Implantation procedure for Real Heart TAH

Henrik C. Ahn

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: $rtificiDO heart; Assist device; Mechanical circulatory support; Heart failure; Transplantation

Introduction

A total DrtificiDO 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 insuﬆcient to secure an adequate circulation. He 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 atrioventricular valve plane is of utmost importance for the heart function, where fiOOing of the blood from the atria to the ventricles helps the valve plane to return to its upward position. His should theoretically be an energ\-eﬆcient pumping action. The Real Heart TAH constructed by Dr. Azad Najar, has shown that DrtificiDO valve planes can move silently and eوٕectiveO\ inside two pumps, which together comprise a TAH. He soiwDre 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 Oei 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 DrtificiDO 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 insuﬆcient to secure an adequate circulation. He 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 fiOOing of the blood from the atria to the ventricles helps the valve plane to return to its upward position. His should theoretically be an energ\-eﬆcient pumping action. He RealHeart TAH constructed by Dr. Azad Najar, has shown that DrtificiDO valve planes can move silently and eوٕectiveO\ inside two pumps, which together comprise a TAH. He soiwDre 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 Oei 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

He characteristics of the Realheart TAH have been described earlier [4,5]. In short, it is comprised of two separate pumps, Oei 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 Oei side and the tricuspid valve on the

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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 afterr 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.

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 grafts 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. He 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.

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.

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