Total artificial heart: case report and operative technique

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The Syncardia total artificial heart (TAH-t) is a pneumatically driven partially implantable system , offers 2 sizes, 70 mL and 50 mL, capable of generating cardiac outputs of up to 9.5 L/m and 7.5 L/min, respectively. This system is used for orthotopic replacement of the native ventricles in patients with irreversible biventricular heart failure. . It is an excellent option in the properly selected patient. The keys to successful device implantation remain patient selection, operative techniques aimed to facilitate orthotropic heart transplantation, centers of high volume and profound knowledge of postoperative management. We present a case that was successfully bridge to OHT with a TAH-t. We will review specific strategies, surgical technique, important operative details, teaching points and pitfalls of the TAH implantation, allowing a less demanding reoperation for orthotopic heart transplantation.

***Key words*: Total Artificial Heart; Syncardia implantation; Surgical technique; Heart transplant.**

El corazón artificial total de Syncardia es un Sistema neumático parcialmente implantable (paracorporeo). Posee dos presentaciones, 70 y 50 ml, siendo capaz de generar gastos cardiacos hasta 9.5 L/min y 7.5 L/min, respectivamente. Este Sistema es usado para el reemplazo ortotópico de ambos ventrículos nativos, en pacientes con falla biventricular irreversible. Representa una excelente opción para pacientes apropiadamente seleccionados. Las claves para implantar este dispositivo exitosamente estriban en una adecuada selección del paciente, una técnica quirúrgica que facilite el subsecuente trasplante, la realización del procedimiento en centros de alto volumen y un profundo conocimiento del manejo postoperatorio. Presentamos un caso que fue exitosamente trasplantado, después de colocarse un corazón artificial total. Revisamos estrategias específicas, técnica quirúrgica, detalles trascendentes de la operación, puntos básicos de enseñanza para la implantación, todo esto con miras a permitir una reoperación menos demandante durante el trasplante cardiaco ortotópico.

***Palabras clave*: Corazón Artificial Total; Syncardia implantacion; Técnica quirúrgica; Trasplante cardiaco.**

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The history of the Syncardia total artificial heart (TAH-t) (SynCardia Inc, Tucson, AZ) is an extraordinary medical and surgical journey of resilience and perseverance, marking the progress to improve the compatibility in the binomial man/machine.

The Syncardia total artificial heart (TAH-t) is a pneumatically driven, partially implantable system used for orthotopic replacement of the native ventricles in patients with irreversible biventricular heart failure resulting either from acute [1] or chronic [2] cardiomyopathy who are at imminent risk of death.

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The TAH-t offers 2 ventricular chamber sizes, 70 mL and 50 mL, capable of generating cardiac outputs of up to 9.5 L/m and 7.5 L/min, respectively. The pneumatically activated diaphragm system automatically balances output between the left and right ventricles and responds to increases in venous return with increased outputs [3]. Each chamber is activated by a separate driveline connected to the external driver.

According with the last report of the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) database, from June 2006 to April 2017, 450 patients received TAHs. The 2 most common diagnoses were dilated cardiomyopathy (50%) and ischemic cardiomyopathy (20%). Eighty-two percent presented risk factors for right heart failure. Most patients were INTERMACS Profile 1 (43%) or 2

Table 1. Indications for total artificial heart

INDICATIONS
Irreversible biventricular failure
Malignant arrhythmias
Restrictive, infiltrative or hypertrophic cardiomyopathies in need of mechanical support
Allograft failure, rejection or severe vasculopathy
Some congenital heart disease
Cardiac tumors

(37%). Of the patients receiving a TAH-t, 266 (59%) eventually underwent transplantation, a success rate comparable to the overall rate of heart transplantation for LVAD. Overall 3 ,6, and 12-month actuarial survival rates were 73%, 62%, and 53%, respectively. Moreover, 24% of the patients were discharged from the hospital. The most common cause of death was multisystem organ failure (36%) and neurologic injury (18%). The incidence of stroke was 22.7% within the first 6 months. Risk factors for death included older age ($p = 0.001$), need for pre-implantation dialysis ($p = 0.006$), higher creatinine ($p = 0.008$), lower albumin ($p < 0.001$) levels, and implantation at a low-volume center (≤10 TAH-ts; $p < 0.001$) [4] .

The keys to successful device implantation remain patient selection and operative techniques aimed to facilitate orthotropic heart transplantation. The most common indications for TAH-t are summarized in **Table 1**. Patient selection is extremely important to successful TAH-t implantation. Patient size is of particular interest, recipients should have a body surface area (BSA) of 1.7 m2 or larger. In the CT, The thoracic diameter, anteroposterior dimension measured from the posterior sternum to the anterior 10th vertebral body, should be greater than 10 cm.

We present a case that was successfully bridge to OHT with a TAH-t. We will review specific strategies, surgical technique and pitfalls of the TAH implantation.

CASE REPORT

A 33 years old african-american male (98 kg, 188 cm, BMI 27.26) was admitted for further management of cardiogenic shock in the setting of advanced chronic non-ischemic cardiomyopathy. He arrived with an intra-aortic balloon pump, and on high doses of mirinone. Despite maximal medical therapy, the patient´s condition continued to declined (INTERMACS 1). The initial echocardiogram showed severe left ventricular (LV) dilatation (over 7 cms) with an LV ejection fraction of < 15%. Moreover, it showed severe LV noncompaction affecting most of the myocardium, severe tricuspid regurgitation with severe annular dilatation (> 5 cm). The initial right heart catheterization showed a right atrial pressure

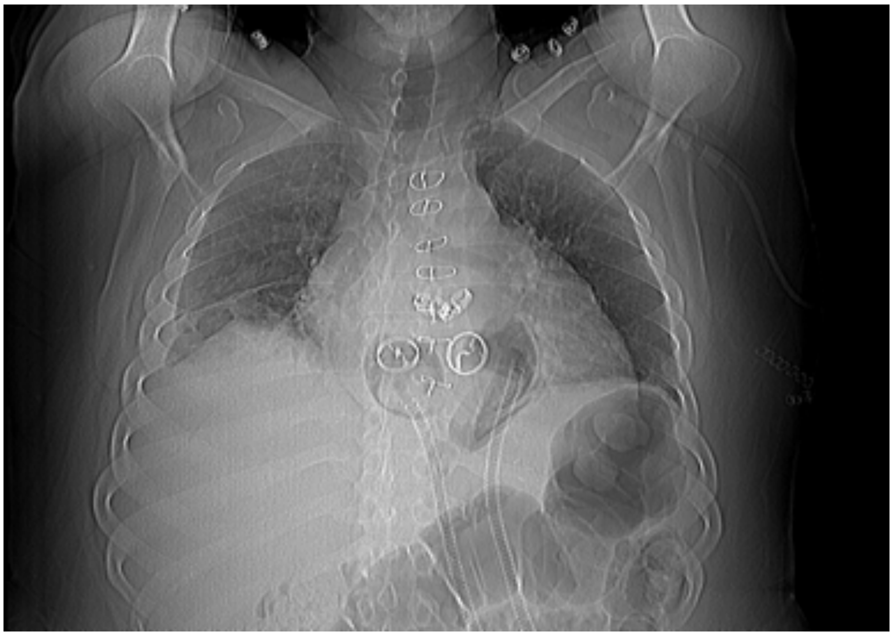

Figure 1. Postoperative CT showing the pneumatics pumps, mechanical valves and drivelines.

of 16 mmHg, pulmonary artery pressure 45/29/36 mmHg with a pulmonary artery occlusion pressure of 25 mmHg. Important laboratory information included a sodium of 125 mMol/lt , BUN/Cr 17/0.8 mg/dl, albumin 3.3 mg/dl, a total bili of 2.5 mg/dl with normal transaminases. Given the extensive LV trabeculations, he was considered a poor candidate for LV Assist Device (LVAD). Instead, He was considered a good candidate for a TAH-t, with subsequent orthotopic heart transplantation.

We implanted a 70-cc TAH-t. The immediate post-op was complicated by hemothorax requiring surgical intervention and multiple blood transfusions. Sternal closure was done 24 hrs after the surgery. Other post-op complications were acute kidney injury, and an ischemic stroke without significant sequelae. The **Figure 1** shows the scout of a computer tomography, showing the ventricles and drivelines. He was transplanted after 62 days of TAH-t support. At the time of transplant, a fluid collection/old hematoma was found next to the TAH-t cannula, which grew Staph epidermidis, and was treated with 8 weeks of intravenous vancomycin. He was discharged 3 weeks post-transplant. He is doing well 3 months after transplantation.

SURGICAL TECHNIQUE

The patient is placed in the supine position under general anesthesia is induced. A single-lumen endotracheal tube, central and arterial lines are placed. The TAH system is prepared on the back table according to manufacturer standards, including biological sealant on the surface of the outflow graft. All components are wrapped in antibiotic-soaked sponges before implantation. Standard sternotomy and pericardiotomy are performed. The pericardium and diaphragm are divided laterally toward the apex of the heart to facilitate device and driveline placement. The patient is heparinized. Distal ascending aorta or proximal arch, as well both vena cavae are cannulated, minimizing the circumferential dissection on both. Just for the caval tapes, CPB is initiated, cross-clamp is applied without cardioplegia as proximally as possible to preserve aorta for eventual transplant.

Ventriculectomy

Excision of the heart consists of 3 steps as follows.

1. Initial incision into the right ventricle, just below the pulmonary valve, 1-2 cm from the atrioventricular groove. With visualization of the tricuspid valve, the right ventricle is detached by cutting a leaflet 1 cm from the annulus. The fat pad is left intact with the right coronary artery until the posterior ventricular septum is encountered.

2. The incision is carried to the base, across the septum, and into the LV. With visualization of the mitral valve, the coronary sinus is preserved if possible. The ventricle is then resected, with special attention preserve the left atrial appendage, this is carried around to the anterior mitral annulus. The LV is detached by cutting the mitral leaflets 1 cm from

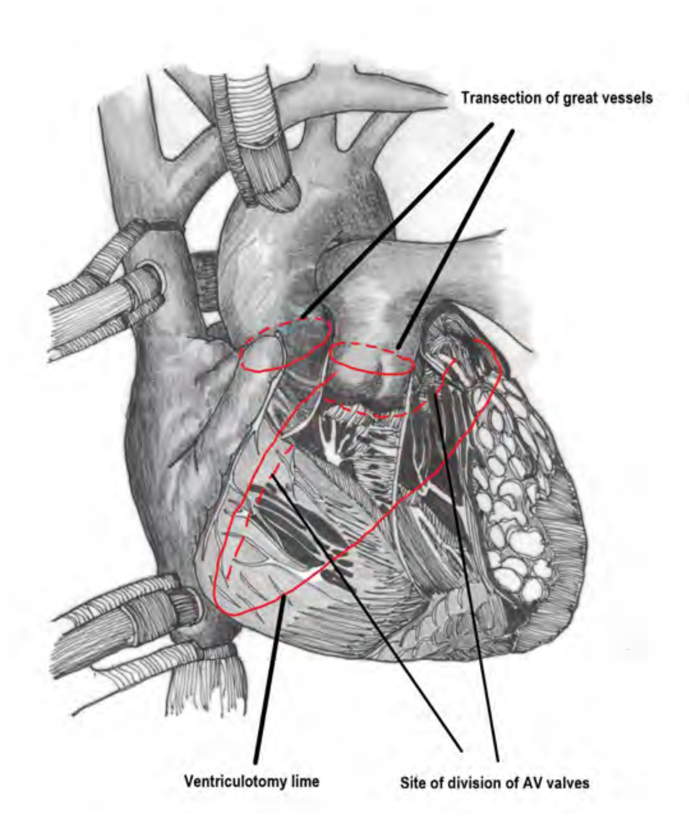

Figure 2. Lines of division of the ventricles, great vessels and atrio-ventricular valves.

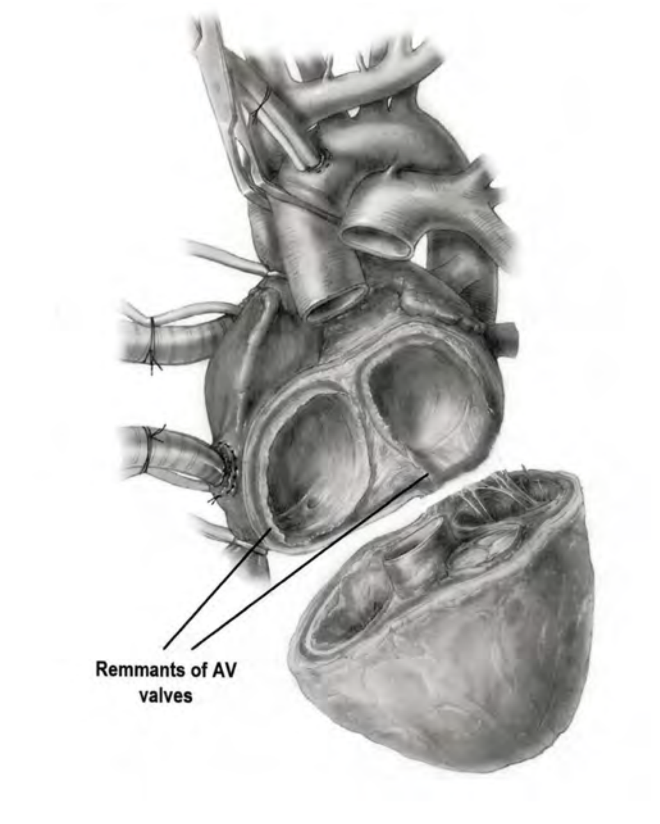

Figure 3. The ventricular incision is distal to the AV groove, both valves are excised, left atrial appendage is preserved.

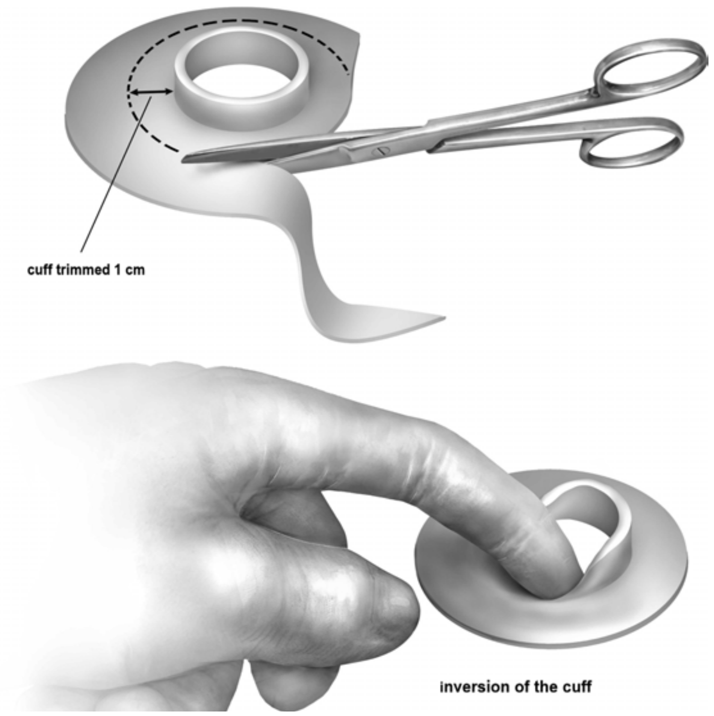

Figure 4. Preparation of the atrial cuffs

the annulus.

3. Incision in both aorta and pulmonary arteries, as far proximally as possible, just above the point of commissural attachment (**Fig. 2**)

From the aortic root, the aortomitral curtain is divided

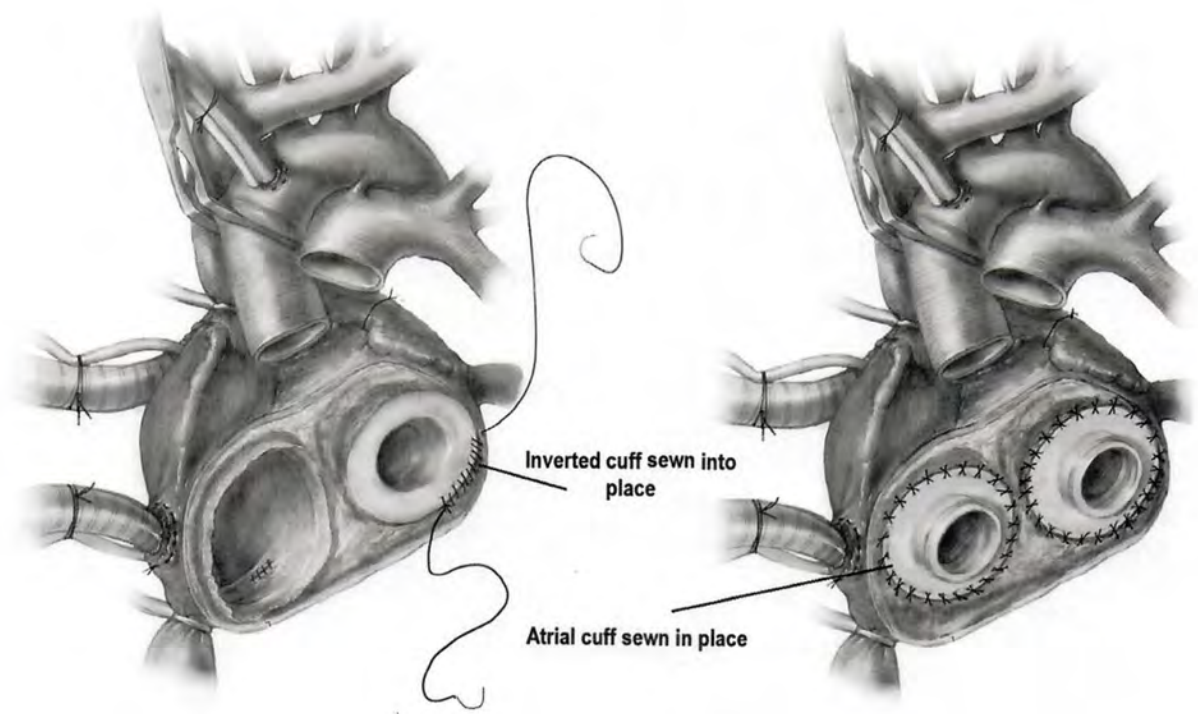

Figure 5. The coronary sinus is oversewn, the inverted quick connecters are sutured to the tricuspid and mitral annulus, after that both connectors are everted and oversewn with a second line.

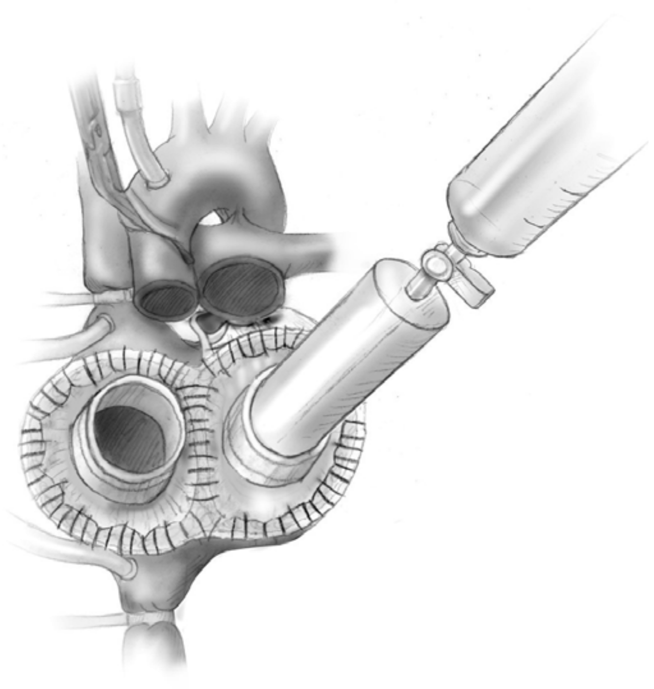

Figure 6. Hydrostatic testing of atrial connectors anastomosis

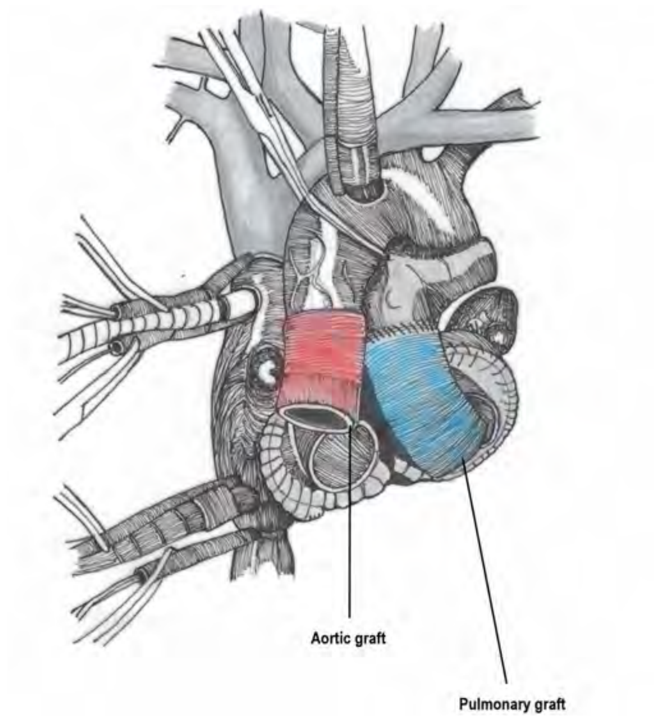

Figure 7. The pulmonary artery graft is usually trimmed to 5-The aortic graft is generally trimmed to 3 cm.

and connected to the annular resection. After cutting through the remnant of the aortic and pulmonary valves, the ventricles are totally excised, with direct visualization of the mitral and tricuspid annuli. (**Fig. 3**).

Pump Connections

Atrial cuffs are trimmed to 1 cm , then inverted, (**Fig. 4**). The inverted cuffs are placed within the cavity of the atria cavity. The coronary sinus is then oversewn. If there is a patent

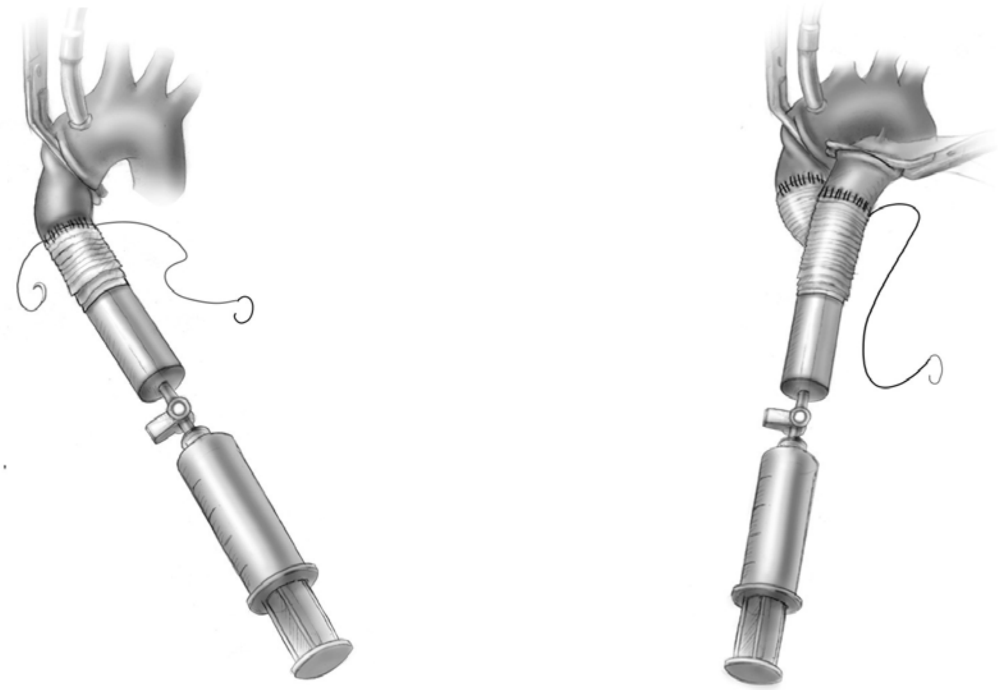

Figure 8. Testing of the great vessels grafts , under hydrostatic pressure.

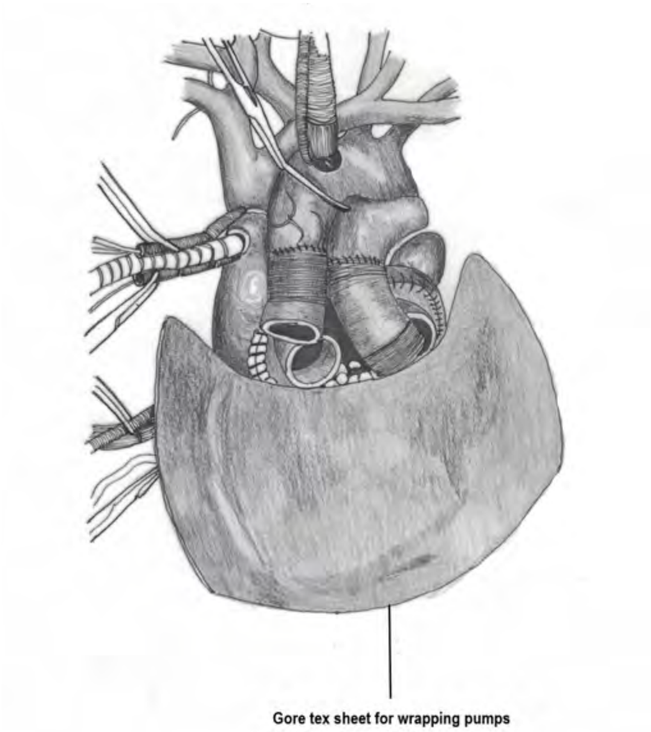

Figure 9. Prophilactyc surgical measurement for prevent adhesions and make ease the transplant (coverage with gore tex sheet).

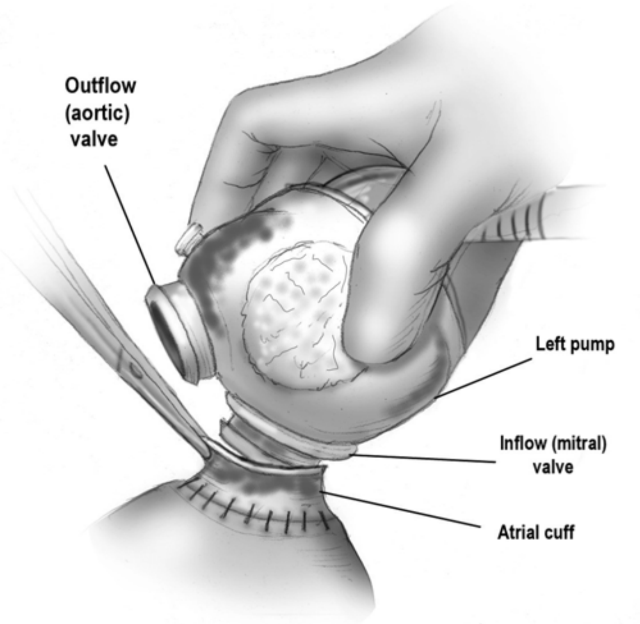

Figure 10. Attachment of the left ventricular pump.

foramen ovale it should be closed and the left atrial appendage is ligated . Left atrial cuff is sutured first for easier access. Both tricuspid and mitral valve annuli are sutured with prolene 4-0, incorporating the epicardium and pericardial adipose tissue. Felt reinforcement for all anastomoses is avoided. Both atrial quick connects are everted and oversewn with a second suture line (**Fig 5**).

After eversion, cuffs can be tested (use needle holder every time that you connect the testers) (**Fig. 6**). Temporary pulmonary vein occlusion by pressure will assist left-sided testing, right side testing is easier, because both cava are occluded. Attention is then made to the great vessels connectors. The pulmonary artery graft is usually trimmed to 5-6 cm and sewn to the pulmonary artery (excessive length in this graft can result in kinking or compression under the sternum). The aortic graft is generally trimmed to 3 cm, The anastomoses are constructed with running 4-0 prolene sutures. (**Fig.7**). Testing is then performed with occlusion of the distal PA and with a Satisnky clamp. The aortic anastomosis testing is easier, as it is already clamped (**Fig. 8**).

In preparation for transplant, a large 15- 20-cm Gore-Tex pericardial membrane (0.01 mm; W. L. Gore & Associates, Flagstaff, AZ) is attached under the IVC and left pulmonary artery along the left atrium (**Fig. 9**). Both ventricular pumps are brought into the field. The driveline exit sites should be 6-8 cm from the left subcostal margin and at least 5 cm apart to prevent skin necrosis between them. The drivelines should be tunneled before connecting to the pumps. The left driveline is tunneled laterally across the anterior abdominal wall, the right driveline is tunneled medial to the left ventricle.

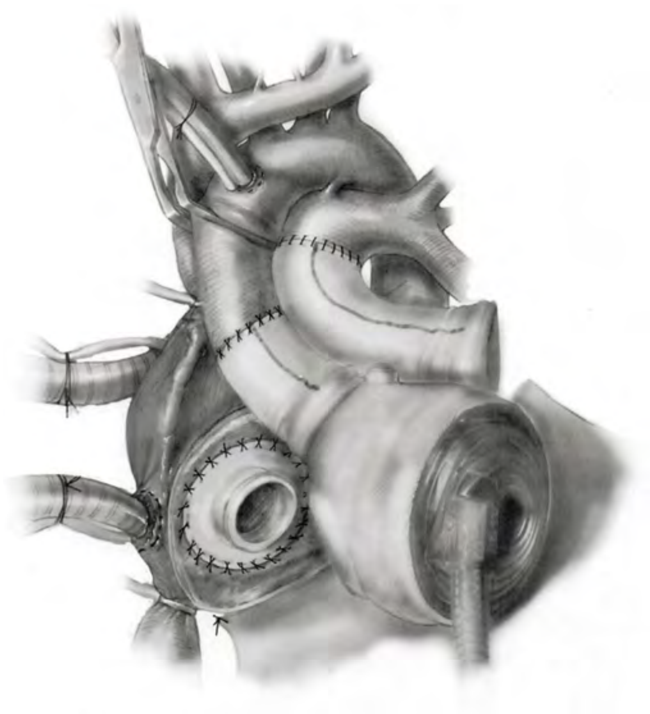

Figure 11. Left ventricle is attached first previous driveline tunneled.

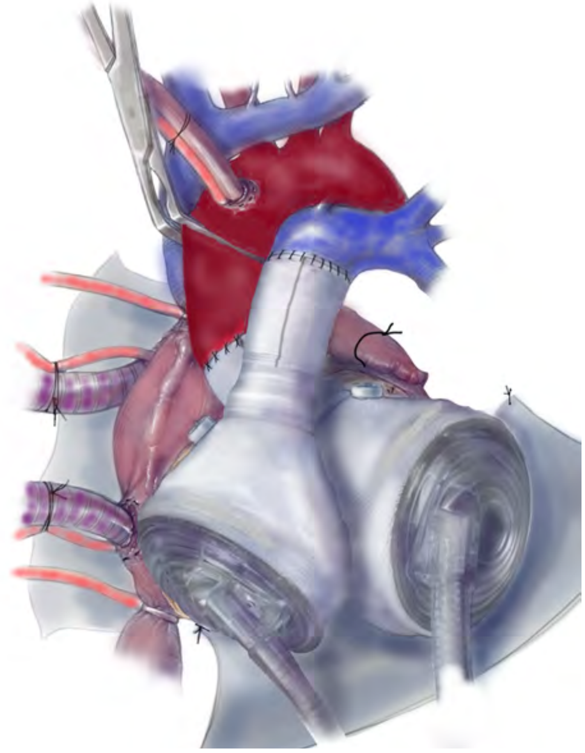

Figure 12. Right ventricle is attached, previous tunneling of driveline medial to the left one.

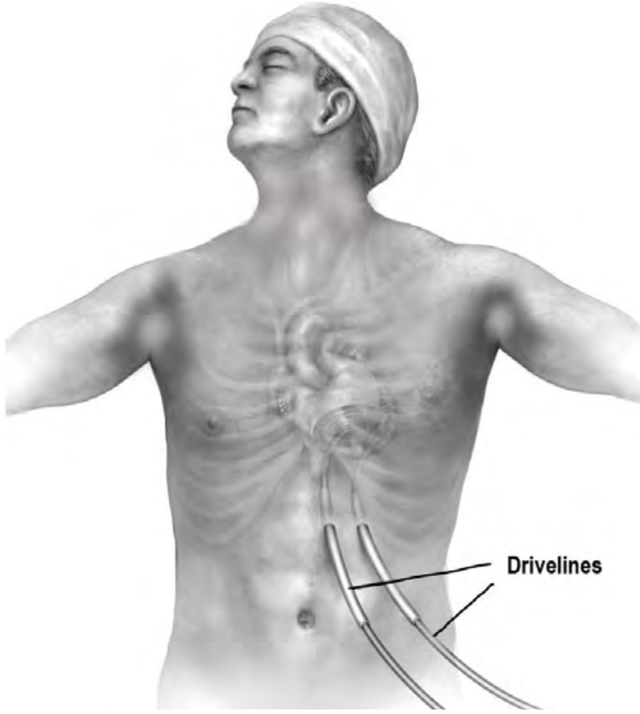

Figure 13. The driveline exit sites should be 6-8 cm from the left subcostal margin and at least 5 cm apart to prevent skin necrosis between them.

A vent for de-airing is place in the ascending aorta. Release of the left pleural attachments of the pericardium will allow the left ventricular pump to be positioned more posteriorly. The left ventricle is attached first, using the quick-connect attachments provided. It is particularly useful to employ needle holders for to connect the pumps (pop sensation) (**Fig.10**).

The ventricle is de-aired with saline. Then the aortic side of the left pump is connected to the aortic graft (oriented towards the patient right shoulder). Care must be taken to ensure that twisting or kinking of the grafts does not occur (**Fig. 11**).

The right ventricle is attached last. Awareness of the compression of the inferior vena cavaby direct pressure from the right ventricular pump should be keep in mind (**Fig. 12**).

Anchoring the ventricle to a rib or fascia may be helpful. Caval snares can be loosened temporarily to allow filling of the atrial chambers. Then both de-airing nipples on the ventricles are ligated. Finally, drivelines are connected to the external driver (**Fig. 13**).

Weaning bypass

With the patient in Trendelenburg position and the aortic cross-clamp in place, the caval tapes are released. The heart allowed is to fill, and the lungs are ventilated. Transesophageal echocardiography is essential for this step to ensure positioning, leak and de-airing. The aortic root vent should be as high as possible. The TAH-t controller is set at 40 beats/min while agitating the ventricles for a few seconds. Once complete, the cross-clamp is removed, CPB is weaned while increasing the TAH-t rate. In general, as the fill volumes remain steady over 35 mL, the rate is increased by 20 beats/min. Ideally, once completely off cardiopulmonary bypass, the TAH-t should be near 120 beats/min with fill volumes above 40 mL, the pressure setting in the console should be 180 and 80 mmhg in the systemic and pulmonic side, respectively. Vacuum can start at -10 mmhg. The goal parameters are: ventricular filling (stroke volume): 50-60 ml, beat rate: 120-130 bpm, CO: 7-8 L/min.

The surgical sites are meticulously examined for hemostasis. There is an intense inflammatory reaction surrounding the surface of the TAH-t, therefore, several additional cares are undertaken to decrease surgical complications at the time of orthotopic heart transplantation. These include wrapping of the TAH-t with Gore-Tex pericardial membrane, and leaving a breast implant inside this wrapping, to prevent extreme inflammation and scarring shrinking of the mediastinal cavity (**Fig. 14**) (**Fig. 15)** (**Fig 16**) (**Fig 17**). If this is not done, we could run into the risk of lack of space for a possible allograft. We also recommend looping Gore-text membranes around both cavae, the aorta and aortic graft, as well on the pulmonary artery anastomosis (**Fig. 14**).

Mediastinal drainage is accomplished with an angled chest tube along the diaphragm, a straight mediastinal chest tube outside of the Gore-Tex beneath the sternum, and a Blake drain inside of the PTFE wrapping. The sternum is closed in a standard fashion. Closure of the chest may change the position of the ventricles and lead to hemodynamic in-

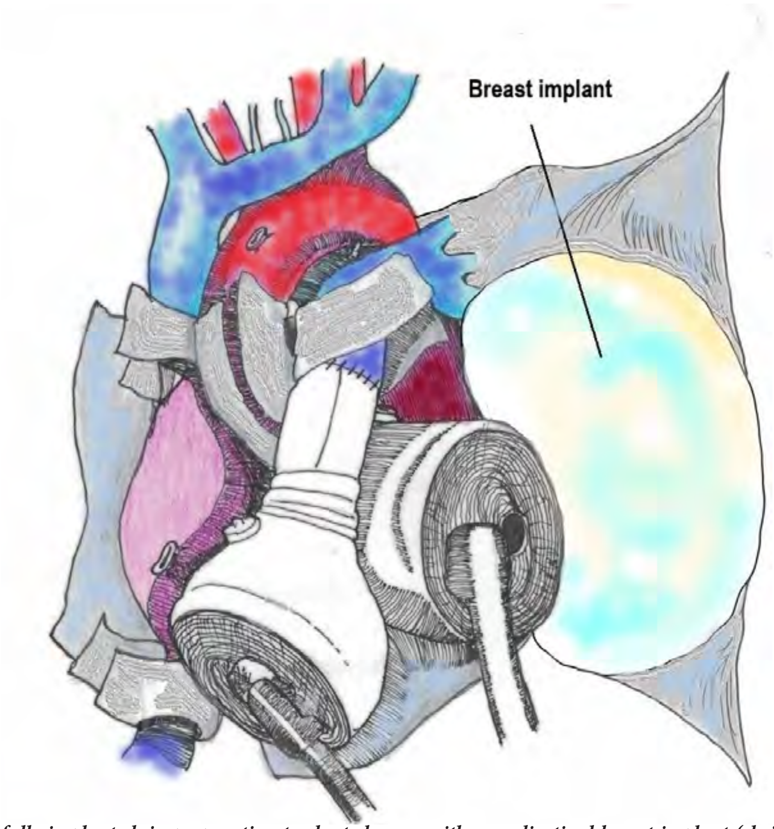

Figure 14. Total artificial heart fully implanted, in preparation to chest closure, with a mediastinal breast implant (shrinking scarring prevention) and PTFE mesh and loops.

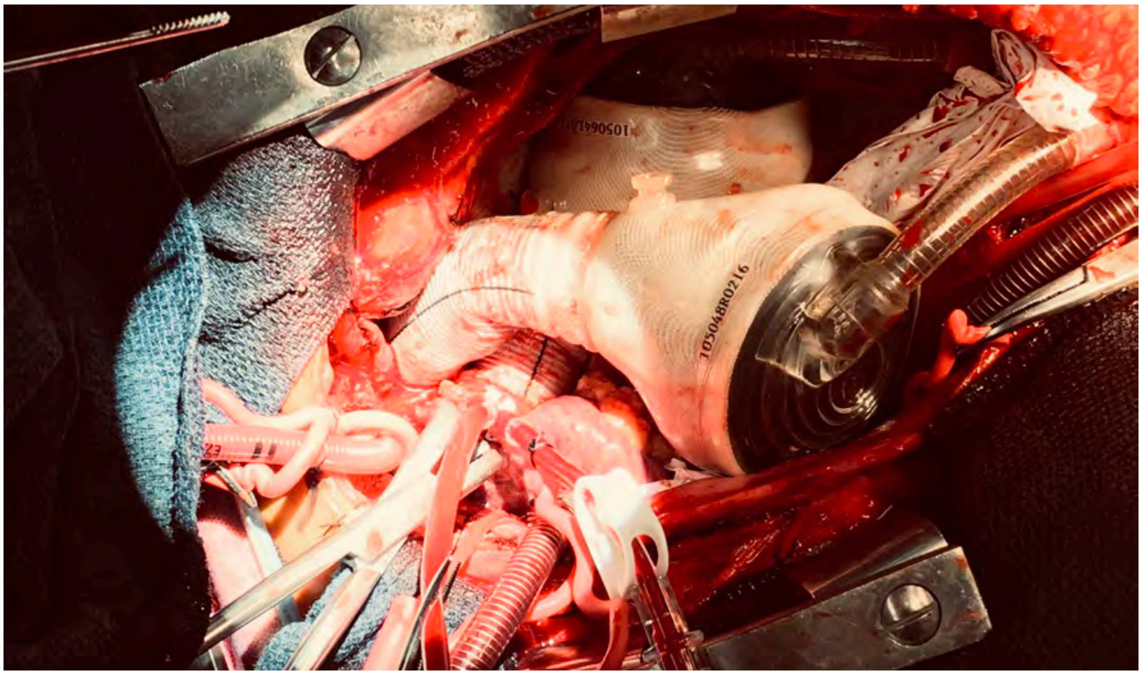

Figure 15. Complete implantation of TAH-t, previous PFTE membrane coverage and sternal closure.

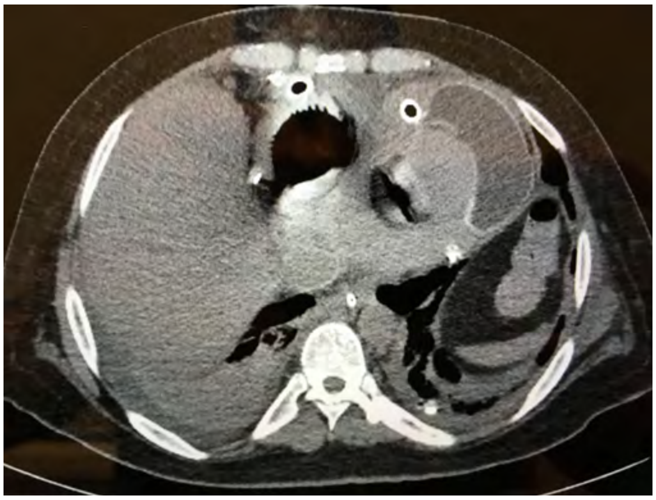

Figure 16. CT axial view showing the implant in the region of the previous apex.

stability. Close monitoring of right atrial pressure and filling characteristics is of paramount importance. Sometimes temporary chest closure with wound vac, or a Gore-tex sheet may be necessary until the chest can be safely closed.

Figure 17. CT coronal view showing the implant in the region of the previous apex.

COMMENT

The TAH-t is a durable device designed to fully support a patient with severe biventricular failure. It is an excellent option in the properly selected patient. LVAD is the most common primary long-term mechanical circulatory support. However, it is not the best treatment for all patients. Right heart failure in patients supported with LVADs leads to worse outcomes [5]. Although there are not randomized data, short-term and midterm survival may be improved with TAH-t compared with BiVAD support [6]. Arabia et al. [4], reported that, patients receiving the TAH-t are generally acutely decompensating (80% on INTERMACS profile 1 or 2, 82% with right ventricular failure, 43% on temporary circulatory support). Despite their seriously condition, with 50% survived to heart transplantation, a success rate similar to LVADs. Likewise, the survival from high-volume centers at 1 year is approximately 66%, and destination therapy LVAD survival at 1 year is 78% [4].

The decision to implant this device is a complex process. We emphasize teaching points, technical aspects and pitfalls of the surgical technique, allowing a less demanding reoperation for orthotopic heart transplantation.

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