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The Hemopump®—A New Cardiac Prothesis Device

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Abstract—**A unique cardiac prothesis device is currently undergoing clinical trials. Called the Hemopump, this device is a radical new design of a temporary left ventricular assist blood pump. It uses a miniature (7 mm diameter) axial flow pump placed transvalvular across the aortic valve which pumps blood from the left ventricle to the aorta. Mechanical power from an external motor is transmitted percutaneously to the pump by a flexible cable contained within a catheter-like sheath. This arrangement allows the pump to be placed through a femoral artery cutdown without requiring major surgery. Development of the Hemopump concept presented significant challenges in pump hydraulic design, bearing, and seal design, as well as materials selection and miniature parts fabrication. Clinical trial results thus far indicate these challenges have been well met and that the Hemopump has the potential to become a widely used safe and effective clinical device.**

Introduction

THE ESSENTIAL premise of the Hemopump is that significant numbers of lives could be saved if a blood pump can be introduced into the circulatory system quickly and without the trauma of major surgery. This device would have the features of an intraaortic balloon pump with respect to low risk of use and ease of application. Yet, it would also be more effective, having significantly more flow capacity, and the ability to generate flow in the presence of cardiogenic shock. From this idea was formed the fundamental Hemopump concept illustrated in Fig. 1; a miniature pump located at the end of a catheter is introduced at a femoral artery site, and threaded up to the heart. The pump's inlet flow cannula passes retrograde through the aortic valve, its tip located in the left ventricle. In operation, blood flow is pulled through the inlet cannula into the pump, whereupon it is pumped up to systemic pressure and discharged into the aorta. In this process the left ventricle is relieved of its major work load.

Successful development of this concept took long and intense effort, one requiring application of a full range of engineering disciplines, covering mechanical and electrical design, fluid flow and journal bearing analysis, and materials and medical science. Now, the original premise of the Hemopump is being tested clinically. Lives have been saved and there has been dramatic demonstration of the pump's effectiveness to provide left ventricular assistance. While additional data are needed to fully substantiate the safety and efficacy of the device, the results thus far are encouraging.

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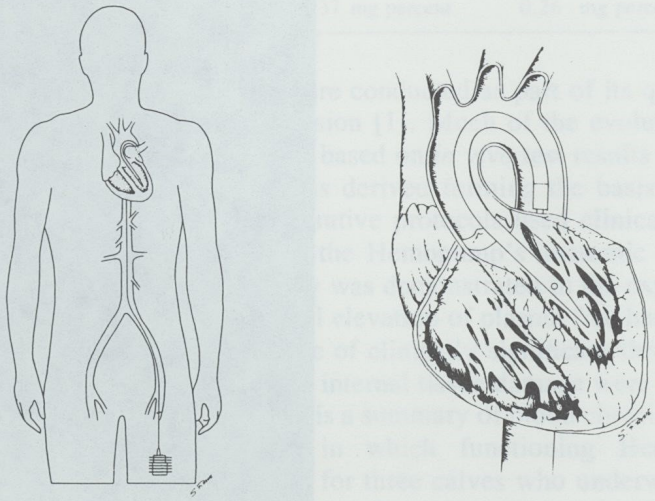

Fig. 1. Femoral placement of the Hemopump.

Hemopump Concept Description

The Hemopump system is shown in Fig. 2. The pump itself is a miniature axial flow configuration consisting of a rotor stage and a stator row. This mechanism is contained within a cylindrical housing 7 mm in diameter by 16 mm in length. The flexible inflow cannula is 20 cm long. At a rotating speed of 24 500 rpm, the pump generates three l/min of blood flow when discharging into an output load of 100 mmHg pressure.

Power to drive the pump is transmitted from an external electric motor through a flexible cable threaded through a sheath. Stiffness of the cable-sheath combination gives the Hemopump's insertable portion a catheter-like feel during placement. To pass the 21 French size pump and cannula, a skin incision is required at the femoral introduction site, and a 12 mm graft is anastomosed here to minimize blood loss during insertion of the Hemopump. The drive motor connected to this end of the sheath is located outside near the patient's leg.

The pump bearings, the pump blood seal, the flexible cable, and the motor bearings all are fluid lubricated with a 40 percent dextrose-water mixture (D-40W, USP). The fluid flows to and from the pump via lumens in the sheath. The sheath is multilumen, with a central bore where the cable is located, and four individual outer capillaries placed peripherally around the bore. Flow distribution of this "purge" fluid is diagramed in Fig. 3. Purge flow, delivered by an external roller pump, enters the sheath through the outer lumens at a site near the motor. This fluid travels down the sheath to the pump's interior bearing cavity. Here the flow splits; approximately two thirds

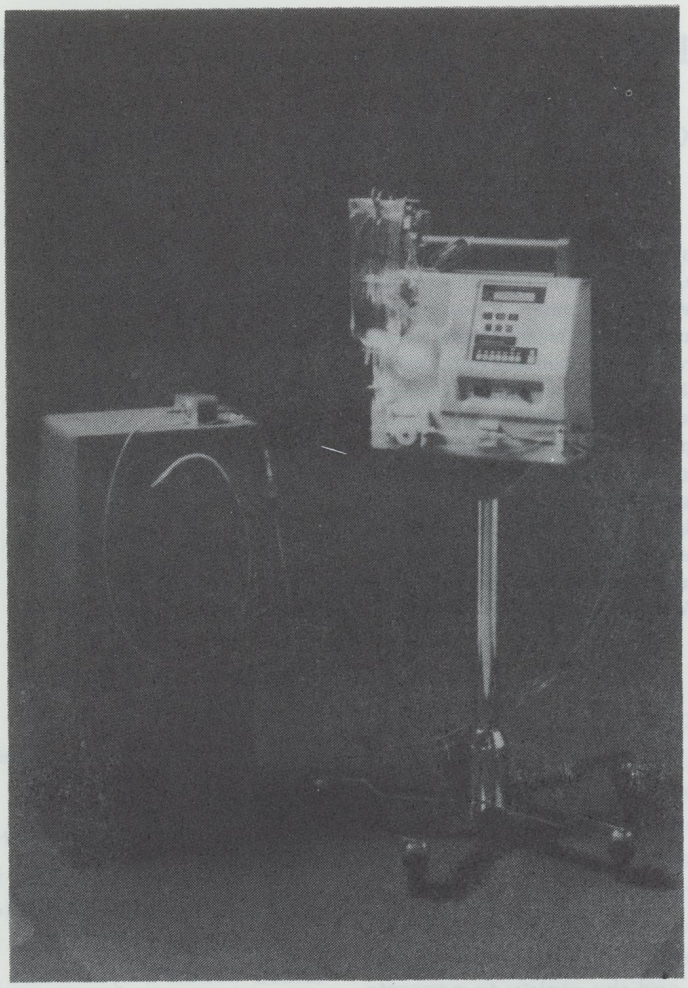

Fig. 2. The complete Hemopump system.

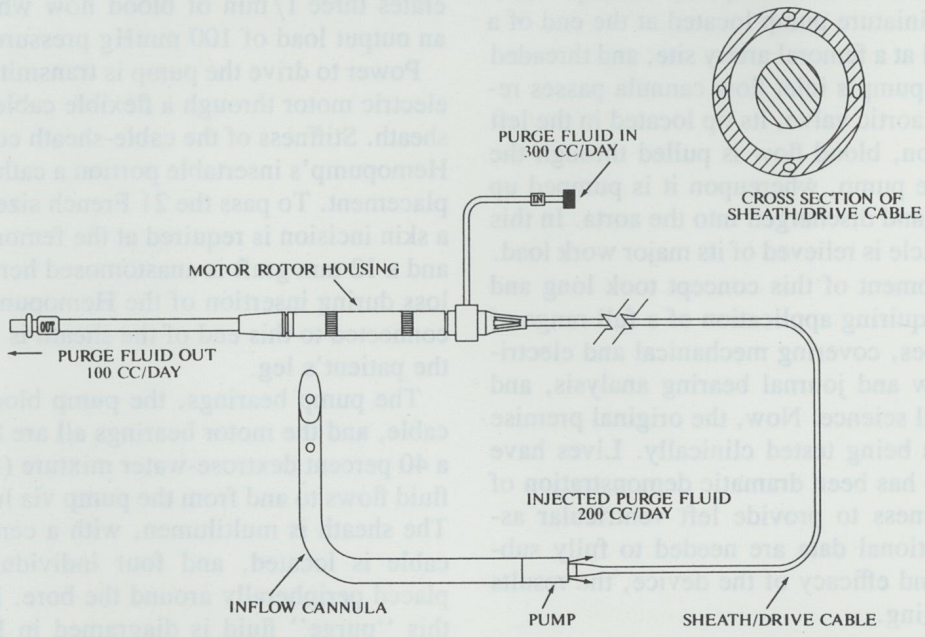

Fig. 3. Purge flow distribution of the Hemopump.

of it passes through the pump, while one third of it enters the central bore and flows back through the sheath.

Total purge flow rate is approximately 300 cc/day. The 200 cc/day passing through the pump is injected into the blood flow through the rotating blood seal. The 100 cc/day flowing retrograde through the sheath bore lubricates the cable and the motor journal bearings then passes out into an external collection bag.

The roller pump which generates the 300 cc/day purge flow rate is mounted on an external console. A second

roller pump plumbed backwards meters the outflow to the 100 cc/day level. The console is an integrated controller that incorporates all of the power, controls, and diagnostic alarm systems required to operate the Hemopump and supply and collect its purge fluid. Weighing approximately 25 lbs, the console is easily portable and can be carried by hand or placed on the patient's bed. Internal batteries provide 60 min of portable operation without external power.

Except for the console and the electric motor's stator, the Hemopump is a disposable one-time use device. The disposable set comes in two individually sterile packages. One contains the pump assembly, consisting of the pump, cable, sheath, and motor rotor. The second is the purge delivery assembly, comprised of delivery and collection tubing and fittings, roller pump cassettes, and collection bag.

Development Methods

Development of the Hemopump required significant technical achievements not only in the concept itself but in the methodology of its test evaluation. For example, a technique used to define the pump flow geometry involved use of miniature probes to measure pressures over flow field regions, and from this determine velocity vectors and blade angles. Also, flow through the pump was visualized through a microscope under stroboscopic lighting. By injecting air bubbles and small particles, areas of separation and recirculation could be defined and blade angles were adjusted accordingly. Using such techniques, along with overall flow performance characterization and *in vitro* hemolysis testing, the many variables associated with the flow geometry were evaluated and a satisfactory configuration evolved. Its design was a far departure from the classical theory-based geometry that was the starting point.

Definition of the blood seal was one of the most difficult development tasks. The seal is essentially a hydrostatic thrust bearing supplied by a constant feed rate lubricant (200 cc/day). This flow supply not only lubricates the running surfaces and maintains the bearing film, but it also flushes blood elements that enter the bearing during pulsatile flow action. Significant progress was made in this area only after the pulsatile induced dynamics of the seal were defined analytically and bench test methods were created in which test pumps could be run in pulsatile loops that flowed actual blood.

Similarly, the evolution of the sheath and cable assembly represents a major accomplishment. Many variables involving mechanical design, material choices, purge fluid choices, and manufacturing processes had to be evaluated before the final design was achieved. Again, special test methods involving pulsatile flow and simulated human anatomy had to be developed to properly test the load carrying capabilities of this component.

In vitro development of the Hemopump was accomplished by extensive *in vivo* testing of the device implanted in calves. Approximately 65 separate *in vivo* tests were run in the course of the development program and an additional 24 tests were conducted as part of its qualification for IDE submission [1]. Much of the evolution of the basic concept was based on *in vivo* test results and important knowledge was derived forming the basis for the surgical and postoperative protocols used clinically. Most essential was that the Hemopump's anatomic and physiologic compatibility was demonstrated in the experimental animals. Minimal elevation of plasma free hemoglobin, minimal evidence of clinically significant thromboembolism, and lack of internal tissue damage were key results. Listed in Table I is a summary of blood chemistry results for 21 calves in which functioning Hemopumps were placed, and for three calves who underwent sham operations without actually putting a pump in place. The small differences between the implant and control group indicate satisfactory blood compatibility of the device.

TABLE I

	Control Group	Implant Group
Plasma free hemoglobin	3.12 mg percent	6.66 mg percent
Platelets	1.04 $\times 10^6/mm^3$	0.65 $\times 10^6/mm^3$
Fibrinogen	243 mg percent	246 mg percent
Blood urea nitrogen (BUN)	1123 mg percent	12.97 mg percent
Creatinine	0.87 mg percent	0.92 mg percent
Total bilirubin	0.37 mg percent	0.26 mg percent

Clinical Trial Results

Currently, clinical trials of the Hemopump are ongoing under an investigational device exemption (IDE) approved by the FDA. In these trials the Hemopump is being used on patients who fail to respond to conventional drug and volume treatment, and who, based on prescribed hemodynamic indicators, generally have a very poor chance of survival (less than 10 percent) unless mechanical support is used. Mostly, the patients come from two major categories, 1) those who cannot be weaned off bypass, and 2) those who have suffered an acute myocardial infarction.

Thus far there have been 40 Hemopump cases. Of these, the pump has been inserted and operated in 32 patients. The effectiveness of the Hemopump, as characterized by improved ventricular function and reversal of shock has been documented in 19 of 23 patients (83 percent). Survival rate overall is 41 percent (13 of 32 patients). Causes of death for nonsurviving patients who had Hemopump support generally fall into categories of 1) other organ failure, 2) biventricular failure, and 3) irreversible left ventricle damage resulting in pump dependency. Of the eight patients in which the Hemopump could not be fully inserted, all died shortly after the attempt. Generally, the reasons for unsuccessful insertion were sclerotic or unusually tortuous and narrow vessels in the pelvis region.

The pump itself and its operation have been tolerated well by the patients [2], [3]. Insertion commonly requires 15–20 min including the cutdown. Longest time of continuous operation in a survivor is 194 h, while the shortest support time prior to weaning is 5 h. Average support time

for patients successfully weaned from the Hemopump is 50 h. There have been no problems maintaining the penetration site and ischemia of the leg has not been observed. Hemolysis attributable solely to pump operation is insignificant, and there has been no evidence of clinically significant thromboembolic events. Autopsy results (nine cases) confirm the latter, plus they indicate no evidence of Hemopump related damage to the endocardium, aortic valve, or aorta. Included in the postmortem results is one patient who was supported for 101 h.

In addition to the two major patient category groups, the Hemopump has been used to support patients who have suffered acute rejection of cardiac allografts. There have been four such cases and in three of the four, the patients recovered normal cardiac function and were successfully weaned from the device. This experience, while very preliminary, suggests that the Hemopump can play a role in the treatment of acute allograft rejection [4]. In addition, there is evidence indicating that the Hemopump may be effective in preserving muscle during myocardial ischemia. This has been confirmed in tests in animals [5], [6], and is supported indirectly by the experience of AMI patients who recovered after only brief periods of Hemopump assistance (as little as 5 h).

Summary and Conclusion

The results of the clinical trials of the Hemopump are encouraging. The safety and efficacy of the device is being tested thoroughly and based on the data developed thus far, it appears that the original premise of the Hemopump is going to hold true. However, additional clinical trial experience and data are required before it can become approved for widespread clinical use. Mortality rates experienced thus far are acceptable, particularly for the class of patients currently being treated with the device. Certainly, based only on the criteria that its use reverses shock and improves cardiovascular function, the Hemopump's record is outstanding. Furthermore, it appears that the Hemopump may be beneficial not only as a life saver but as a cardiac muscle saver as well, and that its application can broaden into preventative cardiology roles. Another important conclusion drawn from the clinical trials is that the Hemopump is basically a safe device. In all the cases treated there has been no incidence of a Hemopump, running under both normal and abnormal operating conditions, harming or injuring a patient.

It is apparent that there are patients in whom inserting the Hemopump is difficult, or impossible. Noninsertions should decrease as users gain experience and become more adroit in the mechanics of pump placement. In addition, a separate 21 French size introducer and a guide wire system are being developed to aid the insertion process.

Clinical trials of the Hemopump are currently ongoing at six major medical centers in the United States. These will be expanded to ten in the near future. Concurrent with the trials, Nimbus is preparing the documentation to submit to the FDA requesting permission to produce the device for commercial use in the United States. Nimbus is also developing other blood pump concepts based on Hemopump technology. One of these is a 14 French size device that is similar in concept with respect to its placement and use. Its size, however, means that it can be introduced and placed percutaneously and that it should pass easier through a patient's vessels than the 21 French size. Other Hemopump related devices under development hold the promise of meeting the needs of patients who require chronic cardiac assistance with truly reasonably sized implant hardware. With the continued success of the Hemopump, this promise should eventually become a reality.

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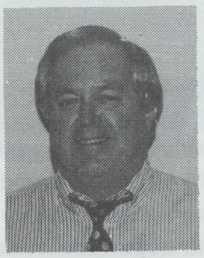
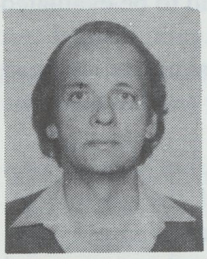


Kenneth C. Butler received the B.S. in mechanical engineering from the University of California, Berkeley, in 1961 and the M.S. degree in mechanical and biomedical engineering from California State University, Sacramento, in 1975.

He is Director of Engineering at Nimbus Medical, Inc. A long-time participant in the area of research and development of mechanical blood pumping systems, he has played a major role in technology advancement of miniature energy converters for implanted energy systems. He currently is Program Director or Principle Investigator for three separate NIH sponsored programs to develop: 1) an electric-powered left ventricular assist system (LVAS), 2) a thermal-powered LVAS, and 3) an electric-powered total heart replacement system. He also was the Project Engineer responsible for development of the Hemopump implanted pump system.

John C. Moise received the Ph.D. degree in mechanical engineering from Case Western Reserve University, Cleveland, OH, in 1952.

He is a co-inventor of the Hemopump and has played a major role in its conceptualization and basic development. He is a noted expert in the field of research and development of miniaturized energy converters and blood pumping devices for implantable left ventricular assist systems and has spent some 17 years actively engaged in this field. He is also a co-founder of Nimbus Medical, Inc. and currently is serving on the staff as Vice President of Research and Development.



Richard K. Wampler received the M.D. degree from Indiana University in 1974.

He conceived the idea of the Hemopump concept and was a key contributor to the mechanical development of the device, as well as its testing and demonstration in experimental animals. He directed the structuring of the clinical trials of the Hemopump and is actively engaged in training new users and providing consultation and guidance to its clinical investigators. He is a member of the staff of Nimbus Medical, Inc., serving as the Director of Medical Affairs.