

ORIGINAL ARTICLE

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# Structural Valve Deterioration After Aortic Valve Replacement with Medtronic Freestyle Stentless Porcine Aortic Root Bioprostheses

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**ABSTRACT** The Medtronic freestyle aortic root bioprosthesis (Medtronic, Inc., Minneapolis, MN, USA) is a stentless valve with an effective orifice area that is larger than that observed on other bioprostheses. However, there have been sporadic reports of structural valve deterioration (SVD), such as aortic root wall rupture, leaflet tearing, and pseudoaneurysm formation. We report five cases of SVD of freestyle aortic root bioprostheses. doi: 10.1111/jocs.12235 (*J Card Surg* 2014;29:22–25)

Due to its special characteristics of being stentless and having a large effective orifice area, the Medtronic Freestyle aortic root bioprosthesis (Medtronic, Inc., Minneapolis, MN, USA) is effective, particularly for treating patients with a small aortic annulus. Many reports have shown excellent outcomes following aortic valve replacement with this bioprosthesis.<sup>1</sup> However, some reports have described early and mid-term structural valve deterioration (SVD), without infection or thrombosis. At our institute, between January 1998 and December 2012, 142 patients underwent aortic valve replacement with freestyle aortic bioprostheses. Five patients underwent reoperation due to SVD. We report five cases of SVD of freestyle bioprostheses (Table 1) and provide a detailed description of each case.

## PATIENT PROFILES

Institutional Review Board permission was obtained to report these cases.

The Medtronic freestyle valve is a stentless valve using a porcine aortic root preserved in 0.2% glutaraldehyde and is treated with  $\alpha$ -amino oleic acid for the anticalcification. There are several surgical implantation

techniques, for example, subcoronary technique, root inclusion technique, and aortic root replacement. The implant techniques were selected by the surgeon's preference or the aortic root pathology.<sup>2</sup>

In this report, postoperative cardiac echocardiography was performed for all these patients and they had no or trivial aortic valve regurgitation.

### Patient 1

A 78-year-old female presented with aortic valve regurgitation after undergoing aortic valve replacement with a 27-mm Medtronic freestyle aortic bioprosthesis (mini root technique) five years previously. She had no symptoms; however, moderate aortic valve regurgitation was detected. There was no instance of fever during this five-year period. As shown in Figure 1A, the left coronary cusp had an approximate 10-mm perforation and the left coronary cusp was very fragile. The 21-mm size easily passed through the aortic annulus; therefore, a 21-mm Carpentier-Edwards pericardial heart valve (Edwards Lifescience, Irvine, CA, USA) was implanted. After the operation, the amount of aortic regurgitation was trivial, and the patient had no complications. She discharged on the 12th postoperative day and had been well for more than two years.

### Patient 2

A 76-year-old male who underwent aortic valve replacement for aortic valve regurgitation using a 27-mm freestyle valve with the subcoronary technique seven years previously presented with rapidly

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**TABLE 1**  
**Clinical and Operative Data in Five Cases**

Patient	Age (at 1st Operation)/ Sex	Duration Years	Operative Findings
1	72/Female	5	Leaflet perforation (left)
2	67/Male	7	Commissure tear
3	67/Female	7	Leaflet perforation (left)
4	53/Male	11	Leaflet tear (left)
5	70/Male	11	Leaflet perforation (left)

progressing dyspnea during exercise. Transthoracic echocardiography (TTE) showed severe aortic valve regurgitation (AR) and a dilated left ventricle. In spite of medical treatment, the valve regurgitation worsened and the patient underwent a second aortic valve replacement. The left coronary cusp was found to be detached from the commissure and the leaflet was prolapsed (Fig. 1B). The patient underwent aortic valve replacement with a 21-mm trileaflet valve (Trileaflet™ valve, St. Jude Medical, St. Paul, MN, USA). His postoperative course was uneventful and he was discharged on the 14th postoperative day. There was no aortic valve regurgitation and he has been well for two years.

#### Patient 3

A 74-year-old female who underwent aortic valve replacement using a 25-mm freestyle valve seven years previously with the subcoronary technique for aortic valve regurgitation complained of palpitations and was detected as having a heart murmur by her family physician. TTE showed severe aortic valve regurgitation and a moderately dilated LV. At the second surgery, the left coronary leaflet was very thin and exhibited a perforation near the valve hinge (Fig. 1C). We performed redo aortic valve replacement with a 21-mm Magna Ease Heart valve (Edwards Lifescience). The patient experienced no complications and was discharged on the eighth postoperative day.

There was trivial aortic valve regurgitation in the postoperative echocardiography and she has no signs of heart failure for two years.

#### Patient 4

A 65-year-old male who underwent aortic valve replacement for aortic valve regurgitation with a 29-mm freestyle valve (subcoronary technique) 11 years previously presented with rapidly progressing dyspnea at rest. He was diagnosed with acute heart failure due to severe AR and treated with diuretics and mechanical ventilatory support. The patient underwent redo aortic valve replacement with a 23-mm Magna Ease Heart valve (Edwards Lifescience).

The left coronary cusp was found to be detached from the annulus, and the noncoronary cusp had a small perforation of approximately 3 mm (Fig. 1D). The patient recovered well from this surgery and was discharged on the 10th postoperative day. He has been well for one year and there was only trivial aortic regurgitation.

#### Patient 5

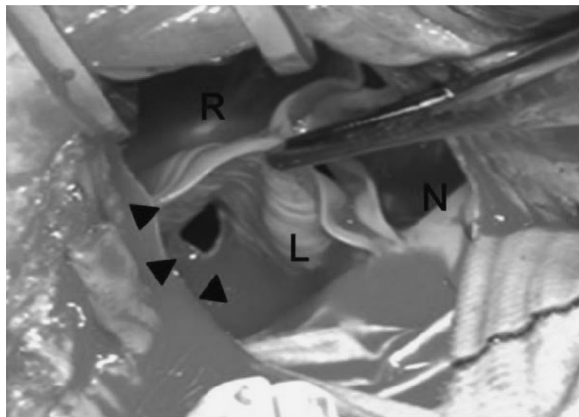
An 80-year-old male who underwent aortic valve replacement for aortic valve regurgitation with a 25-mm freestyle aortic valve (subcoronary technique) ten years previously presented with dyspnea on exertion. TTE showed severe aortic valve regurgitation that was not seen six months before. He had not had any fever during this period. At the second surgery, the left coronary leaflet had a 10-mm perforation (Fig. 1E). We performed redo aortic valve replacement with a 21-mm Epic Heart valve (St. Jude Medical). He experienced no complications and was discharged on the tenth postoperative day. He had trivial aortic regurgitation at the time of discharge. He has been well for about one year.

### DISCUSSION

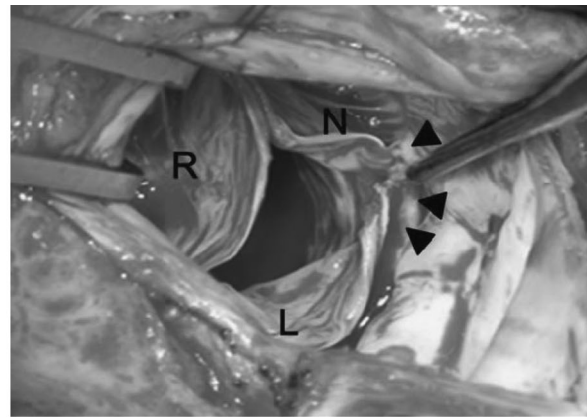
The Freestyle aortic bioprosthesis is associated with good hemodynamic function and provides an adequate effective orifice and excellent long-term results. Bach et al.<sup>2</sup> reported the outcomes of 725 patients who had undergone aortic valve replacement with freestyle valves, with a ten-year freedom from reoperation of over 90%. Mohammadi et al.<sup>3</sup> reported the long-term clinical and echocardiographic follow-up data of 430 patients with freestyle stentless aortic bioprostheses. In their study, freedom from reoperation was 91.0% and 75.0% at 10 and 15 years, respectively, and a total of 51 patients required reoperation. In one study, among 430 patients treated with a Freestyle bioprosthesis, there were 27 cases of SVD including leaflet perforation, leaflet tear and commissure tearing, and the median time to reoperation for SVD was 10.7 years.<sup>4</sup> Interestingly, the pathological findings of deteriorated valves did not reveal any calcified sites. Our findings of the five extracted Freestyle bioprostheses, which are summarized in Table 1, were in line with the aforementioned previous findings.

We do not know for sure but it is unlikely that our five cases involved infective endocarditis based on the pathological studies. No vegetation or infectious signs were detected in any of the five cases. The primary indication for the first AVR was aortic valve regurgitation; therefore, the implanted Freestyle valve size was between 25 and 29 mm. However, due to the thickness of the Freestyle valve wall, we had to downsize the bioprostheses by 4–6 mm.

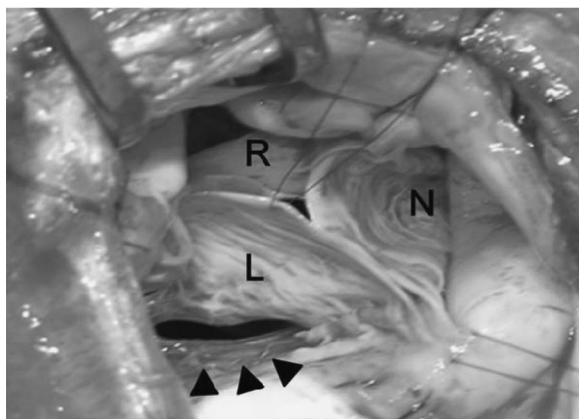
Other articles have reported the dysfunction of Freestyle aortic bioprostheses affecting areas other than the leaflets. Ozaki et al.<sup>5</sup> reported the cases of four patients with Freestyle valve fenestration in the Valsalva sinus in their series of 61 cases of Freestyle valve aortic replacements. Kameda et al.<sup>6</sup> reported



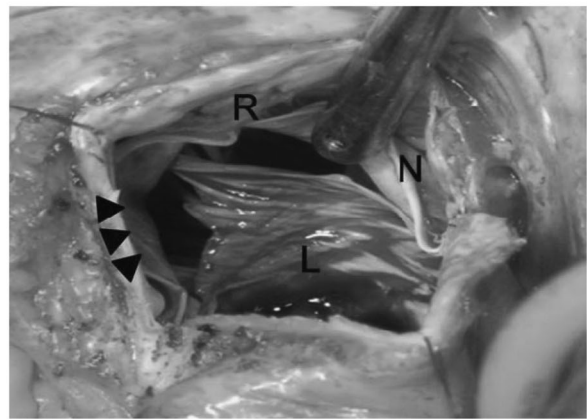
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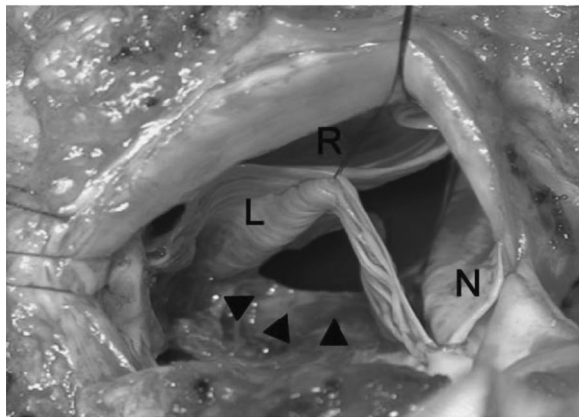
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D



E

**Figure 1.** (A) Perforation of the left coronary leaflet (arrow head); (B) tear of the commissure between noncoronary and left coronary cusp (arrow head); (C) perforation of the left coronary leaflet near the valve hinge (arrow head); (D) tear of the left coronary cusp (arrow head); (E) perforation of the left coronary leaflet (arrow head). L, left coronary leaflet; N, noncoronary leaflet; R, right coronary leaflet.

the development of aortopulmonary fistulae due to freestyle Valsalva wall fenestration. It is presumable that all portions of a Freestyle bioprosthesis, i.e., the leaflet and aortic wall remnant, are vulnerable to SVD.

Recently, the current stented bioprostheses improve the effective orifice area and have excellent long-term durability.<sup>7</sup> Moreover, implantation techniques are very

simple. However, freestyle valves still have hemodynamic advantages, especially in patients with small aortic roots, where they may avoid the need for a root enlargement.

Providing careful and periodic echocardiographic follow-up is necessary for the early detection of valve dysfunction of freestyle aortic bioprostheses and contributes to the long-term survival of patients.

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