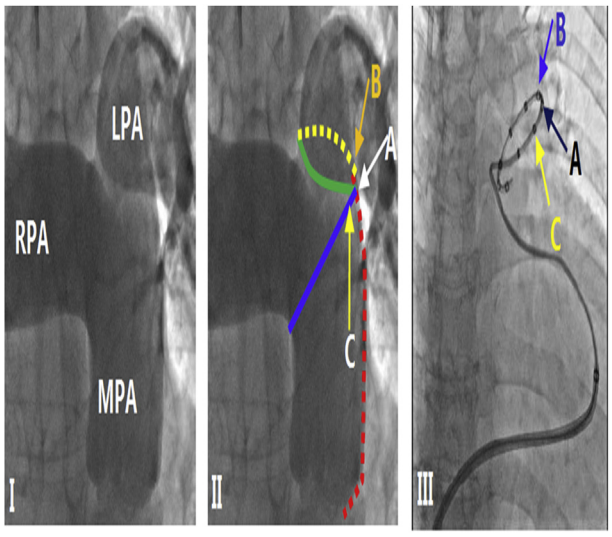
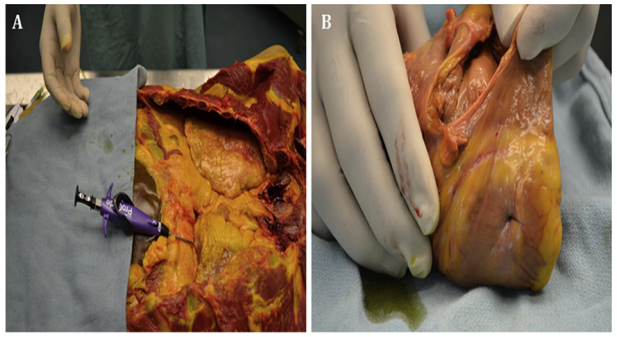


Figure 1. Description of pulmonary artery denervation procedure.



CRT-500.02

Perclose Suture Mediated Closure System to Treat Accidental Pericardiocentesis Drain Entry in to the Right Ventricle

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Pericardial effusion is mainly caused by infection, inflammation or malignancy. Rapid or excessive fluid collection can restrict cardiac filling, resulting in hemodynamic compromise. Percutaneous pericardiocentesis is performed in majority of such patients. One of the dreaded complications during this procedure is the inadvertent insertion of drain into the right ventricular cavity. The currently available treatment for this complication is surgical removal of the drain after thoracotomy, and a purse string suture around the drain site or a patch closure. Open-heart surgery is associated with inherent morbidity and mortality. Isolated case reports have demonstrated feasibility of using an AngioSeal® or vascular plugs to close such defect.

Perclose® suture mediated closure system is commonly used to close large caliber sheath entry sites into the arteries and veins after percutaneous structural interventions. We sought to assess the feasibility and efficacy of Perclose to close the drain entry site into the right ventricle. The local Research and Ethics Board granted approval for this study. We used a pericardial drain set to intentionally enter the 10 Fr sheath (pericardial drain is an 8.3 Fr system) into the ventricular cavity, when the heart was in situ. The sheath was then taken out over the wire and Perclose system was introduced to deploy a suture in a standard fashion. Effectiveness of the deployed suture in closing the defect was assessed after the heart was explanted. Perclose deployed a suture, and effectively closed the sheath entry site into the right ventricle in each of the experiments (n=4), as shown in the image 1B.

Perclose suture delivering system (can be used as) may be an alternative non-operative option to close such a defect caused by inadvertent insertion of the pericardial drain in right ventricular cavity. Further study is warranted.

CRT-500.03

Examining the Remodeling of CorMatrix as a Trileaflet Valve Conduit in Heterotopic Position in Growing Pig Model

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BACKGROUND Porcine small intestinal submucosa extracellular matrix, CorMatrix (CorMatrix Cardiovascular, Roswell, GA) is potentially suitable tissue substitute for cardiovascular use. We investigate the biological reaction and remodeling of CorMatrix, as a tri-leaflet valve conduit in growing pig model. We hypothesized that CorMatrix would maintain a durable architecture as a valve conduit and that it would remodel to resemble the surrounding tissues.

METHODS Using 7x10cm 4ply sheet, we made the conduit, and placed it in the pig's thoracic aorta using an arterial shunt. Testing periods were 3, 4, 5, and 6 months respectively. We examined the explants for biodegradation, degree of replacement by native tissue, and durability by histology, immunohistochemistry and mechanical testing.

RESULTS Four pigs, one per time frame, concluded the study. The conduit lost its original architecture as a tri-leaflet valve and evolved as an arterial wall with the valve segment being thicker. The scaffold's resorption didn't follow a timely process and was incomplete with disorganized degradation even at 6 months. Chronic inflammation persisted, and fibrosis, scaring and early calcifications started at 4 months. The partially remodeled scaffold did not resemble the aortic wall. This suggests impaired remodeling. Mechanical testing showed weaker properties of the tissues over time which was liable to breakage.

CONCLUSION CorMatrix is biodegradable and potentially can remodel. The remodeling process is multifactorial, dependent on the patch, host response and anatomical location. As a valve conduit in an arterial environment; the growth was neither structured nor anatomical. Failure of remodeling explained by the complexity of the conduit structure, and the host's chronic inflammatory response leading to early fibrosis and calcification.