PEDIATRIC AND ADULT FULLY IMPLANTABLE MAGNETICALLY LEVITATED TOTAL ARTIFICIAL HEART

Alexandru Plesoianu (1), Ionut Nistor (1,2), Alberto Bacusca (1,3), Grigore Tinica (1,3), Carmen Plesoianu (1,3)

1. "Grigore T. Popa" University of Medicine and Pharmacy Iasi, Romania; 2. "Dr. C. I. Parhon" Clinical Hospital Iasi, Romania; 3. "Dr. George IM Georgescu" Cardiovascular Diseases Institute Iasi, Romania

Introduction

Total artificial hearts (TAHs) are pioneering solutions addressing the critical challenges of biventricular heart failure. They offer a vital alternative for thousands of patients who are ineligible or remain on the waiting list for heart transplantation [1]. However, the reliability and side effects associated with current devices restrict their application to fewer than 200 cases annually [2].
The project's objective was to design an innovative TAH capable of sustaining enough blood for children and adults while reducing the risks of thrombosis, hemolysis, infection, and malfunction compared to existing TAHs. Key features focused on durability, wireless operation, affordability, and simplicity.

Methods

We employed mathematical modeling to define the pump parameters necessary for the required blood flow. Pumps designed in CFturbo were analyzed using Ansys CFX. Prototypes created in Fusion 360 were manufactured using SLA 3D printing at a resolution of 100 microns and machined from polymethyl methacrylate using a VHF k5+ 5-axis CNC milling machine. We constructed a test bench to conduct in vitro tests in accordance with ASTM F1841-19e1. Anatomical fitting and in silico tests were performed using V-Patient software.

Results

TAH system measuring 50 by 55mm includes a radial pump unit actuated by a radial bearingless slice motor that is powered by a subcutaneous electronic driver and a waterproof wearable smart battery. The motor measures 55 mm in diameter and 15 mm in thickness. Initial in vitro tests using water at 21°C yielded a mean flow of 11.43 liters per minute on the left side and 11.06 liters per minute on the right side. The 3D geometry of the TAH fits optimally in the space of the ventricles. CFD analysis indicated a maximum shear stress of 1.92 Pa and an efficiency of 53% for the left pump. The smart battery provides minimal user interface (battery level and alarms). Detailed information about the system functionality is displayed on a mobile phone via a proprietary app.

Discussion

The compact size of our artificial heart is approximately three times smaller than that of the Bivacor TAH, offering significant advantages for implantation in both children and adults. The wireless operation reduces the risk of infection and enhances patient mobility. Autonomy is further supported by reserve batteries. The impeller clearance of 1 mm minimizes damage to blood cells, thereby reducing the risks of thrombosis and hemolysis. We are developing a new model targeting a 5 liters per minute flow rate to better serve both pediatric and adult patients. Ongoing in vitro testing aims to further assess hemolysis levels. The thermal effect of the TET system on tissues is also under investigation.

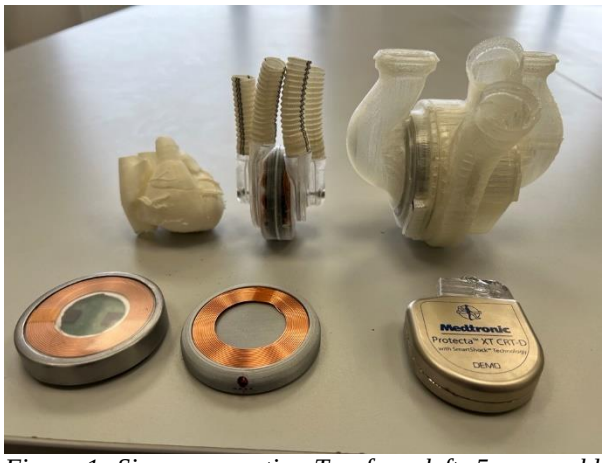

Figure 1: Size comparation Top from left: 5 years old heart model, resulted artificial heart, Bivacor TAH model; Bottom: Subcutaneous driver, smart battery, Medtronic Protecta XT CRT

References

1. Bakhtiyar SS et al, JAMA Cardiol, (11):1227-1235, 2020.
2. Arabía FA et al, Transplant Proc, 55(7):1664-1673, 2023.