

C57. Eight Years Follow-up Of A Tissue Engineered Pulmonary Valve In Eleven Consecutive Patients During Ross Operation

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OBJECTIVES: The Ross procedure is limited by the durability of the valve prostheses used to reconstruct the right ventricular outflow tract. This study was performed to collect prospective safety and effectiveness data of a tissue engineered heart valve to reconstruct the right ventricular outflow tract during Ross procedure.

METHODS: From May 2000 till June 2002, eleven consecutive patients received a tissue engineered heart valve. Two to four weeks prior to the Ross operation a piece of vein was harvested, to isolate, characterize and expand endothelial cells. A pulmonary allograft was decellularized and seeded with autologous vascular endothelial cells, using a specially developed bioreactor. Follow-up was performed by clinical evaluation, transthoracic echocardiography, and multi-slice computed tomography.

RESULTS: Patients mean age was 39.6 ± 10.3 years. Cell seeding density was $1.1 \times 10^5 \pm 0.5 \times 10^5$ cells/cm² with a viability of 93.2 ± 2.1 %. All patients survived surgery. No fever of unknown origin was seen postoperatively and leucocyte count did not increase. Currently all patients are in NYHA class I. Transthoracic echocardiographic evaluation of the tissue engineered heart valve showed a mean pressure gradient of 3.9 ± 1.8 mmHg at 8 years. Multi-slice computed tomography showed no calcification up to 8 years.

CONCLUSIONS: Tissue engineered heart valves showed excellent hemodynamic performance during intermediate-term follow-up. Decellularization of heart valves and seeding with autologous vascular endothelial cells may prevent degeneration of tissue valves.