VOLUME - 11, ISSUE - 04, APRIL - 2022 • PRINT ISSN No. 2277 - 8160 • DOI : 10.36106/gjra

Original Research Paper

Cardiovascular

FLEXIBLE IMPLANTABLE PEDIATRIC TOTAL ARTIFICIAL HEARTS: THE FUTURE IS HERE

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ABSTRACT

In pediatric patients with congenital heart diseases need for ventricular assist devices adds on to risk score, especially in single ventricle situations. If technology provides with devices that could fit into the available pericardial space without venous compression, total artificial hearts would be the acceptable first option in pediatric patients with indications for the same, the repertoire of which is continuously expanding with availability of smaller devices and emerging horizon of drive less artificial hearts. Borderline situations can be very correctly evaluated using virtual fit technologies. Of around 1000 TAH implants worldwide, less than 5% are pediatric, the volume of which would increase exponentially if flexible implantable pumps with adequate hemodynamics emerge in the field. Though initial applications centre on bridge to transplant, emerging technologies would make it feasible as destination therapy. Syncardia 50cc and evolving versions of Saispandan, based on hybrid bearing less switched reluctance motors which are ultra miniaturized are exciting prospects. But the future belongs to flexible artificial organs which would include implantable micro pumps that are centrifugally levitated with specialized impeller coating and CET charging methods. Total artificial hearts would be the gold standard management in horizon for pediatric biventricular failure. Use of soft materials and flexible electronics with tissue compatible materials are emerging fast to revolutionize the domain of cardiac surgical practice. Future is for flexible artificial organs – pediatric total artificial hearts, microfluidac lungs to begin with.

KEYWORDS :

INTRODUCTION

80% of worlds pump production centers around centrifugal pumps that are made of rigid and heavy materials (1).Miniaturization of diaphragm based pumps have already been achieved (2-4). Implantable or wearable devices are the way forward to retain mobility which is a key requirement in pediatric patients. Ergonomic adaptation to body contour and maintenance of pump characteristics with deformation which occurs within body limits are primary requirements. A scaling factor of up to 0.7 which downsizes the adult device to one third of its size is one of the methods to achieve a pediatric total artificial heart. In case of Saispandan it requires miniaturization and then ultra miniaturization of the twin motors that controls the right and left circulations. Pump performance in such situations are dependent of analysis of prototypes rather than simulation studies which tend to over evaluate the performance of up to 3 or 4 times the actual observed values.

Soft materials that pave way for implantable devices is one great option that is technologically feasible (5-8).Flexible electronics coupled with soft materials would provide light weight devices that are ideal options. Excellent bio compatibility should be ensured by ideal material selection (9-11). A magnetically levitated centrifugal pump can be designed by Unibody of origami method design of magnetic rotor and silicone impeller which are driven by a flexible printed circuit board. A shaftless friction free operation is ensured with magnetic levitation regulated by confiners. Varying sized devices can be designed to achieve required hemodynamics which varies in weight from 0.5 – 12 gm and 0.5-12 cm^3 in dimensions which are far superior to available market designs for total artificial heart. Magnetic levitation takes way the friction and provides the ideal platform to consider them in the destination therapy sub segment.

Extended applications of the same technology would extend into extracorporeal membrane oxygenation, ventricular assist devices, donor organ support devices, dialysis machines etc. There would be options to implant multiple pumps in series or parallel as per requirements or add dialysis to existing pump circuit in an implantable way. Easy access locations of implantable sites and provision to leave the native organ intact would allow them to be used effectively for bridge to recovery situations also when the cause of failure is reversible or remodeling chances exists.

Design

The rotor that is made of flexible magnetic membranes with origami unidirectional design and enhanced magnetism and definable magnetic polarities forms a single assembly with the magnetically levitated silicone impeller for blood propulsion(12-15).Six electromagnetic coils that are connected in 3 phases (A,B and C) works as stators. Pulse width modulation signals generated from a flexible printed circuit board controls the pump. The operation is by combined effects of magnetic levitation and field coupling between the rotor and stator (Figure 1). Dynamic equilibrium is maintained by opposite polarity to those of rotor induced in the confiners. Magnetic cylinder and PDMS cone stabilizes the operation further as shown in Figure 1. Magnetic force generated turns the impeller in counter clockwise direction. Once the rotor goes fifteen degrees continuous and stable rotation occurs due to switching of coil phases. Ninety degree rotation is obtained with a full switching cycle of three phase coil. Flexible printed circuits can be made with less than 0.75g weight and around 3-4mm^2x2-3mm^2 dimensions. These implantable pumps allow free mobility and maintain hemodynamics with normal deformation ranges that occur at implant sites.

Rotor designs have Nd2Fe14B and PDMS cut into a eight petal shape followed by alternate teeth folding and uniaxial magnetization with edge effect providing good magnetic field density (16).Special coating and flexible materials like silicone and PDMS reduce the hemolysis that is a major concern with use of rigid pumps (17, 18).Folding techniques provide designs to fine tune the magnetic polarity. When wire diameter is smaller increasing the turns provide increase in flux density. Increasing outer diameter is another method to achieve the increase in flux density in these models. Other design concepts like electro hydrodynamics, dielectric elastomer and piezoelectrics though low in power consumptions and small size are plagued by requirement of high working voltage and low flow rates.

Commercial models available at present are bulky and rigid but have large flow rates.

DISCUSSION

This concept gives acceptable flow rates with low working power, scalability according to growth, lightweight and being implantable covers the concept of destination therapy requirements and provides the necessary belief for the cardiac surgeon to prescribe total artificial heart as a pediatric option for destination therapy in cardiac failure.

Scaling down bigger adult models brings in the challenge of accuracy of fabrication and tolerant errors in assembly. In wearable models nonlinear factors like weight, spatial dimensions, folding properties and flow interactions may be deciding factors in pump performance too. The more smaller the pump more difficult it is to predict or adjust the levitation and rotation. Origami methods place limitations on the thickness. Pump performance optimization requires more complex optimization sequences. Well designed magnetic confiners allows the pump to work at broader tilt angles but one should keep in mind that imbalance of magnetic force, gravity, lift force and buoyancy at a higher rotation speed reduces the tilt angle also. Changes in resistance of coils to deformation loads that occur normally are less than 1.5% with such designs. Operational temperature fluctuations are minimum as in the adult bearing less switched motor designs of Saispandan. Euler or inclination angles becomes less also with increasing rotation speed in such designs. Wobble is at lower speeds which can be explained by procession and rotation as procession radius decreases at higher rotation speed. Induced EMF is used as signal for synchronization. Theoretical consideration of capture of induced EMF as generator does exist with external transformer and rectifier. Initial simulation studies done show encouraging results which would be published later as the design is fully patented. Benefits of implantable wearable designs would lead to new groups of flexible artificial organs in future.

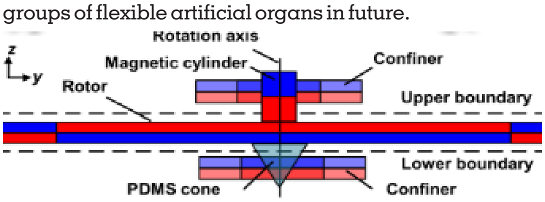

Figure 1 Mechanism of Implantable Centrifugal Pump

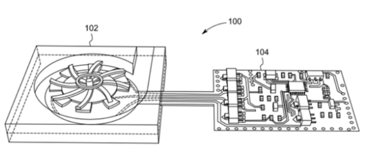

Figure 2 Implantable Pump Design of Pediatric Total Artificial Heart with Flexible Printed Circuit Board (From our patent figure)

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