Publications in Peer-Reviewed Journals Related to the JARVIK 2000® Ventricular Assist System

   - Abstract
   We successfully controlled infection of a left ventricular assist device by performing pump exchange. A 53-year-old man was implanted with DuraHeart for ischemic cardiomyopathy as a bridge to transplantation. Two years later, he was hospitalized with the diagnosis of driveline infection. The blood cultures detected Pseudomonas aeruginosa. During the admission, he developed brain hemorrhage perhaps due to septic emboli. The chest computed tomography scan revealed a small defect inside the outflow graft of the DuraHeart, which was highly suspected of vegetation. He underwent pump exchange, from DuraHeart to Jarvik 2000 with concomitant omentopexy. His postoperative course was uneventful, and he was discharged with no sequela of the brain hemorrhage. Four months after the pump exchange, he successfully underwent heart transplantation. No infectious tissue was observed in the pericardial space at the time of heart transplantation. Pump exchange is an effective way to manage refractory left ventricular assist device infection, and the timing of surgical intervention is of great importance.

   - Abstract
   The Dor procedure (endoventricular circular patch plasty repair) and apex calcification lead to a tricky left ventricle assist device (LVAD) implantation. We believe that the patient’s anatomy should guide not only the settings of the surgical procedure but also the choice of the LVAD. We describe a series of 4 patients in whom an LVAD was implanted after a Dor intervention or a diagnosis of calcified LV apex.

   - Abstract
   The Jarvik 2000 is an intraventricular, axial flow left ventricular assist device (LVAD) that uniquely uses patient-controlled speed settings. Herein, we report the results of the United States non-randomized, bridge to transplant (BTT) clinical trial.

   - Abstract
   It is well known that, in selected patients, survival with LVAD as destination therapy (DT) is able to compete with heart transplantation. Patient selection is usually based on recognized pre-operative parameters. However, the impact of surgical technique is often neglected. The aim of this “all-comers” study is to evaluate long-term clinical outcome of patients with Jarvik 2000 LVAD as DT or bridge-to-candidacy (BTC), in relation to known risk factors, as well as implantation technique.

   - Abstract
   Left ventricular assist devices (LVADs) are increasingly used in long-term therapy. At the time of transplantation or death, we can assess the effect of device on cardiac structural changes. In our
experience, we noted aortic valve (AV) commissure fusion. We hypothesize that the preservation of aortic valve opening prevents fusion and consequent valve-incompetence.

   - Abstract
   Organ shortages and increased numbers of nontransplant older patients have necessitated a search for alternatives to heart transplants. The Jarvik 2000 assist device (Jarvik Heart, Inc., Manhattan, NY, USA), as a small long-term axial flow pump, offers many advantages, such as retroauricular power supply, which minimizes driveline infection risks. When implanted biventricularly, the device may offer support for patients with biventricular heart failure, especially for nontransplant patients as a destination therapy.

   - Abstract
   The Jarvik 2000 is a left ventricular assist device (LVAD) used as either a bridge-to-transplant or destination therapy with the possibility of retroauricular percutaneous power delivery (pedestal). Percutaneous driveline infection in LVAD is a life-threatening complication that affects both the quality and length of life in patients. With its rigid fixation to the bone, the pedestal and the vascularity of scalp skin promote healing and reduce the risk of driveline infection. We describe a technique to remove the skull-mounted percutaneous pedestal of the Jarvik 2000 after heart transplantation.

   - Abstract
   Myocardial failure is generally considered to be a progressive, irreversible medical condition with characteristic ventricular enlargement, spatial alteration of the heart chambers, diminished cardiac inotropy and resultant dysfunctional, mechanically inefficient heart. The Jarvik 2000®, similar to the mechanical pump, is an electrically powered, axial-flow left ventricular assist device (LVAD) designed to enhance the function of the chronically failing heart and, consequently, normalize the cardiac output for a long period of time. We report the case of 70-year-old man with congestive dilated cardiomyopathy and bioprosthetic mitral valve who underwent surgical implantation of the Jarvik 2000® LVAD, using the miniaturized extracorporeal circulation (MECC) system. The LVAD was implanted through a left thoracotomy and the MECC system was used to avoid intraoperative spontaneous hemodynamic instability and/or malignant ventricular arrhythmia. The circulatory support with the MECC system was optimal and no complication in terms of hemodynamic instability and perioperative bleeding was recorded. The MECC system obliterated the adverse effects associated with conventional extracorporeal circulation, which are often fatal in critically-ill patients.

   - Abstract
   Iterative engineering improvements in left ventricular assist device design do affect clinical outcomes

    - Abstract
    In vitro tests demonstrated that the new cone-bearing configuration of the Jarvik 2000 (Jarvik Heart Inc, New York, NY) left ventricular assist device exhibits better hydraulic efficiency than the
previous pin-bearing design. We investigated the long-term outcomes of patients who received the Jarvik 2000 left ventricular assist device, depending on bearing design.

   - Abstract
   The domain of pediatric ventricular assist device (VAD) has recently gained considerable attention. Despite the fact that, historically, the practice of pediatric mechanical circulatory support (MCS) has lagged behind that of adult patients, this gap between the two groups is narrowing. Currently, the Berlin EXCOR VAD is the only pediatric-specific durable VAD approved by the U.S Food and Drug Administration (FDA). The prospective Berlin Heart trial demonstrated a successful outcome, either bridge to transplantation (BTT), or in rare instances, bridge to recovery, in approximately 90% of children. Also noted during the trial was, however, a high incidence of adverse events such as embolic stroke, bleeding and infection. This has incentivized some pediatric centers to utilize adult implantable continuous-flow devices, for instance the HeartMate II and HeartWare HVAD, in children. As a result of this paradigm shift, the outlook of pediatric VAD support has dramatically changed: Treatment options previously unavailable to children, including outpatient management and even destination therapy, have now been becoming a reality. The sustained demand for continued device miniaturization and technological refinements is anticipated to extend the range of options available to children-HeartMate 3 and HeartWare MVAD are two examples of next generation VADs with potential pediatric application, both of which are presently undergoing clinical trials. A pediatric-specific continuous-flow device is also on the horizon: the redesigned Infant Jarvik VAD (Jarvik 2015) is undergoing pre-clinical testing, with a randomized clinical trial anticipated to follow thereafter. The era of pediatric VADs has begun. In this article, we discuss several important aspects of contemporary VAD therapy, with a particular focus on challenges unique to the pediatric population.

   - Abstract
   Speckle tracking echocardiography analysis (STE) has recently allowed an in-depth analysis of right ventricular (RV) performance. The aim of the study was to observe RV function by STE in patients with advanced heart failure before and after left ventricular assist device (LVAD) implantation.

   - Abstract
   Few descriptions of the implantation and management of an implantable ventricular assist device in patients with complex congenital heart disease exist in the literature. The Jarvik 2000 axial-flow ventricular assist device (Jarvik Heart, Inc., NYC, NY, USA) can be placed in either the left or the right ventricle. We present the case of a 60-year-old man with congenitally corrected transposition of the great arteries who underwent successful placement of a Jarvik 2000 axial-flow ventricular assist device in a systemic morphologic right ventricle.

   - Abstract
   Therapy with mechanical ventricular assist devices (VADs) in severe heart failure, opened to discussion decades ago, is now well established for temporary or long time support. The typical VAD candidate is very compromised and may not have sufficient resources to tolerate major surgical insults and trauma. Therefore, device implantation through smaller, less traumatic incisions is a desirable goal. The median sternotomy decreases lung volumes and reduces
thoracic motion with a significant decrease in functional residual capacity and total lung capacity months later. Minimally invasive cardiac surgery was devised to reduce morbidity because of its potentially less inflammatory response, reduced transfusion requirements and minimal scarring with consequent rapid rehabilitation to normal life activity. Additionally, avoiding cardiopulmonary circulatory support (CPB) even for a short period might reduce the release of inflammatory cytokines and their consequences, as most CPB-related damage happens within the first few minutes. We describe the tricks and traps of minimally invasive approach during VAD implantation, by associating mini anterior left thoracotomy in the fifth intercostal space with a mini anterior right thoracotomy in the second intercostal space, without the aid of CPB in paravertebral block regional analgesia combined with mild general anaesthesia.

   - Abstract  
   Although medical protocols exist to promote reverse remodeling in left ventricular assist device-supported patients, there are scant data about device management in these patients. We report the use of a Jarvik 2000 left ventricular assist device (Jarvik Heart Inc, New York, NY) to facilitate myocardial recovery leading to device explantation using a sequential, patient-controlled approach. Sequential conditioning of the left ventricular assist device-supported heart is a promising strategy for bridging patients to recovery and pump removal.

   - Abstract  
   Differences in device design may have an effect on platelet damage and associated clinical complications. We aimed to compare device-specific platelet functionality in 26 heart failure patients supported with three continuous-flow left ventricular assist devices: HeartMate II (n = 8), Jarvik 2000 (n = 9), and HeartWare (n = 9). Intraplatelet reactive oxygen species (ROS) generation, mitochondrial damage, and platelet apoptosis were compared between device types before and after the implantation at every week up to 1 month. Overall, the baseline characteristics, demographics, routine laboratory values were comparable between the three device groups. Intraplatelet ROS, mitochondrial damage, and platelet apoptosis significantly elevated in the HeartWare group in comparison with the other two device groups after implantation. The major bleeding, infections, systemic inflammatory response syndrome, and right ventricular failure were found to be more common among the HeartWare group than others. Intraplatelet ROS and platelet damage levels were returned to baseline in both the HeartMate II and the Jarvik groups, whereas in HeartWare group they remained elevated. The patients with the Jarvik and the HeartMate II experienced less clinical complications and the platelet functionality is not compromised by these devices. Data from this study suggests that the continuous-flow left ventricular assist devices design may exert different effects on platelet function.

   - Abstract  
   Improved survival, recognition, and management of patients with congenital heart disease have increased the number of pediatric patients with ventricular dysfunction. Many of these patients require mechanical support to bridge to transplant or recovery. Development of pediatric ventricular assist devices has lagged behind adult devices. Until recently, adult devices were used in pediatric patients, with suboptimal results in the smaller patient population. Extracorporeal membrane oxygenation can be life saving, but is a poor choice for long-term support. The Berlin Heart EXCOR (Berlin Heart AG, Berlin, Germany) is a paracorporeal device with a variety of pumps for patients of all sizes. The PumpKIN Trial will compare this device to the Infant Jarvik 2000 (Jarvik Heart, New York, NY, USA) in a prospective, randomized study. The single ventricle
population presents unique challenges to placement and proper functioning of assist devices. Data are anecdotal and mortality is high. A registry has been developed to assist in caring for this challenging population.


- Abstract

Duchenne muscular dystrophy (DMD) is an X-linked recessive disorder, characterized by progressive skeletal muscle weakness, loss of ambulation, and death secondary to cardiac or respiratory failure. End-stage dilated cardiomyopathy (DCM) is a frequent finding in DMD patients, they are rarely candidates for cardiac transplantation. Recently, the use of ventricular assist devices as a destination therapy (DT) as an alternative to cardiac transplantation in DMD patients has been described. Preoperative planning and patient selection play a significant role in the successful postoperative course of these patients. We describe the preoperative, intraoperative and postoperative management of Jarvik 2000 implantation in 4 DMD pediatric (age range 12-17 years) patients. We also describe the complications that may occur. The most frequent were bleeding and difficulty in weaning from mechanical ventilation. Our standard protocol includes: 1) preoperative multidisciplinary evaluation and selection, 2) preoperative and postoperative non-invasive ventilation and cough machine cycles, 3) intraoperative use of near infrared spectroscopy (NIRS) and transthoracic echocardiography, 4) attention on surgical blood loss, use of tranexamic acid and prothrombin complexes, 5) early extubation and 6) avoiding the use of nasogastric feeding tubes and nasal temperature probes. Our case reports describe the use of Jarvik 2000 as a destination therapy in young patients emphasizing the use of ventricular assist devices as a new therapeutic option in DMD.


- Abstract

The Jarvik 2000 is a continuous axial flow left ventricular assist device (LVAD) with an impeller type pump. It has a unique power delivery system, which is tunneled to a retro-auricular skull pedestal in order to minimize driveline infections (1).

Conventional implantation of the Jarvik 2000 is performed off-pump through a left postero-lateral thoracotomy, with the outflow conduit anastomosed to the descending aorta. An alternative technique is performed through a full sternotomy, on cardiopulmonary bypass, with the outflow graft anastomosed to the ascending aorta (1-3). In both cases, the pump is implanted at the left ventricular apex. We describe an evolution of the Jarvik 2000 implantation technique, using a less invasive approach to surgery and perfusion


- Abstract

Much of the morbidity and mortality associated with ventricular assist devices (VADs) is due to haemorrhagic and thrombotic complications. To manage antithrombotic therapy, interactions between the patient and pump should be better understood.


- Abstract

The Jarvik-2000 is a non-pulsatile axial-flow left ventricular assist device (LVAD) that is largely used in patients who present in end-stage heart failure, as a bridge to transplant support or destination therapy. From its first utilization, several implantation techniques have been elaborated, starting from a median sternotomy with cardiopulmonary bypass (CPB) support and moving towards a minimally invasive access with an off-pump strategy. Here we present the
favored surgical technique used in our department to implant the Jarvik-2000, in a step-by-step fashion.

   - Abstract
   We describe the surgical technique and treatment of a 59-year-old male with cardiogenic shock, who underwent a minimally invasive off-pump ventricular assist device (VAD) implantation with the aid of paravertebral regional analgesia in bilateral mini-thoracotomies as first procedure described in the literature. He was extubated soon after the procedure, in the operating room, with the aim to reduce the right ventricle impairment. These issues are particularly true for patients suffering from pulmonary hypertension and disease, in whom the shortest time of postoperative intubation is fundamental to allow self-inotropic support and recovery of the right ventricle. We illustrate how a minimally invasive implant may improve the clinical outcomes of VAD patients shortening their return time to active life.

   - Abstract
   Currently available ventricular assist devices are designed primarily for use in patients with left sided heart failure. This study evaluated the efficacy of the Jarvik 2000 ventricular assist device (VAD) as a pulmonary pump to power a Fontan circuit in a large animal model.

   - Abstract
   We report the successful longest biventricular support using dual Jarvik 2000 biventricular assist device (BVAD; Jarvik Heart, Inc., New York, NY, USA) as a bridge to transplant. A 27-year old woman with arrhythmogenic right ventricular cardiomyopathy underwent implantation of two Jarvik 2000s as a left ventricular assist device and right ventricular assist device. Although several BVAD-related complications including haemolysis, hepatic dysfunction, heart failure and pulmonary valve insufficiency developed at a very late stage, she was successfully bridged to heart transplantation after 1245 days of biventricular support, which is the longest in the literature. Despite advances in continuous-flow ventricular assist devices, their long-term use for biventricular support remains limited. We report a successful case of 1245 days of biventricular support with dual Jarvik 2000 axial flow pumps in a patient with a small body surface area.

   - Abstract
   The aim of this study was to evaluate our clinical experience with the Jarvik 2000 axial flow pump (Jarvik Heart, Inc, New York, NY, USA), a miniature axial flow left ventricular assist device (LVAD). The clinical results of eight patients, who underwent LVAD implantation with the Jarvik 2000 (median age 55.0 years; six men) between 2005 and 2010, including two who participated in a multicenter clinical trial in Japan, were reviewed. Two patients underwent LVAD implantation as destination therapy. Four patients underwent Jarvik 2000 implantation via median sternotomy, while the other four underwent implantation via left thoracotomy. There were no major complications during surgery. Four patients were supported for more than 2 years. The longest support duration was 1,618 days. Six patients successfully bridged to heart transplantation after a median 725 days of support. One patient on destination therapy died of a cerebral infarction. The other patient on destination therapy had had the LVAD for 1,618 days. The overall survival rates at 1, 2, and 3 years were 100, 86, and 86%, respectively. The median postoperative serum lactate dehydrogenase level was 860.5 U/L at 1 month, 735 U/L at 6 months, and 692 U/L at 1 year. There were no fatal device-related infections. We found that the Jarvik 2000 with pin bearing
could support patients with end-stage heart failure with acceptable mortality and morbidity rates. Further evaluations of the prevalence of thromboembolic and hemolytic events in patients with the new conical-bearing Jarvik 2000 are required.


- Abstract

A 71-year-old man with a left ventricular assist device, Jarvik 2000 (Jarvik Heart, New York, NY, USA), presented with unusual complications. Preoperative positron emission tomography and computed tomography (CT) scan revealed no signs of osteitis, but intraoperative bacterial cultures identified Enterobacter aerogenes. The retroauricular pedestal was completely detached from the temporal bone (Figs 1 and 2). A new retroauricular pedestal was successfully repositioned after the detachment of the first one.


- Abstract

Blood-pump miniaturization has made amazing progress, reducing the pump diameter to one-tenth of the size of previous positive displacement pumps. In particular, axial-flow-pump technology allows tiny pumps running at high speeds to deliver from 2 to 10 L/min. A review of the background inventions of the Jarvik 2000 technology is presented, together with the reason that making pumps smaller than demanded by the particular application for which they are designed is counterproductive. Pump miniaturization is nearing its practical limit. The optimization of performance and patient outcomes should remain our primary design goal.


- Abstract

The Jarvik 2000 adult ventricular assist device (VAD) is a second-generation blood pump with mechanical contact bearings. The original configuration of the pump employed a pin bearing and a more recent configuration uses a cone bearing. We compare the hydrodynamic performance of the two designs under steady-state and pulsatile flow conditions in vitro. Furthermore, we employ the Intermittent Low Speed (ILS) Flowmaker Controller to demonstrate the effect on pulsatility index (PI) performance of both device configurations. We use an open-loop flow system in both steady-state and pulsatile arrangements, complete with pressure transducers and flow probes. Working fluid was a 3.6 cP blood-analog, glycerin-water solution. Steady-state flow tests were carried out to determine pressure-flow (H-Q) performance curves. Pulsatile tests under normotensive, hypertensive, and hypotensive conditions were executed with controller speed 3 (10710 ± 250 rpm) at 100 beats per minute. Steady-state tests show greater capacity for pressure and flow with the cone bearing, compared with pin bearing, with best efficiency point (BEP) 68% greater for cone bearing. Pulsatile tests show the cone bearing design to yield a 20% increase in Qavg, a 17% decrease in pulsatility index (PIQ), and a qualitative increase in pressure responsivity. The ILS mode (for both bearing designs) decreases Qavg by 68% and likewise increases PIQ by 360% and pulsatility ratio (Rpull) by 200%. The ILS controller regularly reduces the flow, increasing pulsatility index during device operation. The Jarvik 2000 continuous-flow VAD can sustain pulsatile flow under pulsating pressure conditions. The new cone bearing design yields increased flow rates over the earlier pin bearing design.


- Abstract

We report a case of autologous platelet-rich plasma (PRP) application over the driveline site of a left ventricular assist device (LVAD) to treat an infection. The patient, a 47-year-old man with end-stage dilated cardiomyopathy, underwent Jarvik 2000 implantation through a median sternotomy.
A pedestal with power supply and LVAD control was implanted into the mastoid bone. Retroauricular wound dehiscence occurred, and PRP was applied over the wound. Normal healing of the driveline exit site was observed. PRP can be used at a driveline exit site to either prevent or treat wound infection.

   
   - **Abstract**
   
   Left ventricular assist device implantation might require extensive surgical incision and use of cardiopulmonary bypass. Less invasive implantation using smaller incision and extracorporeal membrane oxygenation perfusion in critically ill patients can decrease the rate of complications. One patient with cardiomyopathy received the Jarvik 2000 FlowMaker through an upper T-inverted ministernotomy and left minithoracotomy. The outflow-graft was connected to the ascending aorta, and the Jarvik 2000 was inserted through the apex of the left ventricle on beating heart. The power cable was routed percutaneously through the neck to a retroauricular skull-mounted pedestal.

   
   - **Abstract**
   
   In congestive heart failure (CHF) patients, a profound cardiac autonomic derangement, clinically expressed by reduced heart rate variability (HRV), is present and is related to the degree of ventricular dysfunction. Implantation of a left ventricular assist device (LVAD) can progressively improve HRV, associated with an increased circulatory output. Data from patients studied at different times after LVAD implantation are controversial. The aims of this study were to assess cardiac autonomic function in the early phases after axial-flow LVAD implantation, and to estimate the potential relevance of recent major surgical stress on the autonomic balance.

   
   - **Abstract**
   
   Antithrombotic therapy is essential in LVAD recipients and must be carefully titrated in each patient. Different devices might influence the coagulation system differently. An awareness of this may allow early planning of the most appropriate antithrombotic approach according to LVAD type. We studied the impact of two different continuous flow LVADs on the coagulation system: Jarvik 2000, an axial flow pump, versus HeartWare HVAD, a magnetically levitating centrifugal pump.

   
   - **Abstract**
   
   Recently, the initial therapy for refractory cardiogenic shock has largely been based on use of short-term mechanical devices with later conversion to durable options. The premise is that such patients cannot tolerate cardiopulmonary bypass and the extended surgery needed for implantable left ventricular assist device (LVAD) placement. We have adopted an alternative strategy to implant long-term LVADs as the initial device therapy in such patients.

   
   - **Abstract**
   
   The infant Jarvik 2000 heart is a very small, hermetically sealed, intracorporeal, axial-flow ventricular assist device (VAD) designed for circulatory support in neonates and infants. The
anatomic fit, short-term biocompatibility and hemodynamic performance of the device were evaluated in a neonate piglet model.

   
   • Abstract
   
   A patient with a Jarvik 2000 (Jarvik Heart, Inc., New York, NY) biventricular assist device had massive hemolysis and device insufficiency of the right ventricular assist device (RVAD) after the anticoagulation was temporarily reversed due to cerebral hemorrhage. After the patient's condition was stabilized by bridge use of CentriMag (Levitronix LLC, Waltham, MA) for right ventricle support, the Jarvik 2000 pumps with pin-shaped bearings were exchanged with new conical bearing pumps. Examination of the removed pumps revealed tight thrombus formation around the pin-shaped bearings.

   
   • Abstract
   
   A best evidence topic in cardiac surgery was written according to a structured protocol. The question addressed was whether there is an optimal antithrombotic management for patients supported with axial-flow left ventricular assist devices (LVADs). Altogether, more than 758 papers were found using the reported search, of which 17 represented the best evidence to answer the clinical question. The authors, journal, date and country of publication, patient group studied, study type, relevant outcomes and results of these papers are tabulated. These included seven prospective and three retrospective cohort studies with a total of 538 patients with axial-flow left ventricular assist device (LVAD) (HeartMate II, Jarvik 2000, INCOR, Thoratec assist device) implanted across the world as destination therapy or bridge to transplantation. We conclude that there is a substantial alteration of the prothrombotic profile in patients with axial-flow LVADs. These abnormalities appeared to be reversible with the removal of the device and are likely to be responsible for the high incidence of non-surgical bleeding episodes reported. Warfarin seems to offer a lower thromboembolic risk compared with unfractioned heparin or low molecular weight heparin. There are reports that suggest that managing axial-flow LVAD without anticoagulation, after major bleeding complications, is possible but in all probability, these papers are subject to publication bias as poor outcomes are unlikely to have been reported. All patients with axial-flow LVAD, showed severely impaired platelet function at point of care tests. The use of warfarin (INR target 2.5), in association with aspirin at 100 mg/day, or with point-of-care tests titrated antiplatelet therapy to inhibit 70%, seems to have the best bleeding-thrombosis, and in many cases a very small dose of aspirin of 25 mg twice a day and a dose of clopidogrel of 35 mg/day, were sufficient to achieve a reduction of the maximum aggregation to less than 30%. Finally, we would like to emphasize that such recommendations are addressed only to patients with axial-flow LVAD.

   
   • Abstract
   
   Despite the remarkable advances with the use of ventricular assist devices (VAD) in adults, pneumatic pulsatile support in children is still limited. We report on our experience in the pediatric population.

   
   • Abstract
   
   Infection is a significant source of morbidity and mortality during long term mechanical circulatory support (MCS). The interventricular Jarvik 2000 LVAD shows reduced invasivity and secure post-
auricular cable exit site. To investigate the impact of such design on infection rates we reviewed the data of patients enrolled in the prospective Jarvik 2000 Italian Registry.

   • Abstract
   Until 2010, Japan had been using the Toyobo (Nipro, Osaka, Japan) extracorporeal left ventricular assist device (VAD) developed 30 years ago as a 2-3 year bridge to transplantation (BTT). In contrast, western nations started to use implantable VADs in the 1980s that allow in-home care as destination therapy (DT) as well as BTT. Designated in 2007 as “medical devices in high demand,” the 5 major implantable mechanical hearts are smoothly undergoing clinical testing. The HeartMate XVE (Thoratec Corp., Pleasanton, CA, USA) gained approval from the Ministry of Health in November of 2009, the DuraHeart (TerumoHeart, Ann Arbor, MI, USA) and EVAHEART (Sun Medical, Nagano, Japan) in December 2010, and obtained formal insurance reimbursement in April 2011. The Jarvik 2000 (Jarvik Heart Inc., New York, NY, USA) and HeartMate II (Thoratec) VADs are pending approval. On the other hand, the organ transplantation law allowing explantation of donor organs from brain-dead patients finally passed in July 2009 and was realized in July 2010. This law paved the way to pediatric heart transplants as well as a dramatic increase in overall organ transplantation cases. Because many juvenile patients awaiting donor organs need a VAD as a long-term bridge, development and clinical introduction of pediatric VADs capable of implantation is an exigency. Although expectations for transplants are high, the donor numbers are low. Therefore, the demand for implantable VADs capable of long-term home treatment is extremely high in Japan.

   • Abstract
   Infection in patients supported with left ventricular assist devices (LVAD) is common and it can limit widespread implantation of mechanical assistance as destination therapy (DT). The infection-resistance power delivery system could improve longevity and quality of life. The Jarvik 2000 (Jarvik Heart, New York, NY, USA) driveline design showed a prolonged infection-free survival and a better quality of life compared to those patients supported with traditional LVAD with an abdominal cable. We report a singular driveline complication in a 71-year-old patient supported with a Jarvik 2000. A new retro-auricular pedestal was successfully repositioned after the detachment of the first one.

   • Abstract
   Bleeding remains a major issue in continuous-flow left ventricular assist device (LVAD) recipients. Gastrointestinal bleeding incidence is particularly high and can reach 0.63 per patient-year [1]. Recent data suggest that acquired von Willebrand disease (AvWD) is a common complication for those patients and may explain the high cutaneous-mucosal bleeding rate [2]. High shear stress (design of the pump, continuous flow) is suspected to induce conformational changes of high molecular weight von Willebrand factor (vWF) multimers.

   • Abstract
   The Jarvik 2000, an axial flow ventricular assist device (VAD), is currently under investigation for bridge to transplant (BTT) indications. The principal advantage of the Jarvik device is intraventricular pump placement. This eliminates the inflow cannula and pump pocket and allows
for uncomplicated left ventricular implantation without sternotomy. Here we describe the evolution of our surgical implantation and explantation technique.


- Abstract

Fifteen months after implantation of a Jarvik 2000 left ventricle assistance device, a 60-year-old man developed infection at the percutaneous retroauricular skull-mounted pedestal. PET/CT demonstrated hypermetabolism in the left cutaneous retroauricular pedestal, on the thoracic internal cable, and in the left lung. A second F-18 FDG PET/CT performed after 3 months of antibiotic treatment showed minimal residual hypermetabolism around the proximal and cervical internal cable. The pedestal was then replaced and a third PET/CT scan 3 months after the completion of antibiotic treatment was entirely normal. F-18 FDG PET/CT scan may be useful for monitoring infection in patients with left ventricle assistance device.


- Abstract

Major advances in vascular assist device (VAD) technology and the clinical acceptance of destination therapy for patients with contraindications to transplant raise the questions of what patient benefit is necessary to recommend VAD implant for long-term support in patients who are transplant candidates. What are the appropriate indications for use and timing considerations for long-term VAD therapy in patients who qualify for transplant but are unlikely to obtain a donor? The authors suggest that VAD implantation for the indication of “maintenance therapy” where patients must remain on the VAD for two years before becoming transplant eligible, would constitute an appropriate clinical avenue to study these issues.


- Abstract

Left ventricular assist device (LVAD) placement is a serious surgical procedure. At our center, we accumulated a very large experience with the Novacor LVAD from the very first clinical trial, as well as from more recent experiences with the Jarvik 2000 and the HeartMate II. This article discusses technical issues that are common to all durable LVAD devices, with special emphasis on strategy and technical considerations aimed at avoiding surgical pitfalls.


- Abstract

We describe successful use of a minimal extracorporeal circulation circuit (MECC) as an alternative to conventional cardiopulmonary bypass (CPB) for the implantation of left ventricular assist device (LVAD) in a 65-year-old patient with ischemic dilated cardiomyopathy. A Jarvik 2000 was implanted through a median sternotomy with the outflow graft anastomosed to the ascending aorta. MECC circuit provides optimal circulatory support throughout the procedure and prevents hemodynamic instability caused by marked displacement of the heart for exposure of the left ventricular apex, while minimizing the adverse effects of conventional CPB.


- Abstract

We present our technique for the implantation of the Jarvik 2000 left ventricular assist device (Jarvik Heart, Inc., New York, NY) without cardiopulmonary bypass by the induction of rapid pacing that allows the insertion of the apical device into the left ventricle, minimizing blood loss.
and surgical complications. Although the off-pump implantation of left ventricular assist devices is not new, our experience of rapid pacing has not been previously reported to our knowledge.


- Abstract

A 55-year-old man, who previously underwent surgical ventricular restoration and mitral valve surgery, was referred to our department for management of refractory heart and multiple organ failure. At the time of admission to our hospital, he could not be registered as a candidate for heart transplantation because of severe renal failure with a serum creatinine level of 4.6 mg/dl. We considered that he was a marginal candidate for heart transplantation; thus, it was essential to understand the etiology of renal failure and estimate whether it was reversible. Cardiac catheterization revealed poor hemodynamic function with a systemic pressure of 107/60 mmHg, cardiac index of 2.5 l/min/m², and pulmonary artery pressure of 63/27 mmHg, despite intense medical treatment. Contrary to biochemical examination findings of blood, renal biopsy findings showed no significant glomerular abnormality. Furthermore, the severity of tubular atrophy and interstitial fibrosis in the cortex was mild. These pathological findings suggested that the renal dysfunction in this case was possibly attributable to a hemodynamic factor. His symptoms gradually deteriorated despite an increasing dose of inotropic support; thus, we planned implantation of a Jarvik 2000 axial-flow pump (Jarvik Heart Inc., New York, NY, USA) as a bridge to eligibility, and informed consent was obtained. Because of a tight adhesion on the anterior wall, we placed the device on the lateral wall of the left ventricle, making sure not to direct the pump at the septum. Postoperatively, the implantable left ventricular assist device provided relief from heart failure symptoms as well as recovery of renal function, with serum the creatinine level at 1.2 mg/dl, which allowed the patient to become an appropriate candidate for heart transplantation. At an 18-month follow-up examination, his status was uneventful, and he is now at home awaiting heart transplantation.


- Abstract

To assist the development and application of blood-contacting medical devices, two novel flow-through Couette-type blood-shearing devices have been developed to study the quantitative relationship between blood damage indexes and flow-dependent parameters. One device is an axial flow-through Couette-type device supported by a pair of pin bearings adapted from the adult Jarvik 2000 blood pump. The other is a centrifugal flow-through Couette-type device supported with magnetic bearings adapted from the CentriMag blood pump. In both devices, a rotor spindle was used to replace the original impeller blades so that a small gap was created between the housing and the rotating spindle surface. Computational fluid dynamics simulations have shown that a uniform, high shear stress region can be generated inside the small gap while the shear stresses elsewhere are relatively low. The possibility of secondary blood damage caused by mechanical seals was eliminated due to the use of a magnetic rotor system. Blood flow through the gap was driven by an externally pressurized reservoir. By adjusting the rotational speed and blood flow rate, shear-induced hemolysis was quantified at a matrix of exposure time (0.039 to 1.48 s) and shear stress (50 to 320 Pa). All of the experiments were conducted at room temperature using heparinized ovine blood with a hematocrit value of 30%. The measured hemolysis levels were much lower than those published in the literature, and the overestimation of those earlier studies may be attributable to device-related secondary blood-damaging effects.
A new set of coefficients for the power law model was derived from the regression of the experimental data.

   - Abstract
   We report the successful implantation of dual Jarvik 2000 biventricular assist devices (BiVAD; Jarvik Heart Inc., New York, NY). A 27-year-old woman with arrhythmogenic right ventricular (RV) cardiomyopathy was referred to our hospital and approved for heart transplantation. Her body size was small (body surface area, 1.38 m²) due to cardiac cachexia. Her left ventricular (LV) ejection fraction was 13%, and she had a severely dilated RV with severe tricuspid regurgitation. Thrombus formation was documented in both ventricles.

   - Abstract
   Damage to the blood by mechanical shear stress is a limitation on the use of VADs. We hypothesize the different shear stresses in an axial VAD compared to a centrifugal VAD result in differing blood damage, which influences clinical outcomes. This hypothesis was assessed by calculating stresses in an axial VAD (Jarvik Heart) and a centrifugal VAD (CentriMag) and measuring hemolysis in vitro. While plasma hemoglobin (pHgb) can be a significant clinical outcome it is also an indicator of other mechanically induced damage to the blood; high shear stresses also activate platelets and destroy vWF.

   - Abstract
   Driveline infections are a major source of morbidity during long-term mechanical support. Unlike other currently available LVADs Jarvik 2000 exhibits the unique feature of a power cable exit site at the post auricular area by means of a titanium pedestal firmly secured to the patient's skull. In order to investigate whether this technical solution might reduce the incidence of driveline infections we reviewed the data of patients included in the Jarvik 2000 prospective, controlled Italian Registry.

   - Abstract
   A fundamental characteristic of rotary blood pumps operating at a particular speed is the inverse relationship between the LVAD pressure differential (aortic minus left ventricular pressure) and the LVAD blood flow (i.e. the H/Q curve). However, published data which are derived from different operating conditions, neither allow direct comparison of different devices nor reflect the pulsatile component of LVAD flow induced by left ventricular function. The aim of this study was to derive steady (continuous) flow and clinically representative pulsatile flow H/Q curves for three rotary LVAD designs under standardised operating conditions.

   - Abstract
   A 34-year-old woman with fulminant myocarditis underwent emergent implant with the Toyobo (Nipro, Osaka, Japan) paracorporeal biventricular assist device (BiVAD). The patient had been stable for 6 months, until she started to develop heart failure symptoms due to severe pulmonary insufficiency. Pulmonary valve closure and BiVAD conversion to implantable rotary pumps was
performed. A DuraHeart centrifugal pump (Terumo Heart Inc., Ann Arbor, MI) was used for left ventricular assist, and a Jarvik 2000 axial-flow pump (Jarvik Heart Inc., New York, NY) was used for right ventricular assist. Although strict management was required to balance the flow rates of the two different types of devices, her postoperative course was uneventful and she was discharged home.


- **Abstract**

For some patients undergoing left ventricular assist device (LVAD) implantation, the perfusion tube is anastomosed to the descending aorta instead of the currently more prevalently used ascending aorta. Purpose of this study was to assess retrospectively the outcomes of LVAD patients with descending aortic anastomosis. Between March 2007 and March 2010, six patients underwent LVAD implantation with descending aortic anastomosis with Toyobo or Jarvik 2000 LVAD at our institute. Their average circulatory support time was 434 (range 82-751) days. Both types of LVAD afforded adequate circulatory support, and inotrope treatment and mechanical ventilation were discontinued relatively early. Echocardiograms of the three patients with Jarvik 2000 LVAD revealed antegrade flow in the ascending aorta during the intermittent low-speed period. Among them, one patient developed infarction in the right brain hemisphere because of thromboembolism, whereas another patient developed pneumonia in the left lung followed by a lethal systemic infection. One patient on Toyobo LVAD support reached heart transplantation without morbidity. Another patient implanted with Toyobo LVAD, whose left ventricular function was too poor to generate forward flow through aortic valve, developed thrombus in the ascending aorta. No embolic events were observed in the organs below the diaphragm. In conclusion, descending aortic anastomosis of the perfusion tube can be used for LVAD implantation for some patients, but considerable risks of morbidities, including thromboembolic events and/or infection, should be recognized.


- **Abstract**

A 62-year-old male, affected by ischemic cardiomyopathy, received a Jarvik 2000. Seventeen months later he complained of angina. An electrocardiogram (ECG) presented inferior leads ST-elevation, and blood chemistry showed increased Troponin-I. Angiography (Video 1) showed right coronary thrombosis, venous graft to obtuse marginal, and device in left ventricle apex (Figs. 1(a) and 2 ). After thrombo-aspiration/stenting, thrombolysis in myocardial ischemia-III (TIMI-III) flow was restored


- **Abstract**

A 73-year-old female with a history of surgical ventricular restoration for ischemic cardiomyopathy presented with biventricular heart failure symptoms. After a Toyobo paracorporeal left ventricular assist device (LVAD) was implanted as a bridge, she underwent successful implantation of a Jarvik 2000 LVAD. This device provided excellent symptomatic improvement. This is the first case in Japan of destination therapy using an implantable LVAD.


- **Abstract**

Gastrointestinal (GI) bleeding in ventricular assist devices (VADs) has been reported with rotary devices. The pathophysiological mechanisms and treatments are in evolution. We performed a retrospective review of GI bleeding episodes for all VADs implanted at our institution. Five male
patients experienced GI bleeding age 63.6 ± 3.64 years. VAD type VentAssist n = 1, Jarvik 2000 n = 2, and HeartWare n = 2. All patients were anticoagulated as per protocol with antiplatelet agents (aspirin and/or clopidogrel bisulfate [Plavix] and warfarin (therapeutic international normalized ratio 2.0-3.5). There was no prior history of gastric bleeding in this group. Ten episodes of bleeding requiring blood transfusion occurred in five patients. Some patients had multiple episodes (1 × 5, 1 × 2, 3 × 1). The events occurred at varying times post-VAD implantation (days 14, 21, 26, 107, 152, 189, 476, 582, 669, and 839). Octreotide (a long-acting somatostatin analogue that reduces splanchnic arterial and portal blood flow) was administered subcutaneously or intravenously. Three patients received infusions of adrenaline at 1 µg/min to enhance pulsatility. Anticoagulation was interrupted during bleeding episodes but successfully introduced post bleeding event. GI bleeding is a significant complication of VAD therapy. In this article, we discuss diagnosis and management options.

   - Abstract
   Concerns about the potential impact of the non-pulsatile circulation pattern generated by the new generation axial-flow left ventricular assist devices on neurocognitive function led us to evaluate a patient in whom a Jarvik 2000 pump was implanted. We assessed the patient's baseline neurocognitive function preoperatively as well as at 1-month and 6-month follow-up, using a comprehensive battery of neuropsychological tests. A slight improvement in circumscribed neurocognitive domains was noted, with no evidence of further decline at the end of a 6-month follow-up period.

   - Abstract
   As the use of left ventricular assist devices (LVADs) to treat end-stage heart failure has become more widespread, leaflet fusion--with resultant aortic regurgitation--has been observed more frequently. To quantitatively assess the effects of nonpulsatile flow on aortic valve function, we tested a continuous-flow LVAD in a mock circulatory system (MCS) with an interposed valve.

   - Abstract
   A 32-year-old woman was admitted with signs and symptoms of end-stage heart failure 5 weeks after delivering her first child by cesarian section. Echocardiography showed her to have an end-diastolic diameter (LVEDD) of 65 mm, end-systolic diameter (LVESD) of 55 mm, ejection fraction (EF) of 10% and moderate functional mitral regurgitation. Her cardiac index was 1.3 liters/min/m². Pulmonary capillary wedge pressure, mean pulmonary artery pressure and pulmonary oxygen saturation were 27 mm Hg, 31 mm Hg and 31%, respectively.

   - Abstract
   Recent advances in left ventricular assist device (LVAD) technology have resulted in small, durable, energy-efficient, continuous-flow blood pumps that can support patients with end-stage heart failure. However, the effects of reduced or nonpulsatile flow on end-organ function are unclear. We performed a pilot study in calves with a continuous-flow LVAD to assess the effects of the pump's outflow-graft location (ascending versus descending aorta) on myocardial blood flow.

1. Abstract

Severely symptomatic heart failure is increasingly common as the population ages. Both prognosis and quality of life are poor. These patients have limited options. Few are eligible for cardiac transplantation because of age or the common transplant comorbidities of pulmonary hypertension and renal impairment. In New York Heart Association (NYHA) class IV patients, ventricular resynchronization therapy provides only marginal benefit that is insufficient to improve quality of life. Lifetime circulatory support has a firm evidence base in the REMATCH trial.


2. Abstract

The Jarvik 2000 left ventricular assist device was first implanted in 1999. Since that time, systematic stepwise improvements, based on reported problems and effective corrective actions, were made to reduce the risk of serious adverse events and improve patient outcomes.


3. Abstract

28-year-old white man with history of end-stage heart failure caused by isolated left ventricular (LV) noncompaction cardiomyopathy had been implanted with the Jarvik 2000 LV assist device 3 years previously as a bridge to survival and to decision via a left posterolateral thoracotomy, off-pump, with outflow graft anastomosis to the descending aorta and postauricular pedestal. The patient had an excellent postoperative course free of adverse events for 1.5 years. The pump was operated at a rotational speed of 9000 rounds per minute. Anticoagulation included acenocoumarol aiming for an international normalized ratio of 3 to 3.5 and 100 mg of aspirin daily.


4. Abstract

The power connectors of assist devices that link the controller to the driveline are exposed to extreme mechanical stress, especially if they are implanted for permanent use. We report the case of a successful emergency repair of a power connector of a Jarvik 2000 left ventricular assist device by using a paper-clip in a patient who was supported with the device for >7 years at our institution.


5. Abstract

We tested the hypothesis that a miniaturised axial flow pump with infection-resistant power delivery could improve longevity and quality of life (QOL) in advanced heart failure patients deemed unsuitable for transplantation.


6. Abstract

Little is known about flow patterns in ventricles supported by continuous flow left ventricular assist devices (LVADs), and valuable information can be obtained with simple flow visualization experiments. We describe the application of several experimental techniques for the in vitro study of ventricular flow patterns (e.g., unsteadiness, vortical motions, stagnation regions) in the presence of a continuous flow LVAD. We used dye streaks, particle paths, and hydrogen bubble techniques to visualize fluid flow in an idealized, static, transparent mock ventricle attached to a Jarvik 2000 continuous flow LVAD. We recorded ventricular flow behavior at various pump speeds while independently adjusting pump flow (by varying the afterload) to emulate in vivo pump flow.
at various phases of the cardiac cycle. Changes in ventricular flow behavior at different pump flow rates may be of clinical relevance, because continuous flow pumps are extremely sensitive to inflow and outflow pressures and instantaneous pump flow varies significantly at different points throughout the cardiac cycle. Further work is needed to quantitatively compare the flow behavior of different continuous flow devices in a pulsatile ventricular model.


   - **Abstract**
   
   Axial-flow left ventricular assist devices (LVADs) have a number of advantages over pulsatile LVADs, including their small size and better durability. Although the design of axial-flow pumps should result in fewer serious complications during support, some adverse events persist. Thus, optimizing patient treatment may minimize complications, allowing broader acceptance of these devices. In this study, we analyzed standard blood pressure measurements obtained by cuff and arterial lines and used these values to help establish guidelines for the safe operation of axial-flow LVADs.


   - **Abstract**
   
   The Jarvik 2000 (Jarvik Heart, Inc., New York, NY) is a thumb-sized high-speed impeller pump that is used as a ventricular assist device in patients with terminal heart failure. Because the Jarvik 2000 is designed for long-term use, it is a central question whether the mechanical forces inside the pump affect blood components. This study evaluated the potential association of the high rotational speed of the Jarvik 2000 with platelet activation, which may result in thromboembolic events.


   - **Abstract**
   
   A 57-year-old patient experienced acute decompensation of heart failure and pulmonary edema (Fig. 1). Off-pump implantation of Jarvik 2000 was performed as a salvage procedure as well as bridge to transplantation with immediate clinical improvement (Fig. 2). Use of a short-term VAD for symptomatic relief can be avoided.


   - **Abstract**
   
   A 39-yr-old man presented with decompensated heart failure for placement of a Jarvik 2000 ™ (Jarvik Heart Inc., New York, NY) left ventricular (LV) assist device (LVAD) as a bridge to transplant. He was inotrope-dependent with a LV ejection fraction of 14% and severe right ventricular (RV) dysfunction. The device was placed at the LV apex with the outflow cannula anastomosed to the ascending aorta. He was weaned from cardiopulmonary bypass (CPB) to LVAD support without hemodynamic instability. However, his course was complicated by persistent nonsurgical bleeding.


   - **Abstract**
   
   The increased applicability and excellent results with left ventricular assist devices (LVADs) have revolutionized the treatment options available for patients with end-stage heart failure. Until recently, most patients who have undergone LVAD implantation have been supported by pulsatile
devices. Unfortunately, the use of the latter devices is associated with significant comorbidity, primarily as a result of their large size and limited durability. The HeartMate II and the Jarvik 2000 pumps, both of which incorporate axial-flow and rotary pump technology represent the next generation of devices. The clinical use of these newer axial-flow pumps have resulted in superior outcomes, including significantly reduced complication rates with improved durability. However, as with all new technology, axial-flow LVADs have also introduced a different set of management issues, as well as certain complications, into the mechanical circulatory support arena—issues and complications that were previously absent or unimportant with pulsatile LVADs. Concerns include the effects of continuous-flow on the systemic circulation and end-organ function, risk of thromboembolism and pump thrombosis, increased incidence of gastrointestinal bleeding and ventricular arrhythmias, as well as the effects of partial unloading on pulmonary hemodynamics. Different strategies are required to optimize outcomes with these newer devices.

   • Abstract
   Left ventricular assist devices (LVADs) are now being implanted frequently as a bridge therapy to transplant or a destination therapy. Device technology is also changing in that nonpulsatile axial flow pumps are being used as frequently as pulsatile pumps at many centers. LVADs are effective in restoring circulation and unloading the left heart. LVAD support could result in a potential problem of right to left shunt through the patent foramen ovale (PFO), and the practice of performing transesophageal echocardiography (TEE) looking for PFO at the time of surgery has been well established.

   • Abstract
   We hypothesized that not all subtypes of alpha- and beta-adrenoreceptors undergo similar upregulation and redistribution in human myocardium after mechanical unloading with an assist device.

   • Abstract
   The in vitro sensitivity of continuous flow pumps to preload and afterload pressure has been well characterized. We compared flow in the Jarvik 2000 and HeartMate II continuous flow left ventricular assist devices (LVADs) at different inflow and outflow pressures and different pump speeds. This allowed us to measure the impact of a changing inflow pressure on the pump flow rate at different speeds but against a constant afterload. The resulting preload sensitivity curves showed that, overall, both LVADs have a mean preload sensitivity of 0.07 L/min/mm Hg in the physiologic ranges of pressures and flows encountered during normal operation. The HeartMate II pump had an increased preload sensitivity (up to approximately 0.1 L/min/mm Hg) as the preload was increased. The preload sensitivity of the Jarvik 2000 LVAD was more variable, having several peaks and troughs as the preload was increased. In future LVADs, improved preload sensitivity may allow passive regulation of pump output, optimize ventricular unloading, and decrease the risk of ventricular suction by the pump.

   • Abstract
   Traditional left ventricular assist device (LVAD) implantation requires extensive dissection and use of cardiopulmonary bypass (CPB). Potential adverse effects of CPB in very ill end-stage heart
failure patients include right ventricular dysfunction, end-organ injury, and bleeding. We sought to evaluate the feasibility and outcome of LVAD insertion without CPB.


- **Abstract**
  Implantable left ventricular assist devices (LVADs) are being used to support patients for longer periods because of longer transplant waiting times and the application of LVADs for destination therapy. With longer implant times comes LVAD exchange for component failure or serious device-related infection that cannot be treated medically. LVAD exchange should be performed promptly and planned in accordance with the patient’s condition, the type of device previously implanted, and the type used for exchange, as well as whether total system or individual component replacement is required. Most patients who experience pump failure after extended support are in good condition. Preoperatively, patients must be stabilized using standard inotropic and vasoactive medications and undergo a complete workup, including echocardiography. Coagulation abnormalities should be corrected preoperatively. Intraoperatively, continuous transesophageal echocardiography and standard hemodynamic monitoring should be utilized. After opening the chest, LVAD support should be minimized to prevent air entry. Detailed descriptions of the following exchange procedures are presented: Jarvik 2000 to Jarvik 2000, HeartMate (VE or XVE) to HeartMate (VE or XVE), HeartMate (VE or XVE) to HeartMate II, and HeartMate II to HeartMate II. Although more reliable systems may offer longer support times, the need for exchange procedures will likely continue to increase.


- **Abstract**
  Implantation of a HeartMate II or a Jarvik 2000 FlowMaker left ventricular assist system (LVAS) usually involves a mid-line sternotomy and the use of cardiopulmonary bypass (CPB). In patients with numerous co-morbid conditions, however, surgical trauma may be minimized by implanting the LVAS via a minimally invasive approach, preferably without CPB.


- **Abstract**
  Traditional left ventricular assist device (LVAD) implantation requires extensive dissection and use of cardiopulmonary bypass (CPB). Potential adverse effects of CPB in very ill end-stage heart failure patients include right ventricular dysfunction, end-organ injury, and bleeding. We sought to evaluate the feasibility and outcome of LVAD insertion without CPB.


- **Abstract**
  Limited data exist about the long-term effects of continuous-flow vs pulsatile-flow left ventricular assist devices (LVADs) on end-organ function.


- **Abstract**
  Implantation of a left ventricular assist device through a median sternotomy usually requires cardiopulmonary bypass. However, the biological response to cardiopulmonary bypass is sometimes deleterious in end-stage heart failure patients, as it may compound pre-existing coagulopathy or multiorgan dysfunction. Therefore, there are potential advantages to avoiding cardiopulmonary bypass during left ventricular assist device placement. We describe a technique
for off-pump implantation of the Jarvik 2000 left ventricular assist device (Jarvik Heart Inc, New York, NY) through a median sternotomy.


- Abstract

The need for smaller, more efficient ventricular assist devices that can be used in a more chronic setting have led to exploration of mechanical circulatory support in the pediatric population. The pediatric Jarvik 2000 heart (child size), under development, was implanted in six juvenile sheep and studied for both acute fit and chronic performance evaluation. Daily hemodynamic measurements of cardiac output and pump output at varying pump speeds were taken. In addition, plasma free hemoglobin, lactic acid dehydrogenase, and platelet activation from blood samples were determined at baseline, after implantation, and twice a week thereafter. The measured flow through the outflow graft at increasing speeds from 10,000 rpm to 14,000 rpm with an increment of 1,000 rpm were 1.47 +/- 0.43, 1.89 +/- 0.52, 2.36 +/- 0.61, 2.80 +/- 0.73, and 3.11 +/- 0.86 (L/min). The baseline plasma free hemoglobin was 11.95 +/- 4.76 (mg/dL), with subsequent mean values being <30 mg/dL at postimplantation and weekly postimplantation measurements. Both lactic acid dehydrogenase and platelet activation showed an acute increase within the first week after implantation with subsequent return to baseline by 2 weeks after surgery. Our initial animal in vivo experience with the pediatric Jarvik 2000 heart shows that a small axial flow pump can provide partial to nearly complete circulatory support with minimal adverse effects on blood components.


- Abstract

We report a case of intracardiac thrombus in a patient supported by the Jarvik 2000 Flowmaker successfully treated with a single dose of peripherally administered TNK-tissue plasminogen activator (Tenecteplase, Metalyse, Boehringer Ingelheim). This strategy may be considered in the case of life-threatening VAD associated thrombosis to avoid the need for intracardiac drug delivery or VAD replacement. We also discuss the apparent increased thrombotic risk in patients receiving a VAD for chemotherapy induced cardiomyopathy and the implications this may have for the choice of VAD.


- Abstract

Measurement of systemic blood flow is of crucial importance in patients on mechanical circulatory support (MCS). We reported the case of a 65-year-old female patient in severe cardiogenic shock undergoing left (Jarvik 2000 axial flow pump) and right (Levitronix-Centrimag centrifugal pump) ventricular assist device implant. Evaluation of blood flow was obtained by ultrasonic flowmetry, continuous thermodilution technique, and pressure recording analytical method (PRAM). This pulse contour system allows beat-by-beat systemic blood flow assessment from the analysis of radial artery pressure waveform. At a Jarvik pump speed < or = 10000 rotations per minutes (rpm), thermodilution and PRAM showed similar blood flow values. At a Jarvik pump speed > or = 11000 rpm, the aortic valve did not open and PRAM did not provide blood flow values due to nonpulsatile blood flow. The present paper describes the first experience with PRAM in a single patient on MCS. Further studies are required to assess the validity of PRAM as an additional monitoring system in the setting of ventricular assist device support.


- Abstract
Several strategies for circulatory support have been successfully utilized as bridges to recovery or transplantation after acute myocardial infarction and cardiogenic shock. We report the novel use of a continuous flow left ventricular assist device (LVAD) for successful recovery and bridging to transplantation in a patient who had massive anterior wall myocardial infarction.

   • Abstract
   Despite concerns about the adequacy of support provided by continuous-flow left ventricular assist devices (LVADs), direct comparisons of patient characteristics and outcomes between first-generation pulsatile and second-generation nonpulsatile LVADs are absent. We hypothesized that a nonpulsatile Jarvik 2000 LVAD (Jarvik Heart, Inc, New York, NY) would result in comparable outcomes to those of similarly ill patients implanted with a pulsatile LVAD (Novacor, WorldHeart Inc, Oakland, CA; and HeartMate XVE, Thoratec, Pleasanton, CA).

   • Abstract
   Rotary axial flow pumps have several potential advantages and disadvantages over pulsatile pumps. The Jarvik 2000 is distinctive in being intracardiac. We report our experience in 22 patients.

   • Abstract
   The Jarvik 2000 Flowmaker is an intraventricular continuous axial flow left ventricular assist device. We describe the anaesthetic management and considerations for five patients with end-stage heart failure who underwent implantation of the Jarvik 2000 Flowmaker as a bridge to transplantation or as destination therapy.

   • Abstract
   In 2001, a randomized trial comparing a pulsatile left ventricular assist device (LVAD) with medical therapy for end-stage heart failure reported a median survival advantage of 8.5 months for patients receiving the device.1 The patients' quality of life was limited by serious complications related to the LVAD. In 2000, we began a long-term observational study of circulatory support with a new, miniaturized axial-flow pump. At the time, there were important questions about the reliability of a blood pump powered by a rotary electric motor and the effects of diminished pulse pressure over time.

   • Abstract
   We report the safe use of capsule endoscopy in the detection of obscure GI bleeding in a 59-year-old male patient with ischemic cardiomyopathy supported by a nonpulsatile axial–flow Jarvik 2000 left ventricular assist device (LVAD) (Jarvik Heart Inc, New York, NY). The patient presented with melena and had undergone previous gastroscopy and colonoscopy without localization of a bleeding source. The detection of distal duodenal and proximal jejunal lesions at capsule endoscopy led to a therapeutic push enteroscopy. Endoscopic therapy (application of argon plasma coagulation) and pharmacologic treatment (subcutaneous octreotide 3 times a day and peroral sucralfate) resulted in the cessation of bleeding. No cardiac complications arose from the use of the capsule endoscopy system.
   • Abstract
   No abstract available

   • Abstract
   Device failure is a limitation of permanent mechanical circulatory support. We studied the mechanical reliability of the Jarvik 2000 Heart, an axial flow pump with ceramic bearings designed to provide more than 10 years' durability.

   • Abstract
   This article reviews third-generation blood pumps, focusing on the magnetic-levitation (maglev) system. The maglev system can be categorized into three types: (i) external motor-driven system, (ii) direct-drive motor-driven system, and (iii) self-bearing or bearingless motor system. In the external motor-driven system, Terumo (Ann Arbor, MI, U.S.A.) DuraHeart is an example where the impeller is levitated in the axial or z-direction. The disadvantage of this system is the mechanical wear in the mechanical bearings of the external motor. In the second system, the impeller is made into the rotor of the motor, and the magnetic flux, through the external stator, rotates the impeller, while the impeller levitation is maintained through another electromagnetic system. The Berlin Heart (Berlin, Germany) INCOR is the best example of this principle where one-axis control combination with hydrodynamic force achieves high performance. In the third system, the stator core is shared by the levitation and drive coil to make it as if the bearing does not exist. Levitronic CentriMag (Zürich, Switzerland), which appeared recently, employs this concept to achieve stable and safe operation of the extracorporeal system that can last for a duration of 14 days. Experimental systems including HeartMate III (Thoratec, Woburn, MA, U.S.A.), HeartQuest (WorldHeart, Ottawa, ON, Canada), MagneVAD (Gold Medical Technologies, Valhalla, NY, U.S.A.), MiTiHeart (MiTi Heart, Albany, NY, U.S.A.), Ibaraki University’s Heart (Hitachi, Japan) and Tokyo Medical and Dental University/Tokyo Institute of Technology's disposable and implantable maglev blood pumps are also reviewed. In reference to second-generation blood pumps, such as the Jarvik 2000 (Jarvik Heart, New York, NY, U.S.A.), which is showing remarkable achievement, a question is raised whether a complicated system such as the maglev system is really needed. We should pay careful attention to future clinical outcomes of the ongoing clinical trials of the second-generation devices before making any further remarks. What is best for patients is the best for everyone. We should not waste any efforts unless they are actually needed to improve the quality of life of heart-failure patients.

   • Abstract
   Successful implantation of left ventricular assist devices (LVADs) in patients with previous median sternotomy remains challenging.

   • Abstract
   Axial-flow left ventricular assist devices (LVADs), when inactivated, may result in regurgitant blood flow. We assessed the effects of regurgitant pump flow with the intraventricular Jarvik 2000 Heart
LVAD (Jarvik Heart, Inc., New York, NY) on hemodynamics and patient safety under pump-off conditions.


- **Abstract**

Although mechanical circulatory support (MCS) can improve myocardial function in patients with advanced heart failure, its effects on relative myocardial perfusion are unclear. Using positron emission tomographic imaging techniques, the authors assessed relative myocardial perfusion in patients with ischemic or idiopathic cardiomyopathy who were receiving chronic MCS with a left ventricular assist device (pulsatile HeartMate [n = 2] [Thoratec Corporation, Pleasanton, CA] or nonpulsatile Jarvik 2000 [n = 4] [Jarvik Heart, Inc., New York, NY]). Relative myocardial perfusion was compared at lower and higher levels of MCS (50 vs. 100 - 110 ejections/min for the HeartMate and 8000 vs. 12,000 rpm for the Jarvik 2000). The size and severity of perfusion defects at rest and after dipyridamole stress were measured objectively and subjectively by computer algorithms and visual inspection, respectively. Relative myocardial perfusion increased > 5% from baseline in only one of six patients when MCS was increased. No change in relative myocardial perfusion of > 5% was seen in any of the other five patients, even after subsequent dipyridamole stress positron emission tomographic imaging. These pilot study findings suggest that the decreased metabolic requirements induced by ventricular unloading correspondingly decreased blood flow requirements to physiologically inactive myocardium.


- **Abstract**

Continuous-flow pumps are small, simple, and respond physiologically to input variations, making them potentially ideal for total heart replacement. However, the physiological effects of complete pulseless flow during long-term circulatory support without a cardiac interface or with complete cardiac exclusion have not been well studied. We evaluated the feasibility of dual continuous-flow pumps as a total artificial heart (TAH) in a chronic bovine model. Both ventricles of a 6-month-old Corriente crossbred calf were excised and sewing rings attached to the reinforced atrioventricular junctions. The inlet portions of 2 Jarvik 2000 pumps were positioned through their respective sewing rings at the mid-atrial level and the pulseless atrial reservoir connected end-to-end to the pulmonary artery and aorta. Pulseless systemic and pulmonary circulations were thereby achieved. Volume status was controlled, and systemic and pulmonary resistance were managed pharmacologically to keep mean arterial pressures at 100+/−10 mmHg (systemic) and 20+/−5 mmHg (pulmonary) and both left and right atrial pressures at 15+/−5 mmHg. The left pump speed was maintained at 14,000 rpm and its output autoregulated in response to variations in right pump flow, systemic and pulmonary pressures, fluid status, and activity level. Hemodynamics, end-organ function, and neurohormonal status remained normal. These results suggest the feasibility of using dual continuous-flow pumps as a TAH.


- **Abstract**

Infection remains a major problem following insertion of Left Ventricular Assist Device(LVAD)s. Driveline and pocket infections can lead to multiple readmissions for antibiotics, morbidity and even mortality. Continuous flow pumps have smaller more flexible drivelines and are generally less mobile than previous pumps (due to lack of pulsatility) and hence may be associated with a low rate of driveline infections. In an attempt to clarify this we retrospectively analysed the frequency and impact of driveline and pocket infections in 20 patients who have received the Jarvik 2000 axial flow pump since May 2003 at our institution cumulating in a total of 5052 days experience.
The Pediatric Circulatory Support Program (PCSP) of the National Heart, Lung, and Blood Institute (NHLBI) was established to fund the development of novel circulatory support devices for children with medically refractory heart failure. Before this, developers of circulatory support devices found little incentive to enter the pediatric market because of the small patient numbers that are generally insufficient to justify the significant costs required to develop these devices. As a result of the lack of availability of new devices for circulatory support of pediatric patients, extracorporeal membrane oxygenation (ECMO), which first had been used clinically in the 1960s, remained the most commonly used modality to support these critically ill children during the next 40 years. The most attractive feature of ECMO for pediatric circulatory support is its ability to be used in even the smallest infants and neonates. However, ECMO support is characterized by thromboembolic complications and sepsis in a significant percentage of patients. Perhaps most importantly, ECMO has generally only been suitable for short-term support, limiting its usefulness as a bridge to transplantation, and the size and extracorporeal configuration of the system components usually limit its use to the intensive care unit setting and preclude ambulation and rehabilitation during support.

The clinical and cost-effectiveness of left ventricular assist devices as destination therapy for people with end-stage heart failure is assessed through a systematic review and economic evaluation.

The Jarvik 2000 system of axial-flow LVAD-is implanted for permanent mechanical circulatory support in patients with end-stage heart failure waiting to undergo heart transplantation. The battery is connected with a power plug to the percutaneous skull-mounted footplate, which is monocortically fixated to the retro auricular bone. Patient selection should be highly specific, including careful preoperative evaluation. No device failures have been published so far, but complications can occur due to heparinisation. We describe the procedure from the perspective of the maxillofacial surgeon and give suggestions to prevent surgical complications.

The retroauricular power supply of the Jarvik 2000 (Jarvik Heart Inc, New York, NY) left ventricular assist device is suitable for permanent support, as it is associated with fewer infections than conventional drivelines. Implantation through a left-lateral thoracotomy limits the performance of additional cardiac procedures. We describe a technique that used a sternotomy for the implantation of the Jarvik 2000 with retroauricular power supply in two patients. The retroauricular power supply of the Jarvik 2000 can be provided with an anterior approach, allowing full surgical access to the heart. If the outflow graft to the ascending aorta indeed reduces aortic stasis and thromboembolic events, the anterior approach with retroauricular power delivery might evolve into a standard procedure.

Advanced heart failure: feasibility study of long-term continuous axial flow pump support.
A lack of donor hearts has stimulated interest in using blood pumps to treat severe heart failure. We tested the hypothesis that a new continuous flow circulatory assist device could be employed safely to relieve symptoms of heart failure and evaluated the potential to prolong life.


- Abstract

We assessed the effects of an axial flow left ventricular assist device (LVAD) upon aortic valve opening, pump outflow, and biologic and hematologic parameters when operated in intermittent low speed (ILS) mode. An ILS controller equipped Jarvik 2000 LVAD was implanted in six calves. Pump speed was maintained at 10,000 rpm, and pump outflow was measured throughout the study period (71 +/- 6 days [mean +/- SD]). Hematologic and biochemical parameters were analyzed daily for the first 10 days, weekly for the first month, and biweekly thereafter to monitor for kidney or liver dysfunction, hemolysis, bleeding, or infection. Before study termination, esmolol hydrochloride was infused to induce low cardiac output and totally impair aortic valve opening. Radiopaque cineaortography was performed over 30 second intervals (10 seconds before, 10 seconds during, and 10 seconds immediately after ILS controller activation) to assess the effect of ILS mode upon aortic valve opening. After study termination, major end organs and the major vascular tree were removed and examined macroscopically and histologically for thrombus formation and infarction; the aortic valve was examined for thickening and fusion. All pumps were explanted and examined for thrombus formation. All six calves recovered without surgical or mechanical complications. Hematologic and biochemical parameters did not change significantly between baseline and study termination. The aortic valve successfully opened when ILS mode was activated, even under low cardiac output conditions. No thrombus was detected in the major end organs and vascular tree, except for some small renal infarcts in three calves that did not affect renal function. These results indicate that operating an axial flow LVAD in ILS mode allows aortic valve opening and aortic root washout.


- Abstract

One of the complications that can occur with continuous, axial-flow left ventricular assist devices (LVADs) is thrombosis within the left ventricle, adjacent to the device's inflow conduit, which may cause inflow obstruction and recurrent heart failure. We describe 2 cases in which we used a catheter to continuously infuse recombinant tissue plasminogen activator (tPA) into the left ventricle until signs of successful thrombolysis was achieved. By monitoring the result and administering only as much tPA as necessary to achieve thrombolysis, we were able to successfully lyse the obstructing thrombus with a minimal dose of tPA without causing any significant bleeding problems. This technique may be useful for managing this potentially serious complication while minimizing the risk of treatment.


- Abstract

In 2 patients with the Jarvik 2000 left ventricular assist device (LVAD), we assessed left ventricular systolic function through pressure-volume loops and E(max) at the beginning and end of the support period to potentially predict the possibility of pump removal without transplantation. Immediately before LVAD implantation and explantation, pressure and volume measurements were made with catheters and echocardiography, respectively, the E(max) being calculated from the slope of the pressure-volume loops, and the left ventricular ejection fraction (LVEF) being estimated by echocardiography. Transplantation was performed after 14 and 62 days, respectively, during which the LVEF increased by 75% (from 12% to 21%) in Patient 1 and remained unchanged (from 16% to 18%) in Patient 2, whereas the E(max) increased from 0.63 and 0.42 mm Hg/ml, respectively, to 1.31 and 1.07 mm Hg/ml, reflecting a 107% and 155%
improvement. In these 2 cases, the E(max) was a more reliable indicator of intrinsic myocardial contractility than was the LVEF.


- Abstract

The long-term effects of axial-flow mechanical circulatory support in humans are unclear. We report 3 cases of chronic gastrointestinal bleeding after implantation of a Jarvik 2000 axial-flow left ventricular assist device. The bleeding was refractory to aggressive management and in 2 cases resolved only after orthotopic cardiac transplantation.


- Abstract

From April 2000 through September 2001, we studied 11 patients with the Jarvik 2000--a left ventricular assist device with an axial-flow pump that provides continuous blood flow--to determine the echocardiographic characteristics. All patients underwent complete echocardiographic examination, including outflow-graft flow evaluation 24 hours after implantation and each month thereafter for the duration of support. Data were obtained at each pump setting (8000-12000 rpm in 1000-rpm increments) and with the pump off. Left ventricular dimensions and shortening fraction and the duration of aortic valve systolic opening decreased as pump speed increased. Although the aortic valve remained closed at higher pump speeds, pump outflow-graft flow remained pulsatile, because of the systolic thrust of the assisted ventricle. Systolic dominance of phasic flow was more pronounced at lower pump speeds, due to normalization of the diseased heart's Starling response. When the aortic valve was closed continuously, echocardiographic contrast (indicating blood stasis) was noted in the aortic root. Because of the pump outflow graft's proximity to the chest wall, device output could be measured independently of cardiac contributions. Mean peak outflow-graft flow velocities were 0.75 +/- 0.30 m/s (systolic) and 0.41 +/- 0.13 m/s (diastolic). When the pump was turned off briefly there was minimal regurgitation through the device into the left ventricle. This 1st echocardiographic heart function analysis of the Jarvik 2000 confirms that the device unloads the ventricle and increases cardiac output. Cardiac responses to device-speed changes can be evaluated readily with echocardiography in the early and late postoperative period.


- Abstract

After implantation of a left ventricular assist device (LVAD), right ventricular dysfunction and elevated peripheral vascular resistance may result in right ventricular failure and increased mortality. Right ventricular support may become necessary, as in the following case in which two Jarvik FlowMakers (Jarvik Heart, Inc, New York, NY) provided biventricular assistance.


- Abstract

Research suggests that ventricular assist devices improve quality of life for congestive heart failure patients awaiting heart transplantation. Axial flow ventricular assist devices like the Jarvik 2000 (Jarvik Heart, Inc., New York, NY) represent the newest type of ventricular assist device technology, but their effects on quality of life are not well understood. Therefore, the authors administered the Minnesota Living with Heart Failure Questionnaire to patients who had the Jarvik 2000 implanted as a bridge to heart transplantation. Patients completed the Minnesota Living with Heart Failure Questionnaire immediately before device implantation, 1 month after implantation,
immediately before heart transplantation, and 1 month after transplantation. One month after implantation of the device, the nine patients who completed the study showed significant improvements in physical (p<0.008), emotional (p<0.02), and overall (p<0.008) quality of life. These improvements were maintained until the device was explanted. The authors conclude that implantation of the Jarvik 2000 ventricular assist device can substantially improve quality of life for patients awaiting heart transplantation.


- Abstract

The Jarvik 2000 ventricular assist device (VAD) is clinically efficacious for treating end-stage left ventricular failure. Because simultaneous right ventricular support is also occasionally necessary, we developed a biventricular Jarvik 2000 technique and tested it in a calf model. One VAD was implanted in the left ventricle with outflow-graft anastomosis to the descending aorta. The other VAD was implanted in the right ventricle with outflow-graft anastomosis to the pulmonary artery. Throughout the 30 day study, hemodynamic values were continuously monitored. On day 30, both pumps were evaluated at different speeds, under various hemodynamic conditions. By gradually occluding the pulmonary artery proximally or distally, we simulated varying degrees of high pulmonary vascular resistance, right ventricular hypertension, global heart failure, or ventricular fibrillation. The two VADs maintained biventricular support even during pulmonary artery occlusion and ventricular fibrillation, yielding a cardiac output of 3-11 L/min, left ventricular end-diastolic pressure of 11-24 mm Hg, and central venous pressure of 9-25 mm Hg. End-organ function was unimpaired, and no major adverse events occurred. The dual VADs offered safe, effective biventricular assistance in the calf. Additional studies are needed to assess the effects of lowered pulse pressure upon the pulmonary circulation and to develop a single pump speed controller.


- Abstract

Chronic congestive heart failure is not uncommonly associated with ventricular arrhythmias. In a small percentage of these cases, the arrhythmias may become refractory to medical therapy and exacerbate the patient’s underlying heart failure. The authors report such a case, in which ventricular failure necessitated insertion of a Jarvik 2000 FlowMaker left ventricular assist device (Jarvik Heart Inc., New York, NY). In addition to normalizing the cardiac output, this axial-flow device controlled the previously unremitting ventricular arrhythmia.


- Abstract

Elevated pulmonary vascular resistance (PVR) unresponsive to pharmacological intervention is a major limitation in heart transplantation (HTX). The post-operative course of these patients is associated with an increased risk of life-threatening right heart failure. We evaluated the efficiency of an implantable left ventricular assist device (LVAD) to decrease PVR by unloading the left ventricle and to lower the risk of later orthotopic HTX.


- Abstract

We describe a patient with a previously implanted Jarvik 2000 left ventricular assist device (LVAD), who presented with bacteraemia and with features suspected for aortic dissection at the CT scan. However, transesophageal echocardiography showed competition in the ascending
aorta between the retrograde pump flow and the anterograde transaortic output, which mimicked true aortic dissection and could be resolved by lowering the pump speed. As patients with LVAD are increasing in number, clinicians should be aware of this possible effect.


- Abstract
The Jarvik 2000 axial flow left ventricular assist device (LVAD) is used clinically as a bridge to transplantation or as destination therapy in end-stage heart disease. The effect of the pump's continuous flow output on myocardial and end-organ blood flow has not been studied experimentally. To address this, the Jarvik 2000 pump was implanted in eight calves and then operated at speeds ranging from 8,000 to 12,000 rpm. Micromanometry, echocardiography, and blood oxygenation measurements were used to assess changes in hemodynamics, cardiac dimensions, and myocardial metabolism, respectively, at different speeds as compared with baseline (pump off, 0 rpm) in this experimental model. Microsphere studies were performed to assess the effects on heart, kidney, and brain perfusion at different speeds. The Jarvik 2000 pump unloaded the left ventricle and reduced end-diastolic pressures and left ventricular dimensions, particularly at higher pump speeds. The ratio of myocardial oxygen consumption to coronary blood flow and the ratio of subendocardial to subepicardial blood flow remained constant. Optimal adjustment of pump speed and volume status allowed opening of the aortic valve and contribution of the native left ventricle to cardiac output, even at the maximum pump speed. Neither brain nor kidney microcirculation was adversely affected at any pump speed. We conclude that the Jarvik 2000 pump adequately unloads the left ventricle without compromising myocardial metabolism or end-organ perfusion.


- Abstract
We have been investigating continuous-flow circulatory support devices for 20 years. Unlike pulsatile assist devices, continuous-flow pumps have a simplified pumping mechanism and they do not require compliance chambers or valves. In the 1980s, clinical experience with the Hemopump proved a high-speed, intravascular, continuous-flow pump could safely augment the circulation. Subsequently, a decade of animal experiments with a larger, longer-term continuous-flow pump (the Jarvik 2000) confirmed the safety and efficacy of intraventricular placement, leading to its clinical application.


- Abstract
Despite extensive research and great strides over the past 40 years, the ideal permanent mechanical assist device remains elusive. The incidence of heart failure is increasing, and the number of heart transplants has remained constant. The HeartMate and Novacor are two pulsatile, long-term ventricular assist devices (VADs) commonly used as a bridge to transplantation. Randomized Evaluation of Mechanical Assistance in the Treatment of Congestive Heart Failure is a randomized study of device therapy in heart failure with treatment either with device (HeartMate) therapy or maximal medical therapy which was recently completed and demonstrated a Kaplan-Meier survival rate at 1 year of 52% for the device group compared to 25% in the medical therapy group. The TCI HeartMate is the only device approved for destination therapy, while others such as the Novacor device are in the process of evaluation. Most of these devices are still plagued by mechanical problems, bleeding, thromboembolism and infection. Other promising new devices include smaller VADs using impeller pump technology, such as the Arrow LionHeart, Micromed Debakey pump and Jarvik 2000 pump. The CardioVAD is an interesting chronically implantable balloon pump inserted into the descending thoracic aorta. While experience with the newer implantable pumps is growing, most of them require some
manipulation of the heart perioperatively, in addition to anticoagulation postoperatively and careful monitoring for complications and infection.


- Abstract

The Flowmaker left ventricular assist device (formerly known as the Jarvik 2000) is an axial-flow pump that provides continuous flow from the left ventricle to the aorta. Designed for either temporary or permanent use, the Flowmaker is undergoing clinical trials in the United States and Europe. The goal of this therapy is to provide adequate circulatory flow while partially reducing the left ventricular size and end-diastolic pressure. This gives the native ventricle an opportunity to remodel itself. Those who benefit the most from this technology are patients who require only true left ventricular assistance rather than total capture of the left ventricular output. Because of the Flowmaker's simplicity and safety of implantation, as well as the absence of late pump failure, its use may be justified in severely impaired class III and IV (but not preterminal) heart failure patients.


- Abstract

The Jarvik 2000 axial flow left ventricular assist device (LVAD), under development for the past decade, has the potential to support patients temporarily until cardiac transplantation or as a permanent circulatory support, without the size limitations of other implantable systems.


- Abstract

The Jarvik 2000 Heart(TM) is a left ventricular assist device that produces continuous nonpulsatile axial flow by means of a single, rotating, vaned impeller. Anesthetic and perioperative considerations of the Jarvik 2000 Heart(TM) differ from those of conventional assist devices. The Jarvik 2000 is implanted within the left ventricle through a left thoracotomy, which is aided by left lung isolation. A brief period of cardiopulmonary bypass and induced ventricular fibrillation facilitate implantation. Transesophageal echocardiography is essential to assure proper intraventricular positioning of the device and aortic outflow, confirmed by observation of aortic valve opening in the presence of adequate left ventricular volume. Because continuous flow devices function best in the presence of lower systemic and pulmonary vascular resistance, milrinone was preferentially used as an inotropic drug. In the first group of 10 patients to receive the Jarvik 2000, the pump provided a cardiac output of up to 8 L/min, depending on preload, afterload, and pump speed. There were no early perioperative deaths. The average support duration was 81.2 days; the range was 13-214 days. Seven of the 10 patients survived to transplantation. Survivors underwent complete physical rehabilitation during pump support.


- Abstract

Patients with congestive heart failure who are supported with a left ventricular assist device (LVAD) may experience right ventricular dysfunction or failure that requires support with a right ventricular assist device (RVAD). To determine the feasibility of using a clinically available axial flow ventricular assist device as an RVAD, we implanted Jarvik 2000 pumps in the left ventricle and right atrium of two Corriente crossbred calves (approximately 100 kg each) by way of a left thoracotomy and then analyzed the hemodynamic effects in the mechanically fibrillated heart at various LVAD and RVAD speeds. Right atrial implantation of the device required no modification of either the device or the surgical technique used for left ventricular implantation. Satisfactory biventricular support was achieved during fibrillation as evidenced by an increase in mean aortic
pressure from 34 mm Hg with the pumps off to 78 mm Hg with the pumps generating a flow rate of 4.8 L/min. These results indicate that the Jarvik 2000 pump, which can provide chronic circulatory support and can be powered by external batteries, is a feasible option for right ventricular support after LVAD implantation and is capable of completely supporting the circulation in patients with global heart failure.

   - Abstract
   Each year, thousands of cardiac patients await healthy donor hearts for transplantation. Due to the current shortage of donor hearts (approximately 2300 per year), these patients often require supplemental circulatory support until a transplant becomes available. This supplemental support is often provided by a mechanical heart pump or left ventricular assist device (LVAD). This article explores one type of LVAD, specifically the design and development of axial flow ventricular assist devices (VAD). We discuss the design details, and experimental or clinical experience with the following axial flow support systems: Hemopump, MicroMed DeBakey VAD, Jarvik 2000, HeartMate II, Streamliner, Impella, Berlin INCOR I, Valvo pump, and IVAP. All of these devices demonstrate promise in providing bridge-to-transplant and ultimately destination therapy for adult cardiac failure patients.

   - Abstract
   Feasibility studies are underway for new axial flow ventricular assist systems and with a total artificial heart (TAH). The axial flow pumps provide continuous flow from the left ventricle (LV) to the aorta; the TAH provides pulsatile flow to the pulmonary and systemic circulation. Understanding the differences between these systems is necessary for appropriate patient selection and management. We compared the Jarvik 2000 axial-flow pump and the AbioCor TAH. The Jarvik 2000 pump is placed in the LV with its outflow graft anastomosed to the aorta. This system is used for bridge-to-transplantation and destination therapy. The AbioCor TAH provides complete circulatory support. The AbioCor is used for destination therapy in patients expected to die in less than 30 days. Worldwide, 45 patients have received the Jarvik 2000 as a bridge to transplantation (n = 34) or destination therapy (n = 11) for an average duration of support of 132.8 days (5 to 853 days). In 30 bridge-to-transplantation cases, 14 patients (47%) have undergone heart transplantation, 5 (17%) continue to be supported with the Jarvik 2000 device, and 11 (37%) have died. Five of 7 patients supported by the AbioCor TAH survived beyond the perioperative period; 4 were ambulatory, 2 were discharged from the hospital, and 1 is at home 13 months after implantation. Anticoagulation therapy and infection management are necessary for both systems. Therapy with inotropic agents, vasoactive drugs, a pacemaker, and electrolyte normalization is necessary for Jarvik patients. AbioCor-supported patients do not require medications to support heart function. Vasoactive agents may be useful for controlling blood pressure.

   - Abstract
   Device-related infections remain a considerable problem of left-ventricular support. We compared the device-related-infections between the HeartMate left ventricular assist device (LVAD) and the Jarvik 2000 permanent LVAD, a device with a novel retroauricular power-supply.

   - Abstract
   To evaluate the Jarvik 2000 axial flow left ventricular assist system (LVAS) as a bridge to transplant and as destination therapy.

- **Abstract**

  In this report, we describe successful implantation of a Jarvik 2000 left ventricular assist device (Jarvik Heart, Inc., New York, NY) without the use of cardiopulmonary bypass in a patient who was a member of the Jehovah's Witness faith. To accomplish this, we had to change our implantation technique. The modified technique, which minimizes the risk of bleeding and end-organ dysfunction, can also be used to decrease cardiopulmonary bypass time.


- **Abstract**

  Currently the most common indication for placement of a left ventricular assist device is as a bridge to heart transplantation. One of the new generation axial flow left ventricular assist devices is the Jarvik 2000. This device is placed in the apex of the left ventricle and the outflow graft passes through the left pleural space and is anastomosed to the descending thoracic aorta. The course of the outflow graft presents technical challenges during explant for heart transplantation. Opening the posterior pericardium and use of a vascular stapler to control the outflow graft at the level of the descending thoracic aorta facilitates easy explantation.


- **Abstract**

  Heart failure is now a public health epidemic. Donor hearts are severely restricted in availability. Permanent mechanical circulatory support or bridge to myocardial recovery are emerging alternatives. After extensive laboratory experience we sought to evaluate the intraventricular Jarvik 2000 Heart in patients with endstage heart failure.


- **Abstract**

  Implantable left ventricular assist systems (LVASs) are used for bridging to transplantation, bridging to myocardial improvement, and for permanent circulatory support. Conventional implantable systems have inherent limitations that increase morbidity during support. In contrast, small, efficient, axial-flow pumps, which have been under development for the past decade, have the potential to improve the length and quality of life in patients with severe heart failure. Methods and Results- To assess the safety and clinical utility of the Jarvik 2000, we implanted this device in 10 transplant candidates (mean age 51.3 years) in New York Heart Association (NYHA) class IV. Implantation was achieved through a left thoracotomy during partial cardiopulmonary bypass. The mean support period was 84 days. Within 48 hours postoperatively, the cardiac index increased 43%, pulmonary capillary wedge pressure decreased 52%, systemic vascular resistance decreased significantly, and inotropic support became unnecessary. Eight patients underwent physical rehabilitation and returned to NYHA class I. Their left ventricular dimensions, cardiothoracic ratios, and pressure-volume loop analyses showed good left ventricular unloading. Seven patients underwent transplantation and 3 died during support. No device thrombosis was observed at explantation.


- **Abstract**

  Implantable left ventricular assist systems (LVASs) are used for bridging to transplantation, bridging to myocardial improvement, and for permanent circulatory support. Conventional implantable systems have inherent limitations that increase morbidity during support. In contrast,
small, efficient, axial-flow pumps, which have been under development for the past decade, have the potential to improve the length and quality of life in patients with severe heart failure. Methods and Results- To assess the safety and clinical utility of the Jarvik 2000, we implanted this device in 10 transplant candidates (mean age 51.3 years) in New York Heart Association (NYHA) class IV. Implantation was achieved through a left thoracotomy during partial cardiopulmonary bypass. The mean support period was 84 days. Within 48 hours postoperatively, the cardiac index increased 43%, pulmonary capillary wedge pressure decreased 52%, systemic vascular resistance decreased significantly, and inotropic support became unnecessary. Eight patients underwent physical rehabilitation and returned to NYHA class I. Their left ventricular dimensions, cardiothoracic ratios, and pressure-volume loop analyses showed good left ventricular unloading. Seven patients underwent transplantation and 3 died during support. No device thrombosis was observed at explantation.


- Abstract
  We sought to evaluate the surgical results and effects of continuous support with the permanent Jarvik-2000 left ventricular assist device (LVAD). We report the early outcomes.


- Abstract
  A lifetime mechanical solution for advanced heart failure must be reliable, with a low risk of life-threatening complications. After extensive laboratory testing, we began clinical trials with an axial flow pump for long-term treatment of New York Heart Association class IV, transplant-ineligible patients.


- Abstract
  Percutaneous driveline infection continues to detract from both quality and length of life in patients with a left ventricular assist device. We have pursued an alternative route by using a skull-mounted percutaneous pedestal similar to cochlear implant technology. We have now used this method in patients implanted with the Jarvik 2000 heart (Jarvik Heart, Inc, New York, NY) as destination therapy for end-stage (New York Heart Association class IV) heart failure.


- Abstract
  The Jarvik 2000 Heart is a silent compact axial flow impeller pump which is now undergoing clinical trials for both bridge to transplantation and permanent mechanical circulatory support. The pump is implanted into the apex of the failing left ventricle by left thoracotomy. A vascular graft offloads to the descending thoracic aorta so that only the left pleural cavity is opened. Power supply is through an abdominal drive line or postauricular titanium pedestal according to the treatment strategy.


- Abstract
  The Jarvik 2000 is a new generation heart assist device. We studied whether the quality of life (QOL) of patients supported with a Jarvik 2000 axial flow pump improves during support and in the early post transplantation period. Eight patients supported with the Jarvik 2000 until transplantation were assessed using the Minnesota Living with Heart Failure Questionnaire. The QOL was assessed at four time points: before implantation (baseline), 30 days after implantation,
at time of transplantation, and 30 days after transplantation. The average duration of Jarvik 2000 support was 83 days and the total duration was 1.8 years. Post-transplantation survival was 100% (average follow-up, 7.1 months). From baseline to 30 days after implantation, total, physical, and emotional QOL scores increased by 21%, 22%, and 14%, respectively. From baseline to time of transplantation, they increased by 25%, 23%, and 16%, respectively. From time of transplantation to 30 days after transplantation, total and physical scores decreased by 11% and 15%, while emotional scores increased by 15%. Our data indicate that overall QOL improved in patients with severe heart failure supported with a Jarvik 2000 and that their total and physical QOL scores were better during support than at 30 days after transplantation. This suggests that support with the Jarvik 2000 considerably improves QOL in patients with severe heart failure.


- Abstract
  The Jarvik-2000 is an axial-flow left-ventricular-assist-device (LVAD) designed for permanent use. The power supply is provided by a cable plugged into a skull-pedestal mounted in the retroauricular area. We describe the surgical technique and discuss potential and encountered problems.


- Abstract
  Advances in technology and increased clinical need have led to the development of a new type of blood pump. The Jarvik 2000 Heart is an electrically powered, axial-flow left ventricular assist device that has been developed during the past 13 years. Unlike first-generation left ventricular assist devices, which were developed in the 1970s and were designed to totally capture the cardiac output, the Jarvik 2000 is designed to normalize the cardiac output by augmenting the function of the chronically failed heart for extended periods. Design iterations have been tested in 67 animals, and clinical trials have recently begun. Three patients have received the Jarvik 2000 as a bridge to transplantation, and 1 patient is being supported permanently outside the hospital. All 4 patients have improved from New York Heart Association functional class IV to class I, and 2 of them have been discharged from the hospital after heart transplantation. The experimental and clinical results indicate that the Jarvik 2000 can provide physiologic support with minimal complications and is reliable, biocompatible, and easy to implant.


- Abstract
  No abstract available


- Abstract
  Heart failure is a major public-health concern. Quality and duration of life on maximum medical therapy are poor. The availability of donor hearts is severely limited, therefore an alternative approach is necessary. We have explored the use of a new type of left-ventricular assist device intended as a long-term solution to end-stage heart failure.


- Abstract
Mechanical bridge to left ventricular recovery is an emerging strategy for the treatment of heart failure. We sought to validate the use of a new intracardiac axial flow impeller pump for this purpose.

   • Abstract
   A cable-lead tester and real time bearing tester have been developed with provisions to test future implantable electronics, transcutaneous energy transfer system (TETS), and related interconnect cabling designs. The cable/lead tester, used in 1997 to test a previously considered implantable bellows-connector-cabling system, can test up to 10 samples at a time. X-Y-Z-theta motions are applied to the proximal end of the test specimen with its distal end fixed. The real time bearing tester is of a mock loop configuration with the bearings under test housed in a fully functional, Good Manufacturing Practices assembled axial pump. A simulated left ventricular pulsatile preload is applied to the inflow of the axial pump, while its outflow is subjected to an 80 mmHg aortic afterload by pumping into a fixed height tube with no outflow restriction. The heated blood bath saline used in this system is UV sterilized and mechanically filtered by use of a commercial salt water conditioning system attached external to the main preload fluid reservoir. The cable-lead tester and real time bearing tester design include provisions to house a complete Jarvik 2000 left ventricular assist device (Transicoil Medical, Norristown, PA) for in vitro system testing.

   • Abstract
   Driveline infection limits the event-free survival of patients with a left ventricular assist device. With the evolving prospect of improved left ventricular assist devices in the bridge-to-transplantation or recovery setting, we sought to reduce the risk of driveline complications.

   • Abstract
   This study describes the present state of progress in the development of the Jarvik 2000 ventricular assist system.

   • Abstract
   We developed a system for mechanical circulatory support based on the Jarvik 2000 intraventricular axial flow impeller pump (Jarvik Research, Inc., New York, N.Y.) and percutaneous electric power. The adult pump provides flow at a rate up to 10 L/min with an energy requirement of 7 to 10 watts. The device was implanted into the apex of the left ventricle through a left thoracotomy without cardiopulmonary bypass. A Dacron graft conveyed blood to the descending thoracic aorta. In patients, we will use a skull-mounted carbon pedestal to transmit fine electric wires through the scalp skin. Being highly vascular, the scalp skin is resistant to infection.

   • Abstract
   We investigated the efficacy of the Jarvik 2000 intraventricular assist device (Jarvik Research, Inc., New York, N.Y.) in an ovine model. The device is an axial flow pump measuring 1.8 cm in diameter by 5 cm long, has a displacement volume of 12 ml, and can deliver flow from 2 to 7 L/min. Seven devices were implanted through a left thoracotomy into the left ventricle with an outflow graft to the descending aorta. Animals were treated with warfarin sodium and aspirin to maintain prothrombin times approximately 1.5 times control. Animals were followed up for 3 to
123 days. Two animals died of operative complications at days 3 and 5. One device failed at 58 days because of thrombus formation at the inflow side of the impeller. The remaining four animals were killed at days 19, 42, 42, and 123, respectively, because of broken electric power cables. Hematocrit values rose significantly higher than preoperative levels (22.8% +/- 3.8% to 30.5% +/- 3.4%); pretreatment elevations of values higher than baseline values of plasma free hemoglobin (10.4 +/- 7.8 mg/dl to 17.1 +/- 7.4 mg/dl) and lactate dehydrogenase (391.5 +/- 113.7 units/L to 771.2 +/- 370.8 units/L) were statistically insignificant. Serum creatinine and bilirubin levels were normal. No end-organ dysfunction arising from long-term support was evident clinically or at postmortem examination, nor was there any evidence of embolism or damage to intracardiac structures. We found the Jarvik 2000 intraventricular assist device to be easily implantable, safe, nonhemolytic, and able to provide physiologic flow with power requirements under 10 watts.


  • Abstract

We are studying in vivo an intraventricular axial flow blood pump (Jarvik 2000) designed for long-term left ventricular support. The small (25 cc, 85 g) valveless pump has been placed intraventricularly in seven calves; pumps have functioned for as long as 5 months. In the four most recent long-term studies completed, calves have survived for 70, 120, 155, and 162 days (in that order); weight gain has averaged 0.56 kg/day. One study is ongoing at more than 30 days. Under resting physiologic conditions in the normal calf, the continuous flow pump produces flows of 5-6 L/min with a decreased arterial pulse contour. The device has caused no physiologic complications. Calves in the completed studies had mean free plasma hemoglobin levels of 11.4, 7.1, 6.5, and 4.3 mg/dl, respectively. We have modified the inflow structures of the device, and these results suggest that a thrombus-free design with no pannus at or around the inlet of the pump can be achieved. Histopathologic analyses of the heart and kidneys in studies of as long as 5 months show no deleterious effects of this device. These studies demonstrate the feasibility of a small implanted intraventricular blood pump for long-term use. Future developments for permanent implantation will include implanted physiologic control systems, transcutaneous energy transmission systems, and implanted batteries.


  • Abstract

In vivo studies have begun to evaluate a new intraventricular electric axial flow left ventricular assist device (LVAD), the Jarvik 2000, which is a small, valveless pump that is placed inside the left ventricle through the left ventricular apex. The operation, which is performed through a left thoracotomy, may be done without cardiopulmonary bypass and aortic cross-clamping. Outflow is provided through a 16 mm softly woven, Dacron graft anastomosed to the descending thoracic or abdominal aorta. Pump flow, which varies from 2 to 16 l/min in vitro, is changed by adjusting the speed of pump rotation. Preliminary studies were done to evaluate the ease of implantation, hematologic and anatomic compatibility, and pump performance. The device has been implanted in seven healthy, preconditioned calves (83-138 kg), one of which is currently undergoing support. The implantation procedure averaged 3 hours. There were no operative deaths, and blood transfusions were not required. Postoperatively, anticoagulation was achieved with heparin followed by warfarin sodium to maintain prothrombin time or partial thromboplastin time at 1.5-2.0 times baseline. In the six completed studies, support time ranged from 2 to 120 days (mean, 36 days). The seventh calf has been supported for 30 days. In the four long-term studies (20, 70, 120, > 30 days), the mean plasma free hemoglobin values during support were 11.0, 7.7, 6.6, and 3.4 mg/dl, respectively. Under normal conditions, the average daily flow rate ranged from 5 to 6 l/min. During treadmill exercise (10% grade, 1.5 km/h) lasting 20 minutes, peak flow rates exceeded 8 l/min. These pilot studies suggest that this intraventricular axial flow pump is relatively easy to implant, operate, and control. In addition, it is hemocompatible, provides physiologic flow rates, and may be able to provide long-term circulatory support.