3. Yao DK, Chen H, Ma LL, Ma ZS, Wang LX. Totally endoscopic atrial septal repair with or without robotic assistance: a systematic review and meta-analysis of case series. Heart Lung Circ 2013;22:433–40.

Early Degeneration of Extracellular Matrix Used for Aortic Reconstruction During the Norwood Operation

Ersin Erek, MD, Selim Aydin, MD, Dilek Suzan, MD, Okan Yildiz, MD, Ibrahim Halil Demir, MD, and Ender Odemis, MD

Acibadem University, Medical Faculty, Acibadem Atakent Hospital, Halkali, Istanbul, Turkey

The use of prosthetic patch material is often required during the surgical reconstruction of complex congenital cardiac malformations. Decellularized porcine small intestinal submucosa, a type of extracellular matrix, was recently introduced as a patch for cardiac and vascular tissue repair. Extracellular matrix was used for aortic reconstruction during the Norwood procedure in 8 consecutive neonates with hypoplastic left heart syndrome. Rapid degeneration or aneurysm formation developed in 3 of these patients who came to second-stage surgery. Extracellular matrix should be used cautiously for aortic reconstruction in infants until additional reports from other centers provide confirmation of its safety.

(Ann Thorac Surg 2016;101:758–60)

FEATURE ARTICLES

The surgical treatment of many congenital heart anomalies necessitates the use of prosthetic materials, such as valves, conduits, or patches. Biologic prostheses are often favored because of their handling characteristics. Many kinds of biologic materials have been tried, but all have some inherent drawbacks, including lack of growth potential, shrinkage, calcification, and event potential for degeneration. Patients face repeated surgeries as a consequence of these limitations [1]. A novel bioprosthetic patch derived from decellularized porcine small intestinal submucosa, termed extracellular matrix (ECM) by the manufacturer (CorMatrix, Roswell, GA), was recently introduced as a patch for cardiac and vascular tissue repair.

It has been proposed that ECM might serve as scaffolding that provides a framework for ingrowth of native, living tissues. It has further been hypothesized that in addition to providing the physical structural support for cellular elements, ECM might play a role in delivering signals that influence proliferative, metabolic, and differentiation intracellular pathways. In contrast to the proinflammatory cascade noted in the incorporation of patch or graft materials that result in fibrosis and scar formation, it has been suggested that ECM promotes a regenerative or healing pathway and facilitates tissue remodeling [2]. The utility of ECM for cardiac reconstruction has been described in both animal and human studies [2, 3]. In this report, we describe early degeneration and aneurysm formation of ECM used for aortic reconstruction during Norwood procedures in neonates.

Between May and October 2013, ECM was used for aortic reconstruction during the Norwood procedure in 8 consecutive neonates with hypoplastic left heart syndrome. The ECM patch was opened as a dehydrated sheet from its sterile package, and the rehydration process was performed by soaking the patch in sterile saline at room temperature for 10 minutes, according to the manufacturer's instructions. Once rehydrated, the material became pliable, and was trimmed for aortic reconstruction. Its strength, hemostatic properties, and conformity were acceptable.

From the original cohort, 3 patients were evaluated for second-stage operation. All underwent cardiac catheterization and computed tomography angiography. Two of the patients had aneurysm formation at the ascending aorta and aortic arch, with maximum aortic dimensions of 3.2 cm and 4.8 cm, respectively (Fig 1). The aneurysm in

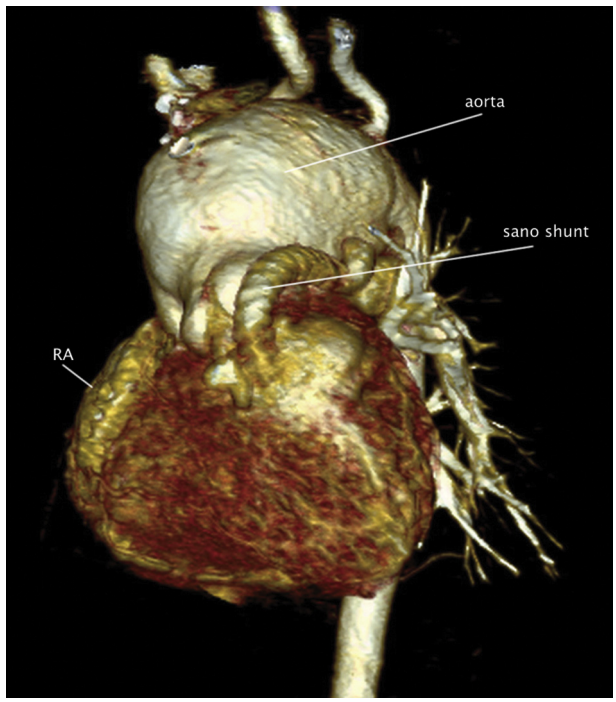

Fig 1. Three-dimensional thorax computed tomography angiography of patient 2. (RA = right atrium.)

Accepted for publication April 8, 2015.

Address correspondence to Dr Erek, Acibadem University, Cardiovascular Surgery Department, Acibadem Atakent Hospital, Halkali Merkez Mah, Turgut Ozal Bulvari, No 16, Halkali 34303, Istanbul, Turkey; email: ersinerek@hotmail.com.

0003-4975/$36.00
http://dx.doi.org/10.1016/j.athoracsur.2015.04.051

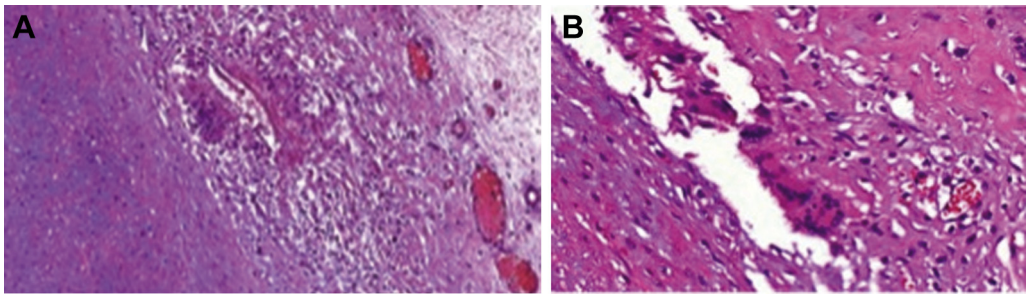

Fig 2. Histologic examination of the CorMatrix extracellular matrix resected from patient 2: (A) original magnification ×10 and (B) original magnification ×40, hematoxylin-eosin staining.

the second patient was so large that it compressed the central pulmonary artery confluence and the distal trachea. The maximum aortic dimension was normal (2.0 cm) in the third patient. The first 2 patients underwent bidirectional superior cavopulmonary connection with ascending aortic and arch replacement with a Dacron (C.R. Bard, Haverhill, PA) patch. In both patients, the whole ECM patch was noted to be quite thin and fragile. The third patient sustained a dissection and rupture in the ECM patch during cannulation for cardiopulmonary bypass, and also had replacement of the original ECM patch with a Dacron patch.

All patients weaned successfully off cardiopulmonary bypass. The first patient had cardiac arrest, due to respiratory insufficiency, on postoperative day 2 and required 6 days of extracorporeal membrane oxygenation support. Although successfully weaned off extracorporeal membrane oxygenation, the patient died of sepsis on postoperative day 24. The second patient required prolonged hospitalization because of pneumonia and right diaphragm paralysis, and eventually underwent right diaphragm plication. The third patient was discharged uneventfully. Both surviving patients were in good clinical condition at 3-month follow-up assessment.

Pathology examinations of the resected ECM material of all patients revealed a consistent appearance: mixed type of inflammation, calcification, foreign body granulomas, giant cells, and chronic inflammation with macrophage accumulation (Fig 2).

Comment

The ideal patch material for reconstruction in congenital heart surgery should be pliable, hemostatic, easy to use, readily available, and have growth potential. It should not induce inflammation and calcification. A wide variety of biologic and synthetic patch materials such as autologous pericardium, bovine pericardium, polytetrafluoroethylene, and Dacron have been tried, but all have significant inherent drawbacks [1]. An ECM obtained from porcine small intestinal submucosa was recently introduced and has been approved by the Food and Drug Administration for vascular repair. Extracellular matrix is an acellular biomaterial that is thought to provide a bioscaffold that enables recipient cells to repopulate. Encouraging results of animal and clinic studies have been published [2, 3]. Quarty and associates [4] described experience with ECM in 26 pediatric patients for cardiac or vascular tissue repair. Successful repairs were achieved in all patients with use of the ECM in either a vascular or a valvular position. None of the patients had any patch-related complication; and after a median follow-up of 13.2 months, there were no cases of patch failure or calcification. One patient required reoperation for reasons not related to the patch; in this patient, the CorMatrix was not calcified, and its function in a vascular position was satisfactory [4]. Scholl and colleagues [2] used ECM in 37 cardiac and great vessel repair cases in patients aged between 2 days and 13 years. No patch-related complications occurred during a median follow-up of 7.8 months. One patient who had tricuspid valve leaflet augmentation underwent reoperation 4 months later, and resorption of the ECM was found, with replacement by organized collagen and associated reendothelialization [2].

The first negative results concerning ECM were published by Weber and colleagues [5], who reported early pseudoaneurysm formation in 3 patients who had undergone carotid artery patch angioplasty with ECM. Histopathology examination revealed postendarterectomy neointima in the artery and disorganized collagen in the pseudoaneurysm. The ECM patch remnants adjacent to macrophage infiltration and neovascularization indicated ongoing processes of degradation and synthesis. Rosario-Quinones and coworkers [6] recently reported that 6 of 25 patients who had received ECM patches during cardiac operations required reoperation owing to hemodynamically significant lesions at the site of the ECM implantation. Explanted specimens demonstrated an intense inflammatory reaction consisting of numerous eosinophils, histiocytes, and plasma cells, accompanied by granulation tissue and fibrosis [6].

In the present report, we describe unsatisfactory results with ECM, with findings of early severe degeneration or aneurysm formation, or both, with intense inflammatory reaction in the aortic patch in all 3 patients who came to second-stage operation. We, therefore, urge caution in the use of ECM as a vascular patch in the aortic position in neonates until additional reports from other centers provide confirmation of its safety.

References

1. Calfa D, Bacha E. New technologies for surgery of the congenital cardiac defect. Rambam Maimonides Med J 2013;4:e0019.
2. Scholl FG, Boucek MM, Chan KC, Valdes-Cruz L, Perryman R. Preliminary experience with cardiac reconstruction using decellularized porcine extracellular matrix scaffold: human applications in congenital heart surgery. World J Pediatr Congenit Heart Surg 2010;1:132–6.
3. Boni L, Chalajour F, Sasaki, et al. Reconstruction of pulmonary artery with porcine small intestinal submucosa in a lamb surgical model: viability and growth potential. J Thorac Cardiovasc Surg 2012;144:963–9.
4. Quarty A, Nardone S, Colaneri M, Santoro G, Pozzi M. Preliminary experience in the use of an extracellular matrix to repair congenital heart diseases. Interact Cardiovasc Thorac Surg 2011;13:569–72.
5. Weber SS, Annenberg AJ, Wright CB, Braverman TS, Mesh CL. Early pseudoaneurysm degeneration in biologic extracellular matrix patch for carotid repair. J Vasc Surg 2014;59:1116–8.
6. Rosario-Quinones F, Magid MS, Yau J, Pawale A, Nguyen K. Tissue reaction to porcine intestinal submucosa (CorMatrix) implants in pediatric cardiac patients: a single center experience. Ann Thorac Surg 2015;99:1373–7.

FEATURE ARTICLES

Upper Sternal Cleft With a Complex Congenital Heart Defect: Repair in a Single Stage

Mohammed Al-Yamani, MD, Frederic Lavrand, MD, Jean-Benoit Thambo, MD, PhD, and François Roubertie, MD

Department of Cardiovascular Surgery, Bordeaux Heart University Hospital, Department of Pediatric Surgery, Pellegrin-Enfant Hospital, and Department of Pediatric Cardiology, Bordeaux Heart University Hospital, Bordeaux, France

Sternal clefts are extremely rare in association with complex congenital heart defects, and their management can be challenging. Complete surgical repair in early infancy, of both anomalies in a single stage, is advocated. Different surgical techniques exist for isolated sternal cleft repair, but they do not consider the difficulties of combining sternal defect closure and a cardiac operation with the unavoidable postoperative cardiac edema. We describe a successful surgical technique to repair a sternal cleft in a 3-month-old infant in a concomitant cardiac operation using an absorbable polyglactin 910 mesh plate and sternal osseous autografting to avoid postoperative cardiac distention.

(Ann Thorac Surg 2016;101:760–2)

A congenital sternal cleft (SC) is a rare idiopathic anomaly. It is the result of failed midline development and incomplete fusion of the mesodermal lateral plates starting from the sixth week of intrauterine life [1]. The association of a sternal cleft defect and congenital heart disease (CHD) has been reported 20 times in the literature: this association represents ~19% of all reported sternal clefts [2]. Various surgical techniques for isolated SC repair have been described, but they carry the potential risk of cardiac compression, which can increase after a cardiac operation because of cardiac edema. The use of an absorbable polyglactin 910 (Vicryl, Ethicon Inc., Somerville, NJ) mesh plate with sternal osseous autografting could effectively improve this cardiac procedure.

A newborn boy was referred to our hospital with a subcomplete superior SC, confirmed by computed tomography (CT) as a V-shaped defect (Fig 1A, Fig 2A) and

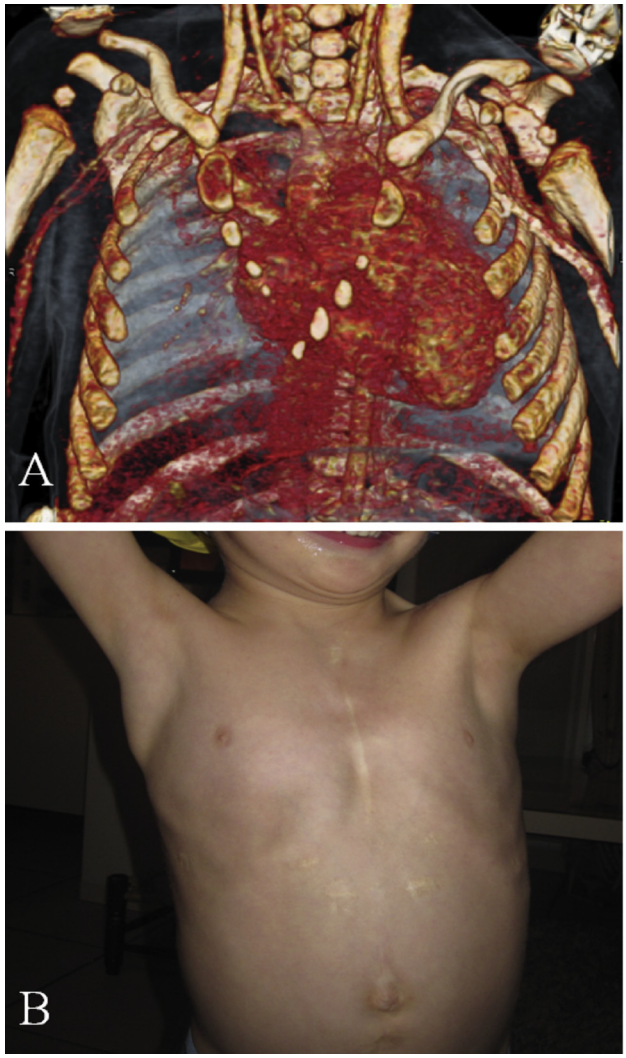

Fig 1. (A) Preoperative computed tomographic scan with three-dimensional reconstruction of the thoracic wall showing a superior sternal cleft with an increased interclavicular space. (B) Postoperative follow-up view showing satisfactory correction of the anterior chest wall with a nearly normal aspect and without paradoxical respiratory movement.

Accepted for publication March 12, 2015.

Address correspondence to Dr Roubertie, Department of Cardiovascular Surgery, Haut Lévèque Hospital, 1 Ave Magellan, 33600 Pessac, France; email: francois.roubertie@chu-bordeaux.fr.

0003-4975/$36.00
http://dx.doi.org/10.1016/j.athoracsur.2015.03.049