Interventional Devices to Treat Newborns With Complex Congenital Heart Disease

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starlight cardiovascular

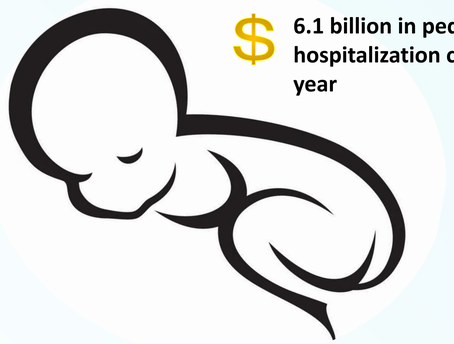
Our Children Deserve The Best to Fix The Little Broken Hearts

Congenital Heart Disease

1 in 100 babies born with congenital heart diseases

25% are critical, requiring immediate intervention

4.2% of all neonatal deaths



$ 6.1 billion in pediatric CHD hospitalization cost per year

Unmet Clinical Need

Figure 1. Open-heart surgery

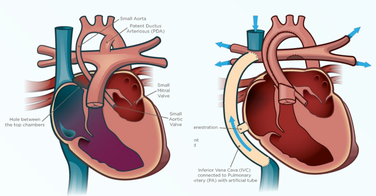


Figure 2. Hypoplastic left heart syndrome (HLHS) and Fontan Procedure

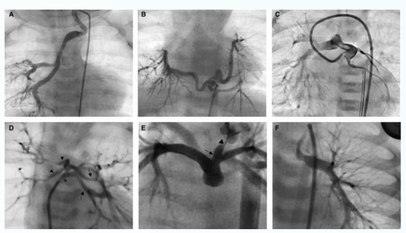


Figure 3. Major aortopulmonary collateral arteries (MAPCA) and a ductus arteriosus.

Septal Conduit

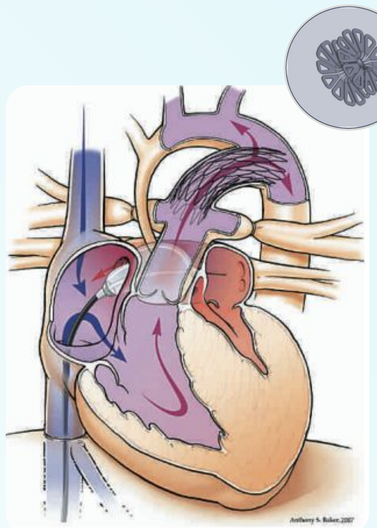


Figure 4. Image of what the hybrid procedure will look like within the heart. (Top right) Preliminary sketch of the features Starlight's septal conduit might have.

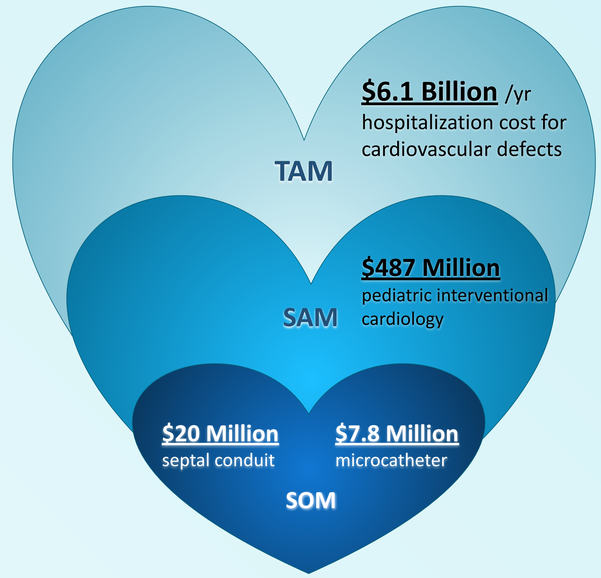
- **Key elements of hybrid procedure for HLHS**
  - PDA Stenting
  - Flow restrictor of pulmonary artery
  - **<u>Atrial septal fenestration by conduit</u>**

Traditional Surgery (Norwood Operation)	Hybrid Approach
Open chest surgery	Non-invasive percutaneous intervention
Significant blood loss	Minimal
No applicable for critical patients	Suitable for critical patients, such as BW <2kg
Longer recovery time and hospitalization	Shortening recovery time
Expensive ($238,989)	Cheaper (~$100,000)

Pediatric Microcatheter

- **Microcatheters designed for babies do not exist**
  - Neurovascular and peripheral microcatheters often adapted for off-label pediatric use
  - Flexible section often longer than entire vascular distance from femoral artery to heart
- **Interventional treatments save lives and money**
  - Open heart surgery especially risky for newborns
  - Microcatheters enable minimally invasive procedures
  - Better microcatheter design saves time and reduces X-ray fluoroscopy exposure

Market Opportunity



References

1) Sara K Pasquali, et al. Variation in congenital heart surgery costs across hospitals. Pediatrics. 2014 Mar;133(3).
2) Alexander A Brescia, et al. Hybrid versus Norwood procedure for hypoplastic left heart syndrome: contemporary series from a single center. J Thorac Cardiovasc Surg. 2014 Jun;147(6):1777-82.
3) CDC. https://www.cdc.gov/ncbddd/heartdefects/data.html
4) Pediatric Interventional Cardiology Devices - Global Market Trajectory & Analytics 2021

Figure 5. Shaun White after he won his third gold medal in halfpipe snowboarding in the 2018 Winter Olympics. White was born with Tetralogy of Fallot, and had three open heart surgeries as an infant.