Porcine Intestinal Submucosa (CorMatrix) for Semilunar Valve Repair in Children: A Word of Caution After Midterm Results

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Surgery for congenital valve anomalies in children is a challenging topic. We aim to assess early and late functional outcomes of CorMatrix scaffold after repair of aortic and pulmonary valves (PV) in congenital heart disease in a prospective nonrandomized clinical study on children with congenital aortic (Group 1) or PV (Group 2) disease. Primary endpoints were reoperation or reintervention on semilunar valves and echocardiographic evidence of regurgitation or stenosis greater than mild. Results of PV repair in tetralogy of Fallot were compared with a control group of patients who underwent PV repair with polytetrafluoroethylene. A total of 22 consecutive selected patients with complex congenital heart disease were included: PV repair in 18 and aortic valve repair in 4. At discharge bidimensional echocardiography, semilunar valve regurgitation was mild in 50% of all patients. At a median follow-up of 23 months (4.3-51.3), reoperation for aortic valve replacement was necessary in 2; right ventricular outflow tract obstruction occurred in 3, requiring interventional treatment in 2. Pulmonary regurgitation degree worsened in most patients of Group 2 at follow up. When comparing patients with tetralogy of Fallot in Group 2 with patients who underwent PV repair with polytetrafluoroethylene, there were no significant differences in PV function at follow up. We conclude that CorMatrix scaffold for semilunar valve reconstruction does not present with significant advantages to traditional materials at mid term follow up. In addition, when used for pulmonary valve reconstruction, CorMatrix seems to show gradual functional deterioration in the mid term.

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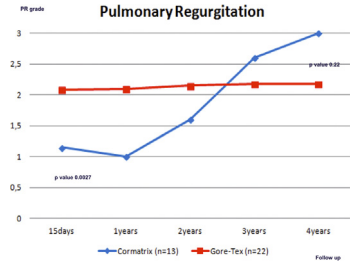

Pulmonary regurgitation increases at follow-up after CorMatrix pulmonary reconstruction.

Central Message

Midterm outcomes of CorMatrix scaffold on reconstruction of semilunar valves is suboptimal, similar to traditional materials.

Perspective Statement

Despite in a limited series, this article outlines clearly the late gradual failing performance of CorMatrix scaffold on pulmonary valve site in the midterm, as it is showed by a comparison with pulmonary unicusp reconstruction with PTFE, in a similar group of patients, in the same surgical era. This may be due to inflammatory tissue remodeling.

See Editorial Commentary pages 446-447.

INTRODUCTION

Surgery for valve repair in congenital heart disease (CHD) is challenging and often requires the use of prosthetic material for reconstruction of valve leaflets. Several different prosthetic materials are commonly used in surgery for CHD, such as autologous pericardium (with or without glutaraldehyde fixation),[1] preserved homograft, bovine pericardium,[2] Polytetrafluoroethylene (PTFE).[3,4]

The extra cellular matrix (ECM) is a material derived from different tissues, which is supposed to provide an interim bioscaffold that enables the patient's own cells to repopulate and repair tissues.[5] The constructive remodeling of subintestinal submucosa (SIS) The ECM scaffold has been reported in animal studies[6] and in human clinical applications.[7,8] However,

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long-term outcomes are still unknown. We describe our clinical experience with CorMatrix ECM scaffold used to repair congenital aortic (AoV) and pulmonary valve (PV) abnormalities.

MATERIALS AND METHODS

Study Design

This is a single-center, prospective, nonrandomized clinical study, designed to evaluate midterm results of valve repair with SIS ECM CorMatrix(CorMatrix Cardiovascular, Atlanta, GA) scaffold. Our study includes patients with AoV or PV anomalies (Group 1 and 2, respectively), isolated or in association with other CHD (ie, tetralogy of Fallot—TOF). Review of medical records was approved by local hospital Ethic Committee on clinical investigation. All patients who accepted inclusion in the study had given informed consent for utilization of SIS ECM CorMatrix.

The CorMatrix scaffold was chosen because its regenerative potential was thought to reduce or delay a reoperation, otherwise inevitable with common prosthetic materials. It was used to reconstruct valve leaflets, according to different techniques,[9] as described in Figures 1 and 2. Intraoperative surgical assessment included handling characteristics, hemostasis, and overall seating of the implanted patch.

Patients were evaluated by echocardiography (iE33 xMATRIX Echocardiography System, Philips Medical System, Andover, MA) preoperatively, at hospital discharge and during outpatient follow-up. Postoperative and follow-up controls aimed at evaluation of CorMatrix scaffold performance on semilunar valve sites. Primary endpoints of analysis were unexpected reoperation or interventional cardiology procedure, or detection of functional valve failure (ie, significant stenosis or regurgitation) at echocardiography. Specifically, in Group 1, significant AoV stenosis was defined when a mean gradient greater than 40 mm Hg occurred. Right ventricular outflow tract (RVOT) obstruction was quantified as mild (grade 1) if pressure gradient was <20 mm Hg and right ventricle/left ventricle (RV/LV) ratio was less than 0.5; moderate (grade 2) if between 20 and 40 mm Hg; and severe (grade 3), if >40 mm Hg or if the RV/LV ratio was more than 0.67.[10] Semilunar valve regurgitation was quantified using Doppler

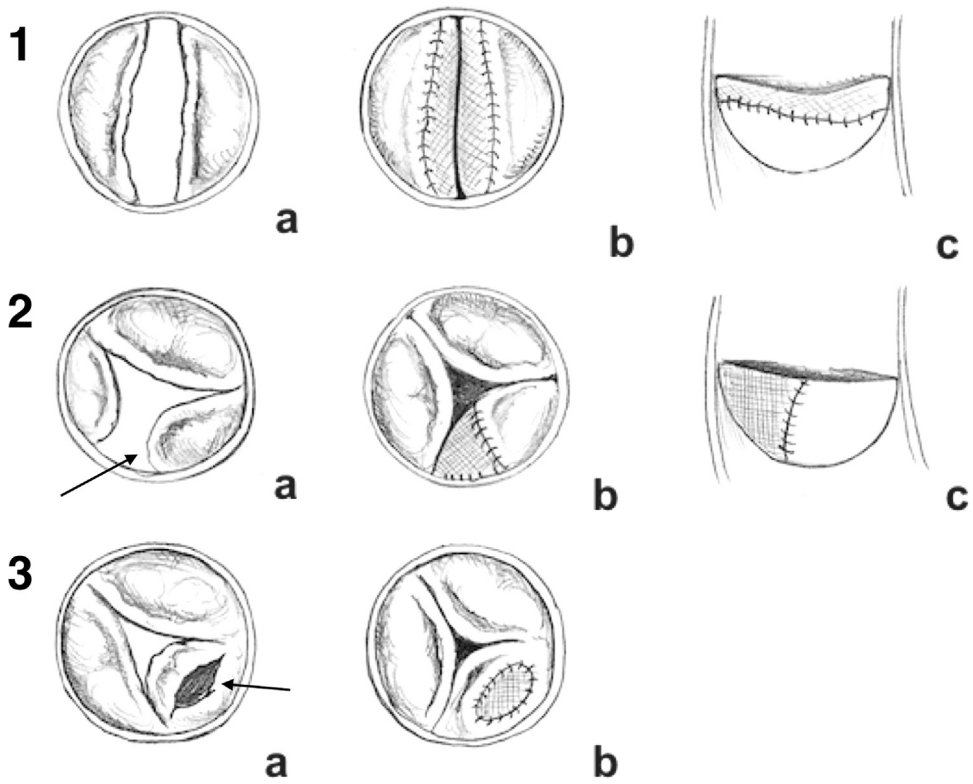

Figure 1. Aortic valve repair techniques. (1) In a bicuspid aortic valve after neonatal balloon dilatation, the 2 dysplastic leaflets are extended with CorMatrix rectangular-shaped patches (extension leaflet technique), as seen from above (b) and laterally (c). (2) In a dysplastic semilunar valve, with 3 leaflets (a) after neonatal balloon dilatation, a deficitary leaflet (arrow) is extended laterally with a CorMatrix patch, as seen from above (b) and laterally (c). (3) In a normal aortic valve, with tear of 1 leaflet (arrow) due to endocarditis (a), the leaflet is repaired with a CorMatrix patch, sutured in vital tissue (b), expanding the belly of the leaflet (augmentation leaflet technique).