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

• 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

- 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
• 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

MRI Frontal Image and 4D Flow

Pt. 01-005 26 months follow-up
Conclusion

• 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