First Successful Implantation of the CARMAT Aeson® Total Artificial Heart as a Bridge to Heart Transplantation in Israel

Daniel Ronen MD PhD[1], Alexander Lipey-Diamant MD[2], Ayman Murar MD[2], Amit Korach MD[2], Ehud Rudis MD[2], Ralitsa Stoynova MD[3], Loui Mahameed RN[2], Meirav Goldstein-Luria BA[2], Yuval Shtark BA[2], Mordechai Golomb MD[1], Offer Amir MD[1], and Rabea Asleh MD PhD MHA[1]

[1]Department of Cardiology, Hadassah Medical Center, Faculty of Medicine, Hebrew University of Jerusalem, Jerusalem, Israel
[2]Department of Cardiothoracic Surgery, Hadassah Medical Center, Faculty of Medicine, Hebrew University of Jerusalem, Jerusalem, Israel
[3]Department of Anesthesiology, Hadassah Medical Center, Faculty of Medicine, Hebrew University of Jerusalem, Jerusalem, Israel

KEY WORDS: CARMAT Aeson®, heart failure, mechanical circulatory support, total artificial heart

IMAJ 2026; 28: 324–328

We report the first successful implantation of the CARMAT Aeson® total artificial heart (TAH) in Israel, performed as a bridge to transplantation in a patient with advanced biventricular heart failure and severe right ventricular dysfunction precluding left ventricular assist device (LVAD) therapy. The CARMAT Aeson® TAH is a next generation bioprosthetic device equipped with biological valves, hemocompatible membranes, and an integrated sensor array that enables autoregulation of stroke volume to balance left and right circulation, thereby reducing thrombogenicity and improving physiological adaptation. Following implantation, the patient demonstrated rapid hemodynamic stabilization, complete weaning from inotropes, and marked functional recovery. Remarkably, during the index hospitalization he underwent successful elective inguinal hernia repair under general anesthesia, a procedure previously deemed prohibitive due to high cardiovascular risk. This patient is the first CARMAT TAH recipient to undergoing a non-cardiac surgical procedure. Perioperative interruption of anticoagulation was achieved safely without thromboembolic complications, underscoring the device's biocompatibility and reduced thrombogenicity compared with continuous-flow VADs. The patient was discharged home on postoperative day 61 in an ambulatory state, clinically stable, and remains actively listed for heart transplantation. This case highlights the feasibility and safety of the CARMAT Aeson® TAH in patients with end-stage biventricular failure, with potential advantages over continuous-flow devices, including pulsatile physiology, autoregulation, and reduced risk of bleeding or thrombotic complications. These advantages strengthen its role as an important bridging strategy to heart transplantation.

Advanced heart failure (HF) remains a progressive and fatal condition, with an estimated 80–90% mortality at 2 years despite optimal medical therapy [1]. Hospitalization for decompensation, particularly in the setting of cardiogenic shock requiring inotropes, implies an imminent risk of death. For these critically ill patients, temporary mechanical circulatory support (MCS), including extracorporeal membrane oxygenation (ECMO) or percutaneous axial-flow devices (e.g., Impella, Abiomed, Danvers, MA), can provide short-term hemodynamic stabilization. However, their use is limited by time-dependent complications, such as bleeding, infection, and thrombosis.

Heart transplantation (HT) remains the gold standard for patients with end-stage HF who are refractory to medical therapy. However, a persistent shortage of donor organs, particularly in Israel, severely limits its availability. Moreover, long-standing HF often leads to progressive end-organ dysfunction, rendering many patients ineligible for HT. Continuous-flow LVADs have revolutionized therapy for patients with isolated left ventricular (LV) failure, providing both bridge-to-transplant and destination therapy options. Nonetheless, their efficacy depends on preserved right ventricular (RV) function. Chronic LV failure frequently results in pulmonary hypertension and RV dysfunction, leaving a narrow therapeutic window for LVAD implantation. Conse-

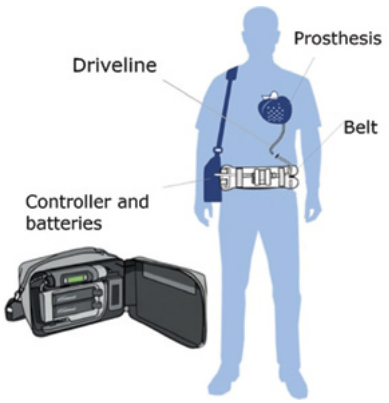
quently, many patients are referred to advanced HF centers only after biventricular failure has developed. In patients with severe biventricular dysfunction as well as those with restrictive cardiomyopathies or complex structural abnormalities, a TAH may serve as the only durable option for bridging to HT.

To address these limitations, CARMAT developed the Aeson® TAH, a pulsatile, bioprosthetic device designed to provide physiologic hemodynamic adaptation and enhanced hemocompatibility [Figures 1A, 1B, 1C]. First implanted in 2015 [2] and approved in Europe in 2022 as a bridge-to-transplant therapy, the Aeson® TAH has now been used in over 100 patients, with reported support durations exceeding 9 months. We report the first implantation of the CARMAT Aeson® TAH in Israel presenting a milestone in the adoption of advanced MCS technologies in regions with limited donor organ availability, highlighting the expanding role of the TAH in addressing unmet clinical needs.

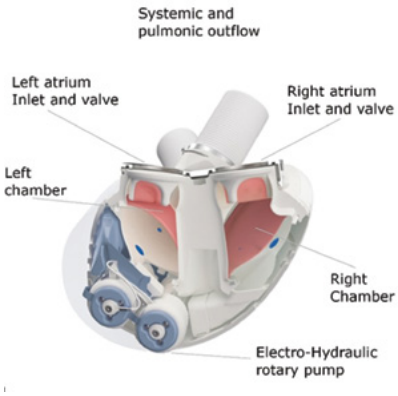
Figure 1. CARMAT Aeson® total artificial heart

TAH = total artificial heart

[A] Schematic illustration of the Aeson® TAH components, including the implanted device, driveline, and wearable mobile controller



[B] Internal mechanism showing the two rotary pumps, left and right chambers, and inflow and outflow connections



[C] CARMAT Aeson® TAH prior to implantation

[D] Ambulatory patient at first follow-up at Hadassah Medical Center, three weeks after hospital discharge

PATIENT DESCRIPTION

A 63-year-old man with severe ischemic biventricular cardiomyopathy was admitted in April 2025 to Hadassah Medical Center with decompensated HF. His past medical history included hypertension, dyslipidemia, heavy smoking, and a large inguinal hernia.

His cardiac history included ischemic heart disease, starting with percutaneous coronary intervention with drug-eluting stent to the left anterior descending (LAD) artery due to acute myocardial infarction in 2006. Consequently, he underwent coronary artery bypass grafting with venous grafts to the LAD, obtuse marginal, and right coronary artery. In 2015, an implantable cardioverter defibrillator (ICD) was placed and later upgraded to a cardiac resynchronization therapy with a defibrillator due to complete left bundle branch block. In 2021, he underwent mitral transcatheter edge-to-edge repair (m-TEER) for persistent HF symptoms and severe mitral regurgitation. Post-m-TEER echocardiography revealed a severely dilated LV (LVEF 20–25%), moderately dilated RV with reduced function, severe bi-atrial enlargement, moderate residual MR, mild mitral stenosis, moderate-to-severe tricuspid regurgitation, and moderate pulmonary hypertension.

He was maintained for several years on maximally tolerated guideline-directed medical therapy (spironolactone, bisoprolol, dapagliflozin, sacubitril/valsartan, and daily high-dose oral furosemide).

CLINICAL DETERIORATION

Starting in July 2024, the patient experienced progressive worsening of HF symptoms, necessitating multiple hospitalizations for decongestion. In April 2025, he presented with dyspnea, peripheral edema, and syncope.

On admission, he was tachycardic (115 bpm), hypotensive (98/52 mmHg), and hypoxemic (88% on room air). Examination revealed elevated jugular venous pressure, bibasilar crackles, and bilateral pitting edema. N-terminal pro B-type natriuretic peptide was markedly elevated (25,587 pg/ml), creatinine was 1.2 mg/dl, lactate was elevated at 32 mg/dl (normal range 4.5–19.8 mg/dl), and troponin was mildly elevated (~900 ng/l). Echocardiography showed severely dilated LV end diastolic diameter 8.6 cm, LVEF ~15%, moderate-to-severe RV dysfunction, severe bi-atrial enlargement, moderate MR with TEER device in situ, severe TR, and moderate-to-severe pulmonary hypertension.

Right heart catheterization demonstrated elevated filling pressures and combined pre- and post-capillary pulmonary hypertension: right atrial pressure 20 mmHg, pulmonary artery pressure 54/30 (mean 38) mmHg, pulmonary capillary wedge pressure 26 mmHg, cardiac index 1.7 L/min/m², pulmonary vascular resistance 2.9 woods units, and pulmonary artery pulsatility index of 1.2. A value < 2 indicates a markedly increased risk of RV failure post LVAD implantation.

Despite aggressive sequential diuretics and inotropes (milrinone, levosimendan, and dobutamine), the patient remained in severe biventricular failure with New York Heart Association (NYHA) class IV symptoms and dependence on high-dose loop diuretics. He presented with recurrent non-sustained ventricular tachycardia and progressive end-organ congestion.

MULTIDISCIPLINARY DECISION-MAKING

A heart team, including HF cardiologists, imaging specialists, cardiothoracic surgeons, anesthesiologists, and intensivists, determined the patient was unsuitable for LVAD due to severe RV failure and anatomical limitations precluding biventricular VAD. He was listed for urgent HT, but persistent inotrope and diuretic dependence, together with arrhythmic instability, rendered him unlikely to survive until a suitable donor would become available. The team therefore elected for implantation of a CARMAT Aeson® TAH as a bridge to HT.

SURGICAL PROCEDURE

First the right femoral vessels were surgically exposed for cardiopulmonary bypass and standby ECMO support. Following redo-sternotomy, the ICD system was explanted. Both ventricles and native atrioventricular valves were excised. The LA appendage was ligated, and a catheter was introduced into the LA for postoperative pressure monitoring.

Aeson® prosthetic valve rings were sutured in place of the native annuli, and the device baseplate was secured to the atria. Anastomoses to the pulmonary artery and ascending aorta were fashioned with Dacron grafts. The driveline was tunneled to the right upper abdominal quadrant. After de-airing, the TAH was gradually brought to full support (5 L/min), and cardiopulmonary bypass was weaned.

Due to persistent mediastinal oozing, the chest was left temporarily open with packing. The patient was transferred to the cardiothoracic surgical intensive care unit on low-dose norepinephrine. Initial TAH performance was satisfactory (4.5–6 L/min, HR 80–120 bpm, LA pressure 8–12 mmHg, central venous pressure 14–18 mmHg, normal lactate). The following day, clot evacuation and definitive sternal closure were performed. A Gore-Tex patch was placed over the right pericardium to limit adhesions. The patient was extubated within 24 hours and weaned off vasopressors, maintaining stable mean arterial pressure (70–80 mmHg).

POSTOPERATIVE COURSE

The patient gradually mobilized with physiotherapy, but his postoperative course was complicated by persistent serosanguinous drainage and a large pleural effusion requiring chest tube thoracotomy. On postoperative day 15, a sudden drop in systemic pressure with TAH alarm (increased bag pressure, reduced flow) prompted emergent re-sternotomy. A large clot compressing the RA was evacuated, immediately normalizing device function and hemodynamics. The chest was re-closed without further complications.

Recovery was progressive. By postoperative day 43, the patient underwent elective repair of his large inguinal hernia under general anesthesia, which was uneventful. He continued to demonstrate clinical and functional improvement, achieving independent ambulation.

ETHICS

Patient-signed informed consent was received prior to publication. Publication was approved by the institutional review board in accordance with the principles of the Helsinki declaration.

OUTCOME

On postoperative day 61, the patient was discharged home in stable condition, fully supported by the TAH. During regular follow-up visits to the heart failure outpatient clinic over 6 months, he was found to be clinically well, with functional improvement to NYHA class II. [Figure 1D]. While in good clinical condition at home, a suitable donor heart became available. The patient subsequently underwent HT at another medical center. The transplant procedure was technically complex and was complicated by significant intraoperative blood loss and prolonged cardiopulmonary bypass time. Following initiation of cardiopulmonary bypass, the patient sustained severe anoxic brain injury and, despite intensive supportive care, died shortly thereafter. Importantly, the fatal complication occurred during the transplant surgery and was unrelated to the prior CARMAT Aeson® TAH implantation or device performance.

COMMENT

Despite significant advances in medical and device therapy, advanced (stage D) HF still affects approximately 10% of patients with HF. To date, HT remains the gold standard therapy for patients with stage D HF, offering the best long-term outcomes for eligible patients. However, donor availability is a major limitation. According to the Israeli Transplant Center Annual Report, only 31 patients underwent HT in 2022, while 97 remained on the waiting list. This imbalance highlights the importance of durable MCS as a bridge to HT.

In patients with isolated LV failure, long-term MCS is most often achieved with an LVAD. However, successful LVAD therapy requires preserved RV function. RV failure (RVF) occurs in up to 20% of patients post-LVAD implantation [3] and remains one of the strongest predictors of adverse outcomes, including mortality. While temporary RV support can be achieved with devices such as Impella RP (Abiomed, Danvers, MA, USA), ProtekDuo (LivaNova, London, UK), or VA-ECMO, no durable RV assist device is commercially available. Thus, in cases of biventricular failure, the only long-term options are either implantation of a TAH or off-label use of two HeartMate 3 pumps (BiVAD/HM6) as a biventricular assist device. Before our case, the only available option in Israel was the use of HeartMate 6. However, this option has several limitations, including the need for vitamin K antagonist anticoagulation, no synchronization between the two devices, the need for two drivelines and two controllers, and battery packs.

The currently available TAH technologies include: CARMAT Aeson® (Carmat SA, Vélizy-Villacoublay, France), a bioprosthetic, sensor-driven pulsatile TAH; Syncardia CardioWest TAH (SynCardia Systems Inc., Tucson, AZ, USA), a pneumatically driven pulsatile device approved as a bridge to HT and destination therapy under humanitarian exemption; Berlin Heart EXCOR (Berlin Heart AG, Berlin, Germany), a paracorporeal pulsatile device mainly used in pediatrics; and BiVACOR (BiVACOR Inc., Houston, TX, USA), a magnetically levitated rotary TAH with first-in-human implantation reported in 2024.

The CARMAT Aeson® TAH represents a new generation of bioprosthetic TAH, offering several distinct advantages over earlier devices. First, the incorporation of bioprosthetic valves and hemocompatible membranes reduces thrombogenicity, allowing anticoagulation with only a prophylactic dose of low-molecular weight heparin [4]. Second, an integrated sensor array enables autoregulation by dynamically adjusting stroke volume to coordinate left and right circulatory flows. Third, device design improvements, including a single driveline, a smaller and lighter external power pack, and the feasibility of outpatient discharge, contribute to a markedly improved quality of life for patients. In a recent multicenter series of 10 patients, 6 were successfully transplanted (support duration 27–191 days), 2 remained on support beyond 240 days, and 2 died [2]. Other reports describe successful bridging after 243–270 days [5]. Importantly, several patients demonstrated functional recovery, including improvements in renal function, pulmonary vascular resistance, and exercise capacity [5]. Up to 60% of Aeson® TAH recipients have been discharged home while awaiting HT [5].

Our patient presented with acute decompensated biventricular HF (INTERMACS profile 3). Severe RV dysfunction precluded isolated LVAD therapy, while anatomical constraints and the complexity of management rendered BiVAD implantation unfeasible. Given the long HT waiting times in Israel, the Aeson® TAH was considered the optimal bridge strategy. Following TAH implantation, the patient achieved full weaning from inotropes, normalization of hemodynamics, and marked functional improvement. Remarkably, he became fit enough to undergo elective inguinal hernia repair during the index hospitalization, a procedure previously deemed prohibitive given his markedly increased cardiovascular

risk. To the best of our knowledge, this represents the first reported case of a CARMAT TAH recipient undergoing a non-cardiac surgical procedure. Anticoagulation was temporarily discontinued around the time of surgery without any complications. This procedure represents a significant advance compared with patients supported by LVADs, in whom interruption of anticoagulation is often associated with increased thrombotic risk. Furthermore, the pulsatile physiology of the CARMAT TAH may mitigate some of the well-recognized complications of continuous-flow devices, such as acquired von Willebrand factor deficiency and gastrointestinal bleeding. The patient was subsequently discharged home on postoperative day 61 following TAH implantation.

The patient maintained stable device function and meaningful functional status for 6 months while awaiting transplantation. Although a suitable donor heart ultimately became available, the subsequent transplant procedure was surgically complex and complicated by intraoperative events that led to a fatal neurologic injury. While the overall course was ultimately unfavorable, the preceding months of stable outpatient support demonstrated the capacity of the CARMAT Aeson® TAH to provide durable hemodynamic stabilization and quality-of-life improvement in patients with otherwise limited therapeutic options. Notably, the adverse event occurred during transplantation and was not attributable to device malfunction or TAH-related complications.

This case illustrates the feasibility of Aeson® TAH implantation in Israel and reinforces its role as a life-saving bridge for patients with biventricular failure who are ineligible for LVAD therapy. Beyond serving as a bridge to HT, TAH implantation may also serve as a potential bailout strategy in cases of refractory RVF post-LVAD. In healthcare systems with limited donor organ availability, the CARMAT Aeson® may provide a promising alternative for extending survival and improving quality of life in end-stage HF cases. This approach was later adopted by the Sheba Medical Center for another patient with biventricular failure who was supported with the CARMAT TAH as a bridge to heart transplantation who underwent successful heart transplantation during the index hospitalization, prior to hospital discharge.

It should be noted that after the implantation of our patient, the CARMAT company encountered financial difficulties, requiring a temporary halt in operations. However, as of December 2025, the company announced the intention to resume operations under new ownership.

Correspondence

Prof. R. Asleh
Dept. of Cardiology, Hadassah Medical Center, Faculty of Medicine, Hebrew University of Jerusalem, Jerusalem 9112001, Israel
Phone: (972-2) 6770-6564
Fax: (972-2) 641-1028
Email: rasleh@hadassah.org.il

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Capsule

HLA class I signal peptide variation predicts strength of NKG2A⁺ NK cell response and disease risk

Lin et al. showed that polymorphisms in HLA class I signal peptides influence the interaction with HLA-E and modulate inhibitory signaling through NKG2A on natural killer (NK) cells. Variations in these peptides altered the strength of NK cell responses to missing-self signals, thereby affecting immune surveillance. These genetic differences were associated with susceptibility to infectious, inflammatory, and autoimmune diseases. The findings highlight a previously underappreciated layer of immune regulation linking HLA genetics to innate immune function and disease risk.

Nat Immunol 2026; 27: 776
Eitan Israeli