



# Implantation Strategies to Protect the Total Artificial Heart for Subsequent Heart Transplantation

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**Abstract:** Re-entry into the chest after one or more previous operative interventions can result in prolonged dissection, blood loss, structural damage, and catastrophic injuries, resulting in MOF and even death. Previous implantation of mechanical circulatory assist devices may lead to development of dense adhesions and solid scar tissue. This is certainly true for cases involving previous placement of the total artificial heart (TAH). Implantation of this device is on the rise, as it is the only viable options for patients with biventricular failure, as the number of heart transplantations is stagnant worldwide. With the new heart transplantation allocation system in the United States, more and more patients with an implanted TAH are waiting for cardiac transplantation. Therefore, patients having an implanted TAH presenting for transplantation are at risk for complications during sternal re-entry or for complications as a result of prolonged ischemic time due to extended times of mediastinal dissection. Thoughtful and preemptive preparation of the surgical field at the time of initial implantation of the TAH has not only the potential, but a proven track record of decreasing operative time, duration of mediastinal dissection as well as risks for complications and adverse events in patients with subsequent heart transplantation. In conclusion, the measures for TAH protection taken at the time of implantation allow for expeditious and safe redo sternotomy, efficient mediastinal dissection, rapid identification and exposure of structures necessary for initiation of cardiopulmonary bypass and finally and importantly expeditious device removal in order to avoid delay in donor organ implantation and prolonged ischemic time.

**Keywords:** Total Artificial Heart, Redo Sternotomy, Heart Transplantation

## 1. Introduction

Re-entry into the chest after one or more previous operative interventions can result in prolonged dissection, blood loss, structural damage, and catastrophic injuries, resulting in MOF and even death [1]. Safe dissection of vital mediastinal structures is crucial for cannulation. Alternative and sometimes emergent cannulation techniques and initiation of cardiopulmonary bypass (CPB) may be required due to difficult and prolonged dissection [2]. Protracted duration of CPB, ensuing coagulopathy, as well as the potential for the need of additional surgical repair of structural injuries may lead to undesirable consequences such as prolonged operation, utilization of blood and plasma

products, end-organ dysfunction, necessity for short-term mechanical circulatory support, prolonged ventilation, as well as extended ICU and hospital stay, and mortality. Previous implantation of mechanical circulatory assist devices especially may lead to development of dense adhesions and solid scar tissue. This is especially true for cases involving implantation of the total artificial heart (TAH). Implantation of this device is on the rise, as it is the only viable options in patients with biventricular failure. The number of heart transplantations is fairly stagnant worldwide. With the new heart transplantation allocation system in the United States, more and more patients with an implanted TAH are waiting for cardiac transplantation. Therefore, more patients presenting for transplantation having an implanted TAH are at risk for complications during sternal re-entry of

for complications as a result of prolonged ischemic time due to extended times of mediastinal dissection. Thoughtful and preemptive preparation of the surgical field at the time of initial implantation of the TAH has not only the potential, but a proven track record of decreasing operative time, duration of mediastinal dissection as well as risks for complications and adverse events in patients with subsequent heart transplantation [3]. Protective measures taken at the time of TAH implantation allow for expeditious and safe sternal re-entry, efficient mediastinal dissection, rapid identification and exposure of structures necessary for initiation of cardiopulmonary bypass and finally and importantly expeditious device removal in order to avoid delay in donor organ implantation and prolonged ischemic time [2-4]. Surgical approaches for the safeguard of the TAH and internal organs have been published previously [3, 4]. Those and similar techniques are used successfully in the pediatric and adult population [5, 6]. A modified surgical strategy for preparation of mediastinal structures especially developed for the TAH at the time of device implantation is presented here. It does facilitate sternal re-entry, mediastinal dissection, explantation of the TAH and timely heart transplantation.

## 2. Surgical Technique

The operation begins with a median sternotomy performed in the routine fashion. Ascending aortic and bicaval cannulation is performed after administration of systemic heparin as usual. The heart is removed at the levels of both ventricles and the TAH implanted as described previously [7]. The protective measures to facilitate mediastinal re-entry at the time of transplantation is based on three concepts. First, the utilization of a Gore (polytetrafluoroethylene (PTFE)) pericardial tissue substitute (20 x 15 cm x 0.1 mm, W. L. Gore & Associates, Flagstaff, AZ). Second, the use of blue polyisoprene bands (BBI; Bioseal, Placentia, CA), and third, the use of surgical grade silicone membrane (0.06 inches thick; Bentec Medical, Woodland, CA). Advanced preparation of the blue bands by standard sterilization packaging and gas sterilization (Sterrad 100S Sterilization System; Johnson and Johnson, Irvine, CA) is executed as described previously [8]. Before the TAH is positioned into the mediastinal cavity, a 0.1 mm thick PTFE sheet is sutured onto the medial aspect of the mediastinum. Prolene sutures are used to secure the PTFE sheet to the areas lateral to the left pulmonary vein. Subsequently, after implantation of the TAH as previously described [7] preparation for future device explantation at the time of transplantation begins before sternal closure. The blue bands are placed circumferentially and freely around aorta, and superior as well as inferior vena cava. Care is taken to cover the entire length of each vascular structure in order to prevent adhesion formation, therefore reducing the necessity for dissecting the structure during the subsequent explantation. These latex free bands minimize adhesion formation and therefore facilitate expeditious exposure and timely cannulation for cardiopulmonary bypass. The band around the superior vena

cava can be trimmed a little narrower in order to reduce the risk of SVC stenosis. An additional advantage of these bands is their blue coloration, which aids in rapid identification of the vascular structure and again, subsequent dissection and cannulation. It is important however, that the placement of the blue bands around these vascular structures is not done in a tight manner. A few centimeters of excess of the free edges of the blue bands placed on top of the vascular structures. The edges are secured with medium metal clips (Autosuture Premium Surgiclip II M-9.75; US Surgical, Norwalk, CT). The upper part of the most cephalad blue band around the aorta is placed onto the innominate vein, thus reducing the risk of injury during subsequent re-entry. Additionally, a piece of the blue band can be positioned into the space between the aorta and the right atrium in order to keep these structures separated. Furthermore, in selected cases another band is used around the pulmonary artery. Alternatively, it can be placed behind its posterior wall in cases of a large and protruding left atrium. Right before sternal closure, additional Gore sheets (the same as used for covering the mediastinum) are utilized to cover the entire TAH device, the right atrium, aorta and both venae cava [3]. The edges of the various sheets are clipped together similarly as described for the blue bands. In order to prevent migration, the membrane covering the right atrium can be secured to the pericardium near the vena cava. Additional metal clips can be placed to secure these sheets to the blue bands if deemed appropriate. In several locations small slits are cut into the Gore membranes in order to facilitate drainage. Drainage tubing per surgeon's preference is placed in a routine fashion and secured. A piece of 1 cm wide surgical silicone membrane is fashioned in the entire length of the sternum. After the sternal wire are placed, it is positioned anterior to the wires and posterior to the sternum. It is important to ensure that the membrane remains in its proper position behind the sternum and does not protrude in between the sternal edges during sternal closure.

## 3. Discussion

It is not uncommon that patients undergoing heart transplantation have had one or more previous operations. It is well established, that these interventions will lead to scar tissue formations, which may render subsequent operations more difficult, if not potentially life threatening. This holds especially true for operations after previous device implantations including the TAH [1, 2, 5, 9, 10, 11]. It is an established concept to prepare for heart transplantation at the time of mechanical circulatory device implantation [2, 3, 5, 7].

Multiple surgical techniques have been introduced to facilitate sternal re-entry, especially after previous device implantations. These include pericardial closure, as well as multiple ways of covering mediastinal structures with various artificial membranes [5, 6, 12-18]. The described techniques have been successfully utilized in the adult and pediatric population, including in patients with previous device

implantations [3, 5, 6, 14, 19]. We have described integrated concepts of complete coverage and protection of previous placed devices and vital structures in order to facilitate safe sternal re-entry [3, 5, 10]. These concepts not only include mediastinal membrane coverage, but also utilize blue bands and the use of a retrosternal silastic membrane [3, 8].

Our technique has been used successfully for over 10 years in multiple institutions and over 200 patients. Preoperative or postoperative antibiotic prophylaxis was not changed.

The first 50 patients who underwent this technique and subsequently transplanted were retrospectively reviewed [3]. For 43 patients, one year data were available. No cultures were performed in 23 of the 50 patients. Two of the remaining 27 patients grew *Staphylococcus epidermidis*. These were considered to be contaminations. *Staphylococcus aureus* from the LVAD pocket, as well as the driveline was cultured in one patient. Long-term antibiotic treatment was initiated in this patient. Another patient grew one colony of *Mycobacterium kansasii* from the TAH aortic conduit. This patient presented with previous aortic dissection and endocarditis. He also was treated with antibiotics. In none of the 50 patients was mediastinitis, infection-related complications or death found [3]. The combined utilization of silicone membranes, blue bands, and thin PTFE sheets allows for safe and expeditious redo sternotomy at the time of transplantation. The use of thicker ( $>0.1\text{mm}$ ) PTFE sheets is known to be associated with scar tissue and adhesion formation. Blue bands are inexpensive and its color allows for easy and rapid identification of crucial vascular structures. Prevention of adhesion formation presents an additional benefit. Rapid access to the aorta, IVC, and SVC is facilitated by inserting umbilical tapes into the edge of the blue bands before their removal. Consequently, this technique aids in timely and easy cannulation for CPB, which in turn may lead to a reduction in patient's operative mortality. The time required for sternal re-entry, mediastinal dissection, separation of the device from surrounding structures, establishment of CPB, and cardiectomy for subsequent HTX can be lowered. In contrast, our own observations and those of others indicate that sternal re-entry in patients with previous device implantations can be tedious and protracted [1, 9]. Even in patients designated for destination therapy, it is not uncommon to have reoperations for device exchanges or cross-over to transplantation. This technique lends itself quite favorable for these scenarios as well. Disadvantages of our technique are a slightly prolonged operative time, the additional cost and the fact that foreign material is left in the mediastinum.

## 4. Conclusion

In conclusion, the measures for TAH protection taken at the time of TAH implantation allow for expeditious and safe redo sternotomy, efficient mediastinal dissection, rapid identification and exposure of structures necessary for initiation of cardiopulmonary bypass and finally and importantly expeditious device removal in order to avoid

delay in donor organ implantation and prolonged ischemic time.

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