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Bioabsorbable Vascular Graft - the First Step Towards Development of the Next Generation Heart Valves

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OBJECTIVE:The bioabsorbable graft material is designed to attract patient's own cells that trigger a cascade of physiological events leading to natural tissue growth. After implantation the graft is gradually replaced by the components of native tissue, developing and organizing themselves into a fully functioning blood vessel. The vascular graft is an essential part of the valved conduit being developed for RVOT reconstruction. This feasibility study evaluated safety and performance of a novel bioabsorbable vascular graft in pediatric patients with univentricular congenital malformation, undergoing hemodynamic correction with an extracardiac cavopulmonary conduit
METHODS: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 biodegradable 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 six 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.