Virtual Total Artificial Heart Implantation for Improved Device Eligibility Criteria

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INTRODUCTION

THE TOTAL ARTIFICIAL HEART

In 1985, SynCardia's Total Artificial Heart (TAH) was approved by the US Food and Drug Administration (FDA) for patients awaiting heart transplantation. Other forms of circulatory support, such as ventricular assist devices, have since emerged as options for pediatric patients. However, the TAH has not been commonly used in pediatrics. In fact, of the 1,061 patients implanted with the TAH, only 21 (2%) were under the age of 18 [1].

TAH SPECIFICATIONS

- Two 70 cc pulsatile pumps that replace the ventricles
- Adjustable ventricular orientation
- 400cc of displaced volume
- Pneumatically driven
- 160 grams

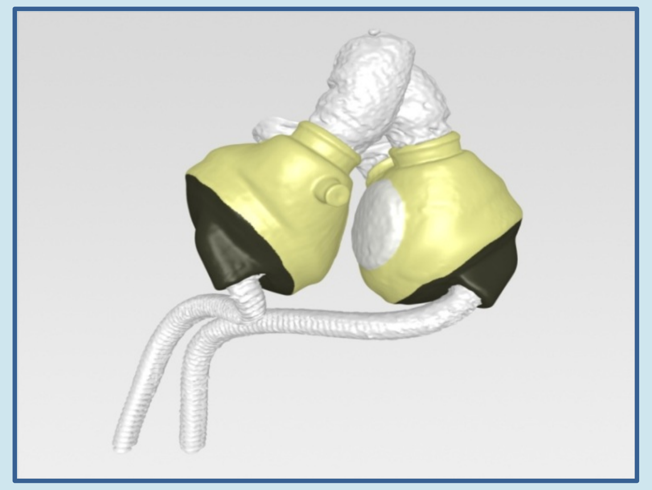


Figure 1: 3D reconstruction of the 70cc TAH. Atrial cuffs, grafts, and pneumatic tubes are attached.

PEDIATRIC CHALLENGES

As implantation of TAH devices increases in pediatrics, the criteria for patient eligibility must be better understood and established. Current eligibility standards recommend a minimum body surface area (BSA) of 1.7 m^2 and 10 cm between sternum and spine at T10 [1]. However, the current standards do not consider the vast differences in cardiovascular, respiratory, and skeletal morphologies among pediatric patients. This case study discusses the use of three-dimensional (3D) modeling with Mimics (Materialise, Leuven, Belgium) to analyze TAH fit and support virtual surgical planning in small patients, with the ultimate goal of avoiding potential complications.

HYPOTHESIS

VIRTUAL SURGICAL PLANNING

Complications due to impedance can be predicted by examining volumetric displacement of anatomical structures after virtual implantation of the TAH. The TAH device can be used in a broader patient population when there are anatomically informed eligibility criteria and implantation configuration is optimized.

METHODS

SEGMENTATION & 3D RECONSTRUCTION

- Phoenix Children's Hospital provided contrast-enhanced CT scans of two patients.
  - The dataset was treated as a blind study as to whether a TAH device would fit.
- Data was loaded into Mimics
  - Individual masks were created for the lungs, trachea, bones (ribs, vertebrae, and sternum), aorta, pulmonary artery, left ventricle, right ventricle, left atrium, and right atrium (with superior and inferior vena cava) as shown in Figure 3.
  - Masks were used to generate 3D computational models in the STL format.

Figure 3: Chest CT – Axial window. Pre-segmentation.

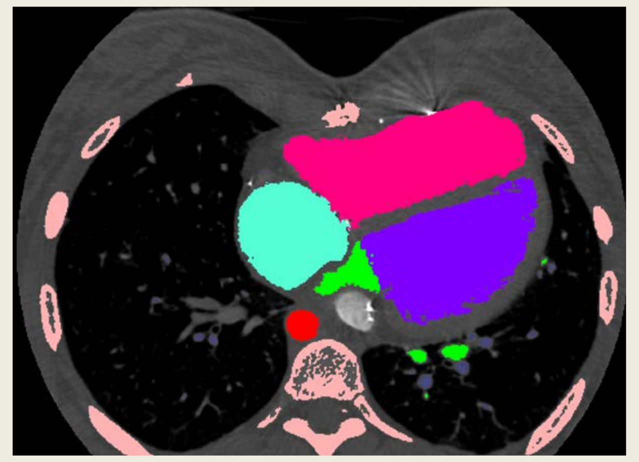


Figure 4: Chest CT – Axial window. Segmentation masks in color.

DEVICE MODELING

- A Surface mesh of the TAH as captured via laser scanning.
  - A surface resolution greater than 0.1mm was achieved with the ZScanner 800 (3DSystems, Rock Hill, SC).

VIRTUAL IMPLANTAION

- Computational models were imported into Geomagic (Morrisville, NC).
- Virtual implantation was performed in a manner similar to actual TAH surgery.
  - Left and right ventricles were removed.
  - Native heart valves were removed.
  - A computation model of the SynCardia TAH device was imported into the virtual environment.
  - TAH implantation was guided by cardiologists.

DISPLACEMENT ANALYSIS

- An intersecting Boolean operation was performed in Mimics between the TAH and surrounding anatomy.
  - Volume was calculated by the intersection of anatomy and TAH.
  - The volume implies displacement of tissue by the TAH in an actual surgery.
  - Displacement of vital structures is recorded.
- Using the standard eligibility criteria along with patient-specific tissue displacement models, surgeons could make a more-informed surgical decision.

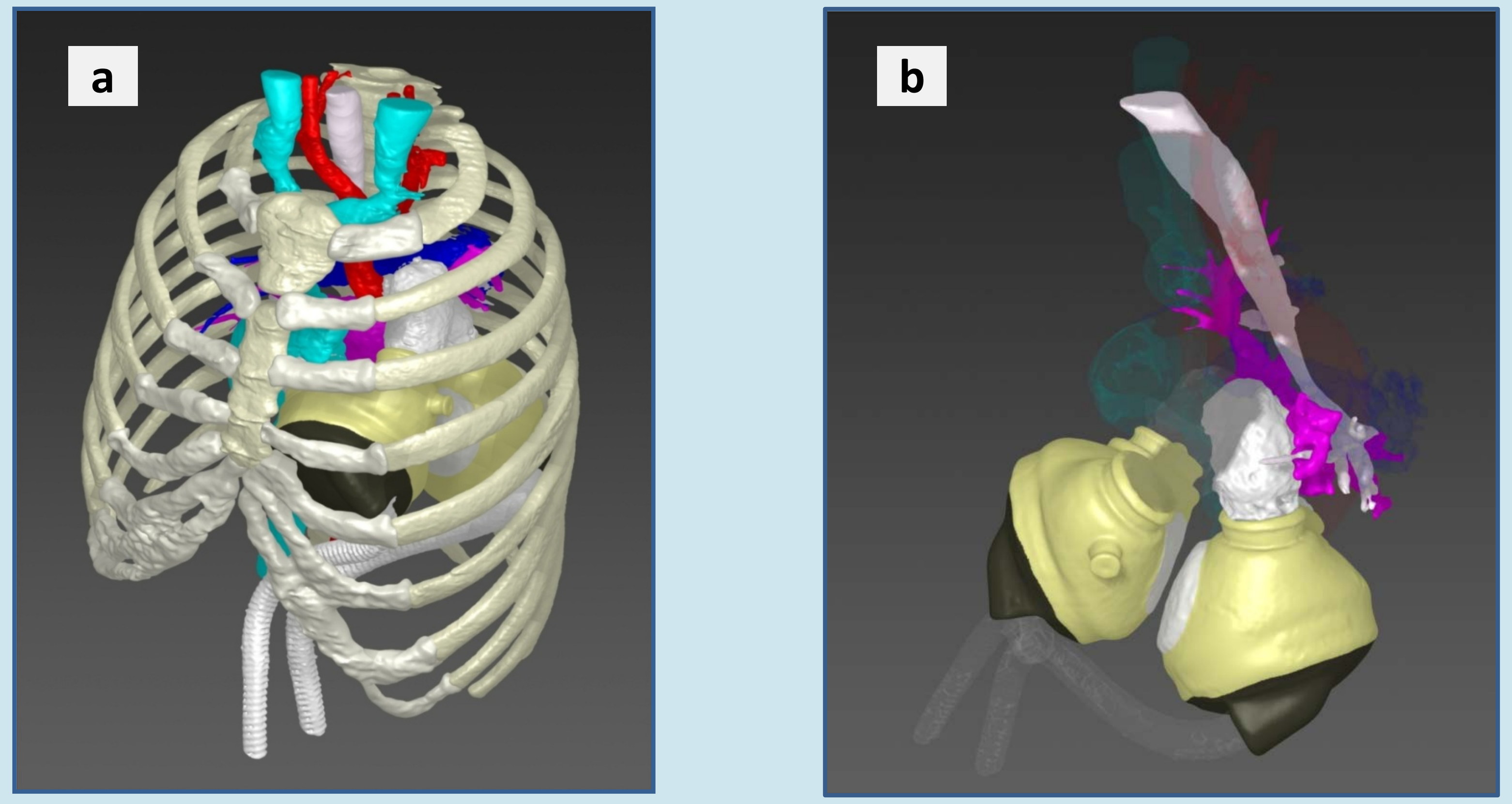


Figure 8: (a) 3D reconstruction of patient data following TAH implantation. (b) 3D reconstruction illustrating bronchi and pulmonary veins. Other cardiac features have been rendered partially transparent.

Figure 6: Wireframe representation of the TAH surface mesh. The mesh was developed through 3D laser scanning.

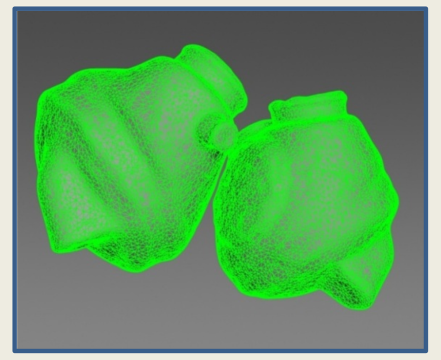
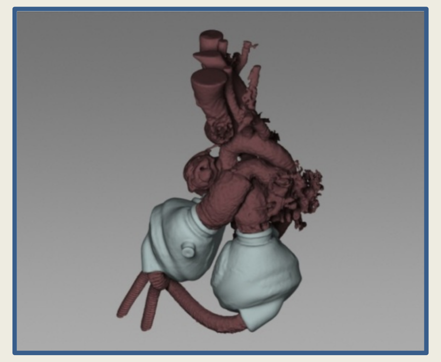


Figure 7: 3D reconstruction remaining cardiac structures with surface scan of 70cc TAH.



RESULTS

TISSUE DISPLACEMENT

Left TAH Lobe

- Volumetric overlap with left lung: .203 mL
- Complete occlusion of one segmental pulmonary artery and one segmental pulmonary vein

Right TAH Lobe:

- Volumetric overlap with left lung: 3.683 mL
- Volumetric overlap with sternum: 1.879 mL
- Extends beyond sternum: 15mm

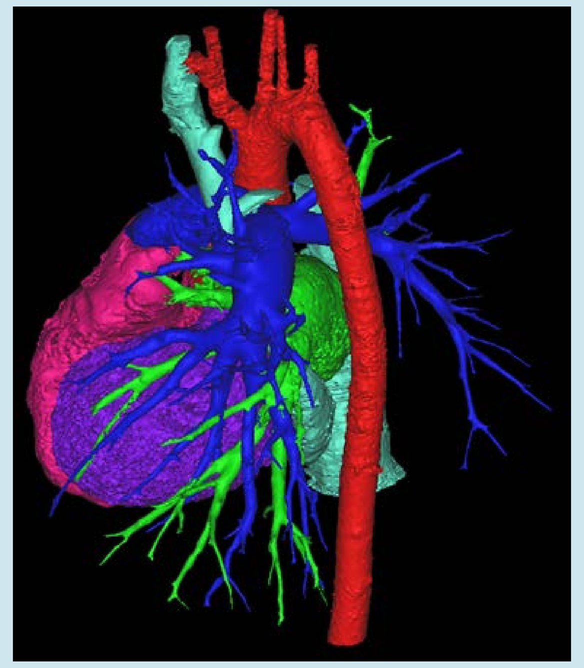


Figure 5: 3D heart model prior to virtual implantation

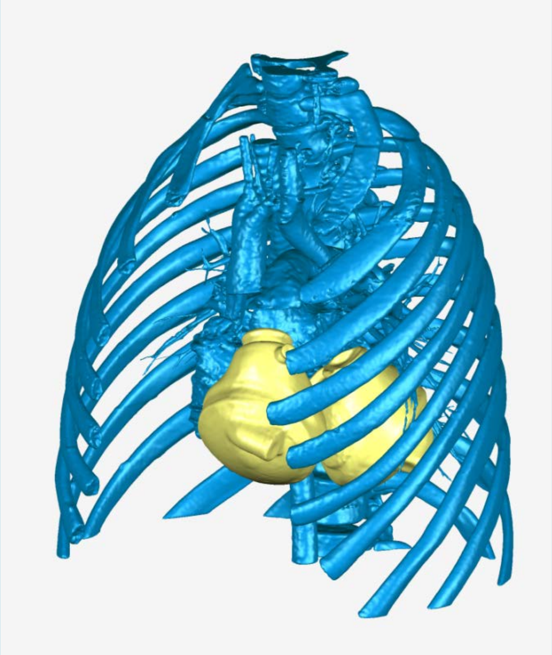


Figure 6: Virtual implantation of TAH

DISCUSSION & CONCLUSION

For the trial dataset, the complete occlusions that occur with the segmental pulmonary artery and vein imply that the blood flow in the vessels would be completely cut off following an actual surgery. The unilateral lung compression implied after virtual implantation would be serious, but not life-threatening [2]. Unfortunately, the volumetric overlap with the sternum would be a major concern; the device would not fit within the thoracic cavity. It is unlikely that the patient would be implanted with this device as the surgeon would be unable to close the chest. If an artificial heart was needed, a different ventricular assisted device would most likely be used.

This trial dataset confirmed that the criteria previously established can be effective in excluding ineligible candidates. However, the virtual surgery went beyond standard criteria by predicting possible complications of an actual surgery. Note that the pediatric patient was well below established threshold criteria; a patient closer to the cut-off may benefit more from virtual surgery.

FUTURE WORK

REGRESSION MODEL

The proposed method provides a wealth of new information to the surgical team, which goes beyond the traditional two-measurement criteria. However, this method still relies heavily on subjective analysis for the ultimate decision of whether or not to implant the TAH. To make the process objective, a regression model will be established. Using statistical information describing quality of life in relation to vessel impedance, such a model could utilize volumetric displacements in optimizing patient eligibility.

REFERENCES

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[2] Ralhan T, Richardson R, Gurevich M, Diab K, Alboliras E. Effectiveness of standardized color-coding of anatomical structures in 3D reconstructions of congenital heart diseases using CCTA. St. Joseph's Hospital and Medical Center Academic Excellence Day, 2010.