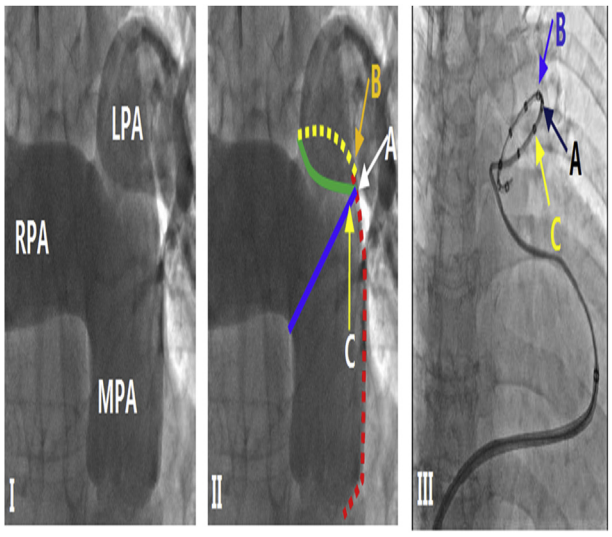
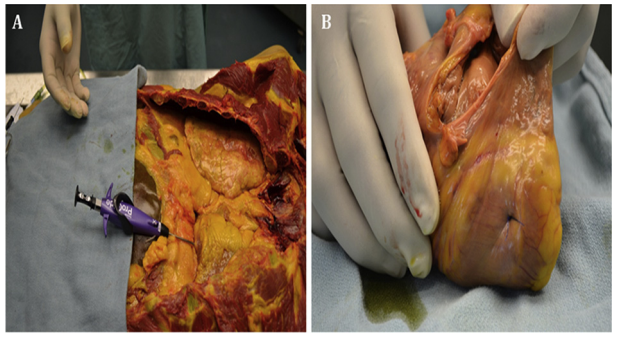


Figure 1. Description of pulmonary artery denervation procedure.



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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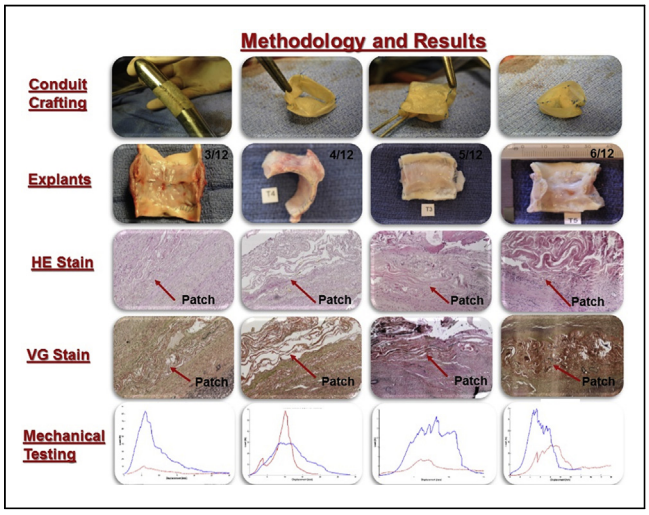
BACKGROUND Porcine small intestinal submucosa extracellular matrix, CorMatrix (CorMatrix Cardiovascular, Roswell, GA) is potentially suitable tissue substitute for cardiovascular use. We investigate the biological reaction and remodeling of CorMatrix, as a tri-leaflet valve conduit in growing pig model. 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.



CRT-500.04

Biodegradation of Subcutaneously Implanted Cardiac Tissue Substitutes in Chronic Swine and Ovine Models

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BACKGROUND To compare biodegradation and local tissue reactions to porcine small intestinal submucosa (CorMatrix; Roswell, GA) and three other commercial cardiac tissue substitutes (porcine pericardium (Vascutek; Scotland, UK); bovine pericardium (SJM; St Paul, MN); and GoreTex (expanded polytetrafluoroethylene.(L. Gore & Associates, Inc., Flagstaff, AZ)) in allograft (pig) and xenograft (sheep) models over one year.

METHODS Three miniature pigs and adult sheep were studied, each representing a time point (1, 3, and 12 months). Materials were implanted subcutaneously and tissue explants processed for histology and immunohistochemistry, and parameters were graded semi-quantitatively (1+ = mild; 2+ = moderate; 3+ = severe).

RESULTS Pig model: At 1 and 3 months, CorMatrix showed gradual degradation (mild to moderate), and was surrounded by dense fibrosis (2+) and severe inflammation (3+). By one year, it was fully degraded and replaced with fibrosis (1+) and subcutaneous tissues. At 1 month, Vascutek was intact, surrounded by moderate fibrosis (2+) and severe inflammatory reaction (3+). By three months, inflammation was mainly perivascular (2+) and increased encapsulating fibrosis (3+). It remained intact at 12 months but with reduced fibrosis (1+) and mild chronic inflammation (1+). SJM explants were similar to Vascutek but with significantly less encapsulating fibrosis (1+) and inflammation at three months, which remained stable thereafter. GoreTex was visible as exogenous material in a fibrotic capsule (2+), which reduced after one month, and moderate inflammation (2+).

Sheep model: CorMatrix was partially fragmented and disintegrated at 1 month, with severe fibrosis and inflammation (3+). Afterwards, the patch was invisible, with moderate inflammation and more severe fibrosis (3+), which reduced by 1 year. Vascutek (intact and encapsulated) and SJM (partially fragmented) explants showed mild chronic inflammation at 1 month which increased at 3 months and 1 year (1+). Fibrosis was moderate (2+) and intensified thereafter (3+). The GoreTex was intact with a fibrotic capsule.

CONCLUSION The biological patches were biocompatible in both models. CorMatrix was resorbed and showed signs of early degradation. All materials except CorMatrix, were encapsulated. Biological materials support healing and remodelling, while GorTex elicits a typical foreign body-type reaction. The processes were accelerated in sheep. We cautiously suggest that CorMatrix, when used as a xenomaterial, exhibits a more intense tissue reaction.

CRT-500.05

ABSTRACT WITHDRAWN

CRT-500.06

Real-time 3D Imaging of Renal Nerves

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Major medical device companies consider renal denervation as a potent solution to reverse high blood pressure in hypertension patients. Despite several supporting positive clinical studies, a recent multi-center large clinical study, Symplicity-3 showed no statistically significant reduction in blood pressure before and after renal denervation, challenging clinical utility and efficacy specifically by RF-based renal denervation. Debate about this study raised, several questions on device and method of denervation, specifically whether a) thermal denervation by RF device is effective, and b) sufficient RF energy reaches nerve target. One of the consensus among physicians is the lack of detailed pre-clinical study on how RF energy is delivered across tissue layers to the nerve and poor understanding of nerve density, geographical location of the nerves in 3D and their accessibility to RF energy may be one of the main reasons for different clinical results. Our group at OCT Medical has developed a method to detect and distinguish renal nerves from surrounding tissue in 3D using a custom built imaging system based on Optical Coherence Tomography. Using this imaging system in a fresh excised pig renal artery, we are able to identify and distinguish renal nerves, blood vessel fat and surrounding tissue clearly and corroborated with histopathology (Figure 1) performed by Dr. Renu Virmai's group at CVPath Institute. This distinction and clarity was retained and enhanced after fixing and treatment with a contrast reagent. Now, we can quantitate in real-time extent of structural and functional nerve damage in nerve and surrounding fat tissue and plan to present data during CRT. This technique offers a real-time feedback to physician extent structural and functional denervation and we plan to develop a device based on this to use in human clinical practice.

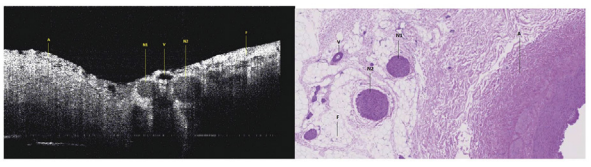

Figure 1. Left OCT image on the surface of a cross-section of a renal artery. Two nerves (N1, N2) and a blood vessel (V) are resting next to the renal artery (A) within the fatty layer (F). A corresponding histology image (Right) demonstrates the correlation and presence of the nerves and blood vessel.

TECHNOLOGY