Circ J 2006; **70:** 1421 – 1425

The DuraHeart VAD, a Magnetically Levitated Centrifugal Pump

—— The University of Vienna Bridge-to-Transplant Experience ——

Tomohiro Nishinaka, MD; Heinrich Schima, PhD*; Wilfried Roethy, MD;
Angela Rajek, MD**; Chisato Nojiri, MD†;
Ernest Wolner, MD; Georg M Wieselthaler, MD

Background The clinical application of the DuraHeart (Terumo Heart Inc, USA) has begun in Europe as a clinical trial of a third-generation implantable centrifugal blood pump. Four successful clinical implants are presented.

Methods and Results Four male patients had end-stage left heart failure and received a DuraHeart VAD as a left ventricular assist device for bridge-to-transplantation. The pump showed good performance with flow rates of 4.9±0.5 L/min after gradual weaning of extracorporeal circulation. The pump flow was then maintained at 6.1±0.5, 5.5±0.3, 5.5±0.1, 5.7±0.1, 5.5, 6.4 and 6.5 L/min at the 1st, 4th, 8th, 12th, 16th, 20th and 24th postoperative week, respectively. No significant elevation of mean plasma-free hemoglobin was detected. The patients were discharged on the 18th, 42nd, 41st and 31st postoperative day, respectively, and all were successfully transplanted on the 202nd, 84th, 128th and 96th postoperative day, respectively. At the time of transplant surfaces of the removed pumps were free from thrombus formation, although intraventricular pannus growth was observed around the inflow cannulae in all patients.

Conclusion The DuraHeart VAD showed stable and sufficient circulatory support for the bridge-to-transplant procedure in this cohort of 4 patients. (*Circ J* 2006; **70:** 1421 – 1425)

Key Words: Continuous flow; DuraHeart; Heart assist device; Heart failure

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.

(Received May 24, 2006; revised manuscript received August 10, 2006; accepted August 24, 2006)

*Department of Cardiothoracic Surgery, *Department of Biomedical Engineering, **Department of Cardiothoracic and Vascular Anesthesia and Intensive Care Medicine, Medical University of Vienna, Vienna, Austria and †Terumo Heart, Inc, Ann Arbor, Michigan, USA*
Mailing address: Georg M Wieselthaler, MD, Department of Cardiothoracic Surgery, Medical University of Vienna, Waehringer Guertel 18-20, A-1090 Vienna, Austria. E-mail: georg.wieselthaler@meduniwien. ac.at

Methods

DuraHeart VAD

The DuraHeart VAD (Figs 1,2) has a displacement volume of 180 cm^3 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

Abbott v. Miracor, IPR2025-00113
Miracor Ex. 2026, p. 1 of 5

Fig 1. Pumping unit. The DuraHeart VAD has a displacement volume of 180 cm^3 and a weight of 540 g. The external dimensions are 72 mm in width and 45 mm in height.

Fig 2. DuraHeart console, which enables monitoring of the system and adjustment of the pump parameters, and can store system and pump data.

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.

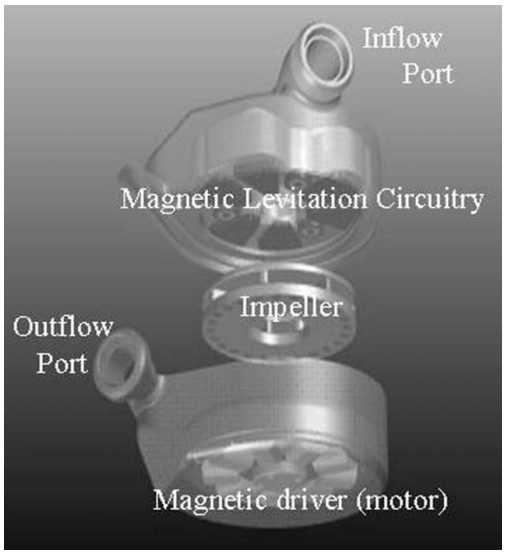

Fig 3. Exploded view of the DuraHeart. The impeller is magnetically levitated by the circuitry mounted in the upper pump housing while simultaneously being driven through an axially coupled magnetic driver in the bottom housing.

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 m^2; (3) New York Heart Association (NYHA) functional class of IV; (4) previous optimal medical treatment; (5) cardiac index less than 2.2 $L \cdot min^{-1} \cdot m^{-2}$ 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 Recieving Duraheart VAD

	Patient 1	*Patient 2*	*Patient 3*	*Patient 4*
Age, years	*60*	*30*	*32*	*36*
Sex	*M*	*M*	*M*	*M*
Disease	*Ischemic cardiomyopathy*	*Dilated cardiomyopathy*	*Dilated cardiomyopathy*	*Dilated cardiomyopathy*
Intra-aortic balloon pump	*No*	*No*	*No*	*No*
Ventilation	*No*	*Yes*	*No*	*No*
NYHA class	*IV*	*IV*	*IV*	*IV*
Aortic pressure, mmHg	*98/66/75*	*101/64/81*	*80/42/52*	*91/57/65*
Pulmonary artery pressure, mmHg	*49/35/41*	*70/44/56*	*56/28/39*	*63/37/48*
Pulmonary capillary wedge pressure, mmHg	*35*	*29*	*19*	*26*
Cardiac index, $L \cdot min^{-1} \cdot m^{-2}$	*2.1*	*1.7*	*2.1*	*1.6*
Pulmonary vascular resistance, $dyn \cdot s^{-1} \cdot cm^{-5}$	*260*	*444*	*305*	*339*
Intravenous mediaction, $\mu g \cdot kg^{-1} \cdot min^{-1}$	*Levosimendan 0.103*	*Levosimendan 0.19, Dobutamine 14.3*	*Levosimendan 0.2*	*No*

NYHA, New York Heart Association.

Abbott v. Miracor, IPR2025-00113
Miracor Ex. 2026, p. 2 of 5

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

	Before suegery	1day	3 days	1 week	2 weeks	4 weeks	8 weeks	12 weeks	16 weeks	20 weeks	24 weeks	28 weeks
Pump flow, L/min		5.3±0.8	5.3±0.5	6.1±0.5	5.2±0.6	5.5±0.3	5.5±0.1	5.6±0.2	5.7±0.3	6.4	6.5	6.0
Pump Speed, rpm		1,598±48	1,638±75	1,679±61	1,656±71	1,642±57	1,643±76	1,661±82	1,613±120	1,598	1,598	1,599
Motor current, A		0.56±0.04	0.57±0.06	0.64±0.03	0.57±0.06	0.57±0.05	0.57±0.05	0.59±0.03	0.55±0.07	0.60	0.50	0.50
Hb, g/dl	13.0±2.2	11.5±0.9	10.1±0.5	9.7±0.3	9.6±0.5	9.8±1.0	11.2±0.9	11.0±1.1	10.4±0.6	12.5	11.7	11.9
fHb, mg/dl	NA	2.3±1.1	4.5±2.9	1.9±1.3	3.0±1.9	1.8±1.4	2.7±2.4	2.6±2.4	3.5±1.8	4.7	6	2.3
LDH, U/L	308±231	539±122	417±99	316±85	246±49	332±44	222±57	229±55	200±18	238	218	238
Cr, mg/dl	1.6±0.5	1.1±0.3	1.0±0.1	0.9±0.1	0.9±0.2	0.9±0.1	1.0±0.2	1.0±0.4	1.1±0.4	1.4	1.3	1.2
Platelet count /L^3	153±15	98±18	100±13	189±26	250±147	223±22	288±81	233±96	196±8	262	180	203

Hb, hemoglobin; fHb, plasma free hemoglobin; NA, not available; LDH, lactate dehydrogenase; Cr, serum creatinine.
Data are mean±SD.

Patients

Four male patients who had end-stage left heart failure received a DuraHeart VAD as a left ventricular assist device (LVAD) for bridge to transplantation (Table 1). All patients were listed for cardiac transplantation and showed signs of acute hemodynamic deterioration and end-organ dysfunction. The protocol for the study was approved by the Institutional Review Board.

Clinical Course

The clinical course, including pump performance, hemodynamic changes, hemolysis (hemoglobin and serum free hemoglobin concentrations) and biochemistry data (serum creatinine, lactate dehydrogenase concentrations, and platelet count), was monitored at least weekly.

Implant Procedure

Similar to other LVAD, the DuraHeart VAD was implanted through a median sternotomy with the use of extracorporeal circulation (ECC) and beating heart. The pump was placed in a left-side, preperitoneal, upper abdominal pocket, and the drive-line was tunneled subcutaneously and exited the skin above the right iliac crest. A sewing ring was attached to the apex of the beating heart with circumferentially placed mattresses sutures. After coring of the apex, an inflow conduit was inserted into the left ventricle and fixed to the sewing ring. The Vascutec outflow graft was placed extrapericardially and anastomosed to the ascending aorta. The VAD was de-aired, and the pump was started while ECC was gradually discontinued. A combined cardiac and pump output was maintained to achieve mixed venous oxygen saturations above 60%.

Anticoagulation

Anticoagulation treatment followed the institution's established regimen.[9–11] During ECC and implantation of the pump the patients received intravenous heparin (300 IU/kg body weight). A heart–lung machine was primed with 1,000,000 IU aprotinin. After discontinuation of ECC, the heparin was reversed with an appropriate dose of protamine. Intravenous heparin was instituted 6–8 h after surgery, when chest-tube drainage was less than 50 ml/h to achieve an activated partial thromboplastin target time of between 60 and 70 s. Platelet anti-aggregation therapy with 100 mg/day aspirin was started on the third postoperative day. The platelet inhibition status was monitored, and the amount of aspirin adjusted after the results of the platelet mapping assay using thromboelastography (Haemoscope, USA). To obtain more than 80% inhibition of the platelet function through the arachidonate-thromboxane A2 pathway, the dose of aspirin was maintained between 100 and 300 mg. 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.

Handling of Explanted Devices

At the time of transplantation, the pumps were removed, washed with saline, and preserved in 2% glutaraldehyde solution. The pumps were then inspected macroscopically and sent back to the company for further investigation.

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, first and first 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 closed. 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

Abbott v. Miracor, IPR2025-00113
Miracor Ex. 2026, p. 3 of 5

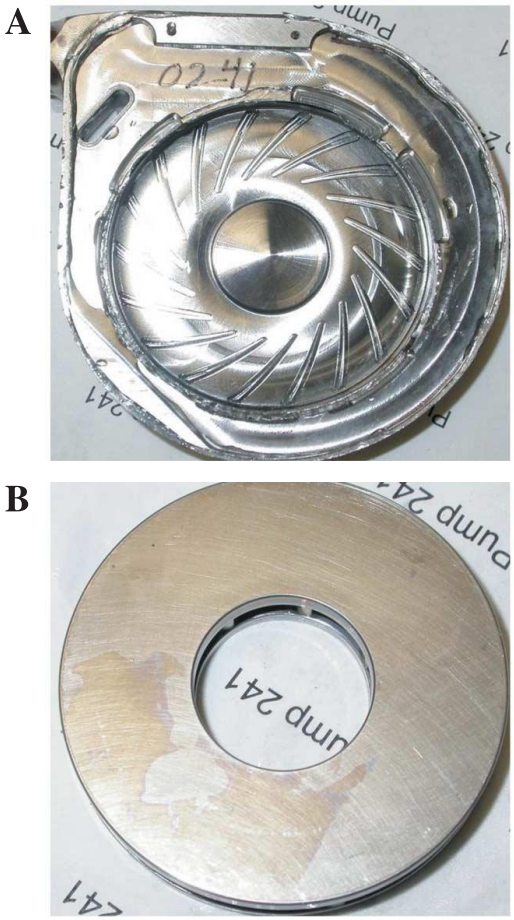

Fig 4. DuraHeart pump chamber (A) and impeller (B) after 202 days clinical use in patient 1. Macroscopic inspection found no evidence of thrombus formation or mechanical wear.

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±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 pump speed was adjusted manually in the early postoperative period to obtain an adequate blood flow and to avoid excess suction with ventricular collapse. The mean pump flows, corresponding pump speed, and motor current are shown in Table 2. No mechanical failures related to the DuraHeart pump system were observed during the entire clinical course of all 4 patients.

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![2,13]

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.

Abbott v. Miracor, IPR2025-00113
Miracor Ex. 2026, p. 4 of 5

Acknowledgment

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

References

1. Wieselthaler GM, Schima H, Hiesmayr M, Pacher R, Laufer G, Noon GP, et al. First clinical experience with the DeBakey VAD continuous-axial-flow pump for bridge to transplantation. *Circulation* 2000; **101:** 356–359.
2. Westaby S, Banning AP, Jarvik R, Frazier OH, Pigott DW, Jin XY, et al. First permanent implant of the Jarvik 2000 heart. *Lancet* 2000; **356:** 900–903.
3. Frazier OH, Delgado RM 3rd, Kar B, Patel V, Gregoric ID, Myers TJ. First clinical use of the redesigned HeartMate II left ventricular assist system in the United States: A case report. *Tex Heart Inst J* 2004; **31:** 157–159.
4. Hetzer R, Weng Y, Potapov EV, Pasic M, Drews T, Jurmann M, et al. First experiences with a novel magnetically suspended axial flow left ventricular assist device. *Eur J Cardiothorac Surg* 2004; **25:** 964–970.
5. Nishimura K, Kono S, Nishina T, Ueyama K, Ikai A, Ikeda T, et al. Compact, reliable ventricular assist device as a bridge to recovery or for semipermanent use. *Jpn J Thorac Cardiovasc Surg* 2001; **49:** 646–651.
6. Nojiri C, Kijima T, Maekawa J, Horiuchi K, Kido T, Sugiyama T, et al. Development status of Terumo implantable left ventricular assist system. *Artif Organs* 2001; **25:** 411–413.
7. Nojiri C, Kijima T, Maekawa J, Horiuchi K, Kido T, Sugiyama T, et al. Recent progress in the development of Terumo implantable left ventricular assist system. *ASAIO J* 1999; **45:** 199–203.
8. Nojiri C, Kijima T, Maekawa J, Horiuchi K, Kido T, Sugiyama T, et al. More than 1 year continuous operation of a centrifugal pump with a magnetically suspended impeller. *ASAIO J* 1997; **43:** M548–M552.
9. Wieselthaler GM, Schima H, Lassnigg AM, Dworschak M, Pacher R, Grimm M, et al. Lessons learned from the first clinical implants of the DeBakey ventricular assist device axial pump: A single center report. *Ann Thorac Surg* 2001; **7:** S139–S143.
10. Bonaros N, Mueller MR, Salat A, Schima H, Roethy W, Kocher AA, et al. Extensive coagulation monitoring in patients after implantation of the MicroMed Debakey continuous flow axial pump. *ASAIO J* 2004; **50:** 424–431.
11. Wieselthaler GM, Schima H, Dworschak M, Quittan M, Nuhr M, Czerny M, et al. First experiences with outpatient care of patients with implanted axial flow pumps. *Artif Organs* 2001; **25:** 331–335.
12. Matsumura Y, Takata J, Kitaoka H, Kubo T, Baba Y, Hoshikawa E, et al. Long-term prognosis of dilated cardiomyopathy revisited. *Circ J* 2006; **70:** 376–383.
13. Shiba N, Watanabe J, Shinozaki T, Koseki Y, Sakuma M, Kagaya Y, et al. Poor prognosis of Japanese patients with chronic heart failure following myocardial infarction. *Circ J* 2005; **69:** 143–149.

Abbott v. Miracor, IPR2025-00113
Miracor Ex. 2026, p. 5 of 5