Initial Experience and Early Results of Mitral Valve Repair With CardioCel Pericardial Patch

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Purpose. **The objective of this study was to assess the performance of a tissue engineering process–treated bovine pericardium patch (CardioCel, Admedus Regen Pty Ltd, Perth, Australia) in the setting of reconstructive mitral valve surgical procedures.**

Description. **Between March 2014 and April 2016, 30 patients (57.2 ± 14.3 years of age; 27% female) underwent mitral valve leaflet repair with a CardioCel patch.**

Evaluation. **Perioperative mortality was 7% (2 patients, non–graft related). In the 28 remaining patients, predischarge echocardiography demonstrated good repaired valve function. At a mean follow-up of 1.7 ± 0.9 years, three additional deaths occurred (two resulting from infective endocarditis and one non–cardiac related). On follow-up echocardiography (follow-up time of 1.7 ± 0.8 years; available for 26 of 28 [93%] hospital survivors), recurrent regurgitation was seen in 2 patients (both with infective endocarditis), and 1 patient underwent reoperation (no infection at the level of patch repair was observed). In the remaining patients, the most recent echocardiogram demonstrated no regurgitation or mild regurgitation and stable gradients. The thickness and echodensity of the implanted patch on follow-up echocardiograms were comparable with postoperative echocardiograms.**

Conclusions. **Initial results with the CardioCel patch in mitral valve repair operations were satisfactory. The resistance to infection and late degeneration will need to be assessed in the future.**

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Technology

Mitral valve (MV) repair is preferred over replacement when good repair durability can be expected. Patch techniques are widely used to replace destructed leaflet tissue or augment valve leaflets in cases of relative tissue deficiency [1, 2]. Concerns about the durability of patch materials used in reconstructive MV surgical procedures have been raised [1–3]. In recent years, the CardioCel (Admedus Regen Pty Ltd, Perth, Australia) bovine pericardial patch has become our material of choice for patch repair of the MV. After harvesting, the CardioCel patch is subjected to a complex preservation process including decellularization, molecular cross-linking with ultralow glutaraldehyde concentrations, and antimineralization treatment with the ADAPT process [4]. No data on the performance of CardioCel in adult patients undergoing MV repair are available. Therefore, we explored our initial experience and early clinical and echocardiographic results of MV repair with the CardioCel patch.

Technique

Patients and Surgical Procedures

A retrospective chart review of patients who underwent MV repair between March 2014 and April 2016 at our institution (Leiden University Medical Center, Leiden, The Netherlands) was performed. Patients whose CardioCel patch was used for leaflet reconstruction or augmentation were included in this study.

A large patch to augment or reconstruct the body of the anterior mitral valve leaflet (AMVL) was implanted in 11 patients; the indication was progression of the infectious process from an aortic root abscess to the AMVL (n = 6), hypertrophic obstructive cardiomyopathy (n = 3), and rheumatic valve disease (n = 2). In 13 patients, a smaller patch, not expanding beyond the scope of a single leaflet

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segment, was implanted. In 2 patients, a larger patch, used to reconstruct an A1 to A2 segment defect of the AMVL, was implanted. In another 2 patients, reconstruction of the anterolateral commissure was performed, whereas in the last 2 patients, multiple CardioCel patches were used to repair both leaflets.

In cases of AMVL leaflet repair, the patch was used to repair the leaflet body in all patients. In cases of posterior MV leaflet repair, in selected patients the patch was also used to reconstruct the leaflet free edge. The patch was implanted using running 5-0 monofilament polypropylene sutures. When it was used to reconstruct a leaflet free edge, neochords were implanted to prevent leaflet prolapse. The neochords were implanted in a standard fashion; each end of the neochord was first passed through the implanted patch twice (2 to 3 mm from the free edge). Thereafter, the length was adjusted to bring the leaflet to the desired height, corresponding to the height of the adjacent segments. The neochords were tied during the final water test. Full, semirigid ring annuloplasty was performed in 28 of 30 patients. Intraoperative transesophageal echocardiography was routinely performed. All patients underwent a transthoracic echocardiographic examination before hospital discharge.

Study Endpoints and Follow-Up

Perioperative mortality was defined as death within 30 days after the operation or during the index hospitalization. Study endpoints were defined according to the American Association for Thoracic Surgery, The Society of Thoracic Surgeons, and the European Association for Cardio-Thoracic Surgery guidelines for reporting mortality and morbidity after cardiac valve interventions [5].

The function of the repaired MV and the implanted CardioCel patch was assessed with transthoracic echocardiography. MV regurgitation (MR) severity was evaluated using a multiparametric integrative approach, including qualitative and quantitative assessments, as recommended [6], and graded on a four-grade scale: mild, moderate, moderate-to-severe, or severe. Residual MR and recurrent MR were defined as $\geq$ moderate. Mean diastolic MV gradient was calculated using continuous-wave Doppler imaging. Additionally, patch function and morphology were assessed. This assessment included patch thickness, mobility (1, comparable to normal leaflet tissue; 2, decreased mobility; 3, no movement), and echodensity (0, comparable to normal tissue; 1, moderately elevated; 2, elevated).

Regular clinical and echocardiographic follow-up was performed at our outpatient clinic. All echocardiograms were reviewed by an experienced cardiologist (N.A.M.). Our institutional Ethical Committee approved the study and waived patient consent because of the retrospective study nature.

Statistical Analysis

Continuous data are presented as means $\pm$ standard deviation or medians and interquartile ranges. Categorical data are presented as counts and percentages. Predischarge and follow-up variables were compared with the Wilcoxon signed-rank test and paired samples Student's t test. Statistical analysis was performed using IBM SPSS Statistics, version 23.0 (SPSS, Inc, IBM Corp, Armonk, NY).

Clinical Experience

Patients' Characteristics and Early Clinical Results

Baseline characteristics are presented in Table 1. In patients with active MV infective endocarditis (IE), nonelective operation shortly after the initiation of antibiotic therapy (median, 12 days [interquartile range, 8 to 19 days] after the definitive diagnosis) was performed. The timing of surgical intervention was determined by our endocarditis team. There were no intraoperative deaths and two (7%) early postoperative deaths. The cause of death was multiorgan failure and malignant heart rhythm disturbance. In both patients the last available postoperative echocardiogram demonstrated good repaired valve function.

Early Echocardiographic Results

On predischarge echocardiography, no residual MR was observed, and the mean diastolic MV gradient was 4.1 $\pm$ 1.6 mm Hg (Table 2). Predischarge echocardiography demonstrated a certain impairment of leaflet mobility (interpreted as related to the repair itself and not a

Table 1. Baseline Characteristics

Characteristics	N = 30
Age (years)	57.2 ± 14.3
Sex (female)	8 (27)
Cause	
Infective endocarditis	
Active	15 (50)
Healed	5 (17)
Rheumatic valve disease	3 (10)
Hypertrophic obstructive cardiomyopathy	3 (10)
Degenerative	4 (13)
Atrial fibrillation	8 (27)
NYHA functional class	
I	7 (23)
II	12 (40)
III–IV	11 (37)
Dialysis	2 (7)
Previous cardiac surgical procedure	6 (20)
Diabetes mellitus	6 (20)
Chronic lung disease	4 (13)
Left ventricular function	
Good (LVEF >50%)	23 (67)
Moderate (LVEF 30%–50%)	7 (23)

Data are presented as n (%) unless specified otherwise.

LVEF = left ventricular ejection fraction; NYHA = New York Heart Association.