**HEART VALVE TISSUE REGENERATION WITH EXTRACELLULAR MATRIX BIO-SCAFFOLD: A NEW SURGICAL TECHNIQUE**

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Objectives: With 100,000 US and 300,000 World-wide valve replacements each year the need for a more bio-compatible and functional valve replacement is great. Introduction: Tissue-engineered heart valves may be the ultimate solution to replace the structure and function of native valves. Porcine extracellular matrix (ECM) is a novel material that provides structural integrity, infection resistance, and a bio-scaffold for native cell re-growth.

Method: ECM (CorMatrix Inc., Alpharetta GA) was rehydrated for 10 minutes in sterile saline and implanted in pericardial, cardiac, and valve positions in 20 animals. Partial ECM replacement of absent or defective pericardial, cardiac, and valve tissue was completed in 400 human patients. The total reconstruction of an infected tricuspid valve was completed in a patient with refractory infective endocarditis. The new tricuspid tubular valve was fashioned from a 7x10 cm ECM sheet.

Results: In animals, the ECM biomaterials demonstrated initial structural integrity and recipient cell in-growth and were completely replaced by native tissues after 3-6 months. In humans, follow-up studies showed restored pericardial, cardiac, and valve structure and function on computerized tomography and echocardiography. The newly implanted complete valve reconstruction functioned well with minimal insufficiency or gradient as demonstrated by intra-operative and postoperative echocardiography. This patient was discharged from hospital in good condition with trace regurgitation.

Conclusions: ECM provides a structural and infection-resistant bio-scaffold for cardiac valve regeneration in patients. Clinical experience with this novel biomaterial to regenerate cardiac valve and other cardiac tissues suggests that a new surgical option and paradigm is upon us.