Most echocardiographic assessments of aortic valve prosthesis performance have been made with the patient at rest. However, this method will not reflect the hemodynamic performance of the valve in response to changing cardiovascular demands during everyday activities involving mild-to-moderate exercise. These changes in the transvalvular pressure gradients, the effective orifice area and valvular resistance can best be observed with exercise Doppler echocardiography. The St. Jude Medical Trifecta aortic valve prosthesis, designed for supra-annular placement, incorporates certain features that may improve hemodynamics. This has not been previously evaluated in a comparative exercise study.

OBJECTIVE

The objective of this study was to determine the hemodynamic performance of the Trifecta aortic valve prosthesis at rest, during exercise and during a 10-minute recovery period in comparison with the Freestyle™ stentless aortic valve, the Ross procedure and a healthy control group.

METHODS

- A total of 32 patients who were implanted with the Trifecta valve meeting eligibility criteria, including normal sinus rhythm, ejection fraction ≥ 45% and stable clinical condition, were enrolled in the exercise stress test study.
- Transthoracic Doppler echocardiography was performed at rest, continuously during supine exercise stress testing and during a 10-minute recovery period.
- Data from 49 patients operated on with the Ross procedure, 39 patients who received the Freestyle valve and 25 healthy controls were chosen for comparison. All of these patients, including the control group, were examined with exactly the same exercise echocardiographic protocol as used with the patients implanted with the Trifecta valve.
- Patient characteristics are shown in Table 1.

RESULTS

- At rest, single-digit mean gradients were observed for both the Trifecta (7.2 ± 3.4 mmHg) and Freestyle (8.7 ± 4.5 mmHg) aortic bioprostheses.
- Measurements of mean systolic pressure gradients, EOA and valvular resistance (VR) for both the Trifecta and Freestyle valves remained relatively constant when measured at rest, peak exercise and recovery.
- However, mean gradients and VR at peak exercise for the Trifecta valve (10.2 ± 4.7 mmHg and 62.6 ± 25.3 dyn s cm⁻⁵) was numerically lower than that of the Freestyle valve (12.4 ± 5.4 mmHg and 82.1 ± 43.6 dyn s cm⁻⁵). The EOA at peak exercise for the Trifecta valve (0.98 ± 0.26 cm²) was larger than that for the Freestyle valve (0.82 ± 0.26 cm²).
<table>
<thead>
<tr>
<th>Group</th>
<th>Rest</th>
<th>Maximum exercise</th>
<th>End of recovery</th>
</tr>
</thead>
<tbody>
<tr>
<td>δp (mmHg)</td>
<td></td>
<td></td>
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<tr>
<td>Control</td>
<td>3.03 ± 0.93</td>
<td>6.05 ± 1.77</td>
<td>2.79 ± 0.92</td>
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<tr>
<td>Ross</td>
<td>3.05 ± 1.65</td>
<td>4.64 ± 2.51</td>
<td>3.32 ± 1.65</td>
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<tr>
<td>Stentless</td>
<td>8.67 ± 4.51</td>
<td>12.37 ± 5.39</td>
<td>11.02 ± 6.25</td>
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<tr>
<td>Trifecta</td>
<td>7.21 ± 3.36</td>
<td>10.21 ± 4.65</td>
<td>8.07 ± 4.01</td>
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<td>υR (dyn s cm⁻⁵)</td>
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<tr>
<td>Control</td>
<td>19.88 ± 5.0</td>
<td>26.68 ± 7.4</td>
<td>18.69 ± 5.0</td>
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<tr>
<td>Ross</td>
<td>17.15 ± 6.1</td>
<td>24.15 ± 8.6</td>
<td>18.17 ± 6.3</td>
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<tr>
<td>Stentless</td>
<td>60.75 ± 29.5</td>
<td>82.14 ± 43.5</td>
<td>71.2 ± 34.7</td>
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<tr>
<td>Trifecta</td>
<td>50.75 ± 23.1</td>
<td>62.58 ± 25.3</td>
<td>54.72 ± 29.3</td>
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<tr>
<td>EOAI (cm²/m²)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Control</td>
<td>1.36 ± 0.32</td>
<td>1.53 ± 0.38</td>
<td>1.43 ± 0.36</td>
</tr>
<tr>
<td>Ross</td>
<td>1.53 ± 0.39</td>
<td>1.62 ± 0.42</td>
<td>1.51 ± 0.39</td>
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<tr>
<td>Stentless</td>
<td>0.8 ± 0.18</td>
<td>0.82 ± 0.26</td>
<td>0.74 ± 0.23</td>
</tr>
<tr>
<td>Trifecta</td>
<td>0.84 ± 0.23</td>
<td>0.98 ± 0.27</td>
<td>0.88 ± 0.24</td>
</tr>
</tbody>
</table>

*T-AVB vs. MF-AVB P < 0.05, *MF-AVB vs. RO P < 0.05, *T-AVB vs. RO P < 0.05. υR: valvular resistance; EOAI: effective orifice area index.

Patients in the Ross procedure and control groups had significantly lower mean gradients and VR and larger EOAI at lower VR at all measurement points (P < 0.05).

Hemodynamic values for the different patient groups at rest, peak exercise and recovery are shown in Table 2.

In terms of hemodynamics during exercise and recovery:

- **Trifecta valve:**
  - Mean pressure gradients increased significantly up to a maximum workload of 100 W and returned to resting values after the fourth recovery minute.
  - EOAI increased significantly until peak exercise was reached and decreased to normal within the first recovery minute.
  - Very high percentage of patients (97%) completely recovered from elevated VR during exercise.
  - This behavior was comparable to that of the Ross procedure and control group.

- **Freestyle valve:**
  - Patients with the Freestyle valve, in contrast, did not return to the initial value throughout the entire recovery period, P < 0.05 rest versus 10-minute recovery.
  - There was no change in EOAI for patients with a stable orifice area throughout the entire exercise and recovery period.
  - Significantly higher VR values than the Trifecta valve during exercise, P < 0.05. A great proportion of patients did not recover until the end of the 10-minute observation period.

**SUMMARY OF KEY FINDINGS**

- Ross procedure patients were hemodynamically similar to the healthy control group and superior to patients implanted with either of the bioprostheses.
- Both the Trifecta and Freestyle valves had mean gradient values—low single digit—at rest.
  - Especially good performance for a stented pericardial bioprosthesis: Trifecta valve.
  - Also consider that the mean valve size for the Trifecta valve was 23 compared with 25 for the Freestyle valve.

**CONCLUSIONS**

- The Trifecta valve provides promising hemodynamic results for a stented bioprosthesis.
- The Trifecta valve post-exercise recovery values and dynamic adaptation of EOAI to hemodynamic load are similar to the results for the Ross-operated patients (Ross is the surgical “gold standard”) and to normal individuals (NYHA – Class I).
- Larger studies with longer follow-up are needed to determine whether the advantages offered by the Trifecta valve translate into better clinical outcomes.

Rx Only

Brief Summary: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications: The Trifecta Valve is indicated as a replacement for a diseased, damaged, or malfunctioning native or prosthetic aortic heart valve. Adverse events potentially associated with the use of bioprosthetic heart valves include: angina, cardiac arrhythmias, endocarditis, heart failure, hemolysis, hemolytic anemia, hemorrhage, leak (transvalvular or perivalvular), myocardial infarction, nonstructural dysfunction (entrapment by pannus or suture, inappropriate sizing or positioning, or other), prosthetic regurgitation, stroke, structural deterioration (calcification, leaflet tear, perforation, or other), thromboembolism and valve thrombosis. It is possible that these complications could lead to reoperation, explantation, permanent disability or death. Long-term low dose aspirin, unless contraindicated, is recommended for all patients with bioprosthetic valves. Long-term anticoagulant therapy, unless contraindicated, is recommended for all patients with bioprosthetic valves who have risk factors for thromboembolism. Please see the Instructions for Use (IFU) for a full description of indications, contraindications, side effects, precautions, warnings and Instructions for Use.

Product referenced is approved for CE Mark.

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