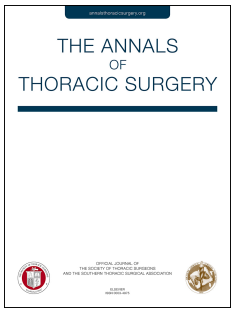

Biodegradable patches: Where are we going now?

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Biodegradable patches: Where are we going now?

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 cardio-vascular indications were published [1]. Later on, from 2010 onwards, a myriad of small sample-size clinical studies have been reported in cardiac indications, with variable results, both as intra-cardiac or extra-cardiac patches [2-4].

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

In this well-designed study, Sood and colleagues [6] were able to provide a longitudinal analysis of implanted **2-ply Cormatrix** patches in the pulmonary vasculature which they refer to as a « pulsatile » environnement, though at rather low pressure. The study comes in line with the group previous publication on their use of **4-ply** Cormatrix in Stage II Hemi-Fontan procedures in UVH 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 4-ply Cormatric, with longer time of implantation (18-26mo), 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. However in the present study, dystrophic calcification and eosinophic infiltration were not found. No explanted Cor-Matrix material showed evidence of ingrowth of native cells or transformation.

Unfortunately, this study comes short of additional IHC staining for endothelial (CD31, vWf) or inflammation (CD45, CD3) markers which could have provided important additional longitudinal information. Because the patch was used to reconstruct the PA 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- of left-sided circulation.

Unfortunately, the current study of Sood and colleagues only comes as one additional small sample-size clinical study in which the use of such biomaterial was not detrimental. Whether or not 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 in valve related diseases is currently not supported by the available literature.

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