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Article

Initial Clinical Experience with Implantation of a New Left Ventricular Assist Device HeartCon

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Abstract

Objective: Heart failure is a major health problem worldwide. We report the initial experience of a new left ventricular assist device (LVAD) Heartcon—a centrifugal pump of magnetic-fluid suspension rotor integrated with the pump and machine. From September 2020 to March 2023, HeartCon was implanted in a total of 78 cases throughout China, 27 were implanted in TEDA International Cardiovascular Hospital. **Methods**: The patient data collected from the medical record included patient demographics, surgical and cardiopulmonary bypass (CPB) data, doses of transfused red blood cells, mechanical ventilation time (h), intensive care unit (ICU) stay time (d), and cardiac function indices assessed by echocardiography, 6-minute walk tests, and N-terminal pro brain natriuretic peptide (NT proBNP) values. **Results**: All patients were in New York Heart Association (NYHA) grade IV before surgery and 21 had a dilated cardiomyopathy. All patients survived the surgery. One patient underwent heart transplantation 10 months after the implantation. Eight patients reported adverse event events. The duration of mechanical ventilation after operation was 37.8 $\pm$ 52.0 h. The incidence of hemorrhagic stroke was 7.4% and the incidence of mediastinal infection was 7.4%. At 90 day followup, 25 patients were in NYHA grade I and the other 2 patients were in grade II. **Conclusion**: We conclude that HeartCon implantation is a safe and useful LVAD for treatment of end-stage heart failure. It provides a shorter duration of mechanical ventilation time, and a lower incidence of hemorrhagic stroke and mediastinal infection.

Keywords

HeartCon; left ventricular assist device; extracorporeal circulation; heart failure

Introduction

A recent study involving patients with heart failure in 195 countries from 1990 to 2017 [1] reported that the number of patients with heart failure worldwide almost doubled from 33.5 million to 64.3 million and that China accounted for nearly one-third of these new cases. Once heart failure is diagnosed, the mortality rate within 5 years is as high as 50% [2] and nearly 10% of the patients will develop end-stage heart failure. These patients have an extremely poor quality of life with a 1-year mortality rate of 25% to 50% [3,4]. Although heart transplantation provides eligible patients with good quality of life, and better survival, the lack of donors and long-term waiting lists limit the availability of heart transplantation.

Mechanical circulatory support (MCS) was developed to limit this shortcoming. There has been great progress in the development of left ventricular assist devices (LVADs) for MCS in the past half century for use as a bridge to transplantation and destination therapy. The first generation of LVADs were pulsatile pumps, which were large in volume and high in power consumption. At present, the excor pneumatic pump from Berlin Heart still provides ventricular assist for some children. However, it is difficult for patients to be discharged from the hospital. The second generation of devices is the mechanical support pump. It uses the mechanical bearing to support the rotation of the rotor; a representative product is HeartMate II. However, it has had mechanical issues and is prone to thrombus formation. The third generation is the suspension pump. It is suspended by the magnetic force of a permanent magnet or the buoyancy of a liquid floating bearing. The representative product is HeartMate III. Compared with the second generation, there are significant advantages of the suspension pump in terms of survival the occurrence of stroke, and the need for pump replacement [5].

The Heartcon blood pump (Fig. 1) is a centrifugal pump with the magnetic-fluid suspension rotor integrated with the pump and machine and is jointly developed by China Aerospace and TEDA International Cardiovascular Hospital. It is connected to an external controller via a per-

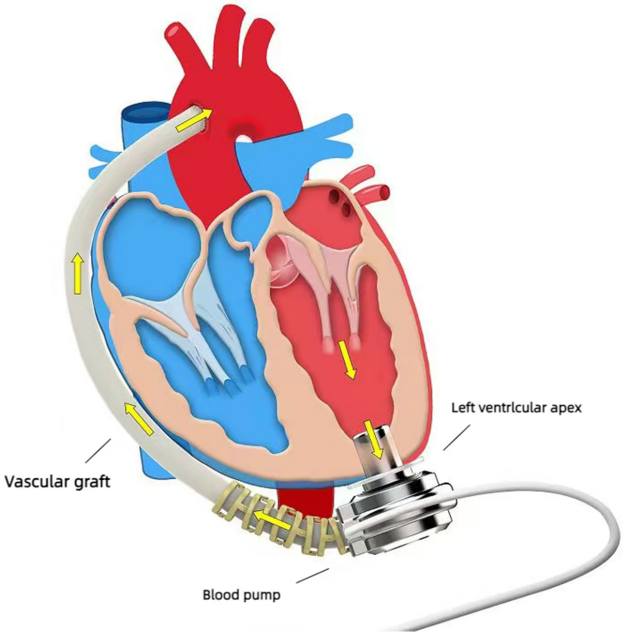

Fig. 1. Schematic diagram of HeartCon implantation (provided by Rocor Medical Technology Co., Ltd.). Yellow arrows: the blood flow direction.

cutaneous lead. The controller (Fig. 2) is powered by an external battery or power adapter and can control the blood pump to set the operating speed. The Heartcon controller weighs only 340 g and the battery weighs 590g, each battery lasts for 8 to 10 hours. Therefore when patients go out, they can put two batteries into the bag and carry them on both sides of the armpit. At the same time, the controller waist bag can be used to fix the controller at the waist for daily carrying (Fig. 3). In March 2009, the 18th Research Institute of China Academy of Launch Vehicle Technology launched the research of the Heartcon system. In 2012, animal experiments were carried out at TEDA International Cardiovascular Hospital, and a total of 48 animal experiments were completed. From October 2017 to June 2018, the Heartcon was inserted into six sheep and all sheep survived for more than 90 days; one of them survived for 180 days. In August 2020, the Center for Drug Evaluation of National Medical Products Administration, China approved 50 cases of 90-day bridge to transplant (BTT) clinical trials. On 15 September 2020, the first implantation was carried out in TEDA International Cardiovascular Hospital. As of 15 March 2023, a total of 78 cases of Heartcon implantation have been performed throughout China, 27 of which were completed at TEDA International Cardiovascular Hospital.

The aim of this study was to report the initial results of the first group of HeartCon implantations in a single center with emphasis on management of cardiopulmonary bypass (CPB) during the HeartCon implantation.

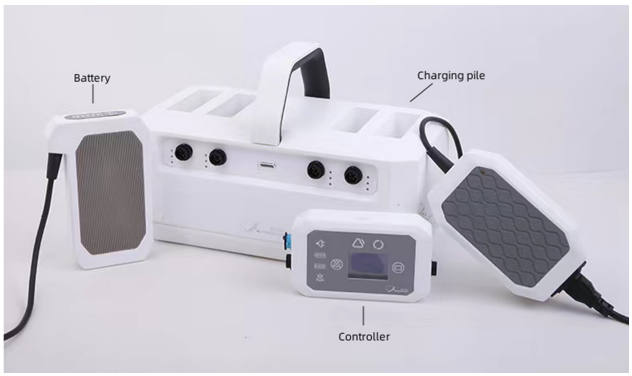

Fig. 2. Controller and battery of HeartCon.

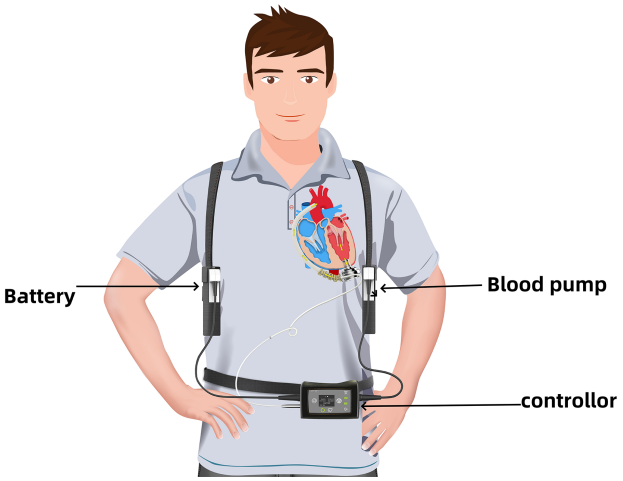

Fig. 3. Schematic diagram of HeartCon *in vivo* (provided by Rocor Medical Technology Co., Ltd.).

Materials and Methods

Study Subjects

From 15 September 2020, to 15 March 2023, HeartCon was implanted in a total of 78 cases throughout China, 27 of which were implanted in our hospital. HeartCon has been the only LVAD used in our hospital.

The inclusion criteria are as follows:

1. age ≥18 years, male or female.
2. body surface area (BSA) ≥1.2 m^2.
3. clinical diagnosis is end-stage heart failure ineffective with drug treatment.
4. voluntary participation in this clinical trial.

The exclusion criteria are as follows:

1. not a candidate for surgery and anticoagulation therapy.
2. severe right ventricular failure.
3. severe cerebral vascular stenosis, or a history of stroke or cerebral hemorrhage within 90 days before operation.

Table 1. Patients' data.

Gender	Male (n = 16)	Female (n = 6)
Age (yrs.)	48.13 ± 15.97	49.33 ± 17.35
Height (cm)	174.53 ± 3.91	163.33 ± 6.86
Weight (Kg)	71.03 ± 16.38	67.80 ± 22.79
Body surface area (m^2)	1.85 ± 0.23	1.62 ± 0.15
NYHA classification (grade)	IV	IV
Left atrial internal diameter (mm)	50.80 ± 7.30	46.70 ± 7.40
Left ventricular end-diastolic internal diameter (mm)	78.30 ± 10.53	72.20 ± 7.60
Ejection fraction (%)	23.10 ± 6.62	22.10 ± 6.30

NYHA, New York Heart Association.

4. uncontrolled infection.

5. severe hepatic or renal dysfunction.

6. moderate to severe aortic regurgitation.

7. pulmonary vascular resistance >400 dynes/sec /cm^5.

8. mental disorders, psychological disorders, or cognitive impairment, and cannot cooperate with the treatment.

9. the presence of other severe, advanced disease, and malignant tumors.

10. refused to participate in this study.

The study was conducted in accordance with the Declaration of Helsinki, and approved by the Institutional Review Board of TEDA International Cardiovascular Hospital ([2019]-1126-1, approved on 19 November 2019). All 27 patients signed an informed consent according to the process, recorded all relevant information and reported adverse event (AE) according to regulations. The patients were followed up for at least 90 days after the operation. The clinical data of the patients are detailed in Table 1.

Surgical Procedures

The blood pump was placed in a 5% glucose heparin solution to test whether it works normally. The grafted vessel was clamped with hemostatic forceps, and the inflow port was covered with the rubber cap. A median sternotomy was performed. Cardiopulmonary bypass was routinely established with cannulation of the aorta, the superior vena cava, and the inferior vena cava. Cardiopulmonary bypass was established when the activated clotting time (ACT) was greater than 420 seconds. When the temperature was reduced to the target temperature (32–33 °C), the ascending aorta was cross-clamped, and the aortic root was perfused with cardioplegic solution. When the cardiac arrest was satisfactory, ice slush was used to protect the myocardium. The position of suture ring was marked by the marking pen and the hole was punched at the cardiac apex. The suture ring was continuously sutured and fixed (Fig. 4). After removing the rubber cap of the blood pump, the inflow tract of the blood pump was placed into the suture ring after fully evacuating the air, and the outflow tract angle was adjusted. The suture ring was then tightened with the screwdriver (Fig. 5). The distal end of the graft vessel was anastomosed to the ascending aorta 2 cm away from the greater curvature of the ascending aorta and the air was evacuated (Fig. 6). During this period, carbon dioxide was blown into the surgical field. The blood pump was started with an initial speed setting of 2000 rpm. The ascending aorta was opened, and the volume, CPB flow, and blood pump parameters were adjusted under ultrasound guidance until the circulation was stable, and then CPB was gradually weaned.

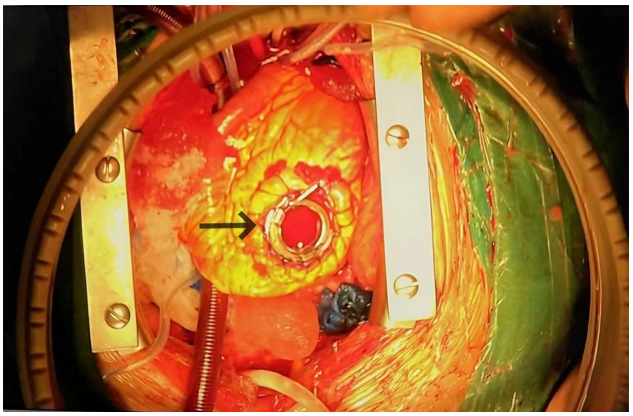

Fig. 4. When the cardiac arrest was satisfactory, ice slush was used to protect the myocardium. The position of suture ring was marked by the marking pen and the hole was punched at the cardiac apex. The suture ring was continuously sutured and fixed. Black arrow: the position of suture ring.

CPB Management

Selection of priming solution. According to whether the valve needed to be treated, mild hypothermia combined with CPB (heart fibrillation) or a moderate hypothermia CPB (cardiac arrest) technique was selected. Instead of colloid, we used a crystalloid compound 1000 mL (Baxter Medical Supplies Co., Ltd., Shanghai, China) during the priming period and added 20% albumin (Behring, Marburg, Germany) 40–60 g with reference to the patients' preoperative albumin level to reduce the inflammatory reac-

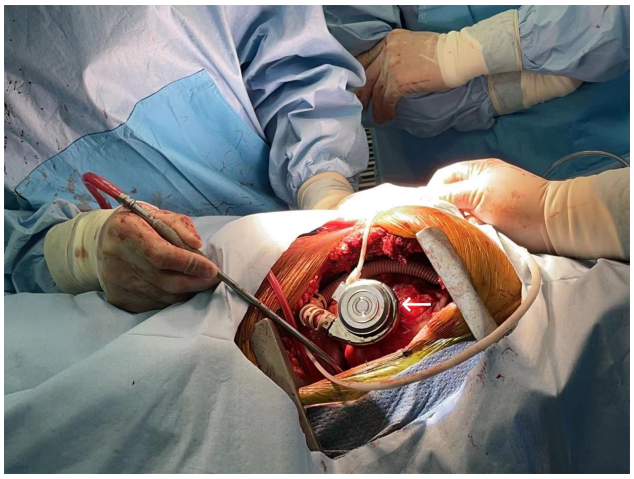

Fig. 5. The view after the implantation of HeartCon. After removing the rubber cap of the blood pump, the inflow tract of the blood pump was placed into the suture ring after fully exhausting the air and the outflow tract angle was adjusted. The suture ring was then tightened with the screwdriver. White arrow: the HeartCon pump.

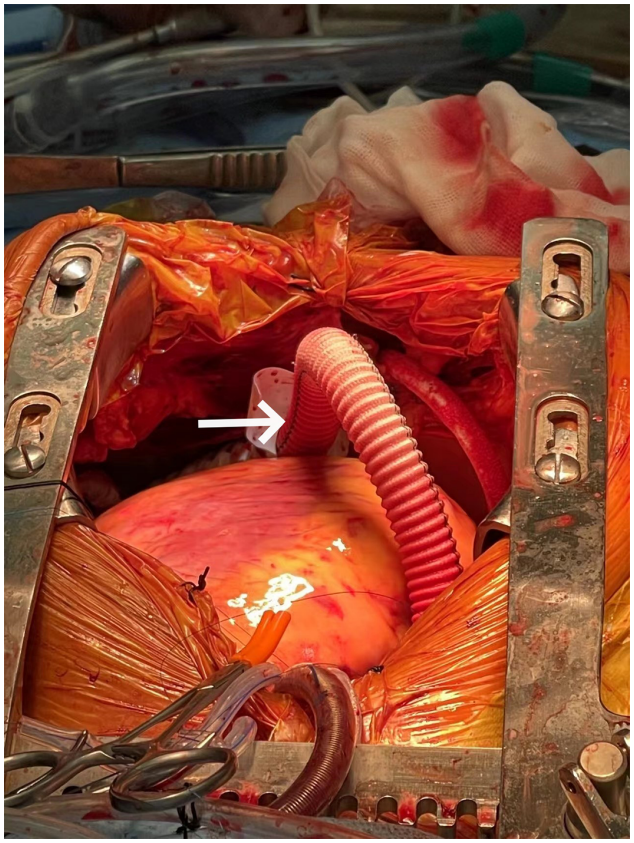

Fig. 6. The view of the graft. The distal end of the graft was anastomosed to the ascending aorta at about 2 cm away from the great curvature of the ascending aorta and de-air was completed. White arrow: the graft which was anastomosed to the ascending aorta.

tion and the need for postoperative red blood cell transfusions [6–8]. We used Ulinastatin (tianpuluoan, Guangdong, Guangzhou, China) 20,000 U/Kg and low-dose methylprednisolone sodium succinate (Pfizer Manufacturing Belgium NV, Brussels, Belgium) 500 mg to stabilize cell membranes and reduce the inflammatory response for organ protection [9,10].

Use of Cardioplegic Solution

We used del Nido cardioplegia (Pittsburgh, PA, USA) for myocardial protection, with 20 mL/Kg for patients weighing less than 50 Kg and 1000–1200 mL for patients weighing more than 50 Kg (flow rate 240–350 mL/min, pressure 180–300 mmHg). A single dose was used for the initial cardiac arrest of 60–90 min, and ice slash was placed on the surface of the heart. If ventricular electrical activity was seen, more cardioplegia was added at any time.

Management during CPB

We routinely used an ascending aortic cannula for arterial perfusion and superior and inferior vena cava cannula for drainage. The mean arterial pressure was maintained at 50–80 mmHg during CPB, ensuring renal perfusion so that the cerebral oxygen saturation (NIRS) was not less than 80% of the basal value (before induction of anesthesia). After the start of CPB, the heart was emptied, and vacuum-assisted venous drainage was applied, and the main pump flow was moderately reduced. After the LVAD was placed, the blood flow was gradually returned to the pump using transesophageal echocardiography (TEE) guidance. Adequate left ventricular volume was required during this period, and CO_2 was filled into the surgical field to reduce the risk of air embolism. During CPB, we used the perfusion needle at the root of the aorta to maintain the left ventricular volume. After opening the aorta, the root of the perfusion needle was used for deairing with suction. During this time, we ensured that there was an adequate volume in the left ventricle to avoid vacuuming. Once the left atrial pressure was lower than 6 mmHg, the possibility of vacuuming in the left ventricle dramatically increases.

Indications for Discontinuation of CPB

The patients were in end-stage heart failure preoperatively with a heavy volume load, low left heart function, hypoproteinemia, and insufficient effective circulating blood volume. Therefore, ultrafiltration according to the patients' blood volume was required to reduce the patients' volume load before coming off CPB. We made changes in right and left heart volume load under the guidance of ultrasound. On average, 12 mmHg of central venous pressure (CVP) in the early stage and 10 mmHg after stabilization were maintained whereas the left atrial pressure (LAP) was kept 2–3 mmHg greater than the CVP. The ventricular septum

was kept at a median position with an average arterial pressure no less than 60 mmHg. In order to maintain an adequate volume postoperatively, we routinely used ultrafiltration and zero balance ultrafiltration intraoperatively and modified ultrafiltration after CPB off to achieve the following goals: hematocrit $\geq$10 g/dL, colloid osmotic pressure (COP) $\geq$25 mmHg, lactic acid (Lac) <4 mmol/L, mixed venous oxygen saturation (SvO_2) $\geq$60%, and urine volume $\geq$1 mL/Kg/h.

Pump Speed Adjustment and Anticoagulation

The location of the ventricular septum, and the size and function of the left and right heart were assessed with echocardiography. After the operation, the blood pump speed was adjusted to be more than 2400 r/min, and the target was that the ventricular septum was in the median and the aortic valve was open at 1:1~3:1. When the tissue perfusion was satisfactory, the target mean arterial pressure (MAP) was maintained to be less than 75 mmHg. After surgery, IV heparin (Changzhou Qianhong Biopharma Co.,Ltd, No. H32022088, Changzhou, China) was given as a bridge until warfarin (Finnish Orion Group Orion Pharmaceutical factory, No. H20171095, Espoo, Finland) anticoagulant therapy was instituted. A step-by-step anticoagulant strategy was adopted. Following surgery, when the daily chest drainage was less than 0.5 mL/kg/h for 3 hours, heparin was started through the intra-venous pump with an activated partial thromboplastin time (APTT) maintained at 40~50 s. If the chest drainage was acceptable on the 1st day after surgery, the APTT was maintained at 50~60 s and oral administration of warfarin was started. The international normalized ratio (INR) was maintained between 2.0 and 2.5 and heparin was discontinued.

Statistical Analysis

SPSS 24.0 software (IBM-SPSS Statistics, Chicago, IL, USA) was used to analyze the data, and the measurement data conforming to normal distribution were expressed as mean $\pm$ standard deviation ($\bar{x} \pm$ SD), and independent samples *t*-test was used for comparison between groups; non-normally distributed data were expressed as quartiles, and the rank sum test was used; count data were expressed as cases or percentages and χ^2 test or exact probability method was used. $p < 0.05$ was considered a statistically significant difference.

Results

Patients

Among the 27 patients, 20 were male and 7 were female, aged 20–67 years. The NYHA classification of cardiac function prior to surgery in all patients was grade IV.

Table 2. Preoperative information of the patients.

Project	Male	Female
Preoperative diagnosis (cases)		
Dilated cardiomyopathy	16	5
Indeterminate cardiomyopathy (myocardial densification insufficiency)	1	1
Ischemic cardiomyopathy	1	0
Cardiac arrhythmia	2	1
Previous history (cases)		
Family history	2	1
Hypertension	4	0
Hyperlipidemia	1	0
Diabetes	1	2
Smoking history	9	2
Drinking history	5	3
Pulmonary hypertension	6	2
History of myocardial infarction	2	0
CABG history	1	0
Valve status (cases)		
AI+MI+TI	1	1
MI+TI	9	1
MI	2	1

AI, Aortic regurgitation; MI, Mitral regurgitation; TI, Tricuspid regurgitation; CABG, coronary artery bypass grafting.

The preoperative diagnosis was predominately dilated cardiomyopathy (21 patients). The other patients were diagnosed with an arrhythmia in 3, undetermined cardiomyopathy (incomplete myocardial dysfunction) in 2, and ischemic cardiomyopathy in 1. These patients had an increased past history of smoking, alcohol consumption, and pulmonary hypertension, 3 had a family history of heart disease (2 cases of dilated cardiomyopathy and 1 case of myocardial dysfunction). Two of the patients had a history of preoperative myocardial infarction and one of them had undergone coronary artery bypass grafting before the LVAD was inserted. Patients also had tricuspid valve regurgitation (10 patients), including 2 patients with concomitant aortic regurgitation. All patients had left atrial and left ventricular enlargement and reduced ejection fraction (EF) (Tables 1,2).

Operation Approach

All patients had a median sternotomy except one who had previous a coronary artery bypass grafting (CABG) and therefore the surgery was performed through the left 6th intercostal space with fibrillation under CPB. The remainder of the patients had del Nido cardioplegic arrest as previously mentioned in the “Methods”. The rate of spontaneous heart resuscitation was 66.7%. The details are shown in Table 3.

Table 3. Parameters in CPB.

Parameters	Results
CPB time (min)	130.86 ± 33.07
Aortic clamping time (min)	77.10 ± 28.45
Spontaneous resuscitation rate (%)	66.70
Urine output during the CPB (mL)	658.10 ± 481.79
Ultrafiltration fluid volume during the CPB (mL)	2476.19 ± 1528.37
Red blood cell transfusion volume during the CPB (mL)	542.86 ± 540.90

CPB, Cardiopulmonary bypass.

Table 4. Postoperative parameters and AE events.

Parameters	Results
Duration of mechanical ventilation (h)	37.84 ± 51.96
ICU Stay (d)	9.80 ± 3.49
Hospital death	0
Heart transplantation	1
Remove LVAD	0
AE Events	
Intracranial hemorrhage	2
Mediastinal infection	2
Renal failure	1
Malignant arrhythmia	1
Acute cholecystitis	1
Spleen rupture	1

AE, Adverse event; ICU, Intensive care unit; LVAD, Left ventricular assist device.

Patient Outcomes

All patients survived with no operative mortality and all were alive at 90 day follow-up. One patient underwent heart transplantation 10 months after the implantation. A total of 8 patients had AE events postoperatively, including cerebral hemorrhage (2 patients). One had cerebral hemorrhage in the right parietooccipital lobe 36 days after surgery and recovered after treatment. Another patient developed a hematoma in the left frontal lobe near the anterior horn of the lateral ventricle 92 days postoperatively, and had bleeding into the ventricular system. The family wanted no further treatment. Two patients had infections. One of them had septic shock 7 days postoperatively and the other had a mediastinal infection 63 days postoperatively. Both were successfully treated and discharged. Other complications included: renal failure after LVAD insertion (1), malignant arrhythmia resulting in hypoxic ischemic encephalopathy (1), acute exacerbation of cholecystitis (1), splenic rupture due to an unknown etiology. These patients were successfully treated and discharged (Table 4). Table 5 summarizes the details of the postoperative results.

Discussion

Based on more than 50 years' experience in aerospace servo technology, the core component of the domestic HeartCon implantable magnetic-hydrodynamic suspension ventricular assist device independently developed by Rocket Heart Technology Co., Ltd. China is a centrifugal blood pump highly integrated with a double stator disc motor. Under the in-fluence of centrifugal force, blood is pumped from the left ventricle through the inlet tube and pumped into the aorta through the graft vessel as the outlet at a certain pressure and flow rate. The Rpm is 2000~3600 rpm, and the maximum output flow is 10 L/min. HeartCon can provide short-term assistance as a bridge to transplantation for patients suffering from end-stage heart failure and facing a high risk of death.

HeartCon adopts a hybrid suspension method of passive permanent magnet suspension and dynamic pressure liquid suspension, integrating a centrifugal pump and a disc motor. The outer diameter of the impeller is 36 mm, which increases the area of the liquid floating bearing by 15%, thereby reducing the impeller speed and shear force. In addition, the highly precise polishing treatment on the mechanical surface increases the smoothness of the impeller that avoids hemolysis and improves blood compatibility. Furthermore, the scientifically designed flow channel avoids the stagnation and turbulence of blood flow and the occurrence of thrombosis.

Our preference is that all operations are performed with cardiopulmonary bypass. A study [11] demonstrated that there is no statistical difference in the duration of hospital stay, complication rate, one-year survival rate, and the probability of replacing the pump between extracorporeal and non-extracorporeal LVAD implantation. With CPB, LVAD implantation may be performed under more stable conditions, facilitating the implantation of the pump body at the apex, and reducing the incidence of stroke and coronary ischemia caused by air embolism which allows for better de-airing maneuvers.

During cannulation for CPB, we tried to insert the aortic cannula as close to the head-side as possible. The placement of the cardioplegic needle should also be placed to the upper left of the ascending aorta to facilitate the anastomo-

Table 5. Comparison of cardiac function 90 days after HeartCon implantation with that before operation.

	Number of patients	Left ventricular end-diastolic internal diameter (mm)	Left ventricular ejection fraction (%)	NYHA grade (number of patients, %)				NT-Pro BNP (pg /mL)	6-minute walking test (m)
				I	II	III	IV		
Pre-operation	27	77.40 ± 9.73	22.70 ± 5.62	-	-	-	27 (100)	4796.45 ± 4355.40	85.81 ± 63.50
90 days post-operation	27	67.50 ± 13.98	34.80 ± 9.76	25 (92)	2 (8)	-	-	2028.65 ± 1752.05	385.20 ± 144.12
p value		<0.001	<0.001	-	-	-	-	0.008	<0.001

NT-Pro BNP, N-terminal pro-B-type natriuretic peptide; Blank indicates that this item is not available.

sis of the LVAD outflow vascular graft. To avoid malpositioning of the anastomotic site due to deformation of the ascending aorta after cross-clamping, the precise anastomotic site should be marked on the right front of the ascending aorta before CPB.

When selecting the location of the cardiac apex puncture site, it should be noted that the myocardium in the apex area where the spiral muscle of the cardiac bulb and that of the sinus converge is the thinnest. During CPB, using finger palpation, a dent that can be palpated at the apex. Both the cardiovascular imaging and the computer calculations of the flow field have shown that this depression is the "earth pole" of cardiac rotation and contraction, and is the site with the lowest mechanical pressure. Functionally, it is located at the intersection of the V-shaped blood flow axes in the inflow and outflow tracts. Despite changes in the shape of the heart after enlargement, the basic principles of anatomy and fluid physiology at this site remain unchanged. Therefore, we usually drill a hole at this site for the LVAD insertion.

Right ventricle (RV) failure occurs in up to 30% of patients after LVAD placement, and it is a significant cause of morbidity and mortality [12]. In order to avoid early acute right ventricular failure and protect the right ventricular function, when the right ventricle is inflated in the early stage of pumping, the number of LVAD rotations should be optimized under the guidance of ultrasound to maintain balanced left and right heart volumes and to keep the lowest speed that may maintain the interventricular septum at the midpoint. Priority should be given to whether the blood pump speed is appropriate and whether vasoactive drugs need to be added. The rate of the "vascular paralysis syndrome" occurs in as many as 44% of patients receiving CPB [13]. A meta-analysis [14] shows that tricuspid valvuloplasty does not reduce the incidence and mortality of postoperative right ventricular failure but it may reduce the incidence of early right ventricular failure. In view of this, we routinely repair the tricuspid valve for moderate and severe tricuspid regurgitation. As the result, none of the patients had postoperative right ventricular failure.

In end stage of heart failure (ESHF) patients, the significantly enlarged mitral annulus can push the atrioventricular crux to the right, leading to preoperative underestimation of the degree of the tricuspid regurgitation. Therefore, we routinely perform a DeVega annuloplasty for the tricuspid annulus in the patients with secondary tricuspid regurgitation. When the patients had severe right heart failure and severe tricuspid regurgitation, an artificial tricuspid annuloplasty ring was used.

Perioperative blood transfusion is associated with a high risk of mortality and acute right ventricular failure [15]. Therefore, the use of red blood cells postoperatively should be limited. However, compared with other patients undergoing cardiac surgery, patients with LVAD implantation are more intolerant of tissue hypoxia due to their underlying co-morbidities [16]. Due to the fact that low hemoglobin combined with low mixed venous oxygen saturation or high lactate concentration indicates insufficient tissue oxygen supply, blood transfusion should be considered under such circumstances [17], although there are no uniform blood transfusion guidelines at present. For patients who may need a blood transfusion, our experience is to raise the patient's hemoglobin concentration to 10 g/dL before coming off CPB. When weaning from CPB, we routinely perform ultrafiltration to further filter out the water in the tissue space, to reduce the patient's weight closer to the standard weight (97% of preoperative weight), and to restore the levels of coagulation factors including platelets and proteins by supplementing plasma with the goal to make the activity equal to 56%–60% of the preoperative levels. It has been reported [18] that this level of the activity of the coagulation factors will prevent additional blood loss following surgery and therefore reduce the use of blood products during perioperative period.

As is the case with all mechanically assisted devices, the use of HeartCon requires long-term anticoagulation therapy. Similar to other kinds of LVAD implantation, postoperative anticoagulation is vitally important. We began to use aspirin for anticoagulation on the first day after HeartCon implantation and used aspirin + warfarin for subsequent anticoagulation with the target of international normalized ratio (INR) 2.0–2.5. The optimal blood pressure for patients who had HeartCon implantation after surgery was 70–75 mmHg. When the heart gradually recovered, the pulse pressure may be appropriately increased. It should be noticed that when antihypertensive drugs were needed

in the hypertensive patients, attention must be paid not to excessively lower the blood pressure that may cause excessive pumping of the LVAD, even causing "suction event". In fact, we have taken particular care on the reasonable anticoagulation in all patients and proper blood pressure reduction in the hypertensive patients in order to reduce the risk of postoperative complications such as stroke, thrombosis in the pump, exec. The patient's stay in the intensive care unit (ICU) was longer (9.80 $\pm$ 3.49 days) than conventional cardiac surgery patients because we did not transfer the patient back to the ward until the drainage tube had been removed.

Postoperative complications are still the main source of increased mortality in these patients. The incidence of hemorrhagic stroke in our experience was 7.4% (2/27, Table 4), lower than reported 15%–20% in the literature [19]. Similarly, the incidence of mediastinal infection in our experience was also 7.4% (2/27, Table 4), lower than the reported incidence of 19–39% [20]. All of our patients had the operation performed under CPB, which provides a more stable and less bloody operative field. The duration of mechanical ventilation after surgery in this series was better than previously reported (37.84 $\pm$ 51.96 h *vs*. 46 $\pm$ 53 h) [21].

Limitations

This report had a number of patients with short follow-up. Nevertheless, this is the first report on the use of HeartCon and may provide some conceptual ideas for this newly developed LVAD. It would be valuable to compare the results presented in this report to the results by using other LVADs. However, due to the fact that in our hospital, HeartCon has been the only LVAD used in the clinical practice, at the moment, such comparison is not feasible. In the future, a multi-center clinical trial may be organized to compare the results of different LVADs.

Conclusion

In conclusion, HeartCon implantation is a safe and useful LVAD for the treatment of end-stage heart failure. In addition, implantation of HeartCon under CPB is safe and reliable. It provides surgeons with a more stable operation field, and results in a shorter duration of mechanical ventilation, and a lower incidence of hemorrhagic stroke and mediastinal infection.

Availability of Data and Materials

All data points generated or analyzed during this study are included in this published article.

Author Contributions

Conceptualization, SG and GWH; methodology, SG, XCL and SFW; validation, SG, XCL, SFW, and GWH; formal analysis, SG, LDH, and GWH; investigation, SG, XCL, SFW and GWH; resources, SG, SFW, XCL and GWH; data curation, SG, LDH, and GWH; writing—original draft preparation, SG, and LDH; writing—review and editing, GWH; supervision, XCL and GWH; project administration, XCL, SFW and GWH; funding acquisition, XCL and GWH. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work to take public responsibility for appropriate portions of the content and agreed to be accountable for all aspects of the work in ensuring that questions related to its accuracy or integrity.

Ethics Approval and Consent to Participate

The study was conducted in accordance with the Declaration of Helsinki, and approved by the Institutional Review Board of TEDA International Cardiovascular Hospital ([2019]-1126-1, approved on November 19, 2019). Informed consent was obtained from all subjects involved in the study.

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Conflict of Interest

The project was supported by Rocor Medical Technology Co., Ltd, China. The funding organization had no role in the study design, data collection, analysis, decision to publish, or preparation of the manuscript. The author GWH joined the editorial board after this article was accepted for publication. GWH declares that he was not involved in the editorial processing of this article and has no access to information regarding its editorial processing.

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