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Challenges in Developing a Blood Pump as an Assist Device for the Human Heart

K. Muralidhar[a*]
[a] Department of Mechanical Engineering, and Gangwal School of Medical Sciences
IIT Kanpur, Kanpur, UP, India
**Presenting author*: kmurli@iitk.ac.in

Congestive heart failure affects over 26 million people worldwide. On one hand, the health data shows that 10-15 heart transplants happen each year in India. On the other, more than 50,000 people lose their lives annually to heart failure. A significant number of patients are deemed ineligible for transplantation owing to age, weight, and comorbidities and there is a pressing demand for a viable and enduring alternative therapy. This data highlights the importance of building left ventricular assist devices (LVADs) – a high performance device that helps the left ventricle pump blood into the aorta. The device is clearly indispensable, serving as a vital and enduring solution for patients afflicted by heart failure. Design, development and testing of such devices poses several challenges in view of the tight tolerances to be achieved in weight, volume, power consumption, noise and durability. A few international products that have emerged over the years suffer biocompatibility issues, such as hemolysis, pump thrombosis, stroke, and gastrointestinal bleeding. These continue to plague commercially available LVADs and are detrimental to patient survival. The talk at the conference will cover progress over the past two years at IIT Kanpur and ongoing effort toward building an indigenously engineered LVAD that has its own aspects of innovation and uniqueness. The methodology adopted and benchmarks attained will be highlighted. There is an immense potential for spin-off technologies and these will be discussed during the course of the presentation. The device is made of titanium with a volume small enough to fit within the pericardial space below the human heart. The impeller blades of the centrifugal pump are polished while the volume casing is sintered and support hemocompatibility aspects of the blood-contacting surfaces. The next development targeted for the prototype will introduce 3D maglev, where the rotor will entirely be supported magnetically without any physical bearing support to run at high speeds, typically 8000 rpm. It is an important design feature that ensures low noise and low power consumption. The device will be capable of delivering 6 LPM flow rate at the pressure head of around 100 mm Hg with low power consumption. The necessary power supply is provided by a rechargeable battery pack attached to the device through a controller unit that will have a display and an alarm system for emergency situations. The entire device requires considerable development of dedicated electronics for both speed and position control and forms a substantial part of the project. In the ongoing *in-vitro* evaluations with the final device prototype, we scrutinize biocompatibility (cytotoxicity, chemical characterizations) and

blood damage profile (RBC damage, platelet activation and infections) by conducting hemolysis loop tests. The data thus generated will enable us to progress into animal trials. A development program for LVAD requires setting up infrastructure and a readily accessible laboratory environment. In this connection, the group working on the project has developed a test-bed including a compliant heart simulator and flow rate and pressure sensors with computer-aided data acquisition where long duration endurance trials can be carried out. In addition, a hemolysis loop has been set-up where tests prescribed by ASTM (and equivalent standards) can be carried out.

Keywords: Left ventricular assist device; pump characteristics, Maglev system, Hemolysis, Intima formation