The importance of in vitro testing of materials used for intracardiac repairs

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Central Message

A deeper understanding of the mechanical forces acting on atrioventricular valve structures and material used for atrioventricular valve repairs is essential to achieve durable results.

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Atrioventricular valve repairs in the congenital patient population can be complex and challenging. Leaflet extensions with patches to achieve better coaptation have become quite common; however, the material used for such repairs varies among centers and surgeons. There is little objective evidence that a single material outperforms competitors when it comes to durability and effectiveness of the repair. In this issue of the *Journal*, Hammer and colleagues¹ report a case of patch dehiscence after left-sided atrioventricular valve repair in a physically active 21-year-old patient, which led them to evaluate the mechanical forces that act on the patch and whether these forces can ultimately affect the stability of the repair. The mechanical testing provided by Hammer and colleagues¹ shows that suture retention in PhotoFix pericardium (CryoLife, Inc, Kennesaw, Ga) can be insufficient, especially when forces act along the weaker second material direction. Unfortunately, it is difficult to assess the pericardium and to orient the patch accordingly in the operating room. A fortiori, a surgeon must rely on appropriate material characteristics.

Pericardial surgical patches are considered medical devices and are subject to approval by the Food and Drug Administration (product code DXZ, intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene). The patch material used in this case report is decellularized bovine pericardium treated with photo-oxidation to increase collagen crosslinking. The FDA's 510(k) device database indicates that the Sulzer Carbomedics CardioFix Pericardium (Sorin Group USA, Inc, Arvada, Col) was the first to receive Food and Drug Administration approval for this particular crosslinking method. Substantial equivalence to predicate devices was established by in vitro performance testing, including uniaxial tension, suture retention, and suture hole elongation.² Interestingly, the 510(k) application of the CryoLife PhotoFix Pericardium used the Sulzer Carbomedics CardioFix Pericardium as predicate to prove substantial equivalence and to achieve a change in the indications for use.³ The

indications for use of the CardioFix patch restricted the material to be used only with a reinforced patch technique (ie, minimum of double thickness), especially when exposed to peak systolic pressure.² This restriction was lifted with the change in indications for use of the PhotoFix 510(k). According to the respective approval letter, performance testing of the PhotoFix patch was limited to chemical characterization testing, biocompatibility testing and packaging shelf-life, but did not include biomechanical testing.³ On the basis of the limited information available, it is inappropriate to conclude that photo-oxidized pericardium is not mechanically strong enough when exposed to high pressure. It would be interesting to know, however, what led to the initial restriction of the indications for use of CardioFix when implanted in high-pressure zones and what clinical data, animal testing, or bench testing led to the extension of the indications for use of PhotoFix. More extensive evaluation of the material characteristics of patches would be helpful to complete the picture. In vitro testing of the mechanical strength of glutaraldehyde-treated autologous or xenogeneic pericardium or even native atrioventricular valve tissue could be compared with testing of photo-oxidized pericardium. Additional studies on the peak mechanical forces acting on the left-sided atrioventricular valve would then allow us to interpret the adequacy of the patch material.

Hammer and colleagues¹ suggest that a narrower spacing of stitches could help to increase the strength of the suture line and to avoid dehiscence; however, the complexity of the atrioventricular valve necessitates many modifications of the surgical technique to ensure a durable repair. Atrioventricular leaflets have distinct histologically different zones with variable thickness.⁴ Long-standing regurgitation may cause fibrosis and thickening of the leaflets. The size of the patch necessary to achieve adequate coaptation can vary significantly, and this affects the forces on the suture line substantially. It is therefore essential to assess each valve individually and to adjust the surgical technique accordingly by using different sutures, spacing stitches more narrowly, adding pledgets, or choosing an alternative patch

material. Studies such as the one presented by Hammer and colleagues¹ help to objectify surgical decision making and can ultimately improve outcomes.

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