Mid-term clinical results using a tissue-engineered pulmonary valve to reconstruct the right ventricular outflow tract during the Ross procedure

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Background
The Ross procedure is mainly 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 the Ross procedure using a tissue-engineered heart valve to reconstruct the right ventricular outflow tract.

Methods
Between May 2000 and February 2003, 23 patients received tissue-engineered heart valves. Two to four weeks before the Ross operation, a piece of forearm or saphenous vein was harvested to isolate, characterize, and expand endothelial cells. A pulmonary allograft (n = 11) or xenograft (n = 12) was decellularized, coated with fibronectin, and seeded with autologous vascular endothelial cells, using a specially developed bioreactor. Follow-up was performed by clinical evaluation, transthoracic echocardiography, magnetic resonance imaging, and multislice computed tomography.

Results
The patient mean age was 44.0 +/- 13.7 years. Cell seeding density was 1.1 x 10(5) +/- 0.5 x 10(5) cells/cm2, with a viability of 90.2% +/- 8.9%. All patients survived the operation. One patient died during follow-up, and 1 patient required reoperation. All surviving patients are currently in New York Heart Association functional class I. Transthoracic echocardiographic evaluation of the tissue-engineered heart valve showed a mean flow velocity of 0.9 +/- 0.4 m/s at 5 years. Multislice computed tomography showed no calcification up to 5 years postoperatively.

Conclusions
Tissue-engineered heart valves showed excellent hemodynamic performance during mid-term follow-up. Decellularization of heart valves and seeding with autologous vascular endothelial cells may prevent tissue degeneration and improve valve durability.