First experiences with a novel magnetically suspended axial flow left ventricular assist device

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Abstract

Axial flow pumps have gained increased acceptance since their first clinical use in 1998. The present report summarizes the clinical experience with patients treated for severe cardiogenic shock for the first time with a newly developed axial flow pump with magnetically levitated bearings. **Material and methods:** The axial flow pump Incor was implanted in 24 patients between June 2002 and June 2003. All except one patient were men. In 16 patients dilative cardiomyopathy, in seven ischemic and in one restrictive cardiomyopathy had been diagnosed. All patients presented with catecholamine-dependent end-stage heart failure, seven of them were on an artificial ventilator and three were dependent on intraaortic balloon pump support. All patients suffered from organ dysfunction resulting from low cardiac output.

**Results:** There were no perioperative deaths. The 30-day mortality rate was 8% (n = 2); 79% (n = 19) of patients reached a condition to be discharged home. The cumulative time on the device is 6.9 years; the longest individual time up to July 1, 2003 is 12.6 months. There were no structural defects or failures of the system. In one case the controller had to be exchanged because of intermittent malfunction. Cardiac output ranged between 4 and 6 l in all instances and there were no cases of infection of the drive-line or the system. Hemolysis was present initially but was not detectable in the later course. There were three instances of transient ischemic attacks. Two patients developed late cardiac tamponade with re-opening of the chest after 9 and 14 days. In one patient persistent gastrointestinal bleeding required re-hospitalization and transfusion therapy. Two patients were weaned from the device after 6 and 7 months of support, respectively.

**Conclusion:** The preliminary clinical experience with Incor is promising. The flow is sufficient for recovery from multiorgan failure and the pump allows long-term hemolysis-free support. The concept of magnetically levitated bearings has proven to be durable and reliable. In the case that the heart may recover through unloading, weaning from the pump is possible.

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1. Introduction

On June 16, 2002, the first patient, a 41-year-old man with advanced ischemic cardiomyopathy (ICM), underwent implantation of the newly developed left ventricular assist device (LVAD) Incor. This LVAD was developed by Berlin Heart, Berlin, Germany, in cooperation with the German Heart Institute Berlin. Incor is an axial flow pump with the special features of a magnetically levitated impeller.

Since the first implantation, 23 more patients have been treated with this device as of June 2003 at our institution.

2. The Incor LVAD

Incor is an axial flow pump for support of the left ventricle and is able to provide a flow of up to 6 l/min against a pressure of 100 mmHg. It was designed with the aims of minimum wear, low energy consumption and reduced damage to the blood components. Table 1 shows technical data of Incor.

The functions of the pump can be described as follows (Fig. 1): Blood is evacuated from the left ventricle through an inflow cannula, which is inserted into the apex of the heart. This cannulated cannula is connected to the pump inlet using a quick snap connector. At the pump inlet the stationary flow straightener helps to even out the blood stream coming from the heart.
The blood stream is then directed to the impeller, which is the only moving part of the pump. Magnetic suspension bearings stabilize the impeller actively in the axial direction and passively in the radial direction. Thus, the impeller has no mechanical contact with the pump housing, and this renders the system completely wear-free and almost silent. The impeller is designed as an Archimedes screw, thus giving propulsion and spin to the blood stream.

The impeller is driven by an ‘air-gap’ motor with an efficiency of more than 90%, which ensures that the pump does not generate any significant amount of heat. The impeller rotates at a preset speed of between 5000 and 10,000 rpm.

The blood leaving the pump passes the stationary diffuser, which is mounted within the pump tube. This reduces the spin of the blood stream and adds to the pressure build-up. The blood is then transported to the aorta through the outflow cannula. Both cannulae are made of medical grade silicon; the pump is of titanium alloy. All blood-contacting titanium surfaces are heparin-coated by the Carmeda process. The Carmeda process results in covalent binding of heparin to the inner pump surface. A section through the pump is shown in Fig. 1A.

Incor has an integrated sensor system to measure the pressure head across the pump. This measurement together with the known speed of the rotor and the geometrical pump dimensions allows precise determination of the flow through the pump. Both sets of information are displayed graphically on the screen of a laptop computer connected to the control unit.

The later version of the system applied in the last eight patients was equipped with an automatic anti-suction algorithm based on the grade of pulsatility of the blood.
flow across the pump. In case of impending suction as detected by a decrease to below a preselected grade of pulsatility, the speed of the pump is reduced by the algorithm. When the danger of suction-related pump stop has thus been overcome, the speed of the impeller is returned to the preset level. This modus prevents back flow through the pump.

The energy supply and pump control are provided by external batteries and the control system, which are both connected to the pump through a percutaneous cable. Two high efficiency rechargeable batteries allow for up to 10–12 h function independent of a stationary unit. The control unit displays alarms and functional pump parameters. Pump settings can be changed after connecting the control unit to the laptop computer. The external parts are carried in a specially designed shoulder-bag and weigh 2.5 kg.

3. Patients

The patients who received the Incor system between June 2002 and June 2003 were 23 men and one woman. Their mean age was 54.1 ± 7.3 years (range, 39–64 years).

The underlying disease leading to end-stage heart failure was dilative cardiomyopathy (DCM) in 17 patients, ICM in 6 patients, and restrictive cardiomyopathy (RCM) in one. In all except one patient Incor was implanted via median sternotomy with the outflow cannula connected to the ascending aorta; in one patient with a previous bypass operation the approach was through left lateral thoracotomy. In one case of a patient with previous median sternotomy during an acute coronary bypass operation 1 month earlier, the decision was made to implant the pump via left thoracotomy. In one patient with previous median sternotomy in 23 patients the LVAD was implanted via median sternotomy, with normothermic extracorporeal circulation (ECC) and induced ventricular fibrillation during the apical cannula implantation. A pulmonary artery vent was used in all cases. Implantation included sewing of a ventricular apex holding ring onto the anterior aspect of the left ventricular apex with 10–12 felt-buttressed 3.0 polypropylene sutures, after which a core of ventricular muscle was excised from within this ring, the ventricular cavity was cleared of any thrombotic material or trabecular structures and the inflow cannula was inserted, adjusted under transesophageal echocardiographic control and sewed to the apex holding ring. The pump structure was then connected to the inflow cannula, the system was de-aired and the heart was defibrillated. The outflow cannula was sutured to the ascending aorta, after partial exclusion clamping and longitudinal incision of the aortic wall, with a continuous 4.0 polypropylene suture secured with 4–5 additional felt-buttressed mattress sutures. The outflow cannula was cut to the appropriate length and, after de-airing, was connected to the outflow part of the implanted pump. The drive line was brought to the outside through a long subcutaneous tunnel at the level of the navel on the right side of the abdomen. The control system and the batteries were connected to this cable, the pump was calibrated and the assist system was started and brought to full flow under gradual reduction of ECC support. This was performed under nitrous oxide insufflation and with monitoring of left atrial pressure, pulmonary artery pressure and central venous pressure. When the LVAD had reached its full flow and hemodynamics were considered acceptable, ECC was terminated, the ECC cannulae removed and heparinization neutralized by the administration of protamine. The chest was closed with continuous transesophageal echocardiographic monitoring, thus ensuring appropriate position of the inflow cannula parallel to the ventricular septum within the left ventricle and adequate drainage of the cardiac cavities.

In one case of a patient with previous median sternotomy for acute coronary bypass operation 1 month earlier, the decision was made to implant the pump via left thoracotomy in the fifth intercostal space and the pump was implanted under femoro-femoral bypass in the left-apex-to-descending-aorta mode, whereby the anastomosis of the outflow cannula was sutured to the proximal descending aorta just below the takeoff of the left subclavian artery [1]. A 3-D rendering of the CT-scan is shown in Fig. 2.

3.1. Surgical procedures

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3.1.1. Anticoagulation regime

The anticoagulation medication was administered according to our established protocol, depending on postoperative studies of aPTT, thrombelastograms and platelet function tests, as previously described [2,3]. The institutional protocol consists of use of heparin in the early postoperative period to keep the aPTT between 60 and 80 s.
and additional administration of aprotinin for 6–12 h. After the thoracic tubes are removed and multiorgan, especially liver, dysfunction is no longer evident, treatment with warfarin is started to maintain the international normalized ratio at 3.5. Aspirin, diprydamol and clopidogrel were given according to the result of thrombocyte activation tests with the intention of keeping the activation by arachidonic acid and adenosine around 30%. The thrombelastogram helped to detect hypo- or hypercoagulability and to judge the effect of heparin.

### 3.1.2. Weaning protocol

All patients were included in our initial weaning protocol. As described for patients on pulsatile LVADs [4], in patients with a continuous flow VAD we also used echocardiographic studies of ejection fraction and left ventricular end diastolic diameter (LVEDD) under complete unloading. If these parameters recovered during the unloading period, the studies were performed with the pump speed reduced to the level that just compensated the back-flow through the pump. If sustained myocardial recovery was demonstrated during repeated studies, the device was explanted.

In patients without myocardial recovery and between echocardiographic studies in patients with signs of recovery the pump speed was maintained to provide full support. However, some grade of pulsatility developed in all patients [5].

### 4. Results

In 19 patients recovery after LVAD implantation was completely uneventful. Nitric oxide could be rapidly reduced and the patients were weaned from the respirator. In three patients with advanced pulmonary vascular resistance, prolonged periods of administration of nitric oxide and i.v. iloprost became necessary. In one patient immediate right ventricular failure required the additional implantation of a right ventricular support system (Berlin Heart Excor). This patient died from multiorgan failure (MOF) 22 days later.

One patient (aged 64 years) died 124 days postoperatively without having recovered from preoperative MOF and one patient (aged 61 years) required re-exploration for late cardiac tamponade and died from secondary MOF after 47 days on support. There was one death from sepsis 30 days postoperatively in a 51-year-old patient. Twelve patients have since been discharged home and nine are awaiting discharge.

The cumulative time on the device is 6.9 years; the longest individual time up to July 1, 2003 is 12.6 months.

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Fig. 3. X-ray of first patient implanted with Incor, in whom the device was explanted 6 months later. (A) before implantation; (B) before explantation; (C) 6 months after explantation.
In two patients so far the LVAD has been explanted following complete recovery of myocardial function. In the first patient, who had advanced ICM, routine repeat echocardiography demonstrated the return of cardiac dimensions and left ventricular ejection fraction to normal values, even after a short period of reduction of the pump flow to a minimum. Repeat coronary angiography was then performed with the LVAD in place after 5 months of pump support and showed complete obstruction of the right coronary artery and of the left descending artery with good peripheral collateral filling. Pump explantation and simultaneous coronary bypass surgery were proposed to the patient and performed 6 months after the initial LVAD implantation with repeat median sternotomy and ECC. The LVAD was explanted leaving the transected apical cannula in place, which was easily occluded using a specially designed self-expanding plug. The occluded inflow cannula was left in place in order not to molest the recovered heart; the outflow graft was completely explanted. A venous aorto-coronary artery bypass graft was placed on the right coronary artery and the left internal mammary artery was anastomosed to the left descending artery (Fig. 3). The second patient, who had dilated cardiomyopathy, showed complete myocardial recovery and normal cardiac dimensions and ejection fraction after 29 weeks of LVAD support. The pump was explanted without ECC by exposing it via median sternotomy as described above. Both patients have maintained normal cardiac function on follow-up now at 6 and 4 months, respectively, after pump explantation.

There were no structural defects or failures of the pump. In one case the controller had to be exchanged due to intermittent malfunction. Cardiac output ranged between 4 and 6 l in all instances and there were no cases of infection of the drive-line or the system. Hemolysis was present initially but was not detectable in the later course (Figs. 4–6) except for some persisting elevation of free hemoglobin.

4.1. Adverse events

There were three instances of transient ischemic attacks with temporary visual disturbances in one patient which,
however, did not result in any lasting damage. Two patients developed late cardiac tamponade with re-opening of the chest after 9 and 14 days. In one patient persistent gastrointestinal bleeding required re-hospitalization and transfusion therapy.

5. Discussion

In this report we describe the initial clinical experience with the new axial flow LVAD Incor, which has been successfully implanted at our institution in 24 patients as of July 2003. This device has been developed in cooperation with the Deutsches Herzzentrum Berlin and produced by the Berlin Heart, Berlin, Germany.

During recent years several types of axial flow blood pumps have been introduced into clinical practice and have since gained increased interest and acceptance, at least for medium-term support. The first patient ever to receive such an axial flow device (MicroMed DeBakey VAD) was operated on at the Deutsches Herzzentrum Berlin on November 13, 1998. The device supported this patient’s circulation well until he died from intracranial hemorrhage 47 days later [5]. So far, more than 200 MicroMed DeBakey VADs and over 50 Jarvik 2000 axial flow pumps have been implanted worldwide [6,7].

Incor differs from the above-mentioned pumps mainly in the mode of suspension of the impeller. Whereas in the other axial flow systems the impeller rotates on mechanical bearings, in Incor the Maglev (Magnetic Levitation) principle has been applied. This means that the impeller moves within a magnetic field, thus avoiding any friction and presumably any wear. Furthermore, energy consumption and heat development are reduced and the pump is almost inaudible. So far this principle, which has been introduced into clinical practice for the first time in our patients, has proven to be durable and reliable.

Some specific features have been introduced to decrease the potential of thrombus formation, including silicon cannulae, relying on the vast experience with the Berlin Heart Excor system [8], the impeller and stator designed by computational fluid dynamic assuring vortex-free flow through the pump system, and coating with covalent bonded heparin by the Carmeda process [9].

Suction of myocardial tissue into the inflow cannula, a phenomenon which is frequently observed in dehydrated patients or during change from supine to upright position, leads to occlusion of the cannula with subsequent flow cessation and/or arrhythmia. Since the automatic suction control algorithm was introduced, no such suction episodes were observed in our patients.

At present the pump is operated by a portable external controller and powered by a pair of rechargeable batteries via a percutaneous cable. A fully-implantable version has been designed and will be introduced in due course.

On the basis of our initial experience with 24 patients and a total of 6.9 years of support time the following conclusions can be drawn:

The system can be easily and safely implanted and can be readily buried either below or anterior to the heart, when used in the apex-to-ascending-aorta mode. Based on our previous positive experience with the MicroMed DeBakey VAD and Berlin Heart Excor [1,10] we also implanted the INCOR device between the apex and the proximal descending aorta through lateral thoracotomy in the left chest below the lung in patients with previous heart surgery through median sternotomy. In these patients no thrombosis or thromboembolic events in the coronary arteries or branches of the aortic arch have been seen. However, we recommend performing a CT scan of the thoracic aorta to rule out significant calcifications, which may cause fatal embolic events.

Except for the one case of intermittent controller dysfunction no technical problems occurred.

Explantation of the device has been facilitated by introducing a self-expanding occlusion plug for the apical cannula which minimizes any disturbance of the recovered heart.

Following our strict rule to reserve assist implantation for patients in a life-threatening stage of heart failure unresponsive to any other kind of treatment, all patients who received the Incor were in such a dismal condition (Table 2). All patients survived the implant operation and the great majority (i.e. 88%) enjoyed reverse of shock-related organ dysfunction. However, three patients with high pulmonary vascular resistance did not respond to our standard regime of NO insufflation [11] or even to infusion of iloprost. The outcome was fatal in two of them and one patient is still dependent on intensive care as of June 2003.

Both the incidence and severity of thromboembolic events were low and there was no evidence of thrombus formation within the pump. So far there have been no incidents of pump and cable infection. This coincides well with our experience with 37 implanted MicroMed DeBakey VADs, where the infection incidence was also very low and certainly lower than that observed with the large implantable pulsatile pumps [12,13]. This observation sheds some light on the importance of pump size and the related tissue trauma.

As already demonstrated by the bulk of experience with the MicroMed DeBakey VAD and Jarvik 2000 systems [6,7,14,15], the continuous flow pattern produced by Incor was tolerated well by the organism and there were no signs whatsoever of any organ dysfunction or circulation dysregulation that could be related to the flow pattern. This was true for both the apex-to-ascending-aorta and the apex-to-descending-aorta mode of implantation.

The adequacy of the flow produced by the pump has been demonstrated by the reasonable level of quality of life and physical activities. Most patients have resumed their daily routine at home.

It has been exciting to see that two patients could be successfully weaned from the device after the heart...
demonstrated complete recovery in size and function. One is a patient with coronary artery disease with an originally extensive amount of hibernating myocardium who also received coronary artery bypass grafts at the time of pump explantation. In the other patient, who had DCM, we followed the concept of pump explantation after heart recovery that was introduced in our institution in 1995 and has since been applied in 33 patients who, however, were treated with pulsatile LVADs [16]. The two patients demonstrated normal heart function 4 and 6 months after pump explantation. It has been recognized with delight that such a recovery process may also be achieved with continuous flow pumps. Since, based on our experience, explantation of an LVAD after myocardial recovery can be achieved in some patients, a special plug for the apex cannula has been developed by the company to facilitate pump removal. As in our earlier experience the left-behind apex cannula has not created any further complications as was initially feared.

The longest follow-up on the Incor pump is now 1 year. Since the waiting time for a donor heart in many European countries is between 10 and 12 months at present, any bridge-to-transplant device should satisfy the requirement of being able to bridge such a time span. As with every sophisticated assist device, the goal is long-term support for ‘destination therapy’. So far Incor appears to justify our hopes for longer and safe support.

6. Limitation of the study

The present study showed good performance of the new LVAD. However, the impact of the device on the course of neurohumoral markers of heart failure has not been presented in this study. Comparison of the impact of different devices on neurohumoral markers of heart failure is of great interest and is underway.

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