Mechanical circulatory support: state of the art and future perspectives

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Mechanical circulatory support (MCS) has been viewed, until recently, as a rescue therapy to be applied when all else fails. Not surprisingly, this has resulted in suboptimal outcomes. Fortunately, the perseverance of a few dedicated groups has produced improved outcomes and the concept of MCS as an elective therapy is now steadily gaining acceptance. This is particularly true in the postcardiotomy setting, where a large number of new options are now available. The recently completed REMATCH study has demonstrated the feasibility and efficacy of permanent MCS as a therapy for end-stage heart failure, despite a high rate of device complications. Donor availability is decreasing and biological solutions will not be available for many years. New generation implantable rotary pumps, a fully implantable left ventricular assist device and a total artificial heart are all undergoing clinical evaluation, and several new exciting designs are in preclinical evaluation. A new paradigm for the treatment of terminal heart failure is emerging, where an unpredictable and expensive medically managed death in an intensive care unit setting is being exchanged for a more predictable high-cost, front-loaded therapy with management from the outpatient clinic. The perfusionist community has much to contribute to this emerging life support field, not only in the perioperative period, but also in providing ongoing technical support to hospital staff, recipients and their families. Perfusion (2003) 18, 159–169.

Background

Congestive heart failure is a major public health issue in the developed world and a rapidly increasing health problem in the developing world. Although mortality from cardiovascular disease, particularly secondary coronary disease, has declined significantly since the 1950s, the impact of heart failure continues to increase. This trend is related to an ageing population and, ironically, by advances in emergency and interventional therapies, which now rescue patients from previously fatal acute events.

The statistics are impressive, showing cardiovascular disease to be easily the number one cause of death in the US, responsible for twice as many deaths as cancer and eclipsing the next seven leading causes combined. The US prevalence is some 4.8 million cases per year and, with 400,000 new cases annually, heart failure is the primary or contributing cause in 260,000 deaths per year. At an annual cost approaching $40 billion in the US, heart failure is the single most expensive health care problem. Despite advances in medical therapy, this is a progressive disease, resulting in increasing disability, more frequent hospitalizations and premature death. The mortality of patients with advanced New York Heart Association (NYHA) class III–IV exceeds 50% at two years, and for end-stage class IV patients, refractory to oral medications and dependent on intravenous inotropic agents, approaches 70% at six months. Similar epidemiological and economic data apply to Europe as a whole.

Heart transplantation provides the only currently available effective therapy, with a five-year survival of approximately 65%. However, the paucity of donors means that less than 5% of patients who could benefit actually receive a donor heart.

So, is there a magic cure just around the corner? The answer is a resounding ‘no’. While gene-based therapies and cell and tissue transplants offer a possible solution for the future, these treatments are many years away from clinical reality.

Mechanical circulatory support (MCS) has been viewed, until recently, as a rescue therapy to be applied when all else fails. Not surprisingly, this has resulted in suboptimal outcomes. Fortunately, the perseverance of a few dedicated groups has produced improved outcomes and the concept of MCS as an elective therapy is now steadily gaining acceptance. The recently completed REMATCH study has demonstrated the feasibility and efficacy of permanent MCS as a therapy for end-stage heart failure.

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failure, despite a high rate of device complications. New generation implantable rotary pumps, a fully implantable left ventricular assist device (LVAD) and a total artificial heart (TAH) are all undergoing clinical evaluation and several new exciting designs are in preclinical evaluation. There are also an increasing number of devices aimed at acute support and a few devices designed to prevent or slow ventricular remodelling.

A new paradigm for the treatment of terminal heart failure is emerging, where an unpredictable and expensive medically managed cardiac death in an intensive care unit (ICU) setting is being exchanged for a more predictable high-cost, front-loaded therapy with management from the outpatient clinic.

The mechanical options

There are a number of ways in which MCS devices can be classified. However, the system outlined in Figure 1 provides a scheme in which devices are classified according to their intended use. **Class I** devices are intended for very short-term use (hours to days) and are used when early functional recovery is expected and minimal intervention is desirable. **Class II** devices are used when an intermediate support time is expected (days to weeks), but functional recovery is expected to take longer. **Class III** devices are intended for extended use (months to years). There are three main subcategories of extended use; as a therapeutic bridge to recovery (BTR) or as a means to provide a chronic boost to native function and, therefore, provide a better exercise response and, hence, improved quality of life (QOL). The bridge to transplant (BTT) category has been where most of the current first generation devices have been tried, tested and evolved as the transplant waiting lists around the world grow longer and average waiting times increase from a few weeks to now nearly nine months. The final category has been variously described as a destination, long-term alternative to transplantation, permanent and definitive (DT) MCS therapy. This application is aimed at patients who are thought to have no prospect of either transplantation or of native ventricular recovery and who will be reliant on a device (not necessarily the same device) for the rest of their lives. Other potential candidates are those who, while fulfilling the transplant criteria, are likely to have poor post-transplant outcomes or those who are likely to be difficult to match because of body habitus, blood group or antibody status. **Class IIIb** includes all devices that do not have direct blood contact and is further subdivided into active and passive devices.

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**Figure 1** This figure illustrates one scheme for the classification of MCS devices, based on the intended application. Class I devices are intended for hours to days, Class II for weeks to months and Class III for months to years. Class III devices are further divided into those that have a direct blood interface (IIIa) and those that do not (IIIb). Class IIIb devices are further divided into active and passive devices.
Class I devices

These pump systems include intra-aortic balloon pumps, catheter-mounted pumps, external pumps and the pump/gas exchanger systems comprising extracorporeal life support systems (ECLS). The catheter mounted pumps come in two generic varieties in which the pumping mechanism is either mounted within the implanted section of the catheter or mounted externally, connected to a coaxial or other specialized catheter system.

Impella CardioSystems AG (Aachen, Germany) is marketing two devices (Figure 2); the left-sided pump (Recover100) is a 9 Fg catheter-mounted 6.4 mm axial pump that can be introduced, via the femoral artery, into the left ventricular cavity. Blood is pumped from the left ventricle into the descending aorta at flows up to 5.0 L/min. The right ventricular assist device (RVAD; Recover600) comprises the same axial pump mounted in a cage designed to be implanted into the right atrium. A polytetrafluoroethylene (PTFE) 8-mm graft connects the output to the pulmonary artery and the pumps can deliver up to 6.0 L/min. Both pumps are designed for up to seven days use.

A-Med Systems (Sacramento, CA, USA) market two pump-catheter systems that employ a small externally mounted centrifugal pump connected to coaxial catheter systems. The left ventricular system (pLVAD) is inserted percutaneously over a guidewire in the femoral artery into the left ventricle and is able to aspirate blood into the aorta at flows up to 4.0 L/min. Distal limb perfusion is accomplished with a 20 Fg shunt catheter. The right ventricular system is inserted via the internal jugular vein and placed so that the take-up ports are in the right atrium and the distal delivery port in the main pulmonary artery. Blood is pumped at up to 4 L/min and both systems are intended for use up to three days.

A number of manufacturers market centrifugal pumps that are mainly used for cardiopulmonary bypass (CPB) applications, including Biomedicus, Terumo, Sarns, Bard, Jostra and Nikkiso.

The TandemHeart Pump (Cardiodynamics, Pittsburgh, PA, USA) is a small centrifugal pump connected to an uptake cannula introduced via the femoral vein trans-septally into the left atrium with a return into the femoral artery.

The DeltaStream Pump (Medos AG, Aachen, Germany) is a diagonal flow pump that is being developed for a number of applications, ranging from CPB to paracorporeal MCS. The pump has an option for pulsatile operation. Cancion Cardiac Recovery System (Orquis Medical Corporation, Lake Forest, CA, USA) is a magnetically levitated centrifugal pump with inflow from the left femoral artery and outflow through the right femoral artery.

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**Impella Class I Devices**

![Impella Devices](image-url)

*Figure 2* Impella market two Class I integrated microaxial pump systems designed for short-term support. The left sided *Recover100* is introduced by way of the femoral artery and placed so that blood is aspirated out of the left ventricle into the aorta. The *Recover600* is used for temporary support of the failing right ventricle. Anticoagulation is provided by a local purge system and both pumps are approved for use up to seven days. (Courtesy of Impella Cardiotechnik AG, Aachen, Germany.)
into the descending aorta. It is used to provide temporary unloading of the left ventricle and circulatory boost for patients suffering from acute decompensated heart failure. Table 1 summarizes the major characteristics of this group of devices.

Class II devices

These pumps usually comprise pump systems that are mounted in the paracorporeal position; the pumps are attached to the outside of the body and connected to the circulation via large percutaneous cannulae. The pumps may be of a rotary or sac/diaphragm design. Patients are usually able to be mobilized, supported by relatively large consoles. Some systems now have a portable driver option, which may even allow discharge home. These systems are characterized by having more versatility than other classes of pumps, in that a variety of cannulation options (Figure 3) are available and both uni- and biventricular support are possible for a wide range of patient sizes. The pneumatically activated pumps use alternate negative and positive pressure to fill and eject blood from sac-lined, rigid pump housings. Inflow and outflow valves are either of a standard mechanical design or trileaflet polymeric construction. Control is usually semi-automatic and triggered in a fill-to-empty mode. Anticoagulation is required. Some designs have a selection of pump and cannula sizes, making pediatric support an option. Disadvantages for chronic use include the use of pneumatic power (size of drivers), large percutaneous drivelines and the use of relatively restrictive inflow and outflow cannulae.

The Abiomed BVS 5000 (Abiomed Inc., Danvers, MA, USA) is an extracorporeal, dual chamber, pneumatically powered pulsatile pump. Blood is drained into the upper 100 mL atrial chamber under gravity. The lower ventricle is ejected according to the filling conditions, using a closed circuit automatic control console. The resistances of the long extracorporeal lines are offset, to some extent, by this arrangement, which allows continuous flow from the heart. The system can provide both uni- or biventricular support.

The Berlin Heart (Mediport, Berlin, Germany) is a family of pneumatically actuated pulsatile ventricles and cannulae. There are five sizes of ventricles, ranging from 12 to 80 mL stroke volumes, allowing a large size range of patients, from neonates to adults, to be supported. A choice of valve types is available: mechanical disk or trileaflet polymeric. The ventricles are heparin-bonded polyurethane. A portable driver (EXCOR) is available.

The Medos VAD (Medos, Aachen, Germany) is similar to the Berlin Heart, but uses different cannulae and does not yet have a portable driver option.

The Thoratec VAD (Thoratec, Pleasanton, CA, USA) comprises a single size (65 mL stroke volume)

### Table 1

<table>
<thead>
<tr>
<th>Device</th>
<th>Power</th>
<th>Pump type</th>
<th>Support</th>
<th>Inflow</th>
<th>Patient size</th>
<th>Ambulation</th>
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<tr>
<td>A-MED pLVAD</td>
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<td>LVAD</td>
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<td>RVAD</td>
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<td>Atrial</td>
<td>Paed/adult</td>
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<td>Cardiodynamics Tandem</td>
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<td>Adult</td>
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<tr>
<td>MEDOS Deltastream</td>
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<td>Diagonal</td>
<td>BiVAD</td>
<td>Atrial</td>
<td>Paed/adult</td>
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<td>Orqis Medical Cancion</td>
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<td>Centrifugal</td>
<td>LVAD</td>
<td>Femoral arteries, descending aorta</td>
<td>Adult</td>
<td>No</td>
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</table>
ventricle and a range of cannulae to facilitate a number of cannulation options (Figure 4). Despite a single ventricle size, patients as small as 17 kg have been supported. An implantable version of the ventricle (IVAD) is undergoing clinical trials. A portable driver option is available.

Table 2 summarizes the major characteristics of this group of devices.

### Class III devices

There are two broad divisions in this group of devices, all of which are designed for extended support times; those that have direct blood contact (IIIA) and those which do not (IIIB). The IIIa systems are either fully or partially implanted and most are electrically powered, allowing for maximum patient mobility and autonomy (Table 3).

In the BTR/QOL application, sac/diaphragm pumps can be used in combination with portable drivers, but if chronic support is required, this is not an optimal solution. For BTT applications, the paracorporeal pneumatically operated pumps, the implanted electrical sac pumps and the implanted rotary pumps all offer potential solutions. However, for the DT application it is imperative to have an implantable system.

### Electrical sac pumps

The wearable Novacor (World Heart Corporation, Ottawa, Canada) and the HeartMate XVE (Thoratec Corporation, Pleasanton, CA, USA) are the only commercially approved and currently available long-term systems, although three rotary pumps (MicroMed DeBakey, Jarvik 2000 and HeartMate II), several other rotary designs, one fully implantable LVAS and one TAH are also currently undergoing trials for this application.

The Novacor system was originally designed as a totally implantable system, but has only evolved as far as the current wearable system (Figure 4). The pump-drive unit is implanted in a pocket created below the diaphragm and unloads the left ventricle via an apical cannula, returning blood to the ascending aorta. A percutaneous driveline, contain-
The wearable controller provides for a number of control options, which can be fine-tuned to the requirements of the recipient, and allows complete autonomous operation. Portable power packs provide for up to seven hours of tether-free operation. (Courtesy of World Heart, Ottawa, Canada.)

Table 2. Class II devices are used for intermediate support times (weeks to months); most are used in the paracorporeal position, attached to the outside of the torso.

<table>
<thead>
<tr>
<th>Device</th>
<th>Power</th>
<th>Pump type</th>
<th>Support</th>
<th>Inflow</th>
<th>Patient size</th>
<th>Ambulation</th>
</tr>
</thead>
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<td>Abiomed BVS 5000</td>
<td>Pneumatic</td>
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<td>BiVAD</td>
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<td>Infant/adult</td>
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<tr>
<td>MEDOS VAD</td>
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<td>BiVAD</td>
<td>Atrial/ventricle</td>
<td>Infant/adult</td>
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<tr>
<td>Thoratec VAD</td>
<td>Pneumatic</td>
<td>Sac</td>
<td>BiVAD</td>
<td>Atrial/ventricle</td>
<td>Adult</td>
<td>Yes</td>
</tr>
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</table>

The **HeartMate** is similar to the Novacor, but differs in that pump actuation is achieved by way of a rotary motor driving a cam-operated single pusher plate, delivering a stroke volume of 80 mL. The other major difference is in the blood contact surface, which is textured to encourage the development of an adherent pseudoneointimal lining. Both these systems allow recipients to return home and to lead near normal lives in the community.

The **LionHeart** (Arrow International, Reading, PA, USA) is the first fully implantable LVAD. The blood pump is based on the Pierce-Donachy design with the addition of a mechanical actuator, comprising an electric motor driving a roller/screw mechanism, controlled by Hall effect sensors. The pump fills passively and the maximum output is 8 L/min with a dynamic stroke volume of 64 mL. The implanted components include the pump drive unit, controller/power pack, a transcutaneous energy transfer system (TETS) and a volume compensator with refill port. The TETS system is placed in
the right chest wall and the volume compensator in the left chest wall (Figure 5). The internal power pack provides approximately 30 minutes complete tether-free operation, allowing MCS patients the chance to swim for the first time.

**Rotary pumps**

Rotary pumps come in three generic forms, axial, diagonal and centrifugal. Hydraulic efficiency is best in the centrifugal designs, but a smaller size can be accomplished with the axial designs for the same outputs. Diagonal designs give mixed benefits and disadvantages. Blood pump design is, therefore, a matter of compromise to meet the application. Two other features of rotary pumps are important in MCS applications; bearings and pump control. First generation rotary pumps all have various forms of mechanical journal bearings and this produces problems of local heating, stasis around the bearing and limited durability. Second generation pumps employ various forms of magnetic or hydraulic bearings, or a combination of both. Control issues are more difficult to solve since the intrinsic function of rotary pumps is to be flow boosters. This means that they have relatively flat pressure/volume curves and are relatively afterload sensitive. The major impact of these characteristics is the difficulty in avoiding high negative pressures on the input side and having a system that responds in a physiological way to changes in flow demand. Other areas of concern revolve around the physiological consequences of chronic nonpulsatile flow and the safety concerns regarding retrograde shunts in the event of a pump stoppage, since these devices have no valves. However, the advantages are small size, simplicity and relatively low cost.

The DeBakey VAD (MicroMed Technology Inc., Houston, TX, USA) is a 95 g, 30 mm diameter axial pump and the first to be used clinically. The pump can produce a flow of 6 L/min against a 100 torr pressure at 10000 rpm. Pump flow is monitored using an ultrasonic flow probe on the outflow graft. Control is by physician-set pump speed.

The Jarvik 2000 (Jarvik Heart Inc, New York, USA) is the smallest of the current axial pumps with a 25 mm diameter and a weight of 90 g. Designed for intraventricular placement through an apical attachment cuff, the pump is implanted through a left thoracotomy as an apioaortic pumped shunt to the descending aorta (Figure 6). The pump is designed to be operated as a true assist system, and the aim is to set the pump output so as to allow the aortic valve to continue to open with each heartbeat. Control is by the recipient who is allowed to change pump speed within a window determined by the physician. Several patients have now been supported for more than two years and one patient, implanted for DT therapy, is doing well after more than three years of support.

The HeartMate II (Thoratec Corporation, Pleasanton, CA, USA) is similar to the other two axial pumps, but larger; 176 g and 40 mm in diameter (Figure 6). This pump can deliver flows of up to 10 L/min against a pressure of 120 torr at 13000 rpm. Pump speed is controlled by the physician.

The INCOR (Mediport, Berlin, Germany) is a magnetically suspended axial pump, 200 g in weight and 13 cm in diameter. The pump can deliver flows of up to 7 L/min against a pressure of 100 torr at 10000 rpm. Pump speed is controlled by the physician.

The SynCardia TAH (SynCardia, Tuscon, AZ, USA) has had a variety of names over the years: Jarvik 7, CardioWest, and now SynCardia. This is a biventricular replacement device (BVRD) even though the more common nomenclature is TAH. The 70 mL pneumatically actuated ventricles are attached via Dacron cuffs to the atraia at the level of the atrial-ventricular valves. Power and control are via a large console by way of percutaneous drivelines. The BVRD approach would seem to be able to confer the advantages of high flow with low preload. Immediately after implantation, which may benefit early secondary organ recovery. The BVRD is also

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Class III devices are for extended applications (months to years)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Device</strong></td>
<td><strong>Power</strong></td>
</tr>
<tr>
<td>Thoratec HeartMate</td>
<td>Elec</td>
</tr>
<tr>
<td>WorldHeart Novacor</td>
<td>Elec</td>
</tr>
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<td>Thoratec IVAD</td>
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<tr>
<td>Arrow LionHeart</td>
<td>Elec</td>
</tr>
<tr>
<td>MicroMed DeBakey</td>
<td>Elec</td>
</tr>
<tr>
<td>Jarvik 2000</td>
<td>Elec</td>
</tr>
<tr>
<td>Berlin Heart INCOR</td>
<td>Elec</td>
</tr>
<tr>
<td>SynCardia</td>
<td>Pneu</td>
</tr>
<tr>
<td>AbioCor</td>
<td>Elec</td>
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</table>

Ilia devices all have direct blood contact and are used for three major applications: for recovery or for boosted output, as a BTT or for definitive (permanent) support. Ilb devices all have no direct blood contact and are not covered in this table.
Figure 5 The Arrow LionHeart is the first fully implantable pulsatile LVAD. This provides the advantages of removing the need for a percutaneous driveline, greatly reducing the infection risk and allowing the recipient the possibility of being completely untethered, for periods of up to 40 minutes. However, the design also requires the implantation of a large amount of equipment, making it only suitable for larger patients. TETS = transcutaneous energy transfer system. (Courtesy of Arrow International, Reading, PA, USA.)

Figure 6 The Jarvik 2000 Flowmaker is the smallest of the implantable axial pumps. This design requires no inflow cannula as it is placed within the ventricular cavity. Arterial return can be to the descending aorta, as illustrated, or to the ascending aorta. Two driveline options are available; a transcutaneous small (4.3 mm) flexible cable or a connection to a behind-the-ear pedestal, based on implantable cochlea technology. (Courtesy Jarvik Heart Inc., New York, USA.) The Berlin Heart INCOR is a second generation axial pump which employs a magnetically suspended impeller, so making for an enhanced potential durability. (Courtesy Mediport, Berlin, Germany.)
the device of choice in patients with morphological myocardial damage, intractable dysrhythmias or fixed high pulmonary vascular resistance.

**AbioCor TAH** (Abiomed Inc., Danvers, MA, USA) is the first electrically powered BVRD that is fully implantable with an associated controller/power pack, volume compensator and TETS (Figure 7). The ventricles are actuated by a compact unidirectional centrifugal hydraulic pump, mounted between the two ventricles, capable of producing blood flows in excess of 10 L/min. A cylindrical rotary valve alternately directs the hydraulic fluid to the right and left ventricle. Balance between left and right blood flow is achieved using a hydraulic balancing chamber attached to the left inflow port and to the right pumping chamber, by way of a shunt. This allows regulation of the right output according to left input pressure. Unidirectional blood flow is achieved using four trileaflet polymeric valves.

**Future perspectives**

A greater variety of simple, inexpensive Class I devices means that acute cardiogenic shock can now be more easily and inexpensively treated, where the overall survival has been less than 25%. Postcardiotomy failure remains at approximately 3%, so that a significant number of patients could benefit from effective therapy. Current Class II devices are likely to be superseded by the small rotary pumps when these have been optimized, since they offer the prospect of easier implantation, less critical management and lower cost. In Class IIIa devices, the field is moving towards fully implantable devices, which will give a reduced incidence of infection complications and an overall greater quality of life. First generation devices with percutaneous drivelines have infection rates in the 40% range, the small rotary pumps with small flexible drivelines have an incidence of less than 10% and the fully implantable systems a rate of less than 5%. However, most current devices, with the exception of Novacor, are not demonstrating the multiyear durability that will be required of a permanent device. This will be overcome by better engineering and by new designs, such as the HeartSaver VAD (World Heart, Ottawa, Canada), where the existing electromagnetic technology, used so successfully in the Novacor, is being adapted to power a new compact design requiring no contact surfaces and no volume compensator (Figure 8). This device could be produced at less than 50% of the cost of

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**Figure 7** The AbioCor Total Artificial Heart is the first fully implantable BVRD. The heart is placed orthotopically and the TETS, controller and rechargeable battery pack are implanted within the abdominal space. This device is under clinical investigation in the US and Europe. (Courtesy Abiomed Inc., Danvers, MA, USA.)
the current device. The current applications for BTT will probably continue for patients requiring inotropic support, as recent literature suggests that postbridge outcomes are superior to inotrope bridged patients, and for the high risk transplant candidates. The application of therapeutic BTR is a fascinating one and evidence is steadily growing that this approach should work for significant numbers of patients.

The development of the Class IIIb devices is also of interest, since these non-blood-contacting devices simplify many of the management challenges of the other systems and can be used adjunctively at the time of conventional surgery.

**Costs**

There has been much concern over how society will pay for the widespread use of DT MCS devices, given that the overall demand is variously estimated at between 30,000 and 200,000 patients per year in the US alone. However, cost data from REMATCH showed that the median overall cost was some $250,000 (including $65,000 for the device), which compares with the current US cost of cardiac transplantation ($205,000), liver transplantation ($250,000) and medical care for NYHA III–IV patients ($500,000). In REMATCH, it was also clear that the high rates of infection (40%) and device failures (35% at two years) were responsible for a significant proportion of the costs. The smaller drivelines in the rotary devices and the lack of drivelines in the fully implantable devices have demonstrated that the potential to reduce this complication down to less than 5% is achievable. The durability and reliability of the first generation Novacor device (1.4% pump exchanges, for any reason, and 26 patients supported for more than two years with the longest ongoing patient supported for more than five years) also demonstrates that designing in these characteristics is entirely feasible. The perception that MCS therapy is extraordinarily expensive is also not borne out by published data, either in absolute terms or in terms of cost benefit.

**Conclusions**

MCS therapy stands on the brink of a new era. A number of simpler and less expensive options are available for acute applications and much has been learned about patient selection and management.
from the first generation devices. With continued improvements in design and function, MCS systems will soon provide a practical off-the-shelf, scheduled, permanent therapeutic alternative for the end-stage heart failure patient with the promise of return to an essentially normal life.

Will extended MCS continue to be a luxury item on the health care budget or will it become a commodity? The evidence points to the latter, but the appropriate strategy for each patient group will need to be worked out from an evidence base.

Certainly, the current practice of multiple sequential expensive interventions on the same patient will need to be rationalized. What about the health care professionals working in the changing world of cardiac repair and replacement? The author believes that MCS therapy offers a new dimension to heart replacement therapy, which perfusionists should embrace with all the enthusiasm and passion brought to bear over the last 50 years and which has made cardiac surgery one of the most successful branches of modern medicine.

References


16 INCOR at www.berlinheart.de


23 Thoratec provides update on Destination Therapy cost data. www.thoratec.com/PubNewsStory


