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30th EACTS Annual Meeting
Barcelona, Spain, 1-5 October 2016

A novel bioabsorbable vascular graft in modified Fontan procedure - mid-term results

Background / Study Objective

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- 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
- 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

Patients

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- 5 patients with single ventricle congenital malformation
- Previously performed bi-directional Glenn anastomosis – 100%
- 3 males (60%)
- Age range 4 – 12 years old (at the time of implantation)
- Follow-up 26 – 31 months

Methods

- Enrolment from October 2013 to February 2014
- Follow-up visits at 1, 3, 6, 9 and 12 months after surgery for the first year and yearly thereafter
- Graft performance evaluation by transthoracic ultrasound
- Optional CT-scan and MRI (including 4D Flow)
- Anticoagulation:
  - Warfarin – 2 patients
  - Aspirin – 3 patients

Results 1

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- All 5 patients have successfully recovered from the procedure and completed 24 months follow-up
- No device related adverse events were reported to date
- Two patients with persistent pleural effusions required catheter based interventions to occlude collaterals between aorta and pulmonary artery
- Ultrasound and MRI demonstrated anatomical (conduit diameter, length and wall thickness) and functional (blood flow pattern) stability of the grafts in all patients at up to 31 months

Results 2

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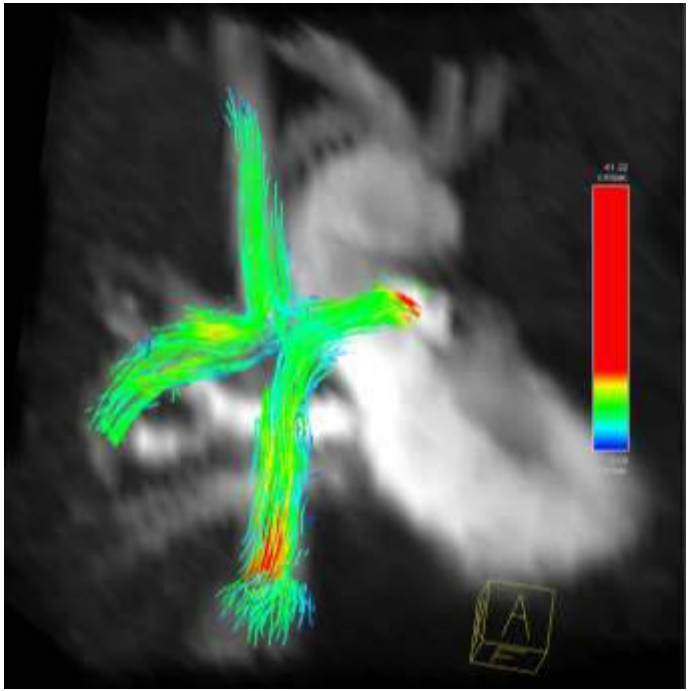
MRI Frontal Image and 4D Flow



Pt. 01-005 26 months follow-up

Conclusion

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- The bioabsorbable vascular conduit demonstrated an adequate hemodynamic performance at up to 31 months follow-up
- The clinical study outcomes suggest that this bioabsorbable polymer technology based on advances of supramolecular chemistry has the potential to improve cardiac and vascular surgical procedures by reducing implant-related complications
- Longer follow-up, however, is needed to fully assess the long-term effectiveness of bioabsorbable vascular grafts including ability to grow
- This is the first step towards development of more complex bioabsorbable devices such heart valves