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A Novel Bioabsorbable Vascular Graft in a Modified Fontan Procedure - the First Clinical Experience

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Abstract:
Objective: To assess safety and performance of a novel bioabsorbable vascular graft in pediatric patients with univentricular congenital malformation requiring hemodynamic correction with extracardiac cavopulmonary conduit.
Methods: The graft material is designed to attract patient's own cells and proteins that trigger a cascade of physiological events leading to endogenous tissue restoration. As it bioabsorbes over time after implantation, components of native tissue, including collagen, endothelial lining and capillary blood vessels, develop and organize themselves into natural functioning tissue. From October 2013 to February 2014 five patients (aged 4 to 12 years) with single ventricle congenital malformation have been implanted with the newly developed bioabsorbable vascular grafts (18 and 20 mm in diameter) connecting inferior vena cava with the right pulmonary artery. Patients were followed for 1, 3, 6 and 12 months after surgery with the graft assessment performed by echocardiography, CT-scan and MRI, including 4-D flow.
Results: All 5 patients have been successfully recovered from the procedure and completed follow-up according to the study protocol. No device related adverse events were reported. Two patients with persistent pleural effusions required catheter based interventions to occlude collaterals between aorta and pulmonary artery. At twelve months postoperatively significant improvement in patients' general condition were noticed. Imaging studies demonstrated anatomical (conduit diameter, length and wall thickness) and functional (blood flow pattern) stability of the grafts in all patients with no significant changes at twelve months compared to early post-operative data.
Conclusions: Initial clinical experience and study outcomes thus far suggest that this novel technology has the potential to improve cardiac and vascular surgical procedures by reducing permanent implant related complications. Longer follow-up, however, is needed to fully assess the long-term effectiveness of biodegradable vascular grafts including ability to grow.