Histology of CorMatrix Bioscaffold 5 Years After Pericardial Closure
Meghan Stelly, and Terry C. Stelly, MD
Clemson University, Clemson, South Carolina, and Department of Cardiothoracic Surgery, Providence Hospital, Mobile, Alabama

CorMatrix is a non-crosslinked, acellular bioscaffold used for pericardial closure and cardiac tissue repair. A redo sternotomy 5 years after bypass grafting and pericardial reconstruction afforded the opportunity to explant the bioscaffold and examine it histologically. Consistent with preclinical evidence, pathology results showed that the bioscaffold had remodeled into viable, fully cellularized, vascularized, non-fibrotic connective tissue similar to native pericardium.


Among the materials commercially available for surgical repair, acellular, non-crosslinked extracellular matrix (ECM) bioscaffolds have been of interest for their purported ability to participate in constructive tissue remodeling within the body [1]. However, most direct evidence of this property has come from either noncardiac clinical applications or preclinical cardiac models. There have been few opportunities to evaluate the long-term fate of such materials in the human cardiovascular environment. We report a case in which CorMatrix ECM (CorMatrix Cardiovascular, Inc, Atlanta, GA) was examined during a redo sternotomy 5 years after it was used for pericardial closure. Gross visualization and histopathology provide insight into the physical and practical results of using this material in humans.

A 60-year-old male underwent uncomplicated coronary artery bypass grafting (CABG) in April 2008. His past medical history was significant for mild aortic stenosis, hypertension, hyperlipidemia, and 3-vessel coronary artery disease with normal left ventricular function. The quadruple CABG included vein grafts to the obtuse marginal and to the left ventricular and posterior descending branches of the right coronary artery, plus a left internal thoracic artery to the left anterior descending coronary artery. After completion of the procedure, the right coronary graft lay on the anterior surface of the heart, directly underneath the sternotomy. Prior to sternal closure, the native pericardium was closed with a CorMatrix ECM patch using 3-0 polypropylene suture (Prolene, Ethicon, Somerville, NJ). The reconstruction closed the entire circumference of the pericardial defect in a watertight fashion.

Computed tomography 3 years postoperatively showed what appeared to be a morphologically normal pericardium with a well-defined retrosternal space (Fig 1). Although the grafts remained patent (Fig 2) and LV function remained well preserved, evidence of gradual but progressive, asymptomatic aortic stenosis prompted redo surgery 5 years after the initial coronary bypass.

On sternal reentry, gross visualization revealed a neo-pericardium that was visually indistinguishable from the native tissue, with margins identifiable only by the nonabsorbable suture used 5 years earlier (Fig 3A). Dissection was facile with minimal epicardial adhesions,
and the previous graft to the right coronary artery was well protected from damage by the sternal saw (Fig 3B).

A sample of the anterior pericardium, including native and implanted material, was excised and submitted for independent pathologic analysis. A new CorMatrix patch was placed at the conclusion of this procedure to once again reconstruct the pericardium. The recovery was uneventful and the patient was discharged 4 days after the procedure.

The tissue sample was processed in paraffin, sectioned, and stained with hematoxylin and eosin, Movat’s pentachrome, and von Kossa for calcification. Immunohistochemistry was performed using antibodies against c-kit for stem cells, von Willebrand factor for endothelial cells and neovascularization, telomerase for evidence of cell proliferation, and CD34 for dendritic cells, endothelial cells, and hematopoietic progenitors.

Histologic analysis of the submitted specimen showed dense, laminated, and streaming fibrous connective tissue consistent with a remodeled ECM pericardial patch (Fig 4). While not structured exactly like native pericardium, the ECM patch area appeared to be viable connective tissue with “striking similarities to pericardial tissue.” It was almost fully recellularized and well integrated, with dense, supporting vasculature and other cellular elements that would be expected in viable and differentiated connective tissue (eg, mast cells, dendritic cells, and fibroblasts). The parietal surface of the ECM patch was tentatively identified based on the presence of adipose tissue but no evidence was found of an endothelial lining on the putative visceral face of the sample. This may have been due to erosion during surgical handling.

Integration of the patch material was nearly complete except for a small, sequestrated, and partially calcified nodular remnant (not shown). There was no appreciable inflammatory response.

Comment

CorMatrix ECM has been implanted in more than 50,000 patients worldwide in a variety of applications from pericardial closure to complex intracardiac reconstructions [2–8]. However, because opportunities for explantation and histologic examination are rare, questions have remained about the material’s fate after implantation.
The present case is unique in that we were able to follow the patient for 5 years, collect radiographic data, and then directly examine the material upon reoperation. We observed maintenance of the retrosternal distance, which has been argued to be important functionally as well as to prevent injury in subsequent surgeries [1]. The material performed well in protecting the heart during dissection, and histology showed clear evidence of constructive remodeling into viable, non-fibrotic connective tissue with no evidence of any destructive inflammatory response.

This case represents, to our knowledge, the most direct and detailed examination of CorMatrix ECM material after long-term implantation in the human pericardial environment. Although anecdotal, our findings support the hypothesis that the ECM is capable of remodeling into a neo-pericardium that appears physically and histologically similar to native pericardial tissue, and thus provides an attractive alternative to Dacron or glutaraldehyde-fixed pericardial products.

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References