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Theoretical considerations on possibilities to develop adaptable centrifugal pumps as total artificial heart for individual body sizes

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Abstract Thanks to the modern imaging techniques used in medical technology, it is now possible to scan a patient's chest without any problems. This should definitely be taken into account when designing a modern total artificial heart. With today's 3D construction programs it is possible to easily, and to the most part automatically, vary the construction of blood pumps. It is thus optimally adapted to the geometric circumstances of a patient.

Keywords: Total artificial heart; long-time centrifugal blood pumps; implantability; design strategy of TAH; virtual fitting of TAH

Introduction

The aim must be to develop total heart replacement (total artificial heart, TAH) in such a way that, as a durable and long-lasting replacement system, it ensures patients an almost normal life with a high quality of life. There will continue to be far fewer donor organs than there is a need for, and there are more and more patients for whom heart transplantation is not an option. Not all of them can be helped with a permanent ventricular assist device (VAD). The TAH should be able to maintain sufficient blood flow for many years without harming the patient's blood or other organs. Ideally, the life of the TAH should therefore exceed the expected life of the patient and possible defects should not immediately lead to the total failure of the replacement system. This first involves a perfect adaptation of the TAH to the patient's physiology. The ideal design of the heart replacement system should be "automatically" adaptable to any human stature. It should not be larger than a natural heart and must fit into the patient's chest. The pressure range of the right ventricle should be 0 to 50 mmHg, the left ventricle 100 to 300 mmHg. The flow volume should be up to 10 L/min for each ventricle, with the pumping capacity automatically adjusting to the patient's current needs. The energy supply should be inductive, without any cable penetration through the skin. A 24-hour operation should be guaranteed, independent of a power outlet. Any shear stress in the blood flow must be so low that blood damage is below a hemolysis level of 10 mg free hemoglobin in 100 litres of blood and no von Willebrand syndrome occurs.

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Development goal: Adaptability of a TAH to any body geometry

One of the essential requirements is that the TAH must fit the patient's chest. From the outside it is not possible to determine the exact placement. Today, imaging techniques are available that allow an exact three-dimensional representation of the body with its inner structure. In the past, it was only possible to determine whether a cardiac support system or a total heart replacement fit spatially into a human chest cavity at all, by trying it out on deceased persons. In rare cases, patients also gave their consent to be tested during their heart transplant operation to see whether an artificial heart would have fitted into their chest cavity. Usually basic size models, and not the real system, are used for this procedure. The Cleveland Clinic has therefore been working since 2006 on procedures to determine whether the intended TAH or Cardiac Support System fits in the human body before surgery. The available space is determined with the help of 3D scans of the chest area. The chest area is scanned using computer tomography (CT) and the data is then processed into a virtual 3D model using appropriate software. The model can then be examined and measured on the computer. All non-relevant parts of the body can be excluded. Instead of using the CT, which works with X-rays, the scan can also be generated using magnetic resonance imaging (MRI). [1-4]

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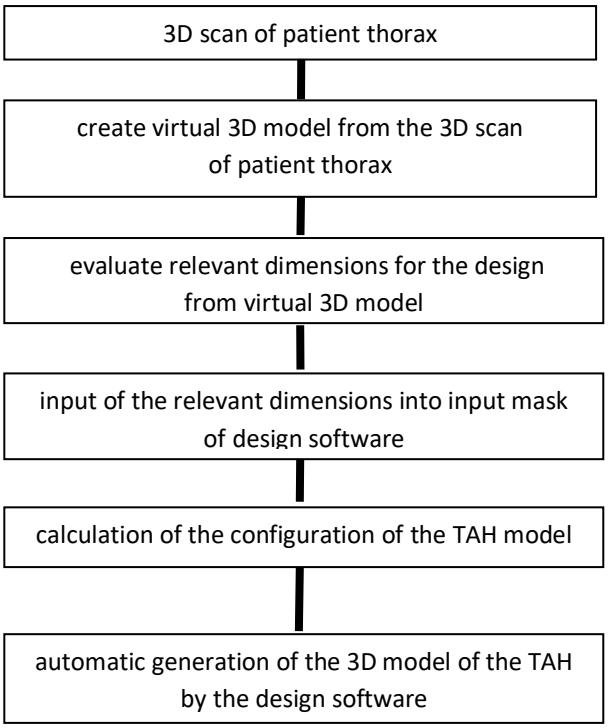

Fig. 1 Flow chart to generate an individual TAH from the data of a 3D scan of the patient thorax.

A patient whose heart is so damaged that only a total heart replacement can guarantee his or her survival, first has his or her chest scanned using a suitable imaging procedure (CT or MRI). These images are then processed into a virtual 3D model using appropriate software. All relevant dimensions for the design of the TAH can then be determined from this 3D model (Fig. 1). The most important dimensions are position and diameter of the aorta, position and diameter of the pulmonary artery, size of the ventricles, size and position of the left and right atria, and the size of the heart as a whole. The dimensions of the TAH are generated from the data with the aid of a corresponding design program. Since blood flows into the atria of the human heart through multiple veins (left atrium with four pulmonary veins, right atrium with two vena cava and cardiac veins from the coronary vessels of the heart), it is not recommended to remove the entire heart of the patient for the implantation of a TAH. Due to the continued use of the atria, only two inflows and outflows each are required at the TAH. [5]

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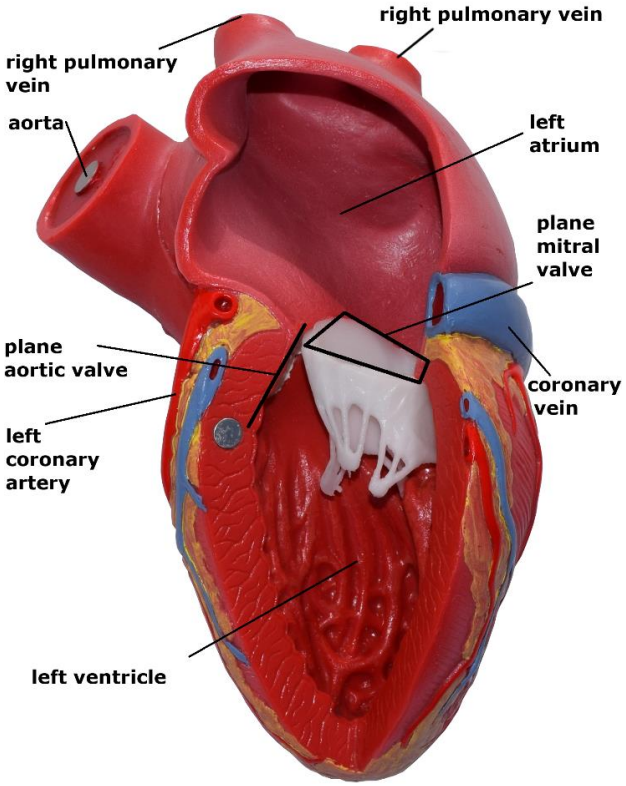

Fig. 2 **Section through left ventricle. Generated with a photography of a natural size heart model (G01 of 3B Smart Anatomy).**

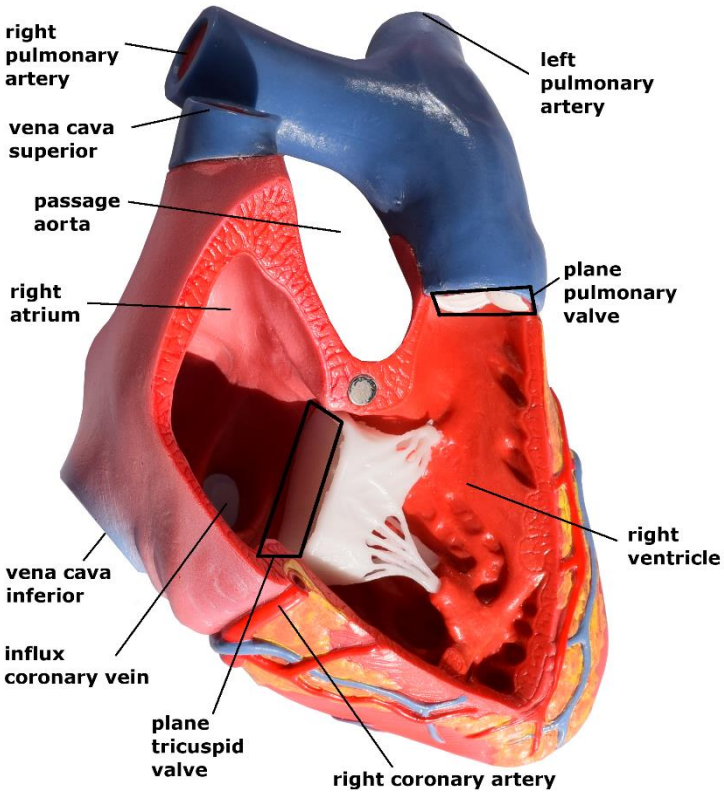

Fig. 3 **Section through right ventricle. Generated with a photography of a natural size heart model (G01 of 3B Smart Anatomy).**

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As a rule, the aorta is not cut directly behind the aortic valve, but slightly above, just below the beginning of the aortic arch. The higher the separation point, the more space is gained for the TAH, but the more difficult it is to sew the aorta back to the donor heart in a heart transplant. The separation point should be above the right atrium, as this should be preserved and the cutting point must be easily accessible (Fig. 2). The cut point of the pulmonary artery is located very close above the pulmonary valve, since the pulmonary artery divides into the left and right branches just above it. This branching should be preserved (Fig. 3). Left and right ventricles are both cut so that both atria with their respective valves are preserved (Fig. 4). The valve attachments in the ventricles must be cut through and cleanly removed. Felt strips are sutured to the cutting points in the atria. The connecting sleeves for the inflow cannulas are then sewn onto these. The corresponding connection cannulas are sutured to the aorta and the pulmonary artery. The TAH can then be attached to the four connections. It is recommended that the connection between the pericardium and the diaphragm be severed to give the TAH a little more room. Once the TAH is in place, it is wrapped with a PTFE foil and the pericardium is closed around it. Morris [6] and Torregrossa [7] have prepared a detailed illustrated description of the surgical technique. Other surgeons point out that the use of felt as an intermediate layer between the heart tissue and the cuffs is not necessary, and also the remains of the mitral and tricuspid valves are completely removed [8].

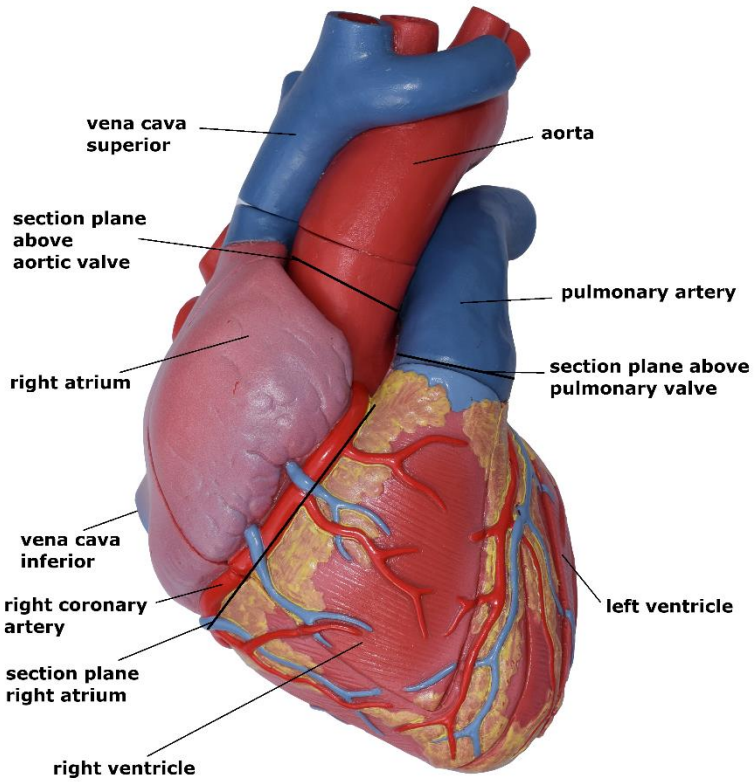

Fig. 4 View on the right ventricle. Marked section planes where the heart has to be cut. Generated with a photography of a natural size heart model (G01 of 3B Smart Anatomy).

With the virtual 3D model from the body scan, the parameters for the available space for the TAH to be implanted are determined. The blood pumps for the left and right circulation, each with its drive and storage, must be accommodated within this limited space. Figure 5 shows a schematic model

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showing the constraints of space for a TAH, corresponding to the heart model from the company 3B Smart Anatomy.

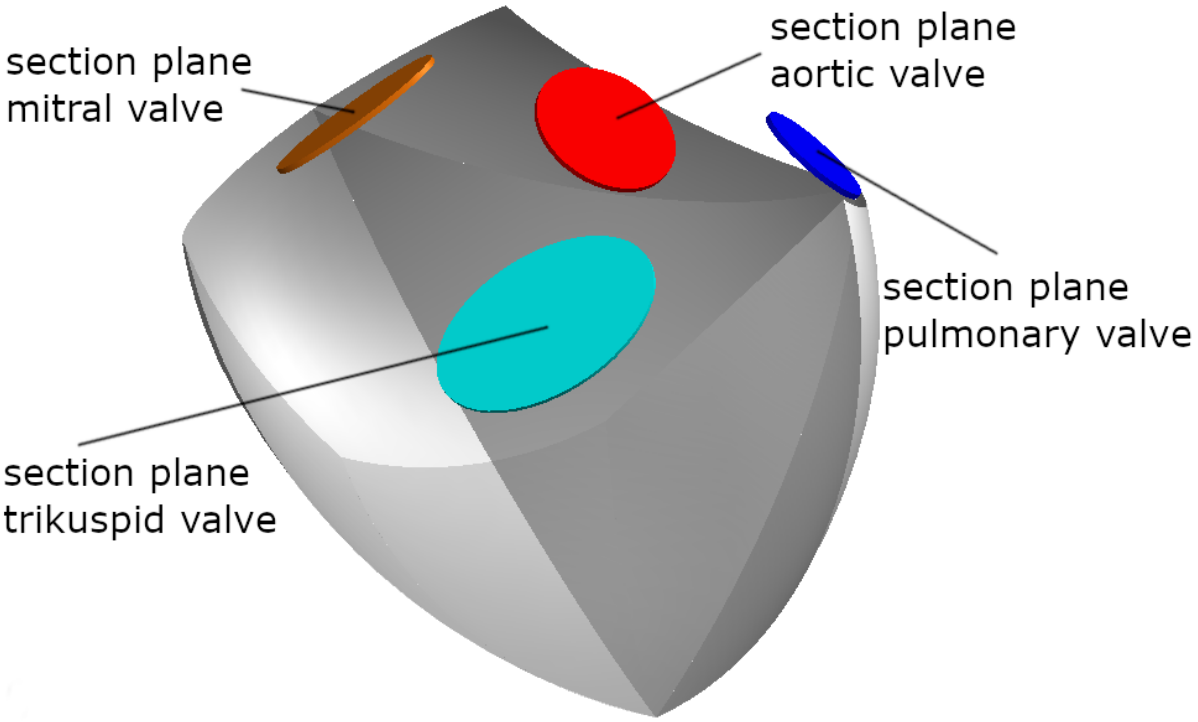

Fig. 5 Boundaries of the space for the TAH, if the human heart will be removed. Generated with the dimensions of a natural size heart model (G01 of 3B Smart Anatomy).

If the TAH consists of two centrifugal blood pumps, they must perform the pumping work for the left and right circulation independently. By continuously monitoring the respective volume flows, the pumping capacity is regulated so that both blood circulations (body and lung) always receive the same amount of blood. As the pressure in the right circulatory system is lower than in the left circulatory system, the right-hand pump can either be designed smaller or run at a lower speed. Both centrifugal pumps must be installed with their connections in the available space in the human body. To measure the scanned cardiac cavity, one point of origin is defined and three origin planes. All relevant points can be defined by three coordinates intersecting the origin point. Surfaces are defined by the coordinates from their center point and three angles to the original planes. This forms the basis for the fitting of the two pumps into the cardiac cavity. (Fig. 6)

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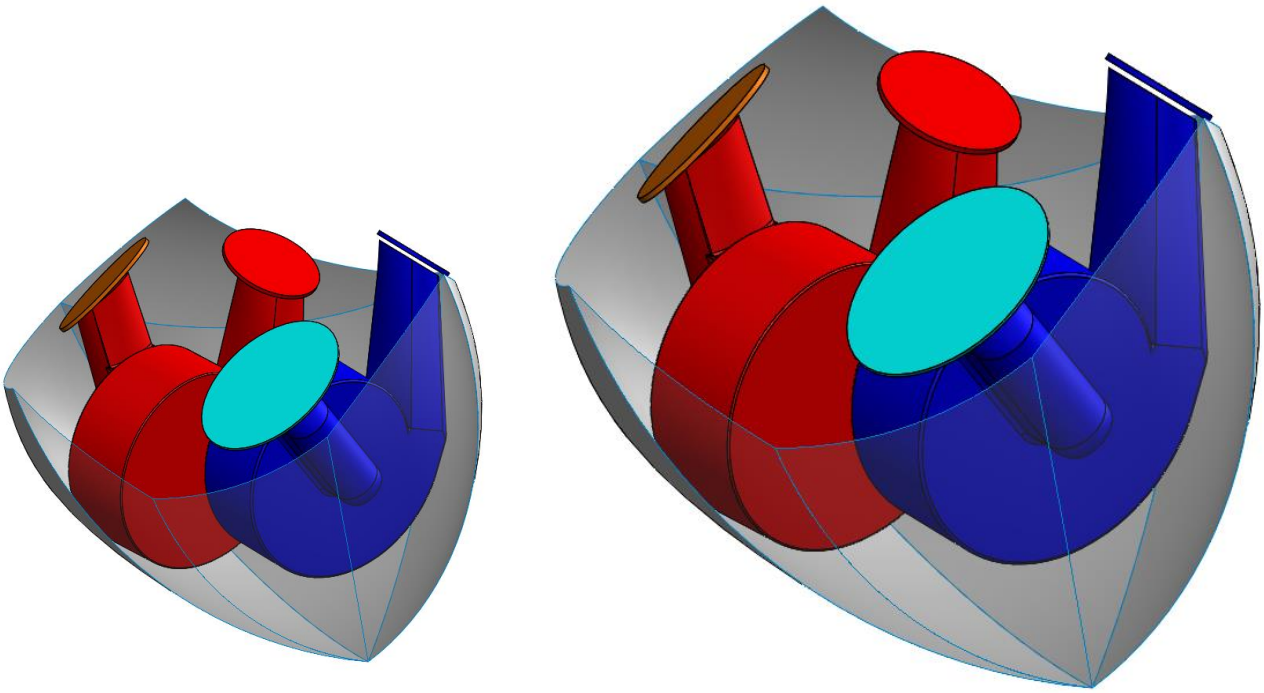

Fig. 6 A TAH, consisting of 2 centrifugal pumps, has been fitted into the available heart chamber from Fig. 5. The centrifugal pump (red) for body circulation is shown on the left and the centrifugal pump (blue) for pulmonary circulation on the right. The left figure schematically shows two small pumps for a small heart chamber, the right figure shows two large pumps for a large person.

In order to adapt blood pumps to the geometry of the heart chamber, other parameters can be changed in addition to the size. Depending on the position of the connections, the diameters of the inlets and outlets and the possibly used cannulas must be adapted to the existing conditions. The angle between the inlet and outlet nozzles can also be changed without affecting the pumping capacity. With today's possibilities of controlling configurations of components by using the appropriate 3D design software, such changes can be carried out easily and quickly and can even be automated. With three basic sizes of pumps, and appropriate modifications, suitable TAH configurations could be quickly produced that would be suitable for the majority of the adult population.

So far, there are no implantable VAD or TAH for small children available. The youngest patient to date with a TAH was 10 years old [9]. In experimental trials, the new, not yet approved Jarvik 2015 (axial pump) was implanted as LVAD in 2 three-year-old children [10]. Only the extracorporeal EXCOR Pediatric of Berlin Heart has been approved for infants [11]. For the development of VAD and TAH for this patient population, much more challenging problems still need to be solved. On the one hand due to the very small body size and on the other hand due to the fact of the rapid body growth.

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Conclusion

Modern imaging techniques in medical technology and today's 3D programs for construction offer new possibilities to develop adapted blood pumps for use as TAH. Thus, the use of TAH could increase in the future and free them from their current niche existence.

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Conflict of interest

The author declare that she has no conflict of interest

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