Journal of Clinical and Experimental Cardiology

Ahn et al., J Clin Exp Cardiolog 2018, 9:12
DOI: 10.4172/2155-9880.1000619

Research Article

Open Access

Evolution of the Implantation Procedure for Real Heart TAH

Henrik C. Ahn[1*], Azad Najar[2], Göran Hellers[2], Jonas Holm[1], Ina Laura Pieper[2] and Zoltán Szabó[1]

[1]*Department of Thoracic and Vascular Surgery, County Council of Östergötland, Sweden, and Department of Medical and Health Sciences, Faculty of Health Sciences, Linköping University, Sweden*

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

[*]**Corresponding author:** Henrik C. Ahn, Department of Thoracic and Vascular Surgery, Faculty of Health Sciences, Heart and Medicine Center, Linköping University, County Council of Östergötland, Sweden, Tel: + +46707256463; E-mail: henrik.casimir.ahn@liu.se

Received date: December 11, 2018; **Accepted date:** December 14, 2018; **Published date:** December 21, 2018

Abstract

The Real Heart TAH (Total Artificial Heart) has shown that artificial valve planes can move silently and effectively inside two pumps, which together comprise a TAH. In this paper we describe the evolution of the surgical procedure for implantation. The first 8 acute implantations of Real heart prototypes were performed with sternotomy using a 60-70 kg porcine model. Due to some limitations observed with this model the technology and the surgical technique have been improved. This paper describes the current implant procedure with the new improved Real heart TAH in a calf model.

Keywords: Artificial heart; Assist device; Mechanical circulatory support; Heart failure; Transplantation

Introduction

A total artificial heart (TAH) is a device that replaces the heart and is typically used to bridge the time to heart transplantation, or to permanently replace the heart in patients with severe biventricular heart failure [1]. In such a case the more commonly used ventricular assist system supporting the native heart may be insufficient to secure an adequate circulation. The Realheart TAH is based on a physiological concept originally published by the Swedish cardiologist Stig Lundback [2]. He suggested that downward and upward movement of the atrio-ventricular valve plane is of utmost importance for the heart function, where filling of the blood from the atria to the ventricles helps the valve plane to return to its upward position. This should theoretically be an energy-efficient pumping action.

The RealHeart TAH constructed by Dr. Azad Najar, has shown that artificial valve planes can move silently and effectively inside two pumps, which together comprise a TAH. The software of this system can independently regulate the two units to balance the pump output based on physiological needs and the units can also be used separately as a right- or left ventricular assist [4]. In this paper we describe the evolution of the surgical procedure for implantation. Each surgical procedure has provided important feedback regarding the design to facilitate the implantation. A total artificial heart (TAH) is a device that replaces the heart and is typically used to bridge the time to heart transplantation, or to permanently replace the heart in patients with severe biventricular heart failure [3]. In such a case the more commonly used ventricular assist system supporting the native heart may be insufficient to secure an adequate circulation. The Realheart TAH is based on a physiological concept originally published by the Swedish cardiologist Stig Lundback [2]. He suggested that downward and upward movement of the atrio-ventricular valve plane is of utmost importance for the heart function, where filling of the blood from the atria to the ventricles helps the valve plane to return to its upward position. This should theoretically be an energy-efficient pumping action.

The RealHeart TAH constructed by Dr. Azad Najar, has shown that artificial valve planes can move silently and effectively inside two pumps, which together comprise a TAH. The software of this system can independently regulate the two units to balance the pump output based on physiological needs and the units can also be used separately as a right- or left ventricular assist [4]. In this paper we describe the evolution of the surgical procedure for implantation. Each surgical procedure has provided important feedback regarding the design to facilitate the implantation.

Material and Methods

The characteristics of the Realheart TAH have been described earlier [4,5]. In short, 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 [4,5]. Each pump has an inlet chamber (artificial atrium) and an outlet chamber (artificial ventricle). The left and the right pump are identical and the valves within correspond to the mitral valve 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.

Porcine Model

The first 8 acute implantations of Realheart prototypes were performed using a 60-70 kg porcine model. The pump technology, preoperative medication and anesthesia have been described earlier [4-6]. The limitations of the previously published studies were related to the grafts and the de-airing procedure. It was problematic to assess the length of the grafts for connection to the outflow of the pump. After all connections were attached to the vessels and natural atria, the pump itself covered all the grafts making it difficult to observe kinking of the grafts. The TAH also had a tendency to compress parts of the grafts. Gradual de-airing of the right and left chambers of the pump was performed by inserting a needle into the de-airing silicon membrane in the ventricle walls of the pump. This maneuver enabled slow filling of the pump ventricles from both atria. Pockets of air in parts of the pump remained even after careful de-airing attempts. The company has the intention to facilitate the surgery and reduce the implantation time and addressed the limitations. The purpose of this study was to develop a surgical methodology to implant the new improved Real heart TAH in a calf model.

Calf Model

Five implant procedures were performed on calves weighing about 100 kg. The procedure is now established as follows: Premedication and anesthesia is administered according to the routines of the lab. A big tube is introduced to empty stomach content. The calf is positioned on right side for left anterior thoracotomy. A cut down is made in the neck to expose left Jugular vein and carotid artery and vessel loops are placed around them. An anterior thoracotomy is carried out with ligation of the internal thoracic artery and prolonged forward to the sternum (Figure 1A). The 5th rib is excised to increase the wound space. A retractor is applied and the heart exposed. The pericardium is incised and cut open all the way to the right pleura. Snares are put around the superior and inferior v. cava and the azygos vein is ligated. After full heparinization, preparation for connection of the heart-lung machine is done. After proximal ligation of the neck vessels an arterial cannula (EOPA™, 20 Fr, Medtronic) is inserted about 5 cm in the carotid artery and a long venous tri-lumen cannula (RAP™, 23/25 Fr, LivaNova) is guided from the jugular vein into the cava sup and then further through the right atrium (RA) to the cava inf, draining blood from the RA and both v cava. The snares are tightened around them to avoid air suction into the venous line. Extra-corporeal circulation (ECC) is started with a maximal flow of about 5 L/min. The aorta and the pulmonary artery are clamped. The left ventricle is incised close to the left appendix, about 1 cm from the left atrium (LA). The incision is prolonged around the ventricle to the septum. The right ventricle is incised and cut in a similar fashion to the septum and the septum is divided saving a rim of 1 cm. The aorta and pulmonary artery are dissected free from each other and divided. The aorta is cut just above the coronary ostia to avoid later bleeding. Then the implantation of the Realheart TAH starts by suturing the prosthetic cuff to the right atrium (Figure 1B). The ventricular muscle as well as the cuff has been trimmed to suite the anatomy. A continuous suture line with 3-0 Prolene™ is carried out. The prosthetic cuff to the left atrium is sutured in a similar fashion. The predesigned graft to the aorta and one part of the pump connector are introduced and the specially formed ends of the left cuff and aortic graft are put into the connector with careful alignment of the border between them (Figure 1B). The desired graft length is decided and the graft sutured end to end to the aorta. A predesigned graft is then sutured to the PA in the same way and the right cuff and PA graft put into a graft connector in a similar way as for the left side connector (Figure 1C). This whole procedure can be done without the need of introducing the pump housings into the wound. The right pump part is then inserted in the wound as far down to the right side of the thoracic cavity as possible without compressing the right lung too much. The driveline is tunneled subcutaneously with customized instrument and withdrawn outside the body. The connector plates are put together manually and secured with customized screws and screwdrivers. Then the left pump part is inserted and the connector plates secured in a similar manner (Figure 1D). A pressure line is inserted in the left atrial appendix and the LA pressure is monitored through the weaning process from ECC. This starts by reducing the ECC flow to about 2.5-3 L/min and filling the animal with blood from the ECC reservoir to create a positive filling pressure in the pump. Small cannulas are inserted in the top of the pump parts for removing air during the filling of the pump. The PA and aorta clamps are removed for further filling of the pump and the snares around the cava are loosened. The pump is slowly started, and the output increased in steps during continuous de-airing and successive reduction of the ECC flow. After finishing ECC the pump output is further increased in steps by following the systemic blood pressure and especially the LA pressure. This should be kept over about 10 mm Hg as a sign of good filling of the LA balanced by an adequate pump output. Transfusion of the blood still in the ECC reservoir can be done during this period. After stabilization of the circulation and control of hemostasis a chest tube for drainage of blood is inserted into the lower part of the wound. The wound is then closed by either suturing the muscle layer and skin or if possible adapting the ribs as a first step. The cannulae in the neck are removed and the wound closed (Figure 1E). If the circulation is stable and other vital parameters are acceptable the decision has to be made to wake up the animal or not.

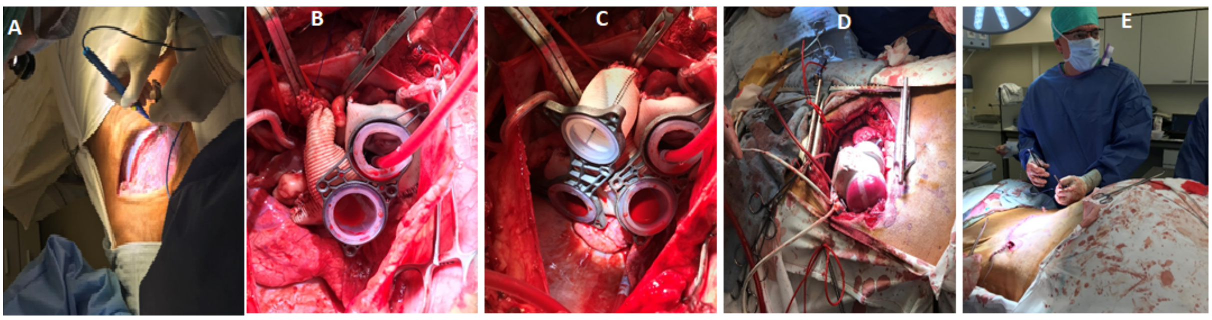

Figure 1: A) Incision between the 5th and 6th rib to perform left anterior thoracotomy. B) Left atrial cuff and aortic outflow graft connected to the left connection plate. C) Right atrial cuff and right pulmonary artery outflow graft connected to the right connection plate. D) Pumps inserted into the thorax, the right pump is hidden below the left which is shown in the image. E) Both pumps are enclosed in the thorax and the chest is closed.

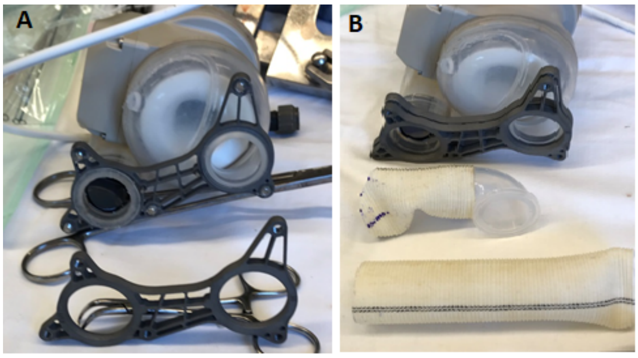

Figure 2: A) Connector plates, dissembled view. B) Connector plates, assembled view. In the front are examples of outflow grafts to be used.

Discussion

During the porcine animal studies we identified a number of problems when implanting this prototype of TAH. Step by step these deficiencies have been addressed in a substantial way. The dedicated graft connectors are a major improvement, facilitating the connection between all grafts and the pump houses. Removal of air within the pump is easier to carry out after redesigning the de-airing membranes. The implant procedure with left thoracotomy, cannulation of the neck vessels for cardio-pulmonary bypass is now a straightforward procedure performed in about 3 hours. The latest experimental work has been done on calves with a weight of about 100 kg. The current size of the TAH is still rather big so we still need to let it take some place in both pleurae as well as filling the pericardial cavity. The pump is very silent when running with only a low frequency noise barely audible before the wound is closed, and only possible to hear via a stethoscope thereafter. Realheart TAH creates a pulsatile flow with an arterial pressure curve similar to the curve pattern of a native heart [4-6]. It also has a potential to be used as separate support for the right and left ventricles [4].

Conclusion

The surgical implant technique of the Realheart TAH has been established. After these reproducible experimental procedures the pump is now ready for more long term studies on animals.

References

1. Jauhar S (2004) The Artificial Heart. N Engl J Med 350: 542-544.
2. Lundback S (1986) Cardiac pumping and function of the ventricular septum. Acta physiol Scand Suppl 550: 1-101.
3. Jessup M, Brozena S (2003) Heart Failure. N Engl J Med 348: 2007-2018
4. Ahn HC, Holm J, Najar A, Hellers G, Szabó Z (2018) A New Total Artificial Heart Concept Allowing Replacement or Support of the Native Heart. J Clin Exp Cardiolog 9: 566.
5. Szabó Z, Holm J, Najar A, Hellers G, Ahn HC (2017) Early Experience of Implantation of a New Pulsatile Total Artificial Heart (TAH) in the Pig. J Clin Exp Cardiolog 8: 510.
6. Szabó Z, Holm J, Najar A, Hellers G, Pieper IL, Ahn HC(2018) Scandinavian Real Heart (SRH) 11 Implantation as Total Artificial Heart (TAH)-Experimental Update. J Clin Exp Cardiolog 9: 578.