The On-X valves were designed to be less turbulent. Low complication rates, less blood destruction and low gradients provide compelling evidence that an inlet flare, near natural valve length and 90° leaflet opening angle provide less turbulence even in larger sized On-X mitral valves. Determining optimal size without gaining increased closing (or trapped) volume was taken into consideration in developing the On-X valves. As you can see in Figure 1, regurgitant closing volume increases greatly for large sizes of a short orifice valve at all heart rates—an undesirable effect.

Larger geometric orifice areas (GOAs) with leaflets in place for the On-X valve

Sizing designations for mechanical valve orifices have not been standardized and have been confusing for the cardiovascular surgical community. A comparison of valve geometric orifice areas listed in the data provided to the United States Food and Drug Administration (US FDA) shows that only one valve manufacturer makes a larger mitral valve orifice than the On-X valve mitral and aortic orifice 25 (Figure 2).

Greater effective orifice area (EOA) and less mismatch

A Canadian study shows less mismatch for the On-X mitral valve overall compared with other valves (Table 1). Figures 3-5 show that even though other valve brands increase the GOA for each size, the gradient and EOA values for all large sized valves are essentially the same. Therefore, increasing GOA beyond optimal flow does not make sense when increased turbulence, blood destruction and noise are a concern. Replacement of mitral regurgitation or stenosis with a prosthetic that has a large trapped volume and a limited EOA is essentially implanting regurgitant disease.

Table 1. Mitral Valve Comparison

<table>
<thead>
<tr>
<th>Valve Brand</th>
<th>Number of patients</th>
<th>EOA</th>
<th>IEOA</th>
</tr>
</thead>
<tbody>
<tr>
<td>On-X</td>
<td>85</td>
<td>2.4</td>
<td>1.3</td>
</tr>
<tr>
<td>SJM</td>
<td>209</td>
<td>2.2</td>
<td>1.28</td>
</tr>
<tr>
<td>CMI</td>
<td>121</td>
<td>2.3</td>
<td>1.26</td>
</tr>
</tbody>
</table>

SJM = St. Jude valve; CMI = CarboMedics valve; IEOA = indexed effective orifice area.

Less mismatch with the On-X mitral valve proves that optimal flow is achieved at a smaller nominal size.¹
Iron man competition for an On-X mitral valve
This optimal flow has been proven to be effective even in a 6’5”, 230 pound man who completed a triathlon 10 months after his implant surgery and continues to propel him through more rigorous exercises like the half iron man competition.

Figure 4. Patient with On-X mitral valve

Lowest mitral complication rates for the On-X valve
In recent trials for FDA approval, the On-X valve showed the lowest overall mitral complication and mortality rates (Table 2). These low rates and reduced LDH levels are evidence of lower turbulence for the On-X valve.3-7,13

Table 2. Comparison of Mitral Hematological Clinical Event Rates 4,6,7,12

<table>
<thead>
<tr>
<th>Clinical Event</th>
<th>On-X (FDA)</th>
<th>On-X 12 year</th>
<th>ATS</th>
<th>CMI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thromboembolism</td>
<td>1.7</td>
<td>0.9</td>
<td>4.0</td>
<td>2.8</td>
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<tr>
<td>Thrombosis</td>
<td>0</td>
<td>0.1</td>
<td>0.5</td>
<td>0.7</td>
</tr>
<tr>
<td>Hemorrhage</td>
<td>1.4</td>
<td>1.0</td>
<td>0.5</td>
<td>2.1</td>
</tr>
<tr>
<td>Mortality</td>
<td>2.2</td>
<td>2.0</td>
<td>3.5</td>
<td>4.4</td>
</tr>
<tr>
<td>Composite</td>
<td>3.1</td>
<td>2.0</td>
<td>5.0</td>
<td>5.6</td>
</tr>
</tbody>
</table>

ATS = ATS valve, CMI = CarboMedics valve

Less mismatch, lower complication and mortality rates, less closing regurgitation and low blood destruction all prove that the On-X mitral valve is the right one for your mechanical valve patients.

References
3. Some values calculated at On-X Life Technologies, Inc. from base data provided by approval submissions.
5. SJM Regent® Valve. Clinical Study Summary (package insert)

On-X aortic and mitral valves are FDA approved.

CAUTION: Federal law restricts this device to sale by or on the order of a physician. Refer to the Instructions for Use that accompany each valve for indications, contraindications, warnings, precautions and possible complications. For further information, visit www.onxlti.com.