Editors' pick

Total artificial heart transplants: future or biding time?

Abstract

Artificial heart transplant machines now provide viable treatment options for heart failure.

The shortage of donor organs has created a need for artificial transplant machines. These machines exhibit increasing success in providing a 'bridge to transplant' period during which a donor organ can be found. Now artificial hearts have improved survival rates to approximately 80%. It is possible that these machines may have a greater role to play as their costs decrease and technological improvements increase reliability. This article outlines the latest advances in both artificial hearts and the role of these devices in the treatment of heart conditions in the future. In addition, there is a brief discussion on competing technologies and their limitations.

Keywords: Artificial, bridge to transplant, heart, SynCardia (CardioWest), transplant.

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Introduction

Heart failure is a syndrome defined by the inability of the heart to eject enough blood to meet the demands of the body. It affects approximately 20 million people worldwide.[1,2] Treatment options, both pharmaceutical and non-pharmaceutical, have evolved over the years, showing promise of a cure. The current gold standard of treatment with regard to end-stage heart failure is a total heart transplant (HTx).[3] With only 10% of the total transplant requirement worldwide met in 2008, the consequence of mortality is a reality for many patients who are awaiting a HTx.[4] From the first heart–lung perfusion machines to the more modern left ventricular assist devices (LVADs), and now total artificial heart transplants (TAHs), this period, known as 'bridge to transplant' (BTT), has become dramatically less associated with mortality.[5] Since the implementation of the SynCardia TAH, bridge to transplant survival rates have increased from 46% to 79%.[6]

In the immediate future, these devices can be extended beyond their use only as BTT devices for more long-term therapy, much as LVADs have already done. There will soon be an FDA-approved total permanent artificial heart transplant as a destination therapy.[7] Clinical trials are underway on the AbioCor implantable replacement heart (IRH), which, in a recent study, was implanted in seven patients.[7] However, this may not become first-line therapy, as smaller LVADs, *in vitro* organ growth, and *in situ* cell replacement therapy could show substantial advancements in the prevention and treatment of heart failure.

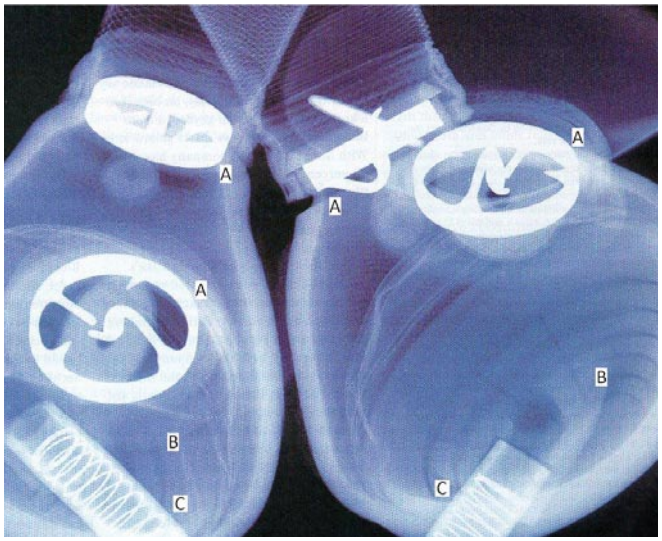

FIGURE 1: Chest x-ray of a patient with an implanted SynCardia device highlighting the replacement of the native valves and the device's pneumatic diaphragm. Note the four prosthetic valves (A), two diaphragms (B) and the two coil-reinforced polyurethane tubes (C). (Courtesy: Syncardia.com.[5])

FIGURE 2: The portable pneumatic driver seen here attached to a SynCardia TAH offers the patient mobility and enables the patient to return home until the heart transplant. (Courtesy: syncardia.com.[5])

Left ventricular assist devices

The first of the modern treatments for heart failure lay in the development of assist devices. These paved the way for the development of more complicated mechanisms such as the TAH. These apparatus do not act to take over the action of the heart; rather, they reduce the stress exerted on the heart, allowing it to rest and recover. Development of these devices accelerated in the 1960s and '70s due to complications and mortality associated with early total HTxs.[8] The evolution of pump technology brought about two main types of devices: pulsatile LVADs, where blood is pumped through the internal device via an external pump mimicking the action of the heart; and, continuous flow pumps (axial and centrifugal), in which a magnetically controlled rotor forces blood through the device. It should be noted that when a continuous flow pump is implanted the patient will employ an abnormal non-pulsatile state, posing difficulties in clinical measurement of pulse and blood pressure. Both types of devices are implanted in the thorax and attached via a cannula to the left and/or right ventricle (RVAD), finally inserting into the aorta.[8]

Mechanical failure is a challenge with these devices and primarily affects the moving parts of the device. A new approach is being implemented in continuous flow pumps where traditional ball bearings are being replaced by hydrodynamic and magnetic suspensions.[8] This allows for only one moving part, the rotor, ultimately decreasing the incidence of mechanical failure. This trend in reducing the number of moving parts can be seen in many heart

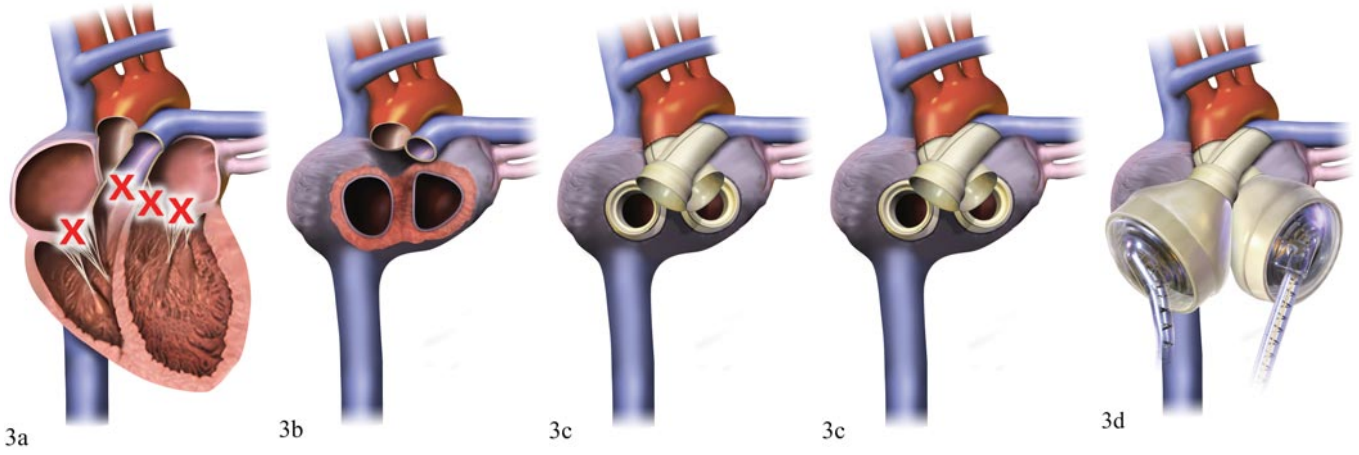

FIGURE 3a-d: The sequence in which the native heart is removed and the SynCardia total artificial heart transplant is placed. (Courtesy: syncardia.com.[5])

Table 1: Occurrence of adverse events in a group of 95 patients who received a SynCardia implant.[9]

Adverse event	Percentage experienced
Infection	77%
Bleeding	62%
Hepatic dysfunction	37%
Respiratory dysfunction	36%
Renal dysfunction	31%
Neurologic event	27%
Operation complications	24%
Reduced blood pressure	19%
Device malfunction	17%
Peripheral thromboembolism	14%
Reduced cardiac index	9%
Fitting complication	5%
Haemolysis	4%
Technical or procedural problem	3%
Other problem	9%

devices.[8] Another complication that plagues similar cardiac apparatus is the risk of thromboembolism.[6,8]
In the future, these devices are predicted to flourish, not only as a cheaper alternative to TAHs but also because improvements in design, making these devices smaller, will make them less invasive.[8] It can be foreseen that future devices will be implemented in the earlier stages of heart failure, acting in a prophylactic manner to prevent the advancement of heart disease.[8]

SynCardia total artificial heart transplant

The SynCardia TAH (also known as the CardioWest TAH) is the only FDA-approved TAH on the market today and has been implanted in approximately 850 patients to date.[5] The device is composed of two symmetrical chambers in which a pneumatically driven diaphragm is depressed and then elevated, causing the injection and ejection of blood at a rate of up to 9.5L/min.[5] This system uses the patient's own muscle tone and body movement to alter its ejection fraction in response to exercise by up to 30%.[5] This allows for increased patient activity in contrast to similar systems. Like the pulsatile LVADs, the device is attached to an external pneumatic driver. This driver is initially non-mobile and upon patient recovery can be switched to a mobile model that can be carried[5] (**Figure 2**).
The implantation of the SynCardia TAH involves bilateral removal of the ventricles along with all four native valves at the ventricular valvular junctions between the atria, pulmonary artery and aorta (**Figure 3a**). The atria, pulmonary artery and aorta are then preserved for attachment to the TAH (**Figure 3b**). Quick connect devices then attach the TAH to the residual portions of the heart via sutures, creating a contact for the TAH (**Figure 3c**). Finally, the TAH is attached and the commencement of artificial perfusion follows (**Figure 3d**).[5]

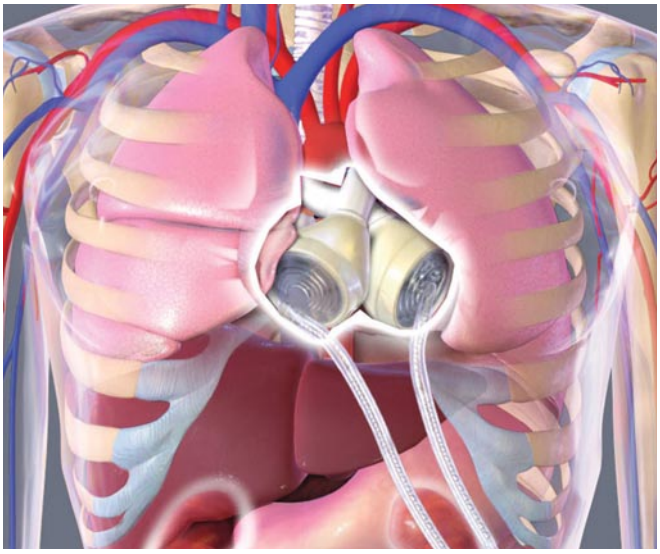

FIGURE 4: Anatomical position of the SynCardia TAH and its pneumatic drivelines. The drivelines enter the patient along the left midclavicular line, approximately 5cm below the costal margin. The TAH lies in the mediastinum attached to the atria, pulmonary artery and the aorta. (Courtesy: syncardia.com.[5])

What sets the SynCardia TAH apart from other devices is its ability to eliminate ventricular, valvular and electrical complications, such as ventricular tachycardia, sinus tachycardia and atrial fibrillation, which are experienced with pacemakers.[9,10] In addition, the apparatus exhibits certain advantages over the use of LVADs, such as its application in patients with recurrent intracardiac thrombi, shunts, structural damage and congenital defects.[11]
As with all prostheses, inherent complications can occur, as outlined in **Table 1**. An overwhelming number of patients acquire post-procedural infections, contributing to a mortality rate as high as 9% in infected patients.[9] Platis *et al.* recorded respiratory infections in up to 40%, genito-urinary infections in up to 22%, and pneumatic insertion line-associated infections in up to 14% of post-procedural patients.[6] Other studies have recorded infection rates as low as 20%.[12] Aggressive antibiotic treatment is the current treatment for these infections, but increasing microbial resistance is a potential challenge.[12] The compounded results of these complications are exhibited in patients experiencing multiple organ failure, which has ultimately resulted in increased mortality rates.[12] Additionally, formation of intra-prosthesis thromboemboli poses a serious threat to the individual.[6] With the current treatment involving the use of anti-coagulative therapy, postoperative bleeding is a significant risk to the patient.[12] The future looks forward to the development of less thrombogenic materials and hence devices that can avoid these complications. The use of diaphragms in future devices is promising, as fewer moving parts may increase durability. Upcoming developments in perfusion-correcting technologies are heralded to reduce many complications, such as those associated with hepatic, renal and mesenteric ischaemia.[12]

Valuation of cost to health systems

Currently, the majority of TAH transplants are privately funded.[13] The current price of a SynCardia TAH transplant is approximately $150,000US, compared to the cost of an LVAD in the range of $100,000US, depending on country.[13] Increasing pressure on public health centres for the best available treatment conflicts with budgetary constraints in many countries. It seems pragmatic to adopt more feasible approaches to heart failure, such as the use of widespread, less effective drug treatments. Such treatments include diuretic regimes that offer only a modest resolution of patient symptoms.[2] With the growing interest by many prosthetic development companies and an increasing demand for artificial heart transplant technology, it seems plausible that devices will become more affordable.[8] Nevertheless, it is unrealistic to say that this technology will be available for all patients with heart failure in the future.

Future advancements

Currently, TAH is implemented as a BTT treatment rather than a destination therapy. The AbioCor IRH is in the process of obtaining FDA approval, but complications associated with thromboembolic events and thrombus formation on its atrial attachments must be resolved before it receives market and professional approval.[6,7] This new device offers a transcutaneous energy transfer (TET) system and a radio communication system, avoiding the use of vents and intra-abdominal ports. Other features include automated monitoring and control of motor speeds, pump rate and flow balance by means of an intra-abdominal sensor system.[7] Future models of LVADs and TAHs will employ these features of transcutaneous current transduction as a means to power devices, thus eliminating the need for intra-abdominal line placement and reducing line infection.[7,14]

Other technologies under development rely on increasing the afterload of the heart by constricting the aorta. The C-Pulse (Sunshine Heart Inc, Tustin, CA) device relies on an inflatable cuff that intermittently expands around the circumference of the ascending aorta, thereby increasing cardiac output.[15] However, the use of intra-abdominal lines may result in line sepsis that can have devastating consequences, contributing to fatality of approximately 1%.[9] This was demonstrated in the case study by Mitnovetski *et al.*[15]

With the current technology, it is plausible that the use of TAHs will increase, as will the development of devices with lower mechanical faults, more systemic control, increased patient freedom and fewer overall complications. Artificial heart transplant machines provide viable treatment options for heart failure, so this medical field warrants further research and development to keep pace with the emerging technology.

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