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POLYMERIC BIOABSORBABLE VASCULAR GRAFT IN MODIFIED FONTAN PROCEDURE – TWO-YEAR FOLLOW-UP

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Background/hypothesis
The bioabsorbable graft material is designed to allow patient's own cells to infiltrate and replace the material by a process called Endogenous Tissue Restoration (ETR) leading to natural tissue growth. After implantation the graft is gradually replaced with the native tissue, developing into a fully functioning blood vessel. This 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.

Materials and methods
Five patients with single ventricle congenital malformation have been enrolled in the study from October 2013 to February 2014. In all patients the bi-directional Glenn anastomosis have been previously performed. The patients' age at the time of implantation were ranged 4–12 years while 60% (n=3) were males. Total follow-up was 26–31 months with scheduled visits at 1, 3, 6, 9 and 12 months after surgery for the first year and yearly thereafter. The device performance evaluation has been performed by transthoracic ultrasound, and optional CT-scan and MRI were performed at several timepoints in all patients.

Results
All 5 patients have been successfully recovered from the procedure and completed 24 months follow-up. No device related adverse events were reported to date. Ultrasound and MRI studies have demonstrated anatomical (conduit dimensions) and functional (blood flow velocity and pattern, absence of thrombosis) stability of the grafts in all patients at up to 31 months.

Conclusions
The study device demonstrated an adequate hemodynamic performance at up to 31 months follow-up. The clinical study outcomes suggest that this bioabsorbable polymer technology has the potential to improve cardiac and vascular surgical procedures by reducing implant-related complications. Longer follow-up, however is needed to fully assess effectiveness of bioabsorbable vascular grafts. This represents the first step towards development of more complex bioabsorbable devices such as heart valves.
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