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Human Fitting Studies of Cleveland Clinic Continuous-Flow Total Artificial Heart

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Abstract

Implantation of mechanical circulatory support devices is challenging, especially in patients with a small chest cavity. We evaluated how well the Cleveland Clinic continuous-flow total artificial heart (CFTAH) fit the anatomy of patients about to receive a heart transplant.

A mock pump model of the CFTAH was rapid-prototyped using biocompatible materials. The model was brought to the operative table, and the direction, length, and angulation of the inflow/outflow ports and outflow conduits were evaluated after the recipient's ventricles had been resected. Thoracic cavity measurements were based on preoperative computed tomographic data.

The CFTAH fit well in all five patients (height, 170 ± 9 cm; weight, 75 ± 24 kg). Body surface area was 1.9 ± 0.3 m² (range, 1.6–2.1 m²). The required inflow and outflow port orientation of both the left and right housings appeared consistent with the current version of the CFTAH implanted in calves. The left outflow conduit remained straight, but the right outflow direction necessitated a 73 ± 22 degree angulation to prevent potential kinking when crossing over the connected left outflow. These data support the fact that our design achieves the proper anatomical relationship of the CFTAH to a patient's native vessels.

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Conflicts of interest: David Horvath is the device inventor. Leonard A.R. Golding is a co-inventor. The technology was licensed to Cleveland Heart, Inc., a Cleveland Clinic spin-off company. If the total artificial heart is successful, the inventors and Cleveland Clinic may benefit.

Keywords

chest; heart failure; total artificial heart; fitting study

Introduction

The development of implantable mechanical circulatory support devices is a complex undertaking. Besides hemodynamic performance and biocompatibility of the device, particular consideration must be given to device fitting and to limitations associated with the anatomical constraints of each patient.¹ The desirable device dimensions may directly correlate with expected device performance, shape, implantability and ease of use in a broad range of patients. The design of the assist device and its functional characteristics may require revision if the pump size requirement is not met. In its turn, the functionality of the device may dictate its configuration, dimensions and shape. Therefore, the proper fit of the pump within the patient's chest cavity is a key part of device development and may be decisive in defining the exact patient population best suited for the device and the full spectrum of its potential applications.

As a part of the development program for the Cleveland Clinic continuous-flow total artificial heart (CFTAH),^{2,3} we evaluated the fit of the device within the thoracic cavity of five patients. The aim was to determine the smallest body size that can accommodate the current CFTAH design. Also, we investigated the best inlet and outlet port orientations and conduit designs that should be suitable for the majority of patients. In addition to physical manipulation of the device, we analyzed the likely best fit using both preoperatively obtained computed tomographic (CT) scans and on-screen three-dimensional (3D) virtual modeling to determine the optimal anatomic fit of the CFTAH and to provide visual information regarding appropriate implantation strategies.

Methods

Patient data

This study was approved by Cleveland Clinic's Institutional Review Board. The subject population consisted of patients with end-stage heart failure who were listed for heart transplantation in our institution. The patients were selected from all-comers from the transplant waiting list in order of heart availability. The particular focus was on smaller patients upon their availability. Potential subjects were identified, and their written consent to participate in the fitting study was obtained prior to the surgical procedure. Five patients were enrolled (three women and two men; average age – 49 ± 14). Mean body weight was 75.2 kg (range, 53-109 kg). Mean height was 170.8 cm (range, 163-185 cm). Mean body surface area (BSA) and body mass index (BMI) were 1.9 m^2 (range, $1.6\text{-}2.1 \text{ m}^2$) and 26.4 kg/m^2 , (range, $21\text{-}33 \text{ kg/m}^2$) respectively.

Device description

The CFTAH is a unique single-piece, valveless, pulsatile, total artificial heart designed to provide a self-balance of the left and right circulation passively without sensors (Figure 1).²

The device's characteristics and functionality under a range of hemodynamic conditions have previously been reported.³ The nominal external dimensions of the CFTAH taken as a reference for this study are 103.7 mm (length), 62 mm (diameter), 170 cc (volume displacement), and 486 g (device weight with cable and connector off the scale).

Pump model prototyping

A mock pump model of the CFTAH was constructed by Proto Labs, Inc., (Firstcut®, CNC Machining, Proto Labs, Inc., Maple Plain, MN) to evaluate the fit of the device within the chest cavity (Figure 2). The CFTAH pump model assembly was made of five ultra-high-molecular-weight polyethylene sections that rotate about a single threaded stainless steel rod. These materials were chosen for their nontoxic characteristics, high resistance to corrosion, and low moisture absorption. The assembly was simply stacked together and tightened with a stainless steel thumb screw. The mock pump was designed this way to make it suitable for easy disassembly, detergent washing, and ethylene-oxide sterilization (for 5.5 hrs at 100° F and de-aired for 12 hrs). The surface texture was smooth and rounded so that the modular components would not promote trapping of blood or tissue. The outlet conduits were made of corrugated ventilator tubing, bonded to a short segment of polyurethane tubing using clear, medical-grade silicone adhesive. The malleable conduits were articulated to adjust the angulation and length. All conduits were discarded after each fitting study.

Human fitting procedure

After the native heart was explanted, the CFTAH model was brought to the operative table and the direction, length, and angulation of the inflow ports, outflow ports, and outflow conduits were evaluated (Figure 3). Baseline right-inlet-to-outlet angle and left-inlet-to-left-outlet angle were 60° and 60°, respectively. The assumption of the best anatomic position was constructed based on our estimation of device size and inflow cannula direction towards the left and right atrial stumps. Once the proper direction of the inflow cannulae was defined, the orientation and (most importantly) the angulations of the outflow conduits were evaluated. The fitting procedure was performed while surgeons were waiting for the arrival of the donor heart or while the donor heart was being prepared for implantation. The fitting procedure itself required approximately 10-15 min in all cases. The port orientations were documented by five-point photography off the surgical table (from each side of the CFTAH mock model mounted on the dedicated holder). Basic patient information such as gender, age, weight, and height was recorded for anatomic correlation parameters.

The length of the ascending aorta, pulmonary artery, sternum length, chest width and circumference were obtained from the preoperative CT scans. Additional measurements consisted of anterior-posterior distances to sternum and diaphragm from pulmonary artery and aorta. Diameters of the atrio-ventricular valves was also analyzed.

All subsequent analysis of pump inflow and outflow port orientation and angles was performed entirely via computer.

Virtual fitting

The 3D modeling techniques have previously been reported by our group.^{4,5} The 3D model of the smallest patient chest cavities was rendered from CT datasets in Digital Imaging and Communications in Medicine format and viewed with Mimics software (Materialise, Leuven, Belgium). The areas of interest (ribcage, heart, and vessels) were selected, and the resultant 3D models were exported into the Solid Edge platform (Siemens PLM [product lifecycle management] Software, Plano, TX) for a complete visualization of CFTAH implant in the chest.

Using Magics software (Materialise, Leuven, Belgium), the 3D CFTAH model was oriented with respect to each patient's anatomy to determine optimal pump fitting and to assess whether the device would interfere with the surrounding structures. Topographic interference of the model with other tissues was identified visually by determining whether or not overlap between the pump model and the anatomical models could be encountered. The dimensions of the virtual CFTAH model used in the current study were similar to the parameters of the mock pump used for the clinical fitting study.

Results

Clinical fitting of the CFTAH

The anatomical dimensions of each patient's chest are summarized in Table 1. All measurements were taken from preoperative CT scans. No anatomical abnormalities or thoracic deformations were encountered, and all patients had a normal anatomical appearance and proportions. The average maximal distance from the internal edge of the sternum to the vertebrae was 141 ± 28 mm. The maximum width of the thoracic cage was 253 ± 29 mm. Chest circumference (measured at the level of the xiphoid process) ranged from 846 to 1187 mm, with mean antero-posterior thickness recorded as 257 ± 51 mm.

Evaluation of the CFTAH fitting in the thorax was found feasible in all cases ($n = 5$). The average right-inlet-to-right-outlet angle was 58 ± 2.7 degrees (range, 55° - 61°). The left-inlet-to-left-outlet angle outlet angle was 59 ± 2.5 degrees (range, 59° - 62°). The left conduit angulation was 8 ± 7.3 degrees and did not seem to require any bending or adjustment (range, 0° - 15°). The angulation of the right conduit was adjusted for up to 73 ± 22.3 degrees (range, 39° - 95°).

Virtual fitting of the CFTAH

CFTAH placement strategies were successfully evaluated in the smallest patient using a 3D device model manipulated inside the chest model rendered from thoracic CT scans. The axial placement of the CFTAH next to the edge of the sternum, lateral to the wall of the right atrium, directing the pump inflow cannula, was validated. The right outflow port direction was adjusted in relation to the assumed plane of the pulmonary arterial stump. The left inflow cannula projection was oriented towards the mid-plane of the left atrial projection. This rendering allowed us to assume the aortic conduit to be straight and shorter, compared to the length of the pulmonary arterial conduit and its shape.

With given positioning, the CFTAH appears entirely implanted behind the chest, with a center shift towards the left, thus having the right part positioned immediately behind the sternum, while the left housing orientation was fitted downward and leftward (rendered in the supine position). These findings are consistent with clinical fitting study estimations. The finalized model of the CFTAH in a patient with a BSA of 1.6 m² is shown (Figure 4).

The comparative analysis shown in Figure 5 implies that, given the device's dimensions, the current CFTAH would fit patients of 159 cm and taller, as well as most adolescents of age 13 and older. Assuming a required cardiac index of 3.5 L/min/m², the CFTAH design requirement of a maximum flow of 9 L/min would provide a sufficient amount of hemodynamic support for a patient with a BSA of 2.5 m² (height, 200 cm; weight, 100 kg). This extrapolation adds to the visual estimation of pump fitting into the human thoracic cavity and provides preliminary insights into potential target patient populations.

Discussion

Issues related to the anatomic fit of implantable mechanically circulatory assist systems are particularly important during the development of devices intended for implantation in patients with heart failure.⁷ The present clinical fitting method showed that the current CFTAH configuration and dimensions should be favorable for the majority of adult patients. The method has allowed quantification of the cannulation strategies for the device. The results of our fitting study suggest that implantation can be fully pericardial, with no space compression or necessity to create a pump pocket to fit the device within the chest cavity, and no compression of the superior mediastinal structures or diaphragm. The device would ideally rest on or above the diaphragmatic surface and can be fully positioned retrosternal, without any major interference from the surrounding tissues.

The advantages of the virtual fitting study is that the inflow and outflow cannulae and the device itself can be virtually placed within the anatomy to determine fit; alternatively, custom cannulas can be designed preoperatively to accommodate the specific anatomy of a given patient. We found the precise virtual manipulation of the device within the chest cavity provided by this technique to be highly reliable for visual estimation and surgical planning for the implant based on CT scans, which can routinely be made available in all patients undergoing heart transplantation or in patients who are candidates for a TAH. The development of modeling techniques can be standardized as a procedure-specific protocol and ultimately these techniques will prove to be a valuable tool to predict device fitting in each patient individually.

The selection of patients for our study required only basic anthropometric parameters necessary for enrollment such as weight, height, and calculated BSA. However, it is important mention that the anterior-posterior distance, width of the chest cage, chest circumference, and maximum diameter between the sternum and vertebra are the most critical measurement when it comes to decision on the actual device fitting algorithm.

Additionally, as shown in Figure 5, all data obtained from this fitting study were related to data on the size of adults and adolescents published in the clinical growth charts of the

Centers for Disease Control and Prevention (CDC).⁶ We compared the vertebra-to-sternum distances at the junction of the right atrium to the inferior vena cava (RA-IVC), with patient height, and also pump orientation in the vertebra-sternum dimension. The comparative analysis suggested that the CFTAH in its current dimensions would fit patients of 159 cm and taller, as well as most adolescents of age 13 and older.⁶

Study limitations include the small number of patients and the absence of candidate patients with a BSA of less than 1.6 m². These limitations were due to the unpredictability of heart transplant waiting list and preparedness of the study team for the changeable implant schedule. Also, no direct interference of the device with surrounding tissues and organs has been assumed. Despite these limitations, the findings of this study met our expectations in confirming the target characteristics of patients who could be implanted with the CFTAH, and the optimal placement strategy, which were the main study goals.

In regards to the mock pump fabrication for similar studies, it is worth mentioning that the 3D printing technology could be a faster and economically advantageous solution to machined mock pump. In our particular case, the 3D printers available in our institution were not capable of printing from polyethylene that was chosen as biocompatible material.

Conclusion

We successfully used a CFTAH mock model for a human fitting study in patients who were prepared to receive a heart transplant. As a parallel evaluation, a 3D modeling and virtual fitting was conducted that allowed verification and rendering of human implant-specific characteristics of the device, such as outflow design and length, proper angles, and device orientation. The human fitting study and obtained data suggest that the current device design and size would accommodate the proportions of a majority of patient candidates before surgery.

In its turn, the CT-based fitting study has proved a powerful tool for visual demonstration of the device inside the human chest and may provide real-time assessment of device implant preoperatively. Also, virtual fitting would decrease the number of actual human fitting studies required to validate the angles and lengths of device conduits.

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References

1. Saeed D, Ootaki Y, Noecker A, et al. The Cleveland Clinic PediPump: virtual fitting studies in children using three-dimensional reconstructions of cardiac computed tomography scans. *ASAIO J.* 2008; 54:133–137. [PubMed: 18204330]
2. Fukamachi K, Horvath DJ, Massiello AL, et al. An innovative, sensorless, pulsatile, continuous-flow total artificial heart: device design and initial in vitro study. *J Heart Lung Transplant.* 2010; 29:13–20. [PubMed: 19782599]

3. Kobayashi M, Horvath DJ, Mielke N, et al. Progress on the design and development of the continuous-flow total artificial heart. *Artif Organs*. 2012; 36:705–713. [PubMed: 22747979]
4. Noecker A, Cingoz F, Ootaki Y, et al. The Cleveland Clinic PediPump: Anatomic modeling and virtual fitting studies in a lamb model. *ASAIO J*. 2007; 53:716–719. [PubMed: 18043154]
5. Noecker AM, Chen JF, Zhou Q, et al. Development of patient specific three-dimensional pediatric cardiac models. *ASAIO J*. 2006; 52:349–353. [PubMed: 16760727]
6. Centers for Disease Control and Prevention. [accessed October 15, 2014] Clinical Growth Charts. Web link: http://www.cdc.gov/growthcharts/clinical_charts.htm
7. Saeed D, Fukamachi K, Duncan BW. Intra-operative fitting study of the PediPump ventricular assist device. *J Heart Lung Transplant*. 2012; 31:109–110. [PubMed: 22035975]

Figure 1.
Cleveland Clinic continuous-flow total artificial heart pump (CFTAH; configuration as of October 2014).

Figure 2. Once the sterile polyethylene parts of the CFTAH were assembled, the pump model was placed on the dedicated holding base.

Figure 3.

After the native heart of the transplant candidate was explanted, the pump model was brought into the operative field. The device model was analyzed for how well it fit within the chest cavity, and configurations of the inflow and outflow ports were recorded while any adjustments were made.

Figure 4. “Virtual fitting” of the CFTAH using three-dimensional reconstructions from preoperative cardiac CT scans was used as an additional measurement and visualization tool.

Figure 5.

The study results were related to the size of adults and adolescents, by comparing the vertebra-to-sternum distance at the RA-IVC junction, patient height, and pump orientation in the vertebra-sternum dimension. The comparison we made implies that the CFTAH would fit patients of 159 cm and taller, as well as most 13-year-old adolescents.⁷

CFTAH fitting study measurements and anatomical dimensions from preoperative CT scan**Table 1**

Measurements and dimensions (mm)	Pt 1 (F)	Pt 2 (M)	Pt 3 (F)	Pt 4 (F)	Pt 5 (M)	Mean	SD
1 Length of ascending aorta	77	75	54	68	68	68	9
2 Sternum length	155	149	148	130	122	141	14
3 Length of main PA	50	65	52	55	38	52	10
4 S×D from center of TV to sternum	32	47	31	36	43	38	7
5 S×D from center of MV to sternum	89	100	70	78	83	84	11
6 S×D from anterior end of PA to sternum	14	14	5	13	13	12	4
7 S×D from anterior end of AO to sternum	41	52	28	21	53	39	14
8 S×D from caudal end of PA to diaphragm	99	89	76	92	88	89	8
9 S×D from caudal end of AO to diaphragm	68	64	67	80	69	70	6
10 Largest D of annulus lines of TV and MV	125	107	111	94	94	106	13
11 Diameter of TV	50	37	51	46	30	43	9
12 Diameter of MV	64	35	56	43	25	45	16
13 Diameter of AO	27	34	24	31	22	28	5
14 Diameter of main PA	37	44	22	37	22	32	10
15 Maximum width of chest cage	252	301	222	242	250	253	29
16 Chest circumference at xiphoid process	1067	1187	853	846	888	968	152
17 Antero-posterior thickness at xiphoid process	285	331	211	213	244	257	51
18 Maximum D between sternum and vertebra	139	186	114	120	146	141	28

AO, ascending aorta; D, distance; F – female; IVC, inferior vena cava; RA, right atrium; M – male; MV, mitral valve; PA, pulmonary artery; Pt, patient; S×D, shortest distance; SD, standard deviation; TV, tricuspid valve.