Initial Experience of Conversion of Toyobo Paracorporeal Left Ventricular Assist Device to DuraHeart Left Ventricular Assist Device

Daisuke Yoshioka, MD; Taichi Sakaguchi, MD, PhD; Shunsuke Saito, MD; Shigeru Miyagawa, MD, PhD; Hiroyuki Nishiyama, MD; Yasushi Yoshikawa, MD; Satsuki Fukushima, MD, PhD; Takayoshi Ueno, MD, PhD; Toru Kuratani, MD, PhD; Yoshiki Sawa, MD, PhD

Background: This report details experience of the conversion of the Toyobo left ventricular assist device (LVAD; Nipro, Osaka, Japan) to the DuraHeart LVAD (TerumoHeart, Ann Arbor, MI, USA) in patients awaiting heart transplantation.

Methods and Results: Eight patients (4 male, 4 female) with Toyobo paracorporeal LVAD underwent conversion to the third-generation centrifugal (DuraHeart) LVAD. The apical cuff of the Toyobo was not exchanged because the size was the same as that of the DuraHeart. All conversion operations were performed safely, but 3 patients who had infection of the Toyobo LVAD cannulation site prior to conversion suffered later pocket infections and 1 patient died because of sepsis. One patient underwent heart transplantation and 6 of 8 patients were awaiting heart transplantation at home.

Conclusions: Conversions from the Toyobo LVAD to the DuraHeart LVAD were performed safely. Considering that implantable LVADs provide superior long-term survival and quality of life, conversion is a reasonable decision for Toyobo LVAD users in whom there are no infections. (Circ J 2012; 76: 372–376)

Key Words: Heart failure; Heart-assist device; Surgery

Left ventricular assist devices (LVADs) provide effective bridge-to-transplant therapy for patients with end-stage heart failure and are increasingly used for destination therapy. Several types of continuous-flow implantable devices have been developed and have demonstrated significantly improved clinical results with reduction in pump-related morbidity and improvement in both survival length and quality of life (QOL). These devices are highly beneficial for patients awaiting heart transplants in Japan, where waiting time exceeds 2 years due to severe donor shortage.

Due to so-called “device lag”, however, implantable VADs have not been available in Japan for a long time, and the Toyobo LVAD (Nipro, Osaka, Japan), a paracorporeal pneumatic device, has been the only choice for most patients. As described in previous reports, long-term use of Toyobo LVADs involves serious problems, including not only a high complication rate of stroke and driveline infection but also low QOL due to very limited ambulation. Thus, the introduction of new-generation implantable LVADs in Japan, where long-term bridges to transplants are needed, is very important.

Currently, several types of continuous-flow LVADs such as DuraHeart (Terumo Heart, Ann Arbor, MI, USA), HeartMate II (Thoratec Corporation, Pleasanton, CA, USA), Jarvik 2000 (Jarvik Heart, New York, NY, USA), and EVAHEART (Sun Medical, Nagano, Japan) have already approved or are expected to be approved soon in Japan. Of these devices, the DuraHeart is the world’s first approved, magnetically levitated centrifugal pump designed for long-term circulatory support. Previous studies found that the DuraHeart was able to provide safe and reliable long-term circulatory support with an improved survival and an acceptable adverse event rate in advanced heart failure patients who were eligible for transplantation.

Recently, this device was approved by the Japanese Ministry of Health, Labor and Welfare.

Considering the long waiting time for patients who have already undergone implantation with a Toyobo LVAD, we believe conversion to an implantable continuous-flow device provides a safer bridge to transplantation and promises higher QOL. Herein, we report our experience with the conversion of Toyobo LVADs to DuraHeart LVADs in patients waiting
Conversion of the Toyobo to DuraHeart LVAD

Methods and Results

Patients
Between November 2009 and July 2011, 8 patients underwent conversion to a DuraHeart LVAD at Osaka University Hospital. These patients had no serious organ dysfunction other than the heart or systemic infections, and were expected to receive good family support while awaiting heart transplantation at home. The protocol and documents for patient informed consent were reviewed and approved by the ethics committee at Osaka University Hospital. The operative risks and benefits were shared with the patients and written informed consent was obtained from all the patients. All conversion-related costs were supported by a Grant-in-Aid for scientific research from the Ministry of Health, Labor, and Welfare of Japanese Government.

Eight patients (4 male, 4 female) using Toyobo extracorporeal LVADs underwent conversion to DuraHeart LVADs. Patient characteristics are summarized in Table 1. The median patient age was 30 years (range, 25–37 years) and all patients were on the transplant list. The median duration of Toyobo support was 224 days (range, 9–335 days). Six patients had idiopathic cardiomyopathy (patients 1–3, 6, 7 and 8) and 2 had fulminant myocarditis and had been supported by Toyobo biventricular VADs (BiVAD) for 174 days (patient 4) and 224 days (patient 5), respectively.

There were 2 patients (patients 1 and 2) whose duration of Toyobo support was <2 weeks. Patient 1 underwent emergency implantation with a Toyobo LVAD for acute hemodynamic deterioration. Patient 2 underwent implantation with a Toyobo LVAD at another hospital and was transferred to Osaka University Hospital for the DuraHeart LVAD implantation. Because pre-LVAD evaluation raised a concern about BiVAD requirement due to severe right heart failure and ongoing multi-organ failure, primary implantation of the DuraHeart LVAD was delayed at that time. Conversion to DuraHeart was electively performed following hemodynamic stabilization and improvement of end-organ function with the Toyobo LVAD.

In patients 3 and 4, the conversion was performed because the patients had developed progressive heart failure even with Toyobo support due to severe aortic valve (patient 3) or pulmonary valve (patient 4) insufficiency. Direct aortic/pulmonary valve closures were added to the implantation of the Toyobo LVAD.

![Figure 1. The DuraHeart inflow cannula was inserted into the Toyobo apical cuff, then the Toyobo outflow graft was amputated near the ascending aorta and the DuraHeart outflow graft anastomosed.](image)
YOSHIOKA D et al.

DuraHeart LVAD.

Having carried out several conversion cases and ensured the safety of the procedure, we extended the indication for conversion to stable patients. Considering the poor long-term results of the Toyobo BiVAD, patient 5 underwent conversion to a DuraHeart LVAD and Jarvik 2000 for right ventricular assist device (RVAD). Patients 6, 7 and 8 experienced no major complications with the Toyobo LVAD during their 224-, 335-, and 113-day support, but it was also anticipated that they would face a wait of >1 year for heart transplantation; conversions were performed with the aim of a safer bridge to transplantation and higher QOL.

Operative Procedure

All operations were performed using a repeat median sternotomy. The heart was dissected and the Toyobo inflow/outflow cannulae were freed. Another skin incision was made vertical to the midline incision across the inflow and outflow cannulae exit site, and the inflow and outflow graft of the Toyobo LVAD were dissected. The skin exit site was trimmed off and the space above the peritoneum was dissected and the left side of the diaphragm was cut at its connection with the anterior chest wall. The DuraHeart pump cable was tunneled s.c. to exit the skin at the left lower quadrant to keep away from the prior cannulation site. After systemic heparinization, a cardiopulmonary bypass (CPB) was initiated with cannulation of the ascending aorta and right atrium. The operative field was flooded with carbon dioxide. The aortic root venting cannula was placed to evacuate residual air. All procedures were performed on a beating heart except in 1 case requiring aortic valve closure (patient 3). The Toyobo inflow cannula was carefully removed from the apical cuff and the left ventricular cavity was inspected. Any mobile wedge thrombi were carefully excised. The Toyobo apical cuff can be used for the DuraHeart device because the sizes of the inflow cannulae of both devices are identical. The sizes of the outflow graft (12 mm) are also the same for both devices. These size similarities make the conversion procedure very easy and safe because the most serious concerns in LVAD implantation procedures are bleeding from the suture line of the apical cuff and from the anastomotic site of the outflow graft. The DuraHeart inflow cannula was inserted into the Toyobo apical cuff and secured with several silk ties. The Toyobo outflow graft was amputated near the ascending aorta and the DuraHeart outflow graft was anastomosed end-to-end using a continuous 4-0 polypropylene suture (Figure 1). The air was then carefully removed, the pump position was adjusted to obtain an optimal flow rate, and CPB was gradually discontinued.

Patient 3 experienced severe aortic insufficiency and developed symptoms of progressive heart failure despite receiving...
maximum medical treatment, including i.v. inotropes. The aortic valve was directly closed with a running 5-0 polypropylene suture under cardiac arrest.

Two patients with Toyobo biventricular support (patients 4 and 5) received conversion to 2 implantable devices: the Dura-Heart as left ventricular support and a Jarvik 2000 axial-flow pump as right ventricular support.15 The Toyobo inflow cuff in the right ventricular free wall had to be replaced with a Jarvik 2000 inflow cuff because of the size difference. Care was taken to position the Jarvik 2000 pump towards the tricuspid valve to avoid flow obstruction by sucking on the right ventricular wall or interventricular septum. The anterior leaflet of the tricuspid valve was excised or sutured to the ventricular free wall. In patient 4, direct closure of the pulmonary valve was also carried out for severe pulmonary insufficiency.

The operative times and postoperative course are summarized in Table 2. The mean operation time of the 5 patients who underwent isolated LVAD conversion was 318±54 min (range, 251–387 min). The mean CPB time of those patients was 65±27 min (range, 39–103 min).

There was no hospital mortality. Chest re-exploration was required for bleeding in 2 patients who underwent conversion to implantable BiVADs. All patients, except patient 5, who required temporal tracheostomy, were extubated on postoperative day 1 or 2. All patients were discharged following a mean postoperative hospital stay of 77 days.

The mean duration of DuraHeart support was 388 days (range, 30–631 days). No neurological complication or significant hemolysis was noted in all patients. One patient (patient 6) successfully received a heart transplant 176 days after the conversion. Six patients are now at home awaiting heart transplantation.

Two patients (patients 2 and 3) developed pump pocket infection. They had a limited local infection or minor erosion around the skin exit site of the Toyobo (Figure 2A), and operative findings indicated no major abcess around the inflow/outflow cannulae. It was necessary for them to undergo an omental flap procedure, however, 2 and 6 months after conversion, respectively. At the time of writing they had no recurrence of infection for 11 months and 19 months, respectively.

One patient (patient 5) died 10 months after the operation. This patient underwent conversion to the implantable BiVAD (DuraHeart and Jarvik 2000) after 224 days of Toyobo BiVAD support. This patient had methicillin-resistant Staphylococcus aureus infection of the Toyobo cannula exit site prior to conversion (Figure 2B). Computed tomography (CT) showed only local infection around the cannula exit site but, during the operation, the infection was found to have reached the Toyobo RVAD inflow cuff and aggressive debridement and an omental flap procedure were added. The postoperative course was uneventful and she was discharged with no sign of infection. This patient was re-hospitalized, however, 10 months after surgery because of the acute onset of spiking fever and eventually died from sepsis. Autopsy showed extensive mediastinitis and pump pocket infection.

One patient (patient 6) experienced a device malfunction and required a device exchange after 259 days of DuraHeart LVAD support. Failure of magnetic levitation occurred through a fracture on a position sensor wire in the percutaneous cable. Device exchange was successfully performed using a subcostal approach without a repeat sternotomy.16

**Discussion**

Although heart transplantation remains the gold-standard therapy for end-stage heart failure, the severe donor organ shortage in Japan forces patients on LVAD support to wait >2 years for transplantation. The Toyobo paracorporeal LVAD, which has been the only device covered by Japanese national insurance for a long time, has many problems in long-term use. We have previously reported that the actuarial survival rate has been improved recently, but actuarial survival rate of patients on Toyobo LVAD support in 2003–2007 was 66.3% at 6 months and 45.9% at 1 year.11 We have also reported that Toyobo LVAD was the independent risk factor for device-related infection, and freedom from LVAD-related infection was only approximately 30% at 6 months and 20% at 1 year. Freedom from cerebral stroke events was approximately 50% at 6 months and 35% at 1 year.12

To resolve this unacceptable situation in Japan, clinical trials of 4 implantable continuous-flow LVADs (DuraHeart, EVAHEART, Jarvik 2000, HeartMate II) have been carried out in Japan, and the results of these trials were favorable. A recently conducted multi-center, randomized controlled trial in the USA demonstrated the superiority of the implantable continuous-flow device compared to the first-generation pulsatile device.7 DuraHeart is the world’s first approved, magnetically levitated centrifugal left ventricular assist system, which eliminates all mechanical contacts between the impeller and the drive mechanism, thereby providing superior durability, with reduced likelihood of thrombus and hemolysis. In an early clinical study managed in Europe, the adverse event rates per patient-years for major adverse events during DuraHeart support were acceptable in comparison with those of the second-generation axial-flow LVADs.8,12,13 Morshuis et al reported that the driveline or pocket infection rate of DuraHeart LVAD was 0.27 per patient-year, which was reduced by 90% compared to that of HeartMate VE, the pulsatile device, and was comparable to that of HeartMate II, a small axial-flow device. The rate of neurological events in DuraHeart was 0.21 per patient-year, which was 50% less than that of HeartMate VE and comparable to that of HeartMateII.14,17

Considering these recent outcomes, it is expected that conversion to implantable LVAD from Toyobo LVAD will provide better survival if the operation is performed safely. In addition, a patient with an implantable LVAD can be discharged home. This holds great advantages for QOL and health economics.

In the conversion procedure, the apical cuff of the Toyobo VAD can be used with the DuraHeart inflow conduit, so it is not necessary to replace the Toyobo apical cuff with that of the DuraHeart, which allows operation time to be shortened and the risk of bleeding reduced. This is especially beneficial in pure LVAD conversion. In 5 cases of isolated LVAD conversion (patients 1, 2, 6, 7, 8), the mean CPB time for those patients was relatively short, and all conversion operations were performed safely with no patients requiring re-exploration for bleeding. For pure LVAD conversion, we consider the operative risk to be relatively low. In the BiVAD conversion, however, operative risk is much higher because some additional procedures are required.15 The present 2 patients required re-exploration for bleeding and prolonged ventilation, but they could be discharged home finally. Considering the poor clinical results of Toyobo BiVAD support, although certain risks remain, conversion to implantable VADs is beneficial for these patients.

Although certain risks of the conversion operation may still remain, we consider the risk of continuing Toyobo device for >1 year to be higher than the operative risk. This strategy, however, also carries a certain risk. In the present series, 3 of
the 8 patients developed device pocket infection. We usually sterilize cannula site every day and in the case of minor erosion or focal infection, repeated culture are examined. If there is an active infection with pus or abscess around the exit site, daily lavage with saline is added. But, as previously mentioned, we reported that Toyobo LVAD was one of the independent risk factors for device-related infection.11 We have also reported that device-related infections at various locations were observed in 68.9% of all Toyobo patients. Inflow/outflow cannula exit site infection was observed in 31.1% of patients. Although the infectious events occurred most frequently in the first 6 months after LVAS implantation, events continued to occur thereafter. The infection-free rate improved by year of implantation, but the infection-free rate was approximately 70% at 6 months and only 50% at 1 year in 2003–2007.11 Therefore, careful attention must be paid to Toyobo exit site infection prior to conversion. One patient (patient 3) had minor tissue erosion around the exit site of the Toyobo cannula and the other 2 patients (patients 2 and 5) had local infection of the Toyobo cannula exit site prior to conversion. Preoperative CT and laboratory data showed no sign of systemic infection or mediastinitis in all patients. During the conversion operation, the skin exit site was carefully removed and aggressive debridement performed if any local infection was noted during the operation. Nevertheless, all 3 patients developed pocket infection. In the debridement and omental flap procedures, a large amount of abscess in the pump pocket was found in all 3 patients. Two patients recovered without any recurrence but 1 patient with biventricular support died from uncontrollable sepsis. Even a superficial infection of the cannula exit site is considered to be a significant risk for developing refractory pocket infection after conversion, which leads to fatal complications. From these experiences, we now consider this procedure to be a contraindication if a patient has any signs of infection at the Toyobo LVAD cannula exit site.

Conclusion
We have reported our initial experience with conversions from the Toyobo LVAD to the DuraHeart. The procedure was performed safely, and clinical outcomes were satisfactory. The replacement of Toyobo LVADs with DuraHeart LVADs will be highly advantageous in patients with Toyobo LVADs without any device infection.

References