss (in percentage).

Forward flow pressure decrease, closing volume, leakage volume, total regurgitant volume, and EOA were calculated as previously published by Walker and colleagues.13 The stroke work loss was calculated as the ratio of the mean systolic aortic pressure to the mean systolic ventricular pressure, as previously published by Voelker and associates.14 All data were expressed as means ± standard deviation. The χ² test was used for statistical comparison.

Results
Measurements for All Valve Models
Table 1 shows the measurements for all valve models by nominal size. The value is a mean measurement made with a very professional ruler. Two different independent investigators measured all the prostheses, and measurements are the expression of a mean value of 3 different valves for each model, including the maximum and minimum values obtained for each valve. We avoided compressing the sewing ring or stretching the stent when we measured the prostheses. Measuring the internal orifice diameter, we also considered the thickness of the tissue composing the cusps and not only the distance in between fabric to fabric.

Internal orifice diameter. The largest internal orifice diameter was observed for the SS valve, and the smallest was observed for the MM valve. When compared with nominal size, the actual internal orifice diameter was 4 mm smaller for the MF and MM valves, 3 mm smaller for the SJME valve, 2 mm smaller for the CEM valve, and 1 mm smaller for the SS valve.

Tissue annulus diameter. The largest tissue annulus diameter was observed for the SS valve, whereas the smallest was observed for the MM valve. The CEM valve showed less thickness of the complex tissue stent fabric because the difference between internal annulus diameter versus tissue annulus diameter was 3 mm. The difference was 3.5 mm for the MF valve and 4.5 mm for the SS valve. The SJME and MM valves showed a difference of 4 mm in both cases.

Sewing ring diameter. The largest sewing ring diameter was observed for the SS valve, whereas the smallest was observed for the MF and MM valves. The thinnest valve was the MF valve because the smallest difference between the sewing ring diameter and internal orifice diameter was observed in this model (7 mm), followed by the CEM valve (7.5 mm), the MM and SS valves (9 mm), and finally the SJME valve (9.5 mm).

Height and aortic protrusion. The MF valve was the highest valve (15 mm), and because of the flat profile in this valve, the aortic protrusion was equal to the height. The SJME valve was the valve with the lowest profile (11 mm) and with the smallest aortic protrusion (14 mm).

Height and coronary sinus protrusion. The MF and CEM valves showed the shortest difference between the base of the valve and the maximal height of the coronary sinus. The SS valve showed the highest profile.

In Vitro Performances
The obtained mean values and standard deviations are expressed according to the 4 COs adopted and are reported in Table 2.

Pressure Differences
The mean and peak pressure differences for each CO are reported in Figure 2. Pericardial valves showed significantly lower gradients than porcine valves, unlike for the SJME valve at 2 L/min. The CEM valve at 2 and 4 L/min showed the lower pressure difference, although not significantly different than the MF and SS valves. At increasing CO (5-7 L/min), the MF valve significantly increased its performances,
TABLE 2. Hydrodynamic performances of the tested valves (mean value ± SD) at COs of 2, 4, 5, and 7 L/min

<table>
<thead>
<tr>
<th>Model</th>
<th>CO (L/min)</th>
<th>MSPD (mm Hg)</th>
<th>PSPD (mm Hg)</th>
<th>TRV (mL)</th>
<th>VLV (mL)</th>
<th>EOA (cm²)</th>
<th>SWL (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carpentier-Edwards Magna, 21 mm</td>
<td>2.00</td>
<td>6.75 ± 1.44</td>
<td>12.51 ± 2</td>
<td>12.64 ± 1.5</td>
<td>9.72 ± 1</td>
<td>0.79 ± 0.09</td>
<td>6.86 ± 1.2</td>
</tr>
<tr>
<td></td>
<td>4.00</td>
<td>9.38 ± 1.3</td>
<td>21.17 ± 1.7</td>
<td>12.92 ± 1.3</td>
<td>11.61 ± 1.3</td>
<td>1.38 ± 0.1</td>
<td>9.71 ± 0.88</td>
</tr>
<tr>
<td></td>
<td>5.00</td>
<td>13.23 ± 0.67</td>
<td>30.96 ± 2.5</td>
<td>12.83 ± 0.9</td>
<td>11.68 ± 0.9</td>
<td>1.48 ± 0.03</td>
<td>13.92 ± 0.7</td>
</tr>
<tr>
<td></td>
<td>7.00</td>
<td>20.85 ± 0.5</td>
<td>38.04 ± 1.7</td>
<td>12.07 ± 0.73</td>
<td>11.10 ± 0.76</td>
<td>1.59 ± 0.01</td>
<td>20.95 ± 0.83</td>
</tr>
<tr>
<td>Sorin Soprano, 20 mm</td>
<td>2.00</td>
<td>7.22 ± 2.3</td>
<td>14.46 ± 2.1</td>
<td>3.42 ± 1.7</td>
<td>2.32 ± 1.3</td>
<td>0.74 ± 0.13</td>
<td>8.70 ± 2.6</td>
</tr>
<tr>
<td></td>
<td>4.00</td>
<td>11.07 ± 2.3</td>
<td>23.1 + 2.9</td>
<td>3.13 ± 1.4</td>
<td>2.24 ± 1.8</td>
<td>1.29 ± 0.15</td>
<td>12.6 ± 2.8</td>
</tr>
<tr>
<td></td>
<td>5.00</td>
<td>13.7 ± 2.1</td>
<td>28.7 ± 3.6</td>
<td>3.4 ± 1.9</td>
<td>2.5 ± 1.6</td>
<td>1.46 ± 0.14</td>
<td>15.2 ± 2.3</td>
</tr>
<tr>
<td>Mitroflow, 23 mm</td>
<td>2.00</td>
<td>7.10 ± 1.6</td>
<td>15 ± 1.4</td>
<td>3.05 ± 1.5</td>
<td>1.7 ± 0.99</td>
<td>0.73 ± 0.09</td>
<td>8.63 ± 2.2</td>
</tr>
<tr>
<td></td>
<td>4.00</td>
<td>9.66 ± 1.7</td>
<td>22.65 ± 0.57</td>
<td>2.95 ± 0.81</td>
<td>1.35 ± 0.5</td>
<td>1.35 ± 0.14</td>
<td>11.73 ± 2.83</td>
</tr>
<tr>
<td></td>
<td>5.00</td>
<td>11.64 ± 1.9</td>
<td>27.37 ± 1.4</td>
<td>2.76 ± 0.61</td>
<td>1.57 ± 0.23</td>
<td>1.57 ± 0.17</td>
<td>13.83 ± 3.16</td>
</tr>
<tr>
<td></td>
<td>7.00</td>
<td>16.89 ± 2.6</td>
<td>31.47 ± 2</td>
<td>2.73 ± 0.57</td>
<td>1.48 ± 0.24</td>
<td>1.79 ± 0.17</td>
<td>17.93 ± 2.74</td>
</tr>
<tr>
<td>SJM-Biocor-Epic-Supra, 21 mm</td>
<td>2.00</td>
<td>7.41 ± 1.8</td>
<td>13.5 ± 2.32</td>
<td>2.29 ± 1</td>
<td>1.84 ± 1</td>
<td>0.76 ± 0.14</td>
<td>9.36 ± 2.7</td>
</tr>
<tr>
<td></td>
<td>4.00</td>
<td>13.06 ± 1.5</td>
<td>24.9 ± 2.3</td>
<td>2.66 ± 1.1</td>
<td>2.15 ± 1.15</td>
<td>1.23 ± 0.11</td>
<td>14.75 ± 2.16</td>
</tr>
<tr>
<td></td>
<td>5.00</td>
<td>17.37 ± 1.8</td>
<td>36.2 ± 4.6</td>
<td>2.78 ± 0.98</td>
<td>2.29 ± 1</td>
<td>1.34 ± 0.12</td>
<td>19.1 ± 2.8</td>
</tr>
<tr>
<td>Medtronic Mosaic, 21 mm</td>
<td>2.00</td>
<td>9.65 ± 0.7</td>
<td>15.91 ± 2</td>
<td>8.05 ± 0.9</td>
<td>6.35 ± 0.67</td>
<td>0.63 ± 0.02</td>
<td>11.25 ± 0.43</td>
</tr>
<tr>
<td></td>
<td>4.00</td>
<td>19.5 ± 0.35</td>
<td>33.94 ± 1.4</td>
<td>7.5 ± 0.67</td>
<td>6.72 ± 0.64</td>
<td>0.99 ± 0.088</td>
<td>20.94 ± 0.24</td>
</tr>
<tr>
<td></td>
<td>5.00</td>
<td>25.8 ± 0.23</td>
<td>52.4 ± 0.86</td>
<td>7.26 ± 1.37</td>
<td>6.72 ± 1.34</td>
<td>1.09 ± 0.005</td>
<td>26 ± 0.27</td>
</tr>
<tr>
<td></td>
<td>7.00</td>
<td>39.98 ± 0.57</td>
<td>70 ± 3</td>
<td>9.2 ± 1.8</td>
<td>8.7 ± 3.7</td>
<td>1.17 ± 0.005</td>
<td>34.7 ± 2.44</td>
</tr>
</tbody>
</table>

CO, Cardiac output; MSPD, mean systolic pressure difference; PSPD, peak systolic pressure difference; TRV, total regurgitant volume; VLV, valve leakage volume; EOA, effective orifice area; SWL, stroke work loss.

showing the lowest pressure differences in comparison with both the CEM and SS valves (P < .05). The SJME valve at each CO had shown significantly lower pressure differences than the MM valve (P < .05).

**Regurgitant Volumes**

The observed total regurgitant volumes are reported in Figure E1. The SJME valve showed the lowest regurgitant volume (<3 mL), which was significantly smaller for each CO when compared with that obtained with the CEM and MM valves (P < .005). On the contrary, the CEM valve showed the significantly highest regurgitant volume (>12 mL) in comparison with the other valves (P < .0005). The results for the SJME, SS, and MF valves were comparable.

**Closure Volume**

All the tested valves showed a decreasing closure volume as CO increased. The highest value was observed with the CEM prosthesis (P < .005). The SJME valve showed the lowest closure volume at each CO, and the results were significantly different in comparison with all the other tested valves, except the MF valve (P < .05).

**Leakage Volume**

The grade of the leakage volume for each tested valve is reported in Figure E2. The MF valve showed the lowest leakage volume, which was significantly smaller for each CO when compared with that obtained with the CEM and MM valves (P < .0005). The leakage volumes observed with the SJME and SS valves were comparable with that of the MF valve. The highest leakage volume was observed with the CEM valve. All the tested tissue valves showed a leakage volume greater than the closure volume.

**Effective Orifice Area**

The calculated EOAs for all valves are reported in Figure E3. The EOA observed with the CEM valve was comparable with those observed with the MF and SS valves (P > .1), but the MF valve had a significantly higher EOA at 7 L/min than the other 2 pericardial valves. The CEM valve showed also higher EOA than the SS valve at 5 L/min, although this was not significant (P = .69). The SJME valve at 2 L/min showed comparable results with the pericardial valves, whereas the difference became significant at 4, 5, and 7 L/min. The MM valve showed a significantly lowest EOA at each CO (P < .005). In all the tested valves, the calculated EOA was larger at increasing CO.

**Stroke Work Loss**

The calculated stroke work loss values for each tested valve are listed in Figure E4. The stroke work loss profile for each valve was similar, increasing concurrently with increasing CO. The results obtained at 2 L/min were comparable for all the pericardial prostheses and for the SJME valve. At 4 to 5 and 7 L/min, the porcine valves showed significantly worse values in comparison with the pericardial bioprostheses. At 2 and 4
L/min, the CEM valve showed the best performances, which, however, were comparable with those obtained with the SS and MF valves. Between 5 and 7 L/min, the MF valve was the best performing valve, showing the lowest stroke work loss, which proved to be statistically significant when compared with both the CEM and SS valves at 7 L/min (*P* < 0.05).

**Discussion**

All valve substitutes, because of design, size, material, and implantation technique, leave some kind of residual stenosis. Recent studies have demonstrated the importance of avoiding severe mismatch, and hence the choice of valve prostheses and implantation techniques become of paramount importance.

The transvalvular gradient is dependent on flow and EOA, and with the EOA clearly related to the internal diameter of the prosthesis, the supra-annular prostheses have been designed with the intention of having a greater internal diameter and a greater geometric orifice area within a defined tissue annulus dimension. However, comparison between different tissue valves is always complicated and sometimes misleading.

It is therefore necessary to compare the performances of these prostheses in relation to the actual tissue annulus diameter and not on the basis of industry-labeled valve size to obtain accurate and clinically relevant data on the hydrodynamic performances of different valve types. Therefore we designed an in vitro study fitting in the pulse duplicator the largest tissue annulus diameter of each different valve model able to superimpose the 21-mm valve holder ring, which would mimic a 21-mm aortic annulus.

**Comparison of Actual Sizer and Valve Dimensions Versus Labeled Diameters**

Our findings parallel those of previous authors because in all the measured valves there was evidence that the actual size and valve dimensions vary considerably from the labeled diameters. Only for the MM valve was the label size equivalent to the tissue annulus diameter. On the contrary, as previously observed, to give the surgeon a quick idea about the appropriate valve, the labeled size of the valve should reflect the tissue annulus diameter. We compared supra-annular tissue valves with a tissue annulus diameter ranging between 21 and 23 mm. In all these prostheses, there was a large variability between internal orifice diameter and sewing ring diameter, between internal orifice diameter and tissue annulus diameter, and between tissue annulus diameter and sewing ring diameter. We found it impossible to test larger prostheses in label size than those tested because larger size would mean a larger sewing ring and higher profile, increasing the prosthesis encumbrance in the sinus portion of the aorta.

We sought to address these limitations by selecting a relatively homogeneous group of valves, using those with the largest tissue annulus diameter that could be superimposed in a definite pulse duplicator ring without forcing the insertion to avoid stent modification because in our experience the distortion of the normal planar geometry of the pericardial prosthesis, induced by fixation with a second not adequate ring, resulted in failure of adequate central leaflet coaptation. This issue was already observed in vivo by other authors. The MM valve was the sole valve with a tissue annulus diameter smaller than 22 mm; nonetheless, an upsizing was impossible. A modification of the cuff has been introduced on the new MM valve, namely the Mosaic Ultra, and further studies will be required on this new model. The valves with the more advantageous ratio between internal orifice diameter versus tissue annulus diameter versus sewing ring diameter were the MF and CEM valves. The valve with the lowest height and aortic protrusion was the SJME valve. At a certain extent, this means that for this model, the implantation technique should be more comfortable. The valves with the
lowest coronary sinus protrusion were the MF and CEM valves, further justifying their easier implantation.

In Vitro Comparison of Hemodynamic Performances of Different Tissue Valves
A recent prospective randomized study has been published by Eichinger and coworkers. The authors showed a significant hemodynamic superiority of the bovine tissue valves compared with the porcine bioprostheses (Carpentier-Edwards Perimount versus MM valves). Moreover, Eichinger and coworkers infer that sometimes an upsizing of the MM valve is possible because the sewing ring diameter of the latter is smaller than that of the Carpentier-Edwards Perimount valve. Our in vitro results show that this upsizing is not possible for the MM valve versus the CEM valve. Further studies will address this issue with the new MM Ultra valve. Seitelberger and colleagues did not find any difference in hemodynamic performances between the MM (supra-annular) and Perimount (intrasupra-annular) valves if the patient’s annulus, as measured with a metric sizer, was chosen as the reference dimension. Botzenhardt and associates, comparing supra-annular tissue valves in a prospective nonrandomized study, indicated the CEM valve as the gold standard in the panorama of supra-annular tissue valves, stating that no advantages could be obtained with the other supra-annular prostheses in comparison with the standard Perimount valve. These conclusions nevertheless clash with our in vitro data.

According to our experimental results, pericardial valve prostheses exhibited the smallest transprosthetic mean and peak gradients and the lowest stroke work loss in comparison with porcine valves. As previously observed by Kuehnel and associates, who compared the Carpentier-Edwards-Perimount valve with the MM valve in a mock circuit, we observed that the pericardial valve, unlike the porcine valve, exhibited an EOA flow dependency. This means that the porcine valve cusps (mostly for the SJME valve in our study) were fully open already under low-flow conditions, showing comparable results to the pericardial valves at 2 L/min, and therefore the porcine prosthesis does not show a CO-dependent effective opening area reserve. This should be the result of the major pliability of the porcine tissue rather than the pericardial leaflets. Therefore at increasing heart rate, we expect a modification of the performances of both models. However, to explain this hypothesis, we are performing new tests and modifying parameters, such as heart rate, stroke volume, and systemic resistance.

Among the pericardial bioprostheses, the CEM valve showed the larger EOA, the lower mean and peak systolic pressure differences, and the lower stroke work loss at a CO of 2 and 4 L/min. However, these results were substantially comparable with those observed with the MF and SS valves, and at increasing CO (7 L/min), the MF valve performed significantly better, exhibiting the largest EOA, the lowest gradients, and the lowest stroke work loss.

Additionally, the MF valve had the lowest total regurgitant volume and the lowest valve leakage volume, proving that the design of this prosthesis, with the pericardium sutured externally to the stent, provides an effective opening area reserve and an adequate central leaflet coaptation. These in vitro results strongly contrast with the conclusions reported by others.

Finally, although in small valves the cause of energy loss is greatly related to the forward flow transvalve pressure difference rather than to the regurgitant flow, the unexpected highest total, closing, and leakage volumes observed with the CEM valve might in some way explain the worse hydrodynamic results of this prosthesis in comparison with the SS and MF valves at increasing COs. Moreover, the high regurgitant volumes observed with the CEM valve might be determined on the basis of a limited central leaflet coaptation, which might explain the lower tolerability of this valve to annular distortion.

This is an in vitro study, and therefore the transfer of these data to an in vivo situation is limited by the fact that the in vivo hemodynamic behavior of a valve might differ from our idealized assumptions. However, we can consider that a good correlation between in vitro and in vivo results exists because in vitro EOAs tend to overestimate in vivo EOAs by 10% to 15%. Moreover, we tested the valves using a saline solution with a lower viscosity than blood.

The second limitation is related to the fixed heart rate selected for all the tests. We mean that it is not realistic to reach a CO of 7 L/min while maintaining a fixed heart rate. Therefore the performance of the pericardial valve, the leaflets of which are less pliable than porcine valves, might be overestimated in this in vitro study. We are planning a new study design in which we will test the valves, modifying concomitantly several parameters (heart rate, stroke volume, and systemic resistance). Nevertheless, we retain this work as important because it could be interpreted as the first in vitro comparison of supra-annular prostheses from whose conclusions new studies might be projected.

Additionally, in vitro comparison of different supra-annular bioprostheses according to the true tissue annulus diameter has not yet been described in the literature to our knowledge. From our results, it became obvious that the pericardial valves show higher hemodynamic performances when compared with the porcine valves, mostly at higher COs. Moreover, at increasing COs, the SS valve shows comparable results to the CEM valve, whereas the MF valve was the significantly superior prosthesis.

Clinical Inferences
This study model, which strictly correlates a definite aortic annulus of 21 mm to a definite spread of supra-annular...
tissue valves, might be useful for patient counseling and for surgical decision making.

References


Figure E1. Total regurgitant volume. CE, Carpentier-Edwards.

Figure E2. Leakage volumes. CE, Carpentier-Edwards.

Figure E3. Effective orifice area. CE, Carpentier-Edwards.
Figure E4. Stroke work loss. CE, Carpentier-Edwards.