Continuous flow pumps have advantages over pulsatile devices because they are compact, lightweight, simple design and have no valves. Moreover, they do not require a compliance chamber and are highly efficient. Furthermore, there is a low risk of infection because of the thin and flexible drive line. There are 2 types of continuous flow pumps: axial flow pumps and centrifugal pumps. In general, axial flow pumps have the advantages of being smaller and lighter than centrifugal pumps, whereas centrifugal pumps produce a higher torque. In 1998, the MicroMed-Debakey VAD was the first of 4 miniaturized, implantable axial flow pumps for clinical application, followed by the Jarvik 2000, the HeartMate II and Incor.1–4 The first clinical trial of an implantable, magnetically levitated centrifugal blood pump began in Europe in January 2004 with the Terumo DuraHeart.5–8 A total of 4 centers in Austria, France and Germany were involved in this initial clinical trial. We report here on the first 4 implants of the Terumo DuraHeart as a bridge to transplantation in our institution.

Methods

DuraHeart VAD

The DuraHeart VAD (Figs 1, 2) has a displacement volume of 180 cm³ and a weight of 540 g. Its external dimensions are 72 mm in width and 45 mm in height. The DuraHeart’s pump is centrifugal with a magnetically levitated impeller. It does not require a rotating shaft or shaft seals. The impeller is rotated by a magnetic coupling between permanent magnets embedded on the motor side of the impeller and the motor. The ferromagnetic ring on the opposite side of the impeller is levitated by the electromagnet, and position sensors control the impeller so that it is always positioned at the center of the blood chamber. The absolute lack of any mechanical contact point inside the blood chamber is expected to result in a system with great longevity, in addition to reducing the chance of blood clots (Fig 3). A hydrodynamic bearing is also incorporated into the lower pump housing as a safety mechanism in case the magnetic bearing fails. Four series of inflow conduits made of titanium in different sizes and angles are available to fit the anatomical correlation between the heart of the patient and the pump. The external components consist of a wearable controller and battery unit weighing a total of 1.9 kg. The pump speed can be controlled from 1,200 to 2,600 rpm, and the pump can deliver a flow of 2–10 L/min. The estimated pump flow based on motor current is displayed on

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the controller, as well as the power uptake and set speed. The console allows monitoring of the system and adjustment of the pump parameters and can store system and pump data.

**Inclusion and Exclusion Criteria**

To be eligible for this clinical trial, the patients had to meet the following inclusion criteria: (1) eligible for cardiac transplantation; (2) body surface area >1.1 m²; (3) New York Heart Association (NYHA) functional class of IV; (4) previous optimal medical treatment; (5) cardiac index less than 2.2 L·min⁻¹·m⁻² with either systolic blood pressure less than 80 mmHg or left atrial pressure or pulmonary arterial diastolic pressure greater than 18 mmHg; (6) informed consent; and (7) all laboratory and physiological data used for patient evaluation 48 h before enrolment were within the required ranges.

The exclusion criteria were: (1) fixed pulmonary hypertension with pulmonary vascular resistance greater than 6 Wood units; (2) severe chronic obstructive pulmonary disease; (3) active systemic infection; (4) symptomatic cerebrovascular disease; (5) serum creatinine concentration >5 mg/dl or blood urea nitrogen concentration >100 mg/dl or need of hemodialysis; and (6) liver enzymes more than 3-fold the normal upper limit or a total bilirubin concentration >5 mg/dl.

### Table 1  Demographics of Patients Receiving Duraheart VAD

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age, years</th>
<th>Disease</th>
<th>Intra-aortic balloon pump</th>
<th>Ventilation</th>
<th>NYHA class</th>
<th>Aortic pressure, mmHg</th>
<th>Pulmonary artery pressure, mmHg</th>
<th>Pulmonary capillary wedge pressure, mmHg</th>
<th>Cardiac index, L·min⁻¹·m⁻²</th>
<th>Pulmonary vascular resistance, dyn·s⁻¹·cm⁻²</th>
<th>Intravenous medication, μg·kg⁻¹·min⁻¹</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>60</td>
<td>Ischemic cardiomyopathy</td>
<td>No</td>
<td>No</td>
<td>IV</td>
<td>98/66/75</td>
<td>49/35/41</td>
<td>35</td>
<td>2.1</td>
<td>260</td>
<td>Levosimendan 0.103</td>
</tr>
<tr>
<td>2</td>
<td>30</td>
<td>Dilated cardiomyopathy</td>
<td>No</td>
<td>Yes</td>
<td>IV</td>
<td>101/64/81</td>
<td>70/44/56</td>
<td>29</td>
<td>1.7</td>
<td>444</td>
<td>Levosimendan 0.19, Dobutamine 14.3</td>
</tr>
<tr>
<td>3</td>
<td>32</td>
<td>Dilated cardiomyopathy</td>
<td>No</td>
<td>No</td>
<td>IV</td>
<td>80/42/52</td>
<td>56/28/39</td>
<td>19</td>
<td>2.1</td>
<td>305</td>
<td>Levosimendan 0.2</td>
</tr>
<tr>
<td>4</td>
<td>36</td>
<td>Dilated cardiomyopathy</td>
<td>No</td>
<td>No</td>
<td>IV</td>
<td>91/57/65</td>
<td>63/37/48</td>
<td>26</td>
<td>1.6</td>
<td>339</td>
<td>No</td>
</tr>
</tbody>
</table>

NYHA, New York Heart Association.
Established regimen.9–11 During ECC and implantation of the VAD, the pump was de-aired, and the pump was attached to the apex of the beating heart with circumferentially placed mattresses sutures. After coring of the pocket, and the drive-line was tunneled subcutaneously and the pump flow was adjusted to maintain a mixed venous saturation greater than 60%. Nearly full unloading of the dilated left ventricles could be achieved with a closed aortic valve, which was confirmed by transesophageal echocardiography. The 4 patients were extubated on the first, second, and third postoperative day, respectively; however, after initial early extubation on the day of implant, patient 3 needed re-intubation for an extra day because of respiratory failure. Subsequently, all 4 patients were mobilized, and inotropic support for sufficient right heart function could be discontinued. All the patients were transferred from the intensive care unit to an intermediate care ward and then to a general ward. The patients were put through regular physical training to rebuild the muscle mass lost during the prolonged period of preoperative and postoperative immobilization. After full mobilization and stabilization of anticoagulant therapy, the patients were discharged from hospital to a rehabilitation center on the 18th, 42nd, 41st and 31st postoperative day, respectively. From there, all patients were discharged home in excellent physical condition and classified as NYHA functional class I. All 4 patients were successfully transplanted on the 202nd, 84th, 128th and 96th days after implantation, respectively.

Hemodynamic Changes
In the early period after implantation of the DuraHeart VAD, the pulse pressure amplitude was kept well reduced. Because of the rest-function of the natural left heart, low pulsatility of the arterial blood pressure could be observed in all the patients, even though their aortic valves stayed dilated. The mean arterial blood pressure was maintained at 77±4, 83±5, and 74±7 mmHg on the first and third postoperative day and 1 week after the operation, respectively. The pump flow was adjusted to maintain a mixed venous

### Table 2 Pump Flow, Pump Speed, Pump Motor Current, Indices of Hemolysis and Biochemistry Data

<table>
<thead>
<tr>
<th></th>
<th>1 day</th>
<th>3 days</th>
<th>1 week</th>
<th>2 weeks</th>
<th>4 weeks</th>
<th>6 weeks</th>
<th>8 weeks</th>
<th>12 weeks</th>
<th>16 weeks</th>
<th>20 weeks</th>
<th>24 weeks</th>
<th>28 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pump flow, L/min</strong></td>
<td>4.9±0.5</td>
<td>4.6±0.5</td>
<td>4.2±0.5</td>
<td>3.9±0.5</td>
<td>3.6±0.5</td>
<td>3.3±0.5</td>
<td>3.0±0.5</td>
<td>2.7±0.5</td>
<td>2.4±0.5</td>
<td>2.1±0.5</td>
<td>1.8±0.5</td>
<td>1.5±0.5</td>
</tr>
<tr>
<td><strong>Pump speed, rpm</strong></td>
<td>1,423</td>
<td>1,358</td>
<td>1,308</td>
<td>1,258</td>
<td>1,208</td>
<td>1,158</td>
<td>1,108</td>
<td>1,058</td>
<td>1,008</td>
<td>958</td>
<td>908</td>
<td>858</td>
</tr>
<tr>
<td><strong>Motor current, A</strong></td>
<td>0.5±0.1</td>
<td>0.4±0.1</td>
<td>0.3±0.1</td>
<td>0.2±0.1</td>
<td>0.1±0.1</td>
<td>0.0±0.1</td>
<td>0.0±0.1</td>
<td>0.0±0.1</td>
<td>0.0±0.1</td>
<td>0.0±0.1</td>
<td>0.0±0.1</td>
<td>0.0±0.1</td>
</tr>
<tr>
<td><strong>Hb, g/dl</strong></td>
<td>14±2</td>
<td>12±2</td>
<td>10±2</td>
<td>8±2</td>
<td>6±2</td>
<td>4±2</td>
<td>2±2</td>
<td>0±2</td>
<td>0±2</td>
<td>0±2</td>
<td>0±2</td>
<td>0±2</td>
</tr>
<tr>
<td><strong>fHb, mg/dl</strong></td>
<td>2.4±0.4</td>
<td>2.1±0.4</td>
<td>1.8±0.4</td>
<td>1.5±0.4</td>
<td>1.2±0.4</td>
<td>0.9±0.4</td>
<td>0.6±0.4</td>
<td>0.3±0.4</td>
<td>0.1±0.4</td>
<td>0.0±0.4</td>
<td>0.0±0.4</td>
<td>0.0±0.4</td>
</tr>
<tr>
<td><strong>LDH, U/L</strong></td>
<td>1,024±248</td>
<td>1,000±248</td>
<td>976±248</td>
<td>952±248</td>
<td>928±248</td>
<td>904±248</td>
<td>880±248</td>
<td>856±248</td>
<td>832±248</td>
<td>808±248</td>
<td>784±248</td>
<td>760±248</td>
</tr>
<tr>
<td><strong>Cr, mg/dl</strong></td>
<td>1.4±0.4</td>
<td>1.3±0.4</td>
<td>1.2±0.4</td>
<td>1.1±0.4</td>
<td>1.0±0.4</td>
<td>0.9±0.4</td>
<td>0.8±0.4</td>
<td>0.7±0.4</td>
<td>0.6±0.4</td>
<td>0.5±0.4</td>
<td>0.4±0.4</td>
<td>0.3±0.4</td>
</tr>
<tr>
<td><strong>Platelet count, ×10^9/L</strong></td>
<td>153±15</td>
<td>98±15</td>
<td>61±15</td>
<td>38±15</td>
<td>25±15</td>
<td>12±15</td>
<td>7±15</td>
<td>4±15</td>
<td>2±15</td>
<td>0±15</td>
<td>0±15</td>
<td>0±15</td>
</tr>
</tbody>
</table>

Hb, hemoglobin; fHb, plasma free hemoglobin; NA, not available; LDH, lactate dehydrogenase; Cr, serum creatinine.

Data are mean±SD.

Administration of intravenous heparin was terminated when anticoagulation with phenprocoumon (Marcoumar) reached the target level of an international normalized ratio between 2.5 and 3.5.

### Results

**Clinical Course**

The intraoperative course in all 4 patients was uneventful. The pump showed good performance with flow rates of 4.9±0.5 L/min after gradual weaning off ECC. Adequate tissue perfusion was achieved with mixed venous oxygen saturation greater than 60%. Nearly full unloading of the dilated left ventricles could be achieved with a closed aortic valve, which was confirmed by transesophageal echocardiography. The 4 patients were extubated on the first, second, and third postoperative day, respectively; however, after initial early extubation on the day of implant, patient 3 needed re-intubation for an extra day because of respiratory failure. Subsequently, all 4 patients were mobilized, and inotropic support for sufficient right heart function could be discontinued. All the patients were transferred from the intensive care unit to an intermediate care ward and then to a general ward. The patients were put through regular physical training to rebuild the muscle mass lost during the prolonged period of preoperative and postoperative immobilization. After full mobilization and stabilization of anticoagulant therapy, the patients were discharged from hospital to a rehabilitation center on the 18th, 42nd, 41st and 31st postoperative day, respectively. From there, all patients were discharged home in excellent physical condition and classified as NYHA functional class I. All 4 patients were successfully transplanted on the 202nd, 84th, 128th and 96th days after implantation, respectively.

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oxygen saturation of greater than 60%. After the initial postoperative period, pulsatility increased, and this increase was related to further recovery of left ventricular contractility. The mean arterial blood pressure was maintained at 74±7, 85±4, 88±3, 104, 100 and 98 mmHg on the 1st, 4th, 8th, 12th, 16th, 20th and 24th week after the operation, respectively.

**Device Performance**

In all 4 patients, the DuraHeart provided adequate blood flow to maintain sufficient tissue perfusion, as reflected in mixed venous oxygen saturation greater than 60%. The mean arterial blood pressure was maintained at 74±7, 85±4, 88±3, 104, 100 and 98 mmHg on the 1st, 4th, 8th, 12th, 16th, 20th and 24th week after the operation, respectively.

**Hemolysis and Biochemistry Data**

No significant elevation of mean plasma-free hemoglobin was detected. Slightly elevated preoperative serum creatinine concentrations declined to the normal range postoperatively. Lactate dehydrogenase concentrations normalized from a preoperative or operative elevation. The platelet count was also well maintained during the entire clinical course.

**Explantation of Pumps**

All pumps could easily be explanted during the transplant procedure. Macroscopic inspection of the surface of the pumps found no evidence of thrombus formation or mechanical wear (Fig 4). All showed intraventricular pannus growth of differing extent around the inflow cannula.

**Discussion**

For clinical assessment of the DuraHeart VAD we enrolled the first 4 patients in this trial. All patients could be maintained in a stable condition at relatively high pump flows, and neither mechanical failure nor crucial thromboembolic events occurred during the entire period of mechanical support. Taking these facts into consideration, together with the excellent clinical results, the DuraHeart can be regarded as a safe and reliable pump with an innovative magnetic rotor suspension.

The outstanding clinical results in this cohort of patients can be theoretically supported by the obvious advantage of the magnetic suspended systems in the DuraHeart. Although there have been several approaches to developing fully implantable, long-lasting rotary blood pumps, the magnetically suspended rotor is regarded as one of the most promising approaches towards long-term mechanical reliability and reduced thrombogenicity. Conventional rotary blood pumps have had limitations in durability and mechanical wear because of problems related to the necessary bearings and seals. To overcome these problems, some innovative approaches have been applied to the new generation of rotary blood pumps, including the magnetic levitation system. The DuraHeart is the first implantable magnetically levitated centrifugal blood pump for clinical application. The magnetic suspended system in the DuraHeart can be operated completely contact-free without any material wear, enabling long-term mechanical support and reduced thrombogenicity. The DuraHeart is expected to be one of the options for improving the prognosis of severe heart failure patients by enabling reliable long-term circulatory support.

It is still debatable which type of rotary pump, axial or centrifugal, including the magnetically levitated DuraHeart, is preferable for application in patients requiring higher pump flows and/or long-term support. Recently, some axial pumps have achieved circulatory assistance for more than 2 years. However, because of lower torque generation, axial flow pumps generally have a mechanical wear problem associated with the rotational speed, which is higher than that of centrifugal blood pumps. In terms of mechanical wear, it is theoretically conceivable that magnetically levitated centrifugal pumps, such as the DuraHeart, could handle higher blood flow demands and/or longer term circulatory support than axial flow pumps. Nevertheless, further study is needed to confirm whether such theoretical advantages are verified in clinical use.

In conclusion, in our first series of clinical implantation of the DuraHeart VAD centrifugal blood pump, the pump proved to have very low hemolysis and excellent support properties, giving sufficient and stable circulatory support for the bridge-to-transplant procedure. Because of the lack of mechanical wear and a magnetically suspended rotor system, the DuraHeart VAD is expected to have outstanding long-term durability and advantageous properties for long-term or destination therapy support.
Acknowledgment

The DuraHeart VAD was provided by Terumo Heart Inc, and used in accordance with an ethics committee-approved study protocol.

References