Animal Trials of a Magnetically Levitated Left-Ventricular Assist Device

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Abstract

The University of Pittsburgh/Magnetic Moments mag-lev left-ventricular assist devices (LVADs), the Streamliner HG3b and HG3c, have successfully been implanted in calves. The first was implanted for 4 hours on July 10, 1998 (Figure 1) and the second for 34 days on August 24, 1999 respectively. The tests confirmed the feasibility of low power levitation (1.5 watts coil power) and very low blood damage in a mag-lev ventricular assist device. In this paper, we describe the unique geometry of this pump and its design. Key features of this LVAD concept are the passive radial suspension and active voice-coil thrust bearing.

I. Introduction

The University of Pittsburgh's McGowan Center for Artificial Organs and Magnetic Moments, LLC, have brought a mag-lev LVAD to the *in vivo* animal testing stage. The first test was 4-hours long and was conducted with the polycarbonate HG3b version of the Streamliner on July 10, 1998 (Figure 1). Following this initial demonstration of feasibility and low blood damage, the titanium HG3c was fabricated and tested for 34 days in a calf following implantation on August 24, 1999. The Streamliner design affords low-power levitation (1.5 watts of levitation coil power) and very high reliability. These successful trials mark a turning point in the efforts of many researchers to devise such a magnetically levitated pump.

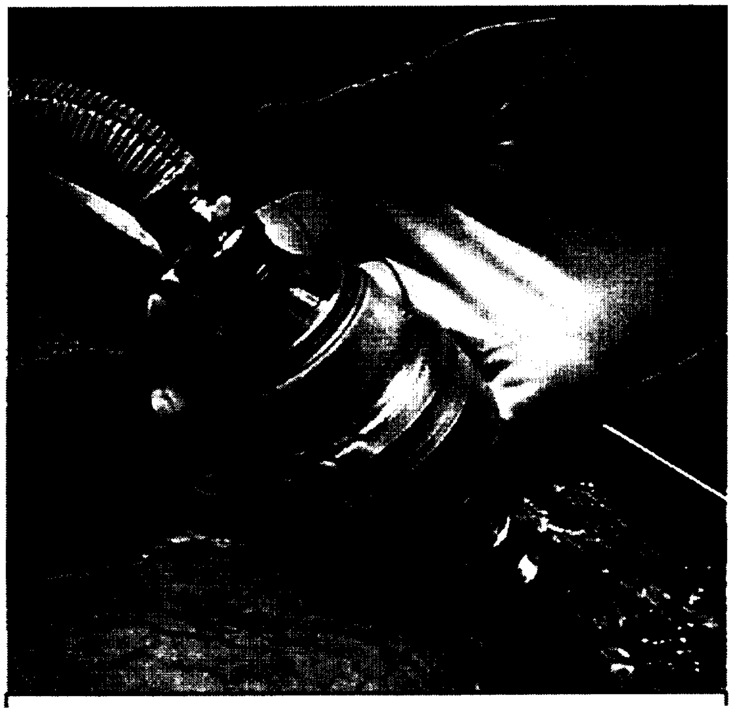

Figure 1. HG3b implant in a calf (July 10, 1998)

The research effort to develop a reliable mag-lev LVAD is motivated by a tremendous human need. In the U.S. alone, 700,000 deaths per year are attributed to heart diseases such as myocardial infarction and cardiomyopathy [Hogness 1991]. It is estimated that at least 35,000 to 70,000 of these lives can be saved with a mechanical cardiac assist device. Further, the worldwide need is an overwhelming 200,000 per year. Technologies for mechanical circulatory support, particularly left-ventricular assist devices (LVADs) have evolved to commercially viable medical devices. However, a *long-term* implantable LVAD has been elusive due to mechanical wear and limited biocompatibility. These two problems can be addressed through

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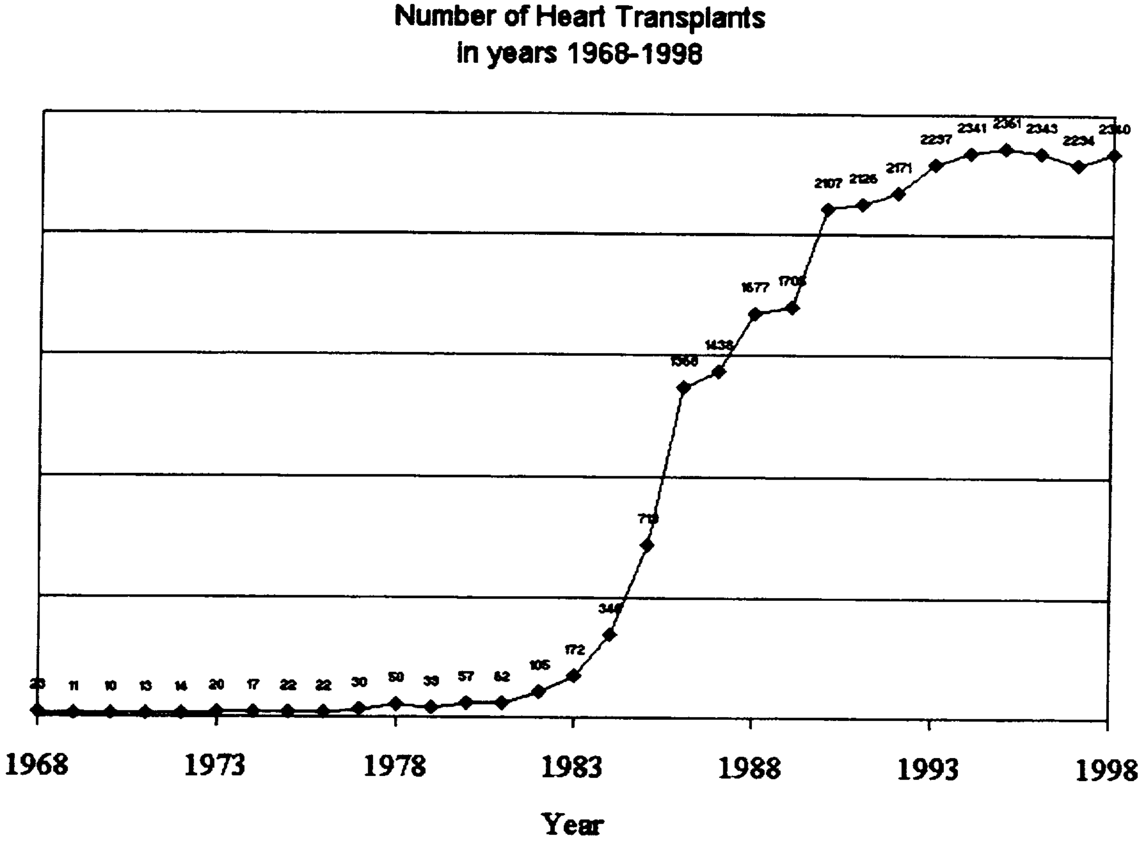
Figure 2.



the application of magnetic suspension technology. Basic mag-lev research at Magnetic Moments in collaboration with NASA, and hemodynamics and pump research at the University of Pittsburgh on the Streamliner artificial heart have created an LVAD capable of meeting the needs of a tremendous number of patients.

The supply of human hearts for transplant is limited to 2,500 per year in the U.S. at best. Once anti-rejection drugs were developed making heart transplantation practical, the treatment grew exponentially, doubling about every year in the mid 1980's until limits in supply capped the growth (see Figure 2). It is reasonable to expect that long-term LVAD use will follow a similar growth curve, but will not be limited by supply. The application of LVADs is much broader than that for transplants, and patients do not need immunosuppressive anti-rejection drugs.

Mechanical circulatory support has a long background with many device types explored and much gained in basic knowledge. The first approach applied in human clinical trials was the total artificial heart (TAH). This is the conceptually simple removal of the human heart and replacement with two mechanical pumps to simulate both the left and right ventricles. Dr. Jarvik, a veterinarian, is credited with the design of the first artificial heart, which sustained a patient for 112 days

Figure 3. Clockwise from upper left: Jarvik-7, Baxter/Novacor LVAD, Streamliner HG3a

[Marshall 91]. His Jarvik-7 TAH (upper left in Figure 3) was used in 3 more patients with limited success. The Jarvik-7 has found a niche as a temporary TAH implanted for interim use while patients and surgeons await a human heart for transplant. This bridge-to-transplant application of assist devices is a beneficial use of mechanical circulatory support, and is seen as a stepping stone market for long-term use for our device. The Baxter/Novacor LVAD (upper right in Figure 3) is the first to receive approval for permanent implantable use, and was granted preliminary market approval (PMA) in 1998 by the FDA. The first Streamliner prototype is shown in the lower center of the Figure 3.

The applications of LVADs can be apportioned into four areas. The term of use for each application varies a great deal:

> **Post-Cardiotomy** (1-2 weeks): Numerous short-term disposable devices currently serve this application. It is therefore not an ultimate target market for the Streamliner LVAD.
>
> **Bridge-to-Transplant (BTT)** (< 1 year): The maximum number of heart transplants in the U.S. is approximately 2,500 per year. Simultaneously, roughly 30,000 patients are awaiting a heart transplant. Thus, for those who are critically ill, it may be advisable to use an LVAD temporarily while the patients await a transplant. Bridge-to-transplant use may become "chronic support" use by default if a transplant does not become available.
>
> **Bridge-to-Recovery** (< 1 year): Remarkably, some patients who receive a ventricular assist device experience marked recovery from their heart failure. In some cases the VAD has been removed and the patient discharged from the hospital.
>
> **Chronic Support** (> 1 year): An estimate of the patient pool needing chronic support with an LVAD is approximately 35,000-70,000 per year in the U.S. This patient group is now served by the Baxter/Novacor LVAD that is only suitable for use up to 2 years due to thrombus and thromboembolism.

It is clear that there are a multitude of patients and applications requiring a high-performance implantable LVAD. By 2005, implantable LVAD's may be as common as pacemakers are today.

II. Background

The HG3 mag-lev LVAD was the first fully magnetically-suspended pump to be implanted as in an *in-vivo* animal trial on July 10, 1998. A second titanium pump was implanted for a 34-day trial in August 24, 1999. Both animal trials were performed at the McGowen Center for Artificial Organs at the University of Pittsburgh. One of the key technical achievements of this design was the efficient magnetic levitation scheme requiring only 1.5 Watts of levitation coil power while pumping. Further the pump design and motor have optimized designs enabling low-power operation.

The Streamliner's success in fully implanted *in vivo* studies follows a number of major contributions by researchers in the area of mag-lev LVADs. Bramm, Novak and Olsen [Bramm 81] appear to be the first to advocate magnetic suspension in LVADs in the literature. Subsequently, a prototype device was successfully levitated as reported by Bramm and Olsen [Bramm 85]. Akamatsu et al [Akamatsu 89, 92, 94] tested a magnetically suspended centrifugal pump in the laboratory. This pump has a magnetically levitated centrifugal impeller magnetically coupled to a conventional bearing supported motor.

The University of Utah/University of Virginia team (P. Allaire, E. Maslen, H. Kim, D. Olsen, and G. Bearnson) developed a fully-levitated LVAD prototype (CFVAD 2) and tested it in water achieving 6 L/min and 100mmHg at 2,400 RPM and 50 Watts of levitation power [Allaire 95, 96]. A subsequent prototype (CFVAD III) has a much more efficient levitation system requiring only 8 watts of power [Hilton 97], [Allaire 98].

There are a number of patents on magnetically levitated blood pumps listed in Figure 4. These are easily accessible at the IBM Patent server site (the current URL is www.patents.ibm.com).

US Patent #	Date	Inventors
4,688,998	08/25/87	Olsen, Bramm, and Novak
4,763,032	08/09/88	Bramm and Novak

4,779,614	10/25/88	Moise
4,994,748	07/31/90	Bramm and Olsen
5,078,741	01/07/92	Bramm and Olsen
5,112,202	05/12/92	Oshima, Nakazeki, Akamatsu, and Niki
5,195,877	03/23/93	Kletschka
5,326,344	07/05/94	Bramm and Olsen
5,385,581	01/31/95	Bramm and Olsen
5,443,503	08/22/95	Yamane
5,470,208	11/28/95	Kletschka
5,507,629	04/16/96	Jarvik
5,695,471	12/09/97	Wampler
5,725,357	03/10/98	Nakazeki
5,840,070	11/24/98	Wampler
5,928,131	07/27/99	Prem
6,015,272	01/13/00	Antaki, Paden, Burgreen and Groom

Figure 4. US Patents on Fully Magnetically Levitated Blood Pumps

III. System Description

The preferred Streamliner LVAD implant configuration is shown in Figure 5 and consists of

- Inflow and outflow cannulae, which connect the pump to the left ventricle and aorta respectively.
- Internal controller, which controls and monitors the pump.
- Small internal battery, which powers the pump for limited periods, allowing complete mobility (such as when taking a shower).
- External controller, for programming and monitoring the pump.
- External battery, which recharges the internal battery and powers the pump for extended periods.
- Transcutaneous energy transmission system (TETS), which transmits power through the skin to recharge the internal battery and/or power the pump.

The TETS also carries the control signals between the external and internal controllers. Therefore, the system is fully implantable and fully self-contained--there are no wires or ports that penetrate the skin. Except for the need to periodically recharge the battery, this system would provide extremely high mobility and quality of life for the patient.

A cross section of the pump is shown in Figure 6 together with a table of parts. The key suspension components are fore and aft passive permanent magnet bearings and the voice-coil thrust actuator. The advantage of this design is that the blood shear is low in the relatively small diameter gap on the inner pump stator section. Note that the rotor is hollow and supported on a fixed shaft supported by the inlet and outlet hubs.

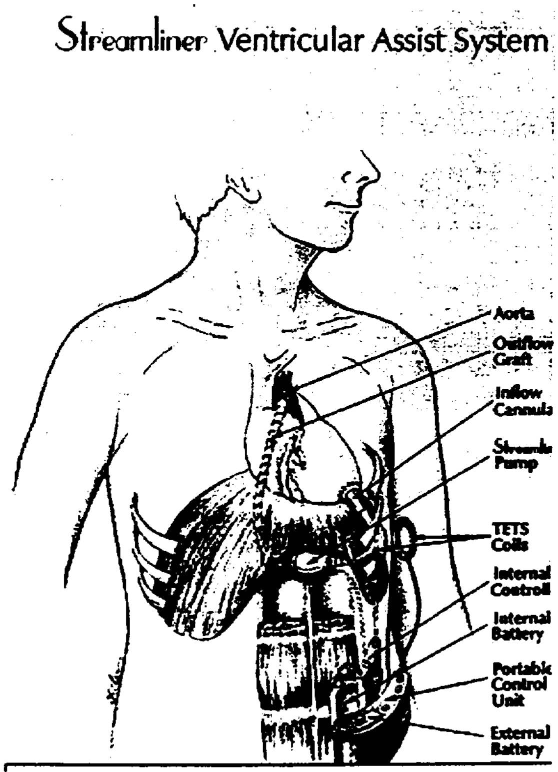
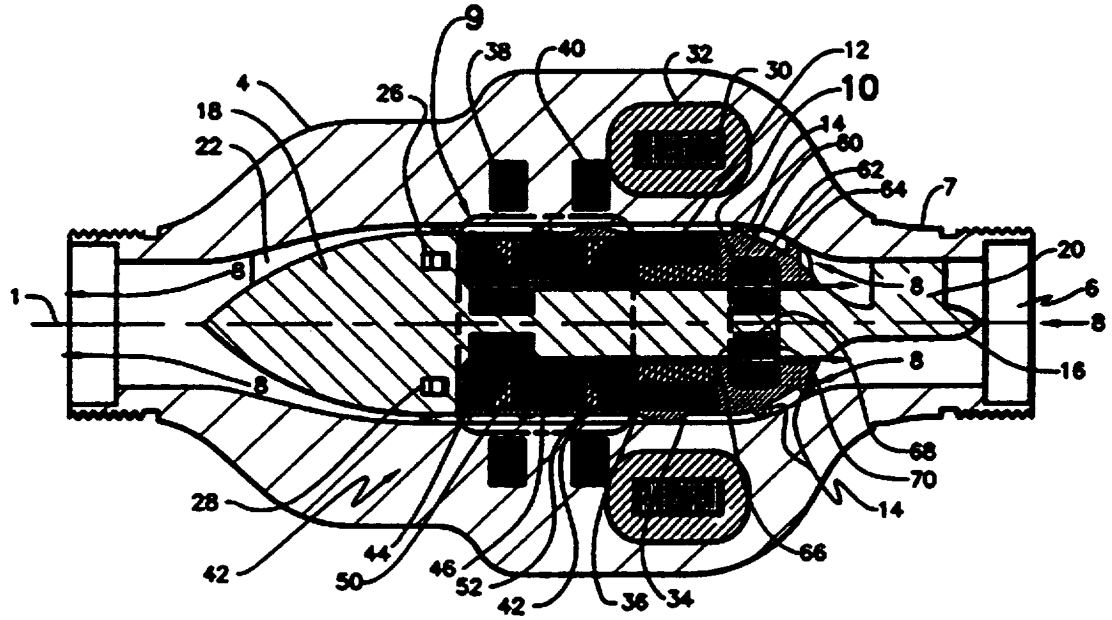


Figure 5. System Configuration

Figure 6. Cross section of HG3c and parts list.



part #	description
1	pump axis of symmetry
4	aft housing
6	inlet
7	fore housing
8	primary blood flow path
9	aft magnet assemblies (two parts). The inner bearing stack forms the inner race of permanent magnet bearing. He outer magnets and pole iron stack serves two purposes: a) it is the outer race of the aft PM bearing, and b) it is the magnet structure for the axial actuator -- it interacts with the coils 38 and 40 to provide thrust force.
10	fore PM bearing stacks
12	magnetically levitated impeller (hollow)
14	impeller blades
16	inlet hub
18	outflow hub
20	inlet stator blade and support
22	outflow stator blade, converts rotational kinetic energy in the blood in to pressure
30	slotless iron laminations of motor stator
32	toroidal winding on slotless 2-pole DC brusless motor stator
34	2-pole DC brushless motor maget

36	motor rotor iron
38	trust actuator coil
40	thrust actuator coil
26, 28	axial position sensor, used for feedback control of the rotor axial position.
42,44,46	voice-coil actuator magnets. The aft two magnets also serve as the outer race of the aft PM bearing
50,52	iron focusing poles direct field toward coils 38 and 40.
60,62,64	outer bearing race magnet
66, 68, 70	inner race magnet rings

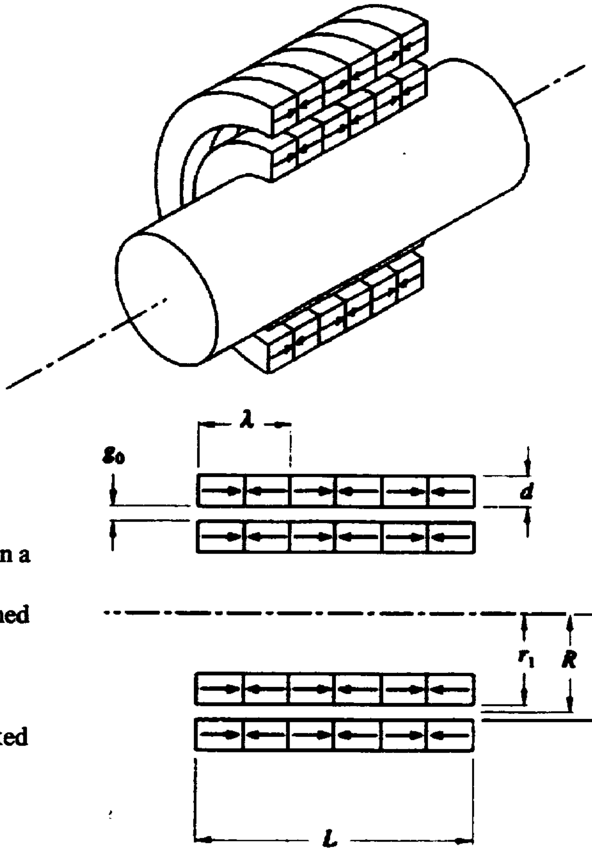
IV. Passive bearings

The design of the passive radial bearings was facilitated with the development of design formulae for passive PM bearings. For passive magnetic bearings with dimensions shown in Figure 7, we derived design equations for the radial restoring force per unit of journal cross section

$$\frac{F(x,g,d)}{2LR}=\frac{4B_r}{\pi\mu_0}\sum_{\substack{n=1\\ odd}}^{\infty}\frac{1}{n^2}\left(1-e^{-n2\pi d/\lambda}\right)e^{-n2\pi g/\lambda}I_1(n2\pi x/\lambda)$$

where the left-hand side of the equation is the radial restoring force divided by the journal cross section. The right-hand side depends on the remanance, B_r, of the magnetic material and the bearing geometry as given in the Figure 7. The function I_1 is the modified Bessel function of order 1.

Figure 7. PM bearing geometry



V. Thrust Bearing and Controller

The active thrust bearing was designed without any stator iron to minimize negative stiffness effects. Once we chose the two-coil structure the dimensions of both the coils and the magnets were optimized using ANSYS. The objective function was the force per root watt for the actuator, and constraints were placed on the dimensions and geometry. The feedback controller is a virtually zero power type loop. Thus as the pump pressure changes, the equilibrium position of the impeller moves several thousandths of an inch. The rotor position is detected with a low-noise Magnetic Moments ECS98S eddy-current sensor.

VII. Conclusion

The HemoGlide HG3b pump (polycarbonate housing) was implanted in a calf for four hours on July 10, 1998 at the University of Pittsburgh's McGowan center for artificial organs. The levitation coils only consumed 1.5 Watts of power not including amplifier losses. Very low blood damage was observed. A second titanium pump, HG3c, was implanted for a 34-day trial in September 1999 in a calf. The pump components showed very minor thrombus formation and the levitation system worked reliably. The titanium HG3c pump is depicted in figure 8 with the housings removed.

References

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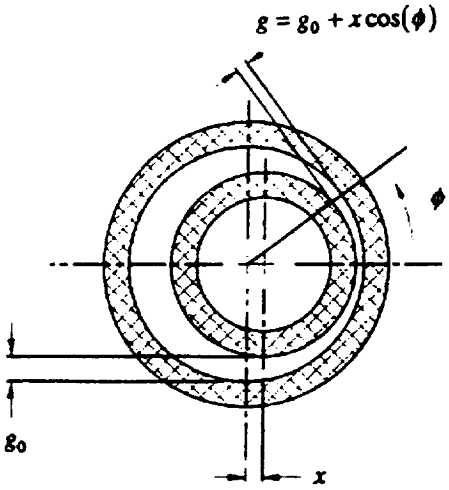
Figure 7. (Continued)



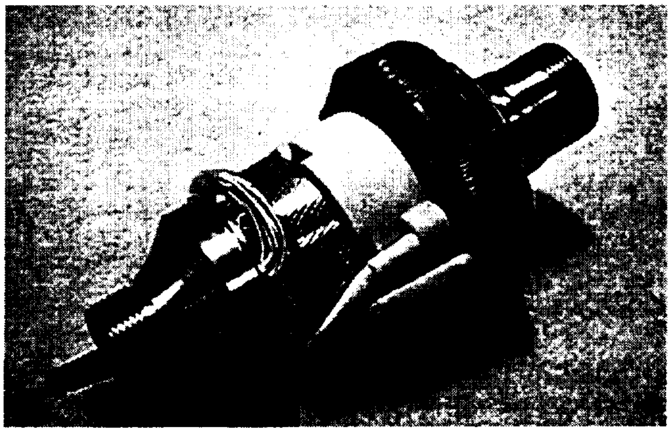


Figure 8. HG3c with housings removed