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A New Total Artificial Heart Concept Allowing Replacement or Support of the Native Heart

Henrik C Ahn[1]*, Jonas Holm[1], Azad Najar[2], Goran Hellers[2] and Zoltán Szabó[1]

[1]*Division of Cardiovascular Medicine, Department of Medical and Health Sciences, Faculty of Health Sciences, Linkoping University, Sweden*

[2]*Scandinavian Real Heart AB, Vasteras, Sweden*

*Corresponding author: Henrik C Ahn, Division of Cardiovascular Medicine, Department of Medical and Health Sciences, Faculty of Health Sciences, Linkoping University, Sweden, Tel: +46707256463; E-mail: henrik.casimir.ahn@liu.se

Abstract

A total artificial heart (TAH) is typically used to bridge the time to heart transplantation. A device designed by Robert Jarvik has been improved through the years and under the name of Syncardia™ this has been the most successful commercially available TAH so far. Since 2008 the Carmat™ heart has been under development in Europe. The Scandinavian Real Heart™ is based on a unique physiological concept where the atrio-ventricular valve plane is of utmost importance in the pumping function of the heart. It consists of two identical parts driven separately by independent motors and in this first animal study we have used one part as a left ventricular assist device. This new concept makes the device flexible as it may be used not only as a TAH but also as a separate pump for left or right ventricular assist.

Introduction

A total artificial heart (TAH) is a device that replaces the heart and is typically used to bridge the time to heart transplantation. It is also used to permanently replace the heart in patients with severe biventricular heart failure where the more commonly used ventricular assist system is unable to secure adequate circulation. In 1964, the National Institute of Health in US started the Artificial Heart Program aimed at putting a man-made heart into a human by the end of the decade. The goal of the program was to develop an implantable artificial heart, including the power source, to replace a failing heart [1]. Since then many attempts have been made to fulfil this goal. On April 4 1969, at the Texas Heart Institute in Houston, Domingo Liotta and Denton A. Cooley replaced a dying man's heart with an intrathoracic mechanical heart as a bridge to transplantation [2]. A device designed by Robert Jarvik has been available and successively improved over many decades, and the Jarvik-7 TAH was successfully implanted in a human in 1982. Under the name CardioWest and later on Syncardia™ this has been the most successful commercially available TAH with about 1700 devices implanted, accounting for more than 600 patient-years support. Since 2008, the Carmat™ heart has been developed in Europe. The first human implant was performed in 2014, and initial pivotal studies are ongoing.

The Scandinavian RealHeart is based on a different physiological concept originally described in a thesis by the Swedish cardiologist Stig Lundback [3]. He suggested that downward and upward movement of the atrio-ventricular valve plane is of utmost importance in the pumping function of the heart, where filling of the the ventricles with blood from the atria partly returns the valve plane to its upper position. This movement is very energy saving. The RealHeart prototype #11 (SRH11) constructed by Dr. Azad Najar has shown that an artificial valve plane can move silently and effectively within the chambers of a pump and that two pumps may be used in parallel as a TAH. The software of this system can independently regulate the two pumps to balance output according to physiologic requirements. Furthermore the pump unit can also be implanted separately for right- or left ventricular assist. The characteristics of the SRH11 are described in this paper as well as the first surgical implantation of a single pump as a left ventricular assist device (LVAD).

Material and Methods

The total artificial heart (TAH) SRH11

The design of SRH11 described in this article mimics the anatomy of the natural heart. It is comprised of two separate pumps, left and right, working as one unit to simultaneously pump blood to the systemic and pulmonary circulation respectively [4]. Each pump has an inlet chamber (artificial atrium) and an outlet chamber (artificial ventricle). The left pump and the right pump are identical and the valves within thus correspond to the mitral valve if implanted on the left side and the tricuspid valve on the right side. The artificial atrium and ventricle of each pump are separated by a mobile cylindrical construction housing the valve plane mechanism.

This valve plane cylinder has an outside wall of hard material and an inside cylinder that houses a silicone bellows construction connecting the chambers. The inner diameter of the silicone construction is the same as the diameter of the mechanical valve within. The valve plane cylinder is comparable to the atrioventricular (AV) plane of the natural heart. The valve plane cylinder is connected to a driving unit that causes movement of the valve plane cylinder backwards and forwards between the artificial atrium and ventricle respectively. When the plane moves towards the artificial atrium, the valve opens causing displacement of blood to the artificial ventricle. The downward stroke towards artificial ventricle causes the valve to shut and blood is ejected from the ventricle. The SRH11 has an external control unit that enables the cycle to be fixed at between 1 and 150 strokes per minute. The

stroke volume from each chamber depends on the stroke distance of the valve plane cylinder and may be fixed between 1 and 45 ml. The cardiac output thus lies between 1 and 6750 ml per minute depending on the pump frequency and stroke distance of the valve plane cylinder.

Results

Surgical procedure

We used pigs weighing approximately 65 kg, specially bred for research purposes. The animal was premedicated with Zoletil®Virdac France, (tiletamine 25 mg/ml + zolazepam 25 mg/ml), and Dexdomitor® Orion Pharma, (0.5 mg/ml dexmedetomidinehydrochloride corresponding to 0.42 mg/ml dexmedetomidine).

Intubation was carried out and the animal was ventilated with air throughout the experiment using a Siemens Servo ventilator 900 D (Siemens, Siemens Healthcare, Stockholm, Sweden).

Anesthesia and monitoring employed have been described in more detail elsewhere [4].

The thorax was opened through a median sternotomy. The aorta was cannulated with a straight 20 Fr armed cannula and a two-stage venous 34 Fr cannula was inserted via the right atrium into the inferior vena cava. CPB was initiated and the procedure was then carried out on the empty beating heart. A body temperature of between 36°C and 37°C was maintained during CPB.
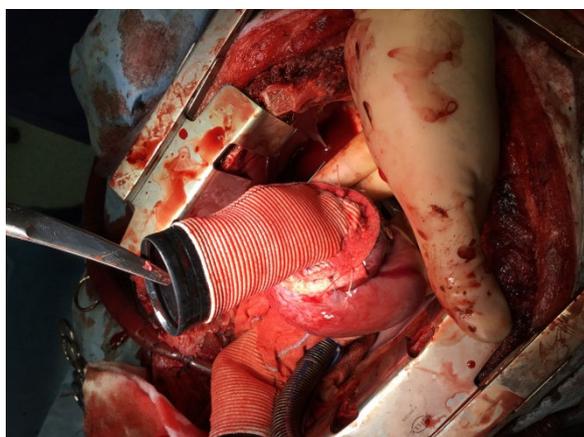
Figure 1: A 1 cm Teflon strip was adapted around the apex of the heart using a continuous suture. The inflow graft including the rubber connecting end was sutured with mattress sutures to the Teflon strip around the apex.

A 1 cm Teflon strip was adapted around the apex of the heart using a continuous suture. The inflow graft including the rubber connecting end was sutured with mattress sutures to the Teflon strip (Figure 1).

Coring of the apex was then made through the graft and a tissue bite with a diameter of 1.5 cm was extracted (Figure 2).

The rubber cuff was connected to the atrial end of the pump. A similar graft was sutured to the ascending aorta and connected to the ventricular end of the pump. Gradual de-airing of the pump was performed by inserting a cannula into the de-airing silicon membrane in the walls of the pump (Figure 3).

This maneuver enabled slow filling of the SRH11 pump atrium and ventricle from the heart. The pump was then started at the lowest valve plane speed and amplitude during continued de-airing via the silicon membrane in the uppermost part of the atrium of the pump. When the pump was functioning with optimal stroke volume and frequency, the arterial and venous cannulae were removed and the animal filled with blood from the heart-lung machine. At the end of the procedure, after pump function had been established and tested, the graft was cut close to the apex to expose the area used for connecting the pump to the apex of the left ventricle (Figure 4).
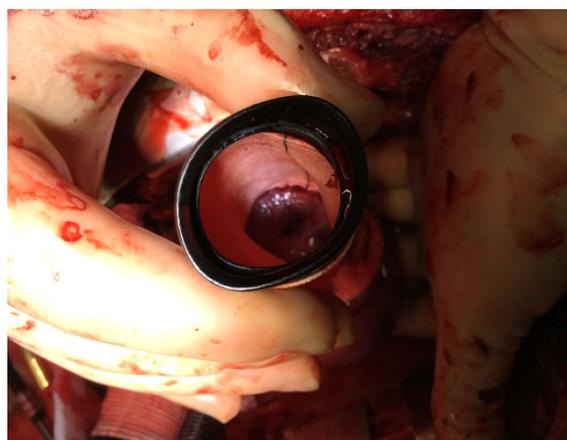
Figure 2: Coring of the apex was made through the graft and a tissue bite with a diameter of 1.5 cm was extracted.
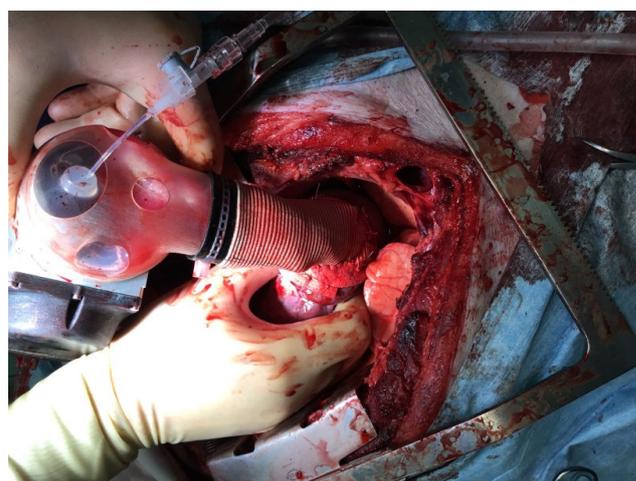
Figure 3: The rubber cuffs of 2 grafts were connected to the atrial and ventricular ends of the pump. Gradual de-airing of the pump was performed by inserting a cannula into the de-airing silicon membrane in the walls of the pump.
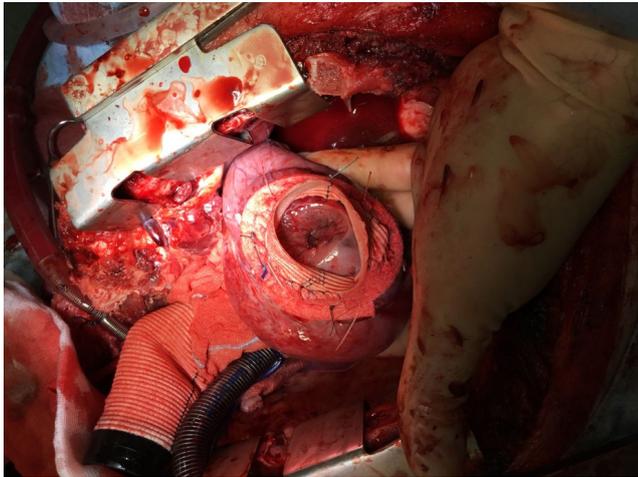
Figure 4: At the end of the procedure the graft was cut close to the apex to illustrate the area used for connecting the pump to the apex of the left ventricle.

Discussion

According to the U.S. Department of Health & Human Services, about 4000 people are waiting for a donor heart transplant on any given day, while the supply of approximately 2300 donor hearts in the U.S annually has been static over the last 20 years. There are about 300,000 patients in the U.S. that suffer from terminal heart failure (HF) and the 2-year mortality rate is high [5,6].

According to the European Commission's Department of Health and Consumers, about 3500 patients are on waiting lists for a donor heart throughout Europe and about 2000 transplants are conducted each year.

Heart transplantation has long been the gold standard for terminal heart failure, but the significant improvement in survival after left ventricular assist device (LVAD) implantation and the increasing number of LVAD systems being implanted worldwide over recent years has led to LVAD rapidly becoming a secondary gold standard [7]. For instance, more than 10,000 patients have been implanted with HeartMate II™ through trial enrollment and commercial use worldwide [8]. The time waiting for a donor organ in Germany is over 1 year with normal priority status and over 100 days with highest priority, and during this period approximately 20%-30% of patients die [9]. LVAD treatment is always available and is suitable for about 80-90% of candidates awaiting transplantation, and of these, 10-20% may require a biventricular assist device [9].

Only two artificial heart designs have been FDA approved: the SynCardia™ TAH and the AbioCor™ replacement heart.

The AbioCor™ has been implanted 15 times; the last implant in 2009.

The SynCardia™ TAH and its direct predecessors account for about 95% of all implants. Up to now about 1700 SynCardia™ hearts have been implanted, nearly 500 of them since 2010 [10].

A device that may be used as a TAH but also as a separate LVAD or RVAD or combined as a BIVAD has potential advantages. In the clinical setting it gives the user flexibility when it comes to treatment of various emergency situations. In most situations the pump is used as a LVAD, but if subsequent RV failure develops a second pump can be implanted as a RVAD.

The SRH is based on the physiologic principles suggested by the Swedish cardiologist Stig Lundback. He emphasized the point that movement of the atrio-ventricular valve plane plays a significant role in the transport of blood through the heart. He further stated that the interventricular septum regulates right and left ventricular stroke volumes to maintain a dynamic balance between the systemic and pulmonary circulation [3].

The SRH TAH consists of two identical pumps that are driven separately by independent motors [4]. The software enables different motor outputs and even theoretically a dynamic output response to the preload of the pump unit. The prototype has a pulsatile output with a curve pattern similar to the systolic arterial curve of the native heart. In this paper we have described the surgical procedure used to implant one pump as a LVAD. We performed this on an empty beating heart with extracorporeal circulation (ECC). In principle this procedure could be done by coring the apex of the left ventricle from inside the graft on a beating heart without the use of ECC. This would shorten the length of the procedure making it suitable in an emergency situation. The SRH11 prototype is now ready for prolonged preclinical survival tests in animals.

Conclusion

The RealHeart™ TAH comprises two separate pumps and is based on a new principle where valve plane displacement is used to drive the blood.

This makes the device flexible since it may be used not only as a TAH but also as a separate pump for left or right ventricular assist.

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