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A Case of 24 Years Longevity of an Ionescu-Shiley Bioprosthesis in the Mitral Position

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ABSTRACT

Valve dysfunction, attributed to primary tissue failure several years after implantation of Ionescu-Shiley bioprostheses, has led to re-operation in most cases. We report a rare case of this bioprosthesis showing stenosis and regurgitation after implantation in the mitral position 24 years previously. No cusp tears, but severe calcification and well-grown neointima over the Dacron cloth of the inner surface were observed. This may explain how the valve functioned for such a long period of time. We replaced it with a Carpentier-Edwards pericardial bioprosthesis.

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INTRODUCTION

Initially, the Ionescu-Shiley bioprosthesis (Shiley, Inc., Irvine, CA, USA) was widely used due to clinical characteristics of good hemodynamics with a virtual absence of thromboembolic complications. However, it became clear that re-valve substitution was needed due to malfunction caused mainly by primary tissue failure such as tears and perforations which occurred near the junction of the leaflets and struts. Presumably, in many cases these problems were associated with defects in the structure of the valve. Therefore, the use of Ionescu-Shiley bioprostheses had discontinued by the mid-1980s, and most reports of re-valve substitution disappeared by the end of the 1990s.

CASE REPORT

A 69-year-old male taxi driver, who had undergone implantation of an Ionescu-Shiley bioprosthesis (27 mm) in the mitral position in August 1980 for mitral regurgitation, was hospitalized with severe heart failure. Symptoms of breathlessness on exertion deteriorated from about three months prior to hospitalization, and an expansion of cardio-thoracic ratio was seen. Echocardiography revealed mitral stenosis

(MVA 0.9 cm²), slight mitral regurgitation, and severe tricuspid valve regurgitation. In addition, the left atrial diameter was expanded to 50 mm.

Medical treatment for acute heart failure treatment was initiated, resulting in only minimal improvement. Due to progressive deterioration of the heart failure, mitral valve re-replacement and tricuspid annuloplasty were performed on the 55th day after hospitalization. Via a median sternotomy, a two-staged venous cannula was inserted from the right femoral vein, with the tip located in the superior vena cava (SVC). After right atriotomy and atrioseptostomy, the mitral Ionescu-Shiley bioprosthesis was carefully examined. The annular ring and struts of the bioprosthesis were completely covered with neointima and severe calcification was observed, however no major perforation or tears were noted. Calcification and hardening of the tissue were considered to be the main causes of the severe mitral stenosis and slight regurgitation. The bioprosthesis was carefully removed.

A 25 mm Carpentier-Edwards Perimount pericardial bioprosthesis (Edwards Lifesciences, Inc., CA, USA)

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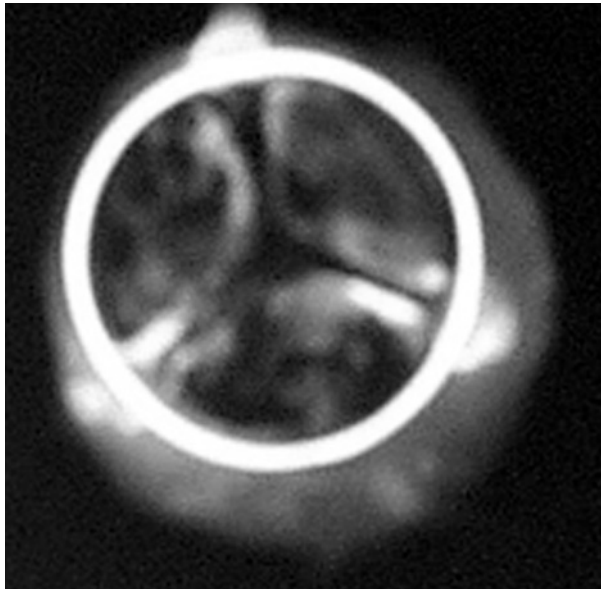


Figure 1. X-Ray examination of the removed valve revealed remarkable calcification observed almost uniformly in all leaflets.

was implanted, and tricuspid annuloplasty was performed using a Cosgrove-Edwards Ring (32 mm diameter) (Edwards Lifesciences, Inc., CA, USA). Postoperative X-Ray examination of the explanted valve revealed almost uniform calcification in all leaflets (Figure 1).

DISCUSSION

The Ionescu-Shiley bioprosthesis was developed by Ionescu in 1971, and marketing was started by Shiley in 1976. Ionescu et al reported malfunction in seven among 336 cases over 10 years of implantation in the mitral position: a low complication rate of 0.6% per patient-year.¹ However in the 1980s, malfunctions especially regurgitation as a result of destruction of leaflets and the resultant hemolysis, were reported within three to five years of use. Consequently the use of Ionescu-Shiley bioprostheses was abandoned. There has been scant mention of Ionescu-Shiley bioprostheses in the international literature subsequent to reports of re-valve substitution by Masters et al (1995), Abe et al (1997), and Machida et al (2001).^{2,3,4} In many reports, the cause of the valve malfunction was attributed to tears and lacerations in the junction of the leaflets, the leaflets themselves, the struts and/or the annular ring of the bioprosthesis.

Gabbay and colleagues reported compelling findings after histologic examination of the excised bioprosthesis. While a mild to moderate degree of disruption in collagen fibers existed in the torn part of leaflet, there was neither severe calcification nor infection. Moreover, neointimal formation was not evident on the Dacron cloth of the ring and struts. Destruction of the leaflet

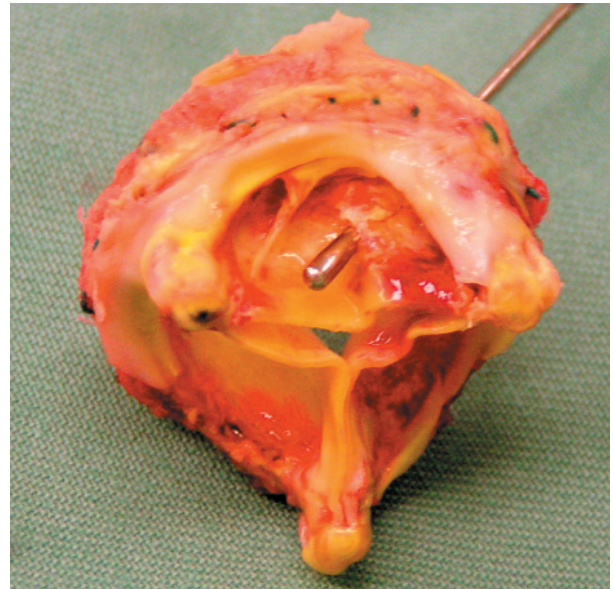


Figure 2. Photograph showing a very small perforation in the center of the leaflet indicated by the metallic probe; the ring and struts are well covered with neointima, and severe calcification is evident.

may have occurred as a result of mechanical factors; such as friction or fatigue within the struts and leaflets, which lacked the neointima.^{5,6}

Schoen et al reported cuspal calcification and defects clearly associated with commissural sutures ("alignment stitches") unique to this valve design. Additionally, gross cuspal thickening and mild stretching and microscopic deep fluid insudation, separation of collagen bundles, and mononuclear inflammation were observed within 7 years postoperatively.⁷

In our case, most portions of the Dacron cloth were covered with well-grown neointima, which might decrease physical stress on the leaflets and be a main reason why the valve functioned over a long period of time without tears or major perforation of the leaflets. We examined the removed valve in detail and found a small perforation, which was not identified during the operation, and very severe calcification and hardening of all the leaflets but no infected vegetation (Figure 2). Such severe calcification is inevitable over a 24-year period due to inherent bio-reaction processes.

We conclude that these findings support the hypotheses of Gabbay et al⁶. It is evident that the design, the materials including chemical fixation, and the technical fabrication are all critical aspects of prosthetic valve development. In addition, this case appears to be the only reported incidence of a prosthetic valve functioning in excess of 20 years, as the mean time to re-operation of most bioprostheses is 11.5 ± 7.1 years.⁸

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