

The Thoratec System Implanted as a Modified Total Artificial Heart: the Bad Oeynhausen Technique

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ABSTRACT

The CardioWest™ total artificial heart (SynCardia Systems, Tucson, AZ, USA) is the only FDA-approved total artificial heart determined as a bridge to human heart transplantation for patients dying of biventricular heart failure. Implantation provides immediate hemodynamic restoration and clinical stabilization, leading to end-organ recovery and thus eventually allowing cardiac transplantation. Occasionally, implantation of a total artificial heart is not feasible for anatomical reasons. For this patient group, we have developed an alternative technique using the paracorporeal Thoratec biventricular support system (Thoratec, Pleasanton, CA, USA) as a modified total artificial heart. A detailed description of the implantation technique is presented.

INTRODUCTION

The CardioWest™ temporary total artificial heart (SynCardia Systems, Tucson, AZ, USA) is the world's first and only FDA-approved total artificial heart (TAH). It received FDA approval in October 2004 following a 10-year pivotal clinical study. The TAH orthotopically replaces both native cardiac ventricles and all cardiac valves, thus eliminating problems commonly seen in the bridge to transplantation with left ventricular and biventricular assist devices, such as right heart failure, valvular regurgitation, cardiac arrhythmias, ventricular clots, intraventricular communications, and low blood flows [Arabia 2001; Leprince 2003; Copeland 2004]. Nevertheless, sometimes anatomical limitations of the patient (eg, body surface area < 1.7 m², especially in adolescents or smaller women) do not allow TAH implantation with placement of the ventricles into the patient's chest. For this special patient population we have developed

an alternative technique using the paracorporeal Thoratec biventricular device (Thoratec, Pleasanton, CA, USA) as a modified TAH.

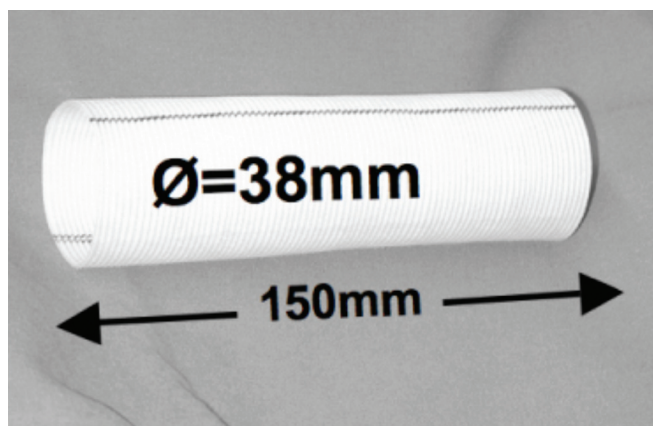


Figure 1. Used Hemashield™ graft (Maquet, Rastatt, Germany).

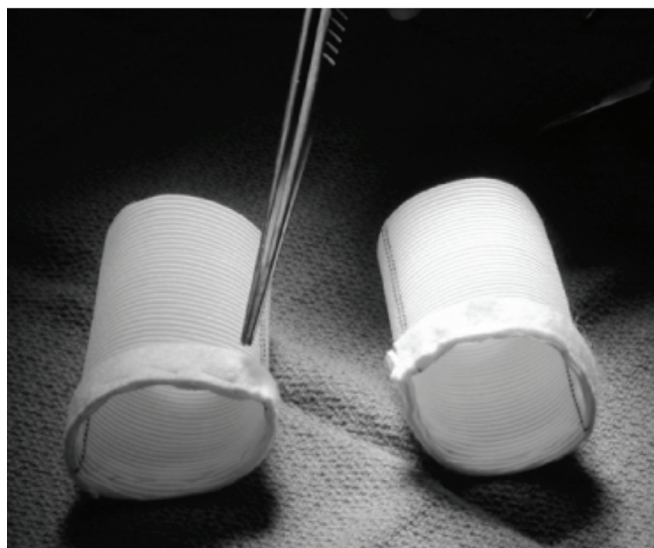


Figure 2. Reinforcement of the cut surfaces using polytetrafluoroethylene (PTFE) felt.

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Figure 3. Anastomosing both reservoirs.

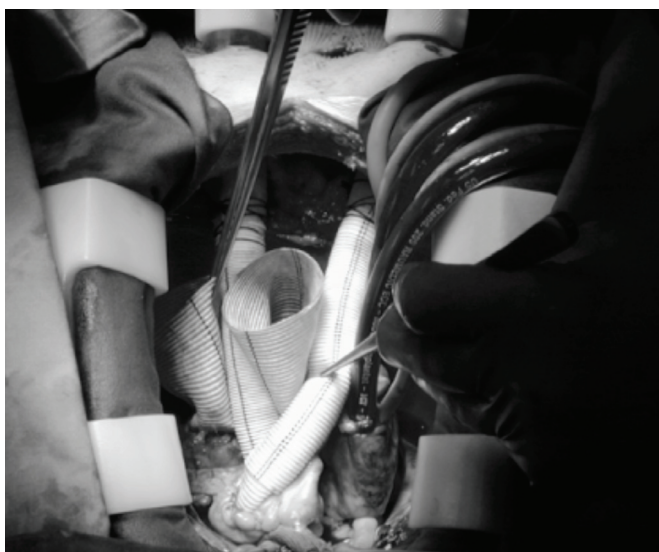


Figure 4. The outflow graft for the aorta and the pulmonary artery are anastomosed end-to-end to the vessels using a running suture.

IMPLANTATION TECHNIQUE

The aorta and both superior and inferior vena cavae are cannulated in a standard fashion. Dissection around the aorta and pulmonary artery is limited to the proximal portion of the aorta in anticipation of later transplantation, thus leaving some untouched areas that will not be very fibrotic. Total bypass is instituted. The heart is fibrillated and the heart is excised. The following technique was developed by the first author (LA).

In order to build an atrial reservoir and to be able to connect to and anchor the apex cannulae, we use a Hemashield™ graft (Maquet, Rastatt, Germany) with a diameter of 38 mm and a length of 70 mm (Figure 1). The Hemashield graft is folded in the middle. Both ends



Figure 5. The apex cannulae are inserted into the left and then right atrial reservoir and fixed with a silk suture.



Figure 6. After the connection and de-airing of the system, the total artificial heart (TAH) can be started.

are cut in an oblique shape. The graft is then cut in the middle and prepared as a reservoir for the left and right atria.

The oblique cut end of the reservoir is reinforced using a polytetrafluoroethylene (PTFE) felt in order to prevent bleeding in the area of stitches. The PTFE felt is fixed using a running suture with 5.0 Prolene (Figure 2).

Both reservoirs are anastomosed using running sutures, and the suture area is again reinforced with PTFE felts (Figure 3). The outflow graft for the aorta and the pulmonary artery are anastomosed end-to-end to the vessels using a running 4.0 Prolene suture (4-0) (Figure 4).

The apex cannulae (extra long with 2 holes) are inserted into the left and then right atrial reservoir and fixed with a silk suture (Figure 5).

The inlet and outlet cannulae exit the body below the costal margin.

The device will rest on the abdominal wall until removal. It is important that the ventricles maintain a midline orientation and do not hang too low. On the left side, the inlet cannula should be located in the mid-clavicular line about 5 cm below the costal margin, and the outlet cannula should be externalized about 3 cm medial to the inlet cannula at the same level.

The exit sites from the heart through the abdominal wall are created by excising a circular portion of skin and subcutaneous fat at the chosen location. The hole should be significantly smaller than the diameter of the cannula to allow a snug fit. The tunneler will facilitate insertion. All cannulae are fixed to the skin with 2 silk sutures.

After connection and de-airing of the system, the TAH can be started and the patient can be weaned off from the heart-lung machine (Figure 6).

All grafts are covered with a surgical membrane. This step will facilitate the consecutive heart transplantation. The wound closure is performed in standard fashion.

CLINICAL EXPERIENCE

Until now, 22 patients (age 15 to 71 years) underwent Thoratec implantation as TAH (mean support time, 52 days). Underlying disease was cardiomyopathy (ischemic or dilative) in 9 cases, irreversible myocardial infarction shock in 4 patients, acute transplant rejection in 3 patients, endocarditis in 3 patients, primary graft failure in 1 patient, acute myocarditis in 1 patient, and Ebstein's anomaly in 1 patient. After the implantation, no complication regarding implantation technique was seen. In all cases, sufficient hemodynamics

were reached immediately after starting support. Nevertheless, the most frequent complication after implantation was multiorgan failure indicating a delayed implantation.

Six patients survived after heart transplantation, 1 patient died after transplantation, and 14 patients died on-device because of multiorgan failure, septicemia, or neurological complications. One young woman died after a gynecological operation.

CONCLUSION

Implantation of the paracorporeal Thoratec support system as a TAH is a reliable technique and can be utilized as a bridge to heart transplantation in patients presenting with anatomical limitations for CardioWest TAH implantation. The implantation technique is relatively easy. The postoperative management is straightforward because there is no need to continue inotropes or antiarrhythmics. A portable driver is available to allow patients mobility and out-of-hospital treatment. Early implantation may prevent development of severe multiorgan failure, thereby improving results.

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