Towards Building an Artificial Ventricle: Conceptual Considerations in the Design and Construction of a Novel, Totally Implantable Mechanical Circulatory Support System

Hisham M.F. Sherif

***Abstract*—We introduce the conceptual design and early steps in our ongoing development of a new totally implantable mechanical circulatory support system. Based on a design emulating the natural anatomic configuration, the device is completely implantable; has a low risk of hemolysis; is composed of readily available materials; has minimal energy requirements and an extended service life on internal power supply.**

Keywords: Ventricular Assist Device, Mechanical Circulatory Support, New Devices

I. Background

Numerous pumps [1-3] exist for mechanical circulatory support in advanced congestive heart failure. However, virtually all have external components traversing the skin and posing an increased risk for serious infections [4] One design obstacle [3] is the availability of a durable, efficient and totally implantable energy source.

II. Purpose

To develop a novel totally implantable mechanical circulatory support system, incorporating internally situated pump, drive mechanisms, power supply and controller. The device is based on the implementation of a new class of materials emulating the structure and function of the native ventricle, has a projected long service life, and is constructed of readily available components.

III. Materials and Methods

The proposed device is composed of the following elements: An outer rigid hermetically-sealed shell made of a biologically inert substance in the shape of a rounded cone. The base of this shell incorporates two cylindrical channels, each housing a bio-prosthetic tri-leaflet pericardial valve. These valves are oriented in opposite directions, making one the Inlet valve and the other the Outlet valve.

Hisham M.F. Sherif, MD, FACS, FICS, FAHA: Cardiovascular Surgery, Newark, Delaware, USA (email: hsherif@hotmail.com)

This shell contains a flexible, similarly-shaped Compliance Chamber composed of a blood-compatible, non-thrombogenic substance .The edges of this chamber are attached to the inner openings of the valve channels. Incorporated in the outer layer of the Compliance Chamber are several Contractile Elements, arranged in one or more layers and are composed of Electro-Active Polymers, arranged around the base of the Compliance Chamber with its finger-like elements at a 45 or 60 degree angle and arranged radially in close contact with the flexible wall of the Compliance Chamber. (Fig.1&2)

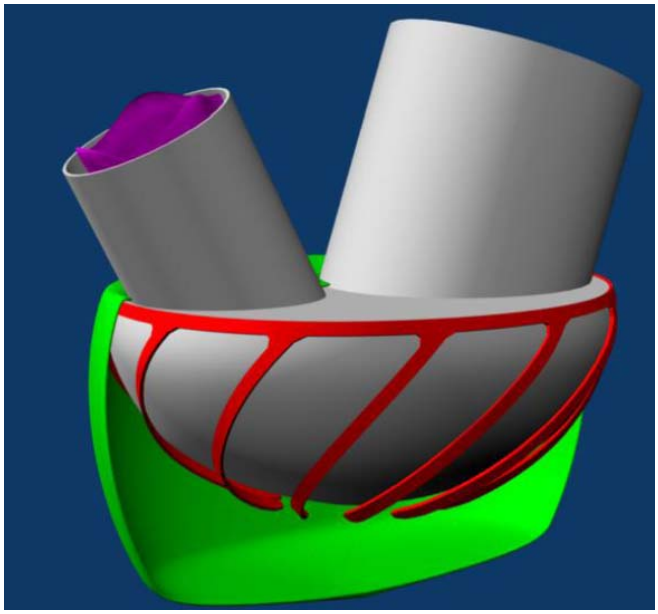

Figure 1: 3-D computer rendering showing the contractile elements and compliance chamber in mid-systole

The elements are activated by a direct electric current at a relatively low voltage applied through a common electrode connected to a permanent pacemaker pulse generator. Application of this cyclic pulse results in a robust contraction of the elements, and compression of the chamber and thus effecting ejection of the blood into the arterial side of the circulation. The pacemaker circuitry will also be capable of automatic regulation of the device pump rate depending on the physiologic needs of the patient.

ISBN: 978-988-17012-9-9
ISSN: 2078-0958 (Print); ISSN: 2078-0966 (Online)

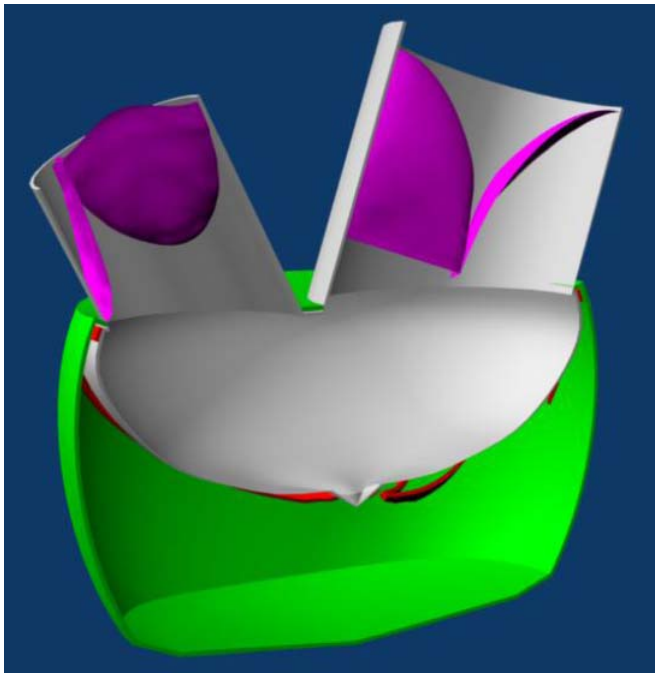

Figure 2: 3-D computer rendering depicting a cut-out view of the device, the opposite orientation of the closed inlet valve and open outlet valve and the compliance chamber in late systole.

The device is implanted using familiar surgical techniques where the inlet graft is connected to the ventricular apex or the atrial wall (systemic or pulmonary) and the outlet graft is anastomosed to the aorta or pulmonary artery, respectively. When implanted, the proposed system will be completely internalized, with all its drive elements, control circuitry and power supply completely inside the body with no components traversing the patient's skin.

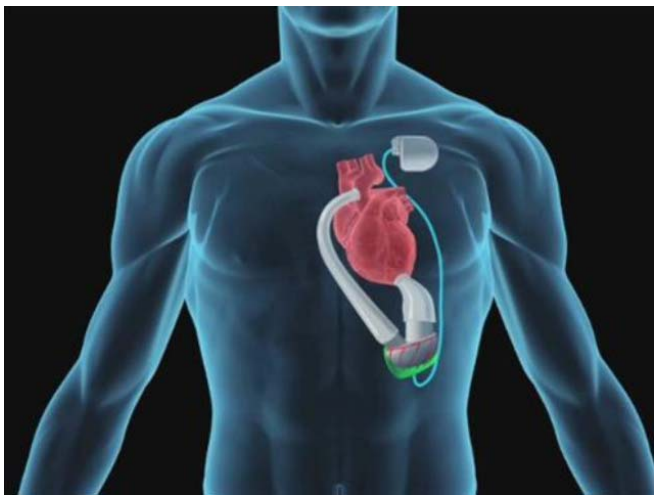

Fig. 3: Computer rendering depicting the configuration of the proposed system inside the body

IV. Discussion and Conclusions

Ever since the first external pneumatically-driven left ventricular assist device developed and implemented by the late Dr Michael DeBakey in 1967 [4] to rescue a patient from postcardiotomy cardiogenic shock, the significance of mechanical circulatory support systems in the treatment for advanced or end-stage congestive heart failure has been well established [1-6]. However, almost all current mechanical circulatory support pumps have significant limitations because of their external components, mainly the power supply and drive mechanisms. The presence of drive lines, vent lines and/or sensor/controller cables traversing the skin presents a higher risk for infection, which remains the major cause of death in mechanical circulatory support patients [3, 6]. Furthermore, virtually all existing mechanical circulatory support systems also have energy sources of limited service life, mainly due to their high energy demands. Thus patients are obligated to remain within a short distance from a power outlet or face the need to change battery packs every few hours, further limiting their mobility and daily activities.

The ideal mechanical circulatory support device [5-7] should be easily implantable, be able to support or replace one or two ventricles; be able to produce a physiologic perfusion pattern; be completely implantable without any protruding drive, vent or control cables; has a reliable internal power supply and should have a long projected service life. In addition to these criteria, and although still intensely debated [8,9], some researchers have suggested the beneficial effects of a pulsatile flow pattern with regard to ventricular unloading and overall outcomes[10-12].

In addition to providing the optimal functionality as discussed above, the ideal mechanical circulatory support device should mimic or duplicate the normal native structural and functional anatomy of the ventricle. The principle of the contracting myocardium arranged in a helical pattern and twisting sequentially has been well established [13-15]

To duplicate the structure and function of the human ventricular Torrent–Guasp muscle loop, we utilized the peculiar properties of a fairly new class of materials known as the Electro-Active Polymers [16-19]. First described in the late 1990s, these materials have attracted attention mainly in the field of robotics as actuators and are currently being pursued for many other applications in several programs around the world. These compounds exhibit efficient mechanical properties making them suitable for drive mechanism configuration at comparatively low energy expenditure (150 W/kg for some, 200 Joules/cm3 at a current of 3-6 volts for others) [20]. When compared to mammalian skeletal muscles, some members of this class of materials perform favorably in terms of the mechanical stress and efficiency and speed of response at low voltage requirements [21].

Emulating the natural anatomic configuration of the human ventricle, the contractile elements are arranged in one or more layers in the wall of the chamber in a helical configuration, thus further amplifying the mechanical efficiency of the electro-active polymers, making it conceivable to generate an effective mechanical displacement at low voltage requirements. Because of this flexible design of the contractile elements, the device can be configured in various sized for different patient age populations.

In conclusion, we report the early initial steps in our ongoing development of a novel, completely implantable mechanical circulatory support system that is composed of

ISBN: 978-988-17012-9-9
ISSN: 2078-0958 (Print); ISSN: 2078-0966 (Online)

readily available materials; has minimal energy requirements and an extended service life on internal power supply.

ACKNOWLEDGMENTS

We wish to thank Professor Ahmed Sharkawy, PhD, of the University of Delaware and Mr. Eric Blair of Mission Media/Mission Film, Inc., Baltimore, MD, USA, for their expert assistance with the graphics.

REFERENCES

[1] US Department of Health and Human Services. Artificial heart and assist devices: directions, needs, costs, societal and ethical issues. Bethesda, MD: National Institutes of Health 1985.p.25-7

[2] Hunt SA, Abraham WT, Chin MH, et al: ACC/AHA 2005 Guideline update for the diagnosis and management of chronic heart failure in the adult—summary article. Circulation 2005; 112:1825

[3] Rose EA, Gelijns AC, Moskowitz AJ, et al: Long-term use of left ventricular assist device for end-stage heart failure. N Engl J Med 2001; 345:1435.

[4] DeBakey M. The odyssey of the artificial heart. Artif Organs 2000;24:405

[5] James F. Antaki, Victor Poirier, Francis Pagani. Engineering concepts in the design of mechanical circulatory support. In: Mechanical circulatory support. ISHLT Monograph Series, vol. I. Elsevier 2006. O.H. Frazier & James K. Kirklin, Editors.

[6] Aggarwal SI , Cheema FI , Oz M CI , Naka YI . Long-Term Mechanical Circulatory Support. Cohn LH, ed. Cardiac Surgery in the Adult. New York: McGraw-Hill, 2008:1609-1628

[7] M. C. Deng. The challenges of generating evidence to guide mechanical circulatory support-based management of advanced heart failure. Eur. Heart J., May 2, 2005; 26(10): 953 - 955.

[8] Nose Y. Is a pulsatile cardiac prosthesis a dying dinosaur? Artif Organs 1992;16(3):233-4 9.

[9] Ündar A. Myths and truths of pulsatile and nonpulsatile perfusion during acute and chronic cardiac support Artif Organs 2004;28:439-443.

[10] S Klotz, M Deng, J Stypmann, J Roetker, M Wilhelm, D Hammel, H Scheld, and C Schmid Left ventricular pressure and volume unloading during pulsatile versus nonpulsatile left ventricular assist device support. Ann. Thorac. Surg., Jan 2004; 77: 143 - 149.

[11] J. Haft, W. Armstrong, D. B. Dyke, K. D. Aaronson, T. M. Koelling, D. J. Farrar, and F. D. Pagani. Hemodynamic and Exercise Performance With Pulsatile and Continuous-Flow Left Ventricular Assist Devices. Circulation, September 11, 2007; 116(11_suppl): I-8 - I-15.

[12] S. Crow, R. John, A. Boyle, S. Shumway, K. Liao, M. Colvin-Adams, C. Toninato, E. Missov, M. Pritzker, C. Martin, et al.Gastrointestinal bleeding rates in recipients of nonpulsatile and pulsatile left ventricular assist devices.J. Thorac. Cardiovasc. Surg., January 1, 2009; 137(1): 208 – 215 13.

[13] G Buckberg. Basic science review: The helix and the heart. J. Thorac. Cardiovasc. Surg., Nov 2002; 124: 863 - 883.

[14] G Buckberg, A Mahajan, S Saleh, J Hoffman, C Coghlan. Structure and function relationships of the helical ventricular myocardial band. J. Thorac. Cardiovasc. Surg., September 2008; 136: 578 - 589.

[15] R Anderson, D Sanchez-Quintana, P Niederer, P Lunkenheimer. Structural–functional correlates of the 3-dimensional arrangement of the myocytes making up the ventricular walls. J. Thorac. Cardiovasc. Surg., July 2008; 136: 10 - 18.

[16] Y. Bar-Cohen, T. Xue, B. Joffe, S.-S. Lih, P. Willis, J. Simpson, J. Smith, M. Shahinpoor, and P. Willis, ―Electroactive Polymers (EAP) Low Mass Muscle Actuators,‖ Proceedings of SPIE, Vol. SPIE 3041, Smart Structures and Materials 1997 Symposium, Enabling Technologies: Smart Structures and Integrated Systems, Marc E. Regelbrugge (Ed.), ISBN 0-8194-2454-4, SPIE, Bellingham, WA (June 1997), pp. 697-701.

[17] Smart structures and materials 2003: Electroactive polymer actuators and devices [EAPAD]. Yoseph Bar-Cohen, Editor. Proceedings of the SPIE, vol 5051;2003

[18] Electro-active polymers (EAPs) actuators as artificial muscles: Reality, potential and challenges. Yoseph Bar-Cohen, Editor. SPIE press monograph, vol. PM98, 2001.

[19] World Wide Electroactive Polymer Actuators Webhub. Available at: http://eap.jpl.nasa.gov/

[20] Comparison chart of different electro-active polymers. Available at: http://ndeaa.jpl.nasa.gov/nasa-nde/lommas/eap/actuators-comp.pdf

[21] Comparison chart of properties of electro-Active Polymers and skeletal muscles. Available at: http://ndeaa.jpl.nasa.gov/nasa-nde/lommas/eap/PPY-v-2004-03-Perfromance-MIT.pdf