The St. Jude Medical (SJM) mechanical valve is a bileaflet valve that is constructed using pyloric carbon to achieve the concept of “one valve in one life.” Since its development in 1977, the SJM valve has become the most used mechanical valve in Japan and throughout the world. Because of its excellent durability, the SJM valve is typically used for relatively young patients, and its high performance and low event rate during long follow-ups have been reported previously (Table). The long-term outcomes are of specific interest, and cardiac surgeons are especially interested in the rates of thromboembolism, bleeding, reoperation, valve-related deaths, and valve-related complications (pannus formation, paravalvular leakage with hemolysis, valve thrombosis, and prosthetic valve endocarditis). According to the Society of Thoracic Surgeons/American Association for Thoracic Surgery (STS/AATS) guidelines for reporting mortality and morbidity (vs. 2.0–3.0 for mitral mechanical valves and atrial fibrillation [AF]). Although the PT-INR target was the same as in the Japanese guidelines, the frequency of PT-INR control within the optimal range was not ascertained in this study. Unfortunately, PT-INR tends to drift, which can lead to thromboembolic and bleeding events. Furthermore, for very long periods of warfarin administration, it may be important to quantify the maintenance of the target PT-INR (eg, the time in the therapeutic range for PT-INR, which has been used for AF). Moreover, the risk of thromboembolic and bleeding events varies according to age, and it is possible that the specific optimal range for PT-INR might vary according to the patient’s age.

One complication of mechanical valve use is pannus formation during the follow-up. Although many factors are involved (eg, inflammation, thrombus formation, and turbulence around the valve), the precise cause of pannus formation has not been determined. Therefore, given that reoperations are rarely performed for mechanical valves, the frequency of pannus formation is very important. In this context, the SJM mechanical valve, which has been used for relatively young patients, is an excellent model.

Table. Long-Term Outcomes of Aortic Valve Replacement With St. Jude Medical Valve Reported in Japan

<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Structural valve deterioration (%/pt-year)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Nonstructural dysfunction (%/pt-year)</td>
<td>0.16</td>
<td>0.4</td>
<td>0.02 (%)‡</td>
</tr>
<tr>
<td>Valve thrombosis (%/pt-year)</td>
<td>0.05</td>
<td>0.14</td>
<td>0</td>
</tr>
<tr>
<td>Thromboembolism (%/pt-year)</td>
<td>1.35</td>
<td>0.85</td>
<td>1.1</td>
</tr>
<tr>
<td>Bleeding (%/pt-year)</td>
<td>0.1</td>
<td>0.4</td>
<td>1.0</td>
</tr>
<tr>
<td>Operated valve endocarditis (%/pt-year)</td>
<td>0.21</td>
<td>0.4</td>
<td>0.5 (%)‡</td>
</tr>
</tbody>
</table>

‡Actual rate.
The St. Jude Medical cardiac valve prosthesis has a pivot guard that protrudes into the left ventricle outflow tract, which might cause pannus formation (Figure). Although the frequency of pannus formation in patients with SJM aortic valves is only 0.7–1.4%, the protruding pivot guard has the potential for pannus formation, especially when it is near the mitral valve or septal wall. In this study, the most common reason for aortic valve reoperation was pannus formation (1.5%), and the deaths from unknown causes might have been related to pannus formation. Therefore, additional data collection might be warranted.

The follow-up rate in their report is slightly lower (84.1%) than in previous reports. However, given the recent enforcement of the Personal Information Protection Law, it might be difficult to analyze and collect information from patients over a long follow-up. Therefore, given the multicenter design, high-volume analysis, the data collection methods (data may have been collected from family doctors), and long follow-up period, this follow-up rate could be acceptable.

References