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CONGENITAL HEART

Biodegradable Patches: Where Are We Going Now?

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Invited Commentary:

In 1992, the initial experimental studies reporting on patches made of extracellular matrix (ECM) derived from small intestinal submucosa (SIS) and used as a scaffold for tissue repair in cardiovascular indications were published.[1] Later on, from 2010 onward, myriad small sample-size clinical studies have been reported for cardiac indications, with variable results, both as intracardiac or extracardiac patches.[2-4]

The heterogeneity among clinical responses to SIS-ECM use at different sites highlighted the need for further work to determine optimal indications for SIS-ECM use. Most of the recent experimental work seems to confirm the implantation of such material triggers a proinflammatory and profibrotic response. Last year, in the *Journal of Cardiovascular and Thoracic Surgery*, van Rijswijk and colleagues[5] reported a chronic valvular experimental sheep model in which they clearly demonstrated the persisting limitations of such a biomaterial.

In this well-designed study, Sood and colleagues[6] were able to provide a longitudinal analysis of implanted two-ply CorMatrix patches in the pulmonary vasculature, which they refer to as a pulsatile environment, although at rather low pressure. The study comes in line with the group's previous publication on their use of four-ply CorMatrix in stage II hemi-Fontan procedures in univentricular heart patients. The duration of implantation varied from 4.3 to 10.3 months, so that one can speculate that most of the remodeling was terminated, at least in patients with the longest implantation. As in their earlier study on the four-ply CorMatrix, with longer time of implantation (18 to 26 months), the authors demonstrated that remodeling of the biomaterial ended up with fibrosis, acellular material, chronic inflammation, disorganized elastic fibers, and foreign body giant cell reaction in all explanted specimens. In the present study, however, dystrophic calcification and eosinophic infiltration were not found. No explanted CorMatrix material showed evidence of ingrowth of native cells or transformation.

Unfortunately, this study comes short of additional immunohistochemistry staining for endothelial (CD31, von Willebrand factor) or inflammation (CD45, CD3) markers that could have provided important additional longitudinal information. Because the patch was used to reconstruct the pulmonary artery bifurcation where the area is quite large, it is difficult to infer that the material would behave favorably in the setting of stenotic vascular segment requiring patch augmentation, being in the right side of left-sided circulation.

Unfortunately, the current study of Sood and colleagues[6] only comes as one additional small sample-size clinical study in which the use of such biomaterial was not detrimental. Whether this substitute will prove to be more than one of the many biomaterial available to the congenital surgeon is still speculative, and its long-term efficacy for valve-related diseases is currently not supported by the available literature.

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