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NO-REACT* ANTICALCIFICATION TISSUE TREATMENT RESULTS WITH STENTLESS HEART VALVES IN TWO ADOLESCENTS

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Implantation of prosthetic heart valves in children is challenging. Calcification may lead to mechanical failure.[1] The No-React formula, (Shelhigh Inc, Millburn, NJ), a new tissue preservation process applied to a wide range of bioprosthetic products, involves treating the tissue with glutaraldehyde, which is rinsed out, and then impregnating it with heparin and surfactant. This process supposedly prevents mineral deposition within the implants.

The No-React process was shown to have anticalcification properties in a subcutaneous implantation model of treated tissues in rats.[2] We therefore began in 1994 a clinical study at the Rambam Medical Center in Haifa, Israel, on the use of No-React products. We report here our experience with 2 children in whom porcine BioCor heart valves (BioCor, Belohorizonte, Brazil) treated with No-React were implanted.

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*No-React is a trademark of Shelhigh Inc, Millburn, NJ.

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Clinical summaries

PATIENT 1. A 13-year-old girl with a long history of rheumatic heart disease and a recent history of suspected bacterial endocarditis was admitted to our institution on December 10, 1994, with congestive heart failure. Echocardiograms showed vegetations on and gross incompetence of the mitral and aortic valves.

On December 27, 1994, we replaced the mitral and aortic valves with 2 porcine stentless valves treated with No-React. Results of blood and tissue culture were negative. The patient's clinical condition improved. Reduction in the size of the left ventricle caused a slight prolapse of the anterior mitral leaflet and a mild degree of mitral incompetence. She was readmitted on May 14, 1997, with severe congestive heart failure, atrial fibrillation, and severe mitral and aortic regurgitation. We replaced both valves with mechanical bileaflet prostheses. The explanted mitral valve, which was calcified and immobile, had almost fixed leaflets and 1 of the chordae tendineae was torn (Fig 1). The stentless aortic valve had 1 torn cusp and mild calcification. The No-React pericardial patch that had been used to enlarge the aortic root was severely adherent on both sides to the surrounding structures. The patient was discharged on the ninth day after the operation.

PATIENT 2. A 13-year-old boy with a history of rheumatic heart disease was admitted to our hospital on May 23, 1995,

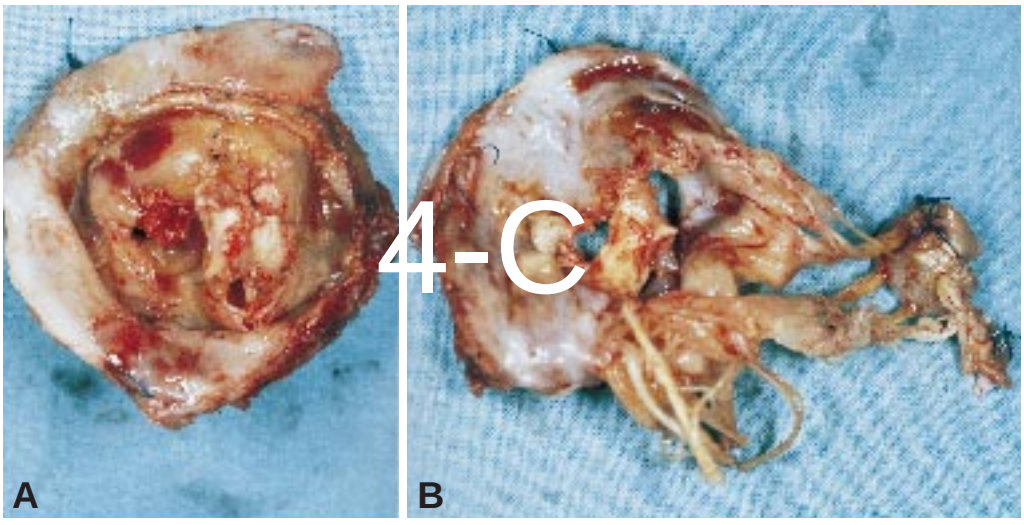

Fig 1. Heavily calcified explanted stentless BioCor mitral bioprosthesis treated with No-React as viewed from **(A)** left atrial side and **(B)** left ventricular side. Note thickening and rupture of chordae tendineae.

with pulmonary edema resulting from severe mitral regurgitation. Blood cultures grew *Acinetobacter* species. Aortic regurgitation and a ruptured posterior mitral leaflet without vegetations were seen on an echocardiogram. On May 30, 1995, we replaced both valves with stentless BioCor porcine valves treated with No-React. We saw no signs of bacterial endocarditis on the leaflets of either explanted valve. On June 2, 1997, an echocardiogram showed good valvular motion, minimal mitral regurgitation, no aortic regurgitation, and no mitral stenosis. However, on August 6, 1997, he was readmitted with pulmonary edema related to severe mitral regurgitation caused by ruptured chordae tendineae of both mitral leaflets. On August 10 we replaced the stentless mitral valve, which was calcified and immobile with torn chordae tendineae and calcified leaflets, with a mechanical bileaflet valve. The aortic valve, which showed no signs of malfunction or calcification, was left in place. He was discharged 10 days later.

Discussion. In our study the time from implantation to explantation of the 2 stentless porcine mitral valves treated with No-React and the 1 stentless aortic valve ranged between 26 and 29 months, similar to the duration reported for glutaraldehyde-preserved bioprostheses used in children.[3]

The finding of native valve endocarditis in both our patients raises the question of whether implantation of any bioprosthesis in an infected, inflamed area might enhance biodegradation. We found that the explanted stentless mitral valves were significantly more calcified and immobile than were the aortic valves. In the first patient the torn cusp, which indicates biodegradation,[4] was the indication for replacement rather than calcification. The uncalcified aortic valve in the second patient was not replaced. Whether the difference in the rate of calcification between the mitral and aortic No-React bioprostheses is selective or dependent on design remains unclear. The tissue overgrowth on the chordae tendineae was similar to that seen in prosthetic chordal replacement with polytetrafluoroethylene* or in other bioprostheses preserved in glutaraldehyde after failure. Both sides of the No-React pericardial patch used to enlarge the aortic root had massive adhesions.

We based our study on studies in the juvenile rat model.[2] Because of our poor outcome we question the validity of the rat model for predicting calcification in children. In a recent comparative study Shen and associates[5] reported that the rabbit subcutaneous model was a better predictor of clinical outcome with respect to calcification than was the rat model. Our findings raise questions regarding the anticalcification properties of the No-React process, especially in adolescents.

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*Gore-Tex patch; Gore-Tex is a registered trademark of W. L. Gore & Associates, Inc, Flagstaff, Ariz.