

A Case of Early Failure of the Freestyle Stentless Bioprosthesis Due to Cuspal Tear

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We report an unusual case of early structural failure of the Freestyle stentless bioprosthesis 22 months after initial implantation. A 71-year-old woman, who had undergone stentless valve implantation by the subcoronary method, presented with a new diastolic murmur and progressive congestive heart failure 20 months after the initial implantation. Reoperation was performed using a stented bioprosthesis. The explanted prosthesis showed a tear along the annulus in one cusp. There were no findings of bacterial endocarditis or other macroscopical changes including calcification, thrombus attachment and pannus formation. It is believed that the cause of the cuspal tear was primary tissue failure. Further study is needed to clarify the incidence of this event. (Ann Thorac Cardiovasc Surg 2004; 10: 382–5)

Key words: Freestyle stentless bioprosthesis, reoperation, cuspal tear

Introduction

The Freestyle stentless bioprosthesis (Medtronic, Inc., Minneapolis, MN) has been widely used around the world since the human trials for it began in 1992. Stable mid-term results^{1,2)} are presented by this stentless prosthesis because of superior hemodynamic performance with a wide effective valve orifice area in comparison with a conventional stented valve. However, reoperation has been reported to be necessary according to some of the mid-term results.³⁾ In most cases, reoperation is necessary due to early dehiscence of the proximal suture line.⁴⁾ The onset of structural deterioration as a cause of reoperation has been rare, and details about such cases have scarcely been reported. We observed a case of structural deterioration in a 71-year-old woman that occurred 22 months after the implantation. The excised prosthesis showed a tear of one cusp along the annulus. This kind of structural deterioration has not been previously presented.

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Case Report

A 71-year-old woman presented with dyspnea on effort due to aortic valve stenosis. Aortic valve replacement was carried out using a 23-mm Freestyle stentless bioprosthesis in the subcoronary position. The perioperative course was unremarkable. Echocardiogram performed on postoperative day 7 showed neither aortic valve regurgitation nor valve dehiscence. Peak pressure gradient across the aortic prosthesis was 26 mmHg. She left the hospital on postoperative day 13. She remained asymptomatic for the subsequent 18 months. However, she was found by a local doctor to have a new diastolic murmur, and echocardiogram suggested mild prosthetic valve regurgitation. Because the patient was aware of breathlessness on exertion, she was readmitted in postoperative month 20. At the time of readmission, chest X-ray showed a cardiothoracic ratio of 63% with mild pulmonary congestion. Echocardiogram revealed significant vibration of the Freestyle's cusp positioned in her left sinus, and a leakage flow was confirmed in the locus. Symptoms of congestive heart failure progressed rapidly after hospitalization and she ultimately developed orthopnea. Reoperation was performed six days after readmission. The previous aortotomy site was opened and a thread of the outflow suture line was taken off. The adhesion be-

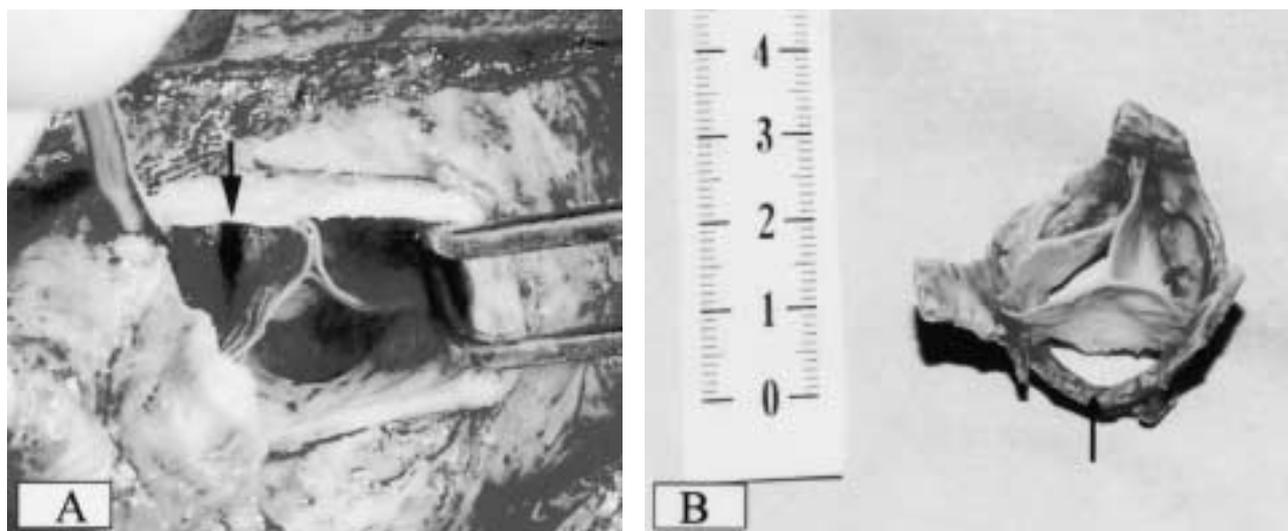


Fig. 1.

A: Intraoperative finding. The Freestyle's cusp positioned in the patient's left sinus showed a cuspal tear (arrow).
 B: Explanted Freestyle stentless bioprosthesis. Tear along the annulus in one of the cusps is observed (arrow).

tween the native and prosthetic coronary sinus was moderate and it was carefully separated down to the inflow suture line. No prosthetic dehiscence was observed. The prosthesis was excised after removal of the inflow suture. By direct observation, the Freestyle's cusp positioned at the patient's left sinus showed a tear along the annulus, which caused massive regurgitation. Every cusp was soft and mobile (Fig. 1).

Valve replacement was carried out with a No.21 bovine pericardial stented prosthesis. In a precise examination of the excised prosthesis, the findings of bacterial endocarditis and the other macroscopic changes including thrombus attachment and pannus formation were not observed in any of the 3 cusps. Cuspal calcific deposits, as examined through soft X-rays of the bioprosthesis, were additionally not found in any of the 3 cusps or in the aortic wall. Microscopic observation was performed afterwards to compare the torn cusp with the non-torn cusp. Normal thickness and corrugation with 3 layers was found in both cusps. One difference between these cusps was the quantity of elastic staining. The amount of elastic staining in the ventricularis layer was less in the torn cusp than in the non-torn cusp (Fig. 2).

The patient was noted to be well immediately after operation, but subsequently developed left cerebellar infarction caused by paroxysmal atrial fibrillation on the 3rd postoperative day. As she underwent rehabilitation program, her neurological symptoms gradually improved,

and she was able to leave the hospital on foot on the 52nd postoperative day.

Discussion

Clinical studies on the Medtronic Freestyle stentless bioprosthesis commenced in 1992. Many reports^{2,5)} have demonstrated its hemodynamic superiority of having a wide effective orifice area in comparison with stented valves. On the other hand, some reoperation cases have been reported among the early results of the Freestyle stentless bioprosthesis. Doty²⁾ reported that reoperation necessitating explant of the prosthesis is observed in 20 out of 1,100 implanted patients. He reported that the most common cause for reoperation was endocarditis, followed by technical factors. According to the initial results of the Freestyle stentless bioprosthesis in other reports,^{1,4)} the most common cause for reoperation is a valve dehiscence due to failure of the inflow suture line, especially in the noncoronary sinus. Thus, the primary cause of reoperation in the early period can be attributed to technical problems, especially those relating to the subcoronary method. In our case, we performed replacement by the same subcoronary method for aortic valve stenosis. Neither a regurgitant flow nor a valve dehiscence was detected on transthoracic echocardiogram at the time of discharge and during the early follow-up period. The first regurgitant murmur was noticed suddenly 18 months

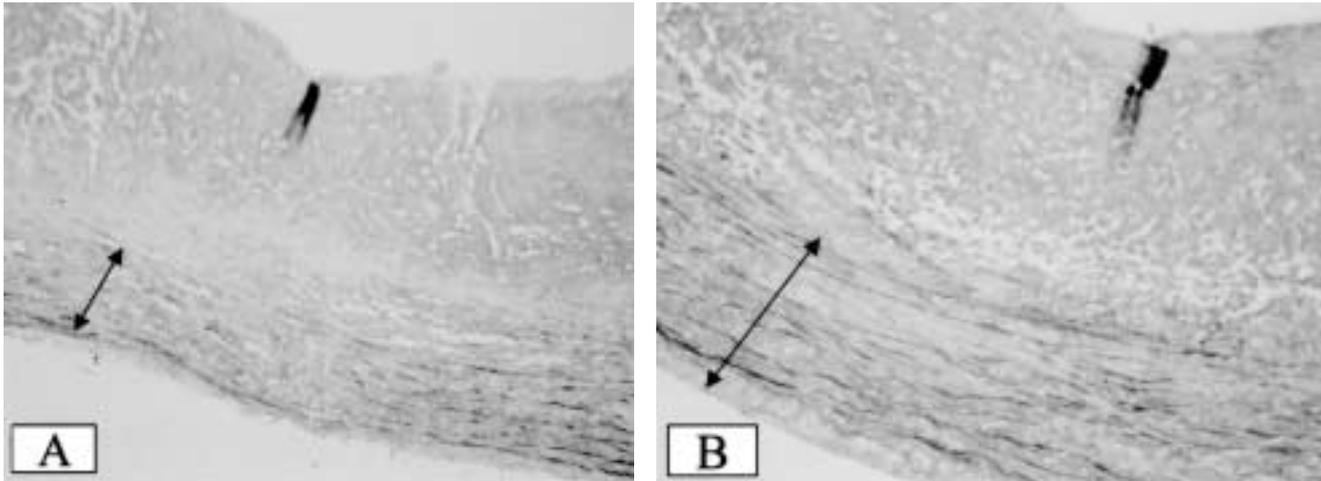


Fig. 2. Photomicrograph from a valve cusp. The amount of elastic staining in the ventricularis layer was less in the torn cusp (A) than in the non-torn cusp (B).

Arrow: showing the extent of the ventricularis layer (elastic stain, original magnification $\times 200$)

after the operation. Echocardiography showed typical cuspal vibration due to a tear, and structural deterioration was suggested as a cause. Since the patient's heart failure became aggravated very rapidly after the first regurgitant murmur was noticed, reoperation was performed one month later. Generally, most bioprostheses undergo degeneration slowly in cases of primary tissue failure. The rapid hemodynamic aggravation observed in our case suggests that, when a cuspal tear is present, there exists a possibility of rapid deterioration even in the case of primary tissue failure.

Fyfe⁶⁾ performed a pathological analysis of 67 removed Freestyle stentless bioprostheses with implant duration of up to 49 months. In his report, common microscopic alterations in a cusp were the loss of cuspal corrugation, and fibrosis of lamina spongiosa, and the loss of elastic tissue staining were also noticed as one of the basic microscopic alterations. In addition, he reported that calcification was rare and found only in the infected valve of 2 cases. With regard to the aortic wall, the degenerative change was minimal, and limited to focal loss of medial smooth muscle cells. We didn't observe these pathological findings except for some loss of the elastic fiber staining in the torn cusp.

Structural deterioration as a cause of reoperation is very rare in comparison with technical problems. Doty²⁾ reported that structural deterioration was observed only in 2 (0.18%) out of 1,100 implanted cases, but details re-

garding these 2 cases were not described. Kajiwara⁷⁾ reported a case in which reoperation was due to valve regurgitation of Freestyle stentless bioprosthesis, which had developed 27 months after implantation by the subcoronary technique. A cuspal tear from the commissure part toward the center had developed in the left coronary cusp, and he concluded that the cause was primary tissue failure. We are unable to find any other reports of structural deterioration. Our case may be the second instance in which the details of structural deterioration of the Freestyle stentless bioprosthesis are described. Since there were no technical problems or acquired changes such as calcification and endocarditis, it was thought that the cause of the cuspal tear might be unknown primary tissue failure. We obtained a microscopical finding of decreased elastic fiber at the torn cusp, but could not conclude that decreased elastic fiber was the cause of the failure because we were unable to ascertain whether the decrease originally existed or was acquired later. It is necessary to carefully follow the implanted cases of the Freestyle stentless bioprosthesis in future. It is also necessary to investigate the pathological findings in a larger number of cases to confirm the cause of this failure.

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