Structural Valve Deterioration in a Starr-Edwards Mitral Caged-Disk Valve Prosthesis

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Background: The durability of the Starr-Edwards (SE) mitral caged-disk valve, model 6520, is not clearly known, and structural valve deterioration in the SE disk valve is very rare.

Methods and Results: Replacement of the SE mitral disk valve was performed in 7 patients 23–40 years after implantation. Macroscopic examination of the removed disk valves showed no structural abnormalities in 3 patients, in whom the disk valves were removed at <26 years after implantation. Localized disk wear was found at the sites where the disk abutted the struts of the cage, in disk valves excised >36 years after implantation in 4 patients. Disk fracture, a longitudinal split in the disk along its circumference at the site of incorporation of the titanium ring, was detected in the valves removed 36 and 40 years after implantation, respectively, and many cracks were also observed on the outflow aspect of the disk removed 40 years after implantation.

Conclusions: Disk fracture and localized disk wear were found in the SE mitral disk valves implanted >36 years previously. The present results suggest that SE mitral caged-disk valves implanted >20 years previously should be carefully followed up, and that those implanted >30 years previously should be electively replaced with modern prosthetic valves.

Key Words: Caged-disk valve; Disk fracture; Disk wear; Prosthetic heart valve; Structural valve deterioration

The first clinical application of the original Starr-Edwards (SE) caged-ball valve prosthesis in 1960 and several subsequent major modifications in materials and design of prosthetic heart valves represented a great contribution to the development of surgical treatment for heart valve disease.1–3 The bulky cage of an SE caged-ball valve, however, limited its clinical use in some patients requiring mitral valve replacement (MVR). To overcome this limitation, a low-profile SE caged-disk valve prosthesis was developed in the early 1970s for MVR in patients with a small or normal-sized left ventricle. Although the use of the SE caged-disk valve was universally discontinued after a short period of clinical application, some patients are still carrying this disk valve. Recently, we replaced SE mitral caged-disk valves implanted >30 years previously in 3 patients and found a unique form of prosthetic valve failure in the removed prosthetic valves.

In this article, we describe our experience with 7 patients who underwent replacement of the SE disk valve >20 years after implantation, and discuss structural valve failure in the SE mitral disk valve.

Methods

The current study was approved by The Ethics Committee of Munakata Suikokai General Hospital and Kurume University, and individual patient consent was waived.

Between 1996 and 2012, in total, 7 patients underwent replacement of the SE mitral disk valve >20 years after implantation. Clinical characteristics of these 7 patients are summarized in Table. Four (patients 1–4) of the 7 patients had been previously reported upon.4,5 Subjects consisted of 1 man and 6 women, ranging in age from 53 to 71 years, with a mean of 62.4 years. An SE disk valve, model 6520, had been used in all 7 patients and the valve size was 3M in 5 patients and 4M in 2. All patients had been on oral anticoagulation using warfarin with or without an antiplatelet agent after MVR, and the thrombo-test level was maintained at around 20%. Preoperative cardiac and prosthetic valve function was evaluated on cineradiography, echocardiography and/or cardiac catheterization in all 7 patients. The motion of the disk was assessed as movement of a titanium ring incorporated within the disk on cineradiography.
the disk valve ranged from 2.2 to 10.2 mmHg (mean, 6.4±2.6 mmHg), and the calculated mitral valve orifice area (MVA) was 0.9–2.3 cm² (mean, 1.5±0.5 cm²). The MPG was >5 mmHg in 5 of the 7 patients and the MVA was ≤1.8 cm² in 5 of 6 patients (Table).

Replacement of the SE disk valve was performed 23–40 years (mean, 31.9 years) after implantation, and the causes of replacement were prosthetic valve stenosis without valve dysfunction in 4 patients, thrombus formation in the left atrium in 2, paraprosthetic valve regurgitation associated with mechanical hemolysis in 2, progression of aortic stenosis in 1 and entrapment of the disk in 1. At surgery, pannus overgrowth extending onto the sewing cuff was present, but no invasion into the valve orifice or the struts of the cage was detected in any of the 7 patients. In 1 patient (patient 4), cineradiographic findings of impingement of the disk due to a calcified mass were confirmed during the operation.

On macroscopic examination of the excised SE disk valves, no valve thrombosis or thrombus attached to the disk or the cage struts was found. No structural abnormalities such as strut fracture or disk wear were detected in 3 of the 7 patients (patients 1–3; Figure 1). In these 3 patients, the disk valves were removed at 23, 24, and 26 years after implantation, respectively. In the remaining 4 patients (patients 4–7) undergoing replacement of the SE disk valve 37, 36, 37, and 40 years after implantation, respectively, minor-to-moderate localized wear (depression) of the disk was found around the outflow perimeter of the disk. Localized wear was detected at the sites where the disk abutted the struts of the cage (Figure 2). In 1 patient (patient 4), localized wear was also found at the site where the disk came into contact with a calcified mass. In addition, fracture, a longitudinal split in the disk along its circumference at the site of incorporation of the titanium ring, was detected in 2 of the 4 patients (patients 6, 7; Figure 3). Their SE disk valves were removed 36 and 40 years after implantation, respectively. Furthermore, a number of irregular linear cracks were also observed on the outflow aspect of the disk in 1 patient (patient 7), in whom the disk valve was removed 40 years after implantation.

No early deaths within 30 days after redo MVR occurred, and postoperative recovery was uneventful in all 7 patients. Anticoagulant therapy with warfarin and an antiplatelet agent was maintained in every patient, and the international normalized ratio was kept at around 2.0 in patients with a mechanical
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valve in the left heart and at 2.5–3.0 in patients who underwent TVR.

Discussion

The low-profile SE mitral caged-disk valve prosthesis was developed during the early 1970s to overcome some of the limitations encountered in MVR when using the SE ball valve. Approximately 3,600 of these disk valves were implanted between 1970 and 1976, and some patients bearing this disk valve are still alive.

The SE disk valve, model 6520, consists of an ultra-high-molecular-weight polyethylene disk within a Stellite alloy 21 cage. A thin titanium ring is encapsulated within the polyethylene disk to allow the in situ visualization of disk motion using fluoroscopy. In our experience, analysis of disk motion on cineradiography was exceedingly helpful for clinical diagnosis of prosthetic valve dysfunction.

Because its clinical use was limited to a short period, few studies of the postoperative long-term results of MVR with the SE disk valve have been published, but various valve-related complications, which necessitated replacement of the disk valve, have been reported. In our experience, prosthetic valve stenosis without valve dysfunction was the primary or secondary indication of replacement of the mitral SE disk valve in 4 of the present 7 patients. The SE disk valve, model 6520, was designed to provide hydraulic function almost equal to the model 6120 SE ball valve, for every valve size. Kremkau et al, however, showed that the resting MPG was 7.9 mmHg (range, 4.2–13.3 mmHg) and the MVA was 1.9 cm² (range, 1.7–2.0 cm²),
and concluded that the MPG is larger and the MVA is smaller for the disk valve than for the ball valve. In the present patients (excluding 2 with paraprosthetic leakage), the average MPG was 5.4 mm Hg and the average MVA was 1.5 cm² at rest. These data suggest that the SE disk valve is intrinsically slightly stenotic compared with modern bileaflet valves.

Among valve-related complications, structural valve deterioration (SVD) of the SE disk valve is very rare. Malouf et al. described a case of fracture and localized wear (a depression) in the polyethylene disk of an SE disk valve removed 27 years after implantation. In their patient, a longitudinal split along the circumference of the disk at the site of incorporation of the titanium ring, and a localized depression in the disk corresponding to where the disk abutted the struts of the cage, were detected. We also previously presented a case of localized disk wear at sites where the disk abutted the cage struts and also abutted a calcified mass in the SE disk valve 37 years after implantation. In reviewing the present 7 patients, no obvious localized disk wear was detected in the disk valve removed ≤26 years after implantation, but minor-to-moderate localized disk wear was found in the disk valves implanted >36 years previously in 4 patients, and in 2 of the 4 patients a longitudinal split of the disk was present in the SE valves excised 36 and 40 years after implantation, respectively. Furthermore, in the disk valve removed 40 years after implantation, many cracks were also observed in the disk. These facts suggest that wear of the polyethylene disk may gradually progress with time. Although the causal relationship between the progression of disk wear and occurrence of the split and cracks in the disk is not clearly understood, progression of the localized damage may subsequently result in a longitudinal split and cracks in the disk at ≥25 years later after implantation. The pathogenic mechanism of development of a longitudinal split in the disk is not clear. Although how the titanium ring was incorporated into the disk is unknown, a polyethylene disk in an SE disk valve seems to be composed of 2 thin polyethylene segments, including an inflow segment and an outflow segment, which are joined directly. Thus, in cardiac diastole, both abrupt deceleration of disk motion by impingement of a disk against the cage and accelerated blood flow through a stenotic prosthetic valve orifice may work as forces to separate the 2 segments. Consequently, ≥25 years after implantation, a longitudinal split in the disk along its circumference at the site of incorporation of a titanium ring may develop. Considering the pathogenic mechanism, these structural abnormalities, a longitudinal split and localized wear, in a polyethylene disk may be a common form of SVD in the model 6520 SE disk valve.

In conclusion, we have reported on 7 patients who underwent replacement of an SE mitral caged-disk valve >20 years after implantation. Wear of the polyethylene disk was found in 4 of the 7 patients, whose disk valves removed >36 years after implantation, and disk fracture, a longitudinal split in the disk, and localized disk wear were detected in disk valves implanted 36 and 40 years previously, respectively, in 2 of the 4 patients. These structural abnormalities in the disk may be a common form of SVD in the SE disk valve. The present results suggest that SE mitral caged-disk valves implanted >20 years previously should be carefully followed up, and that SE disk valves implanted >30 years previously should be electively replaced with modern prosthetic valves.

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