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12/14 Hybrid BSRM based Saispandan Total Artificial Heart As Destination therapy Device: Advantages of embedded fully implantable electronic controls

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Abstract

With increasing number of patients in end stage biventricular heart failure requiring transplantation and as conventional transplantation is unable to fulfill the demands the need for total artificial heart as destination therapy is on the forefront. Technological advances have made this approach a reality. External or tethered devices limit quality of life (1). Models like Saispandan which are totally implantable offer multitude of advantages and improves quality of life. To achieve this goal a rectifier for transcutaneous energy transmission and autonomous operation with biocompatible materials is a must. Motor driver electronics, LiFePo4 battery pack with charger, microcontroller that monitors and controls the functions, along with stable operation on TET and battery supply with safe switch modes is also essential. TET efficiency is around 20% and 30% on battery power. This would enable the device to enter into animal trial phase.

Introduction

Limitation of donor allograft is the Achilles heel of the gold standard procedure in end stage biventricular failure. As a bridge to final procedure mechanical circulatory support in the form of total artificial heart has withstood the test of time for over three decades. Extended use as destination therapy was limited by the pneumatic design with tethered devices, valves in the design, infection and thrombotic tendencies. Optimal design modifications with technological support have overcome most of these limiting factors.

Wireless coupling can be achieved between 2 coils 60mm inner diameter and outer diameter of 80mm one which is implanted subcutaneously and the other which is secured to patient skin and is inductively coupled. The risk of infection due to percutaneous lines can thus be circumvented. Implanted back up batteries remove all tethering augmenting mobility to fullest enhancing quality of life added to these recipients. AbioCor TAH and the Lion Heart Left Ventricular Assist Device (VAD) and recently the Rein Heart and Carmat TAH work on similar technological principles (2, 3, and 4).

When you use TET system the control unit should also be implanted. The configuration and design of such units are unique to the model. Prototype validation in a mock circulatory loop with mechanical, hydrodynamic and electrical attributes have to be worked upon when such devices are planned for clinical use.

Description

Extracorporeal to implantable unit adaptation requires prototype evaluation with a test set up.TET transmission from external coil to implantable coil is achieved by passing alternating current in the external coil by inductive coupling causes a electrical voltage in the implantable coil. There is no tissue disruption or penetration at the TET site, so there is no chance of infection being induced.

Saispandan works on principles of a hybrid 12/14 miniaturized design with twin motors that control the impellers separately (Figure 1). The right and left heart support systems are run by separate a controller that gives better control of auto regulation of flows without compromising the other. The chamber that houses the batteries is below the impeller and the two units are held by an interlocking design that allows separation. Pressure and flow sensors regulate the flow to the pump. For the smooth switch from extracorporeal to intracorporeal design multiple parameters have to be looked into.

Driver electronics need to the powered at all times. For wireless energy transmission a changing flux density is produced by application of alternating current in the external coil so that alternate voltage is induced in the implantable coil that is rectified to stable direct current. There should be an implantable alternative power back up in case of primary power transmission failure. It would be ideal if a back power requirement of up to an hour can be met (5). Durability of the battery with multiple recharge cycles is something which could require alternative designs once technological support evolves in various multidisciplinary modalities on the same(6).For design models like Saispandan an additional back up of power by direct charging through a point provided behind the ear is an useful design adjunct that would provide additional power back up up to 18 hours.

Continuous run of the centrifugal pump with design modification to produce pulsatility should continue inspite of varied input and output pressures to ensure absolute safety. Low energy consumption with high efficiency and minimal thermal losses that is unique to BSRM is an ideal requirement at this stage.

For most designs the pumping units take up most of the space and design fabrication and separate implantation is necessary. For Saispandan since the motor and impeller occupies limited space, the electronic components are placed in the specific space provided below the motor on each side, which is a distinct advantage over contemporary designs. Here since it internal and compartmentalized only the outer shell of the TAH device comes in contact with the body. None of the electronics components are in direct contact with the body which is again another unique design advantage. Safety and efficiency is thus built in the design features of models like Saispandan. Software control is needed in the mock circulatory loop (MCL) for the parameters of systemic and pulmonary resistance and compliance as well as venous volume (7).Additional evaluation can be done using comparison of flow distribution for the FSI simulation and PIV measurement.

Systemic and pulmonary resistance, systemic arterial and pulmonary arterial compliance, and the venous volume of the MCL were controlled by a computer. Standard solution of water 57.5% and glycerin 42.5 % with viscosity of 3.663 mPas was measured at room temperature. Aortic pressure of 100mmHg and right sided pulmonary pressures of 25 mmHg are used. Pressure sensors monitor the fluid filled pressure lines. Ultrasonic flow meters can capture the flow, after setting the desired beat rate.

For the clinical prototype circuit board control unit should include input power, battery charger, driver electronics, microcontroller and voltage level shifter. Additional layers in circuit board would achieve noise optimization. Cells of lithium-iron phosphate (LiFePo4) of capacity of 1.1 Ah operate as the internal battery as it would provide a high power density, low self-discharge rate, a long cycle life, and a safe operation(8). As the BSRM voltage requirement is 12 V, four cylindrical LiFePo4 cells with a single nominal voltage of 3.3 V are connected in series. Most literature refers to the DC voltage generated as the TET Voltage for easy description. Direct supply without a voltage shifter can minimize losses.TET and battery voltage is connected in parallel.

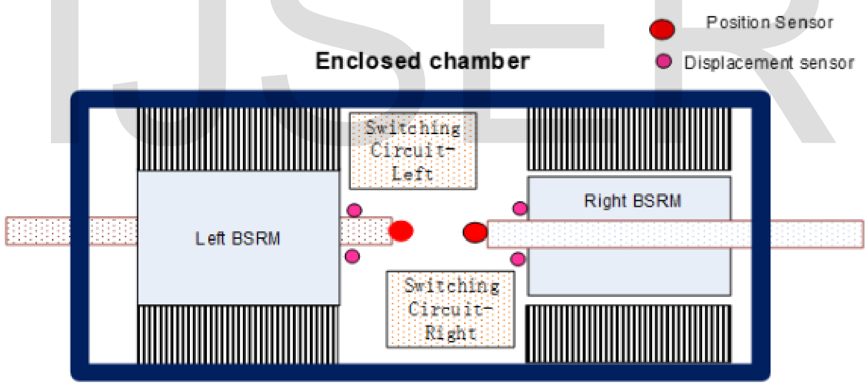
The power switch actively switches diodes and eliminates short circuit to battery voltage. Inspite of a changing input the microcontrollers provide the steady parameters for motor power electronics. Charging process is microcontroller controlled and is of constant-current– constant-voltage charging that suits LiFePo4 batteries. The battery is considered full when the charging current drops below a particular value and the process is terminated by the microcontroller. Over the charging period, the battery voltage increases continuously. Overcharging has to be controlled and balanced out. Design of Saispandan with advanced dynamic slide mode controls without sensors for rotor position is again ideal for saving power in such situations. Information stacking on a single microcontroller guarantees that the system is never running low on energy and detects electronic faults before they clinically manifest. The intercoil distance was set at 16mm. Control voltage with input switching also needs to be evaluated. A smooth and fast transition between TET and battery voltage also should be ensured. Implemented balancers ensure proper individual charging of cells. An aortic flow of 5 L/min can be achieved by a power of 20 W. 90% control unit efficiency can be achieved in efficient designs with hydraulic power efficiency of around 45%, if BSRMs are used as motors. Higher rpms can achieve higher outputs at the cost of rotor damage if sustained for longer bouts. For Saispandan total artificial heart proposed global sliding mode controller-based SMO offers very less chattering phenomena more stable and accurate rotor displacement, position and speeds under any unexpected changes of reference, and loading conditions. Global sliding mode controller (GSMC) is proposed to control the speed and position of BSRM and also sensor less operation with sliding mode observer (figure 2). In this method, rotor displacement tracking error functions are used in the sliding mode switching functions and the new sliding mode displacement control and speed tracking equations are obtained with an extra exponential fast decaying nonlinear function along with conventional linear sliding mode switching surface (figure 3 and figure 4). In addition to the improvement of performance characteristics when compared to sliding mode controller, GSMC cancels the reaching mode, reduce the chatting, and overcome the disturbance and the time delay(figure 5).

Conclusion

Control units that are fully implantable should ensure safe switch modes advanced controller strategies. Compared with other TAH models Saispandan has a built in space within the device which is a unique design advantage. Data transmission to an external user interface on a cloud platform would enable sustainable support at all times. Complete transformation to fully implantable circuits would give the physician the courage to pen destination therapy using circulatory assist devices as a reality very soon. We are the doorstep of generation of complete artificial organs and a full fledged Bionic Human too.

Figure 1

Twin Motor Design of Saispandan Total Artificial Heart for Destination Therapy using 12/14 Hybrid BSRM



(Obtained with Special Permission of Department of Cardiothoracic and Vascular Surgery Saispandan Team Gitam University) Saispandan: Very unique design with control units within device

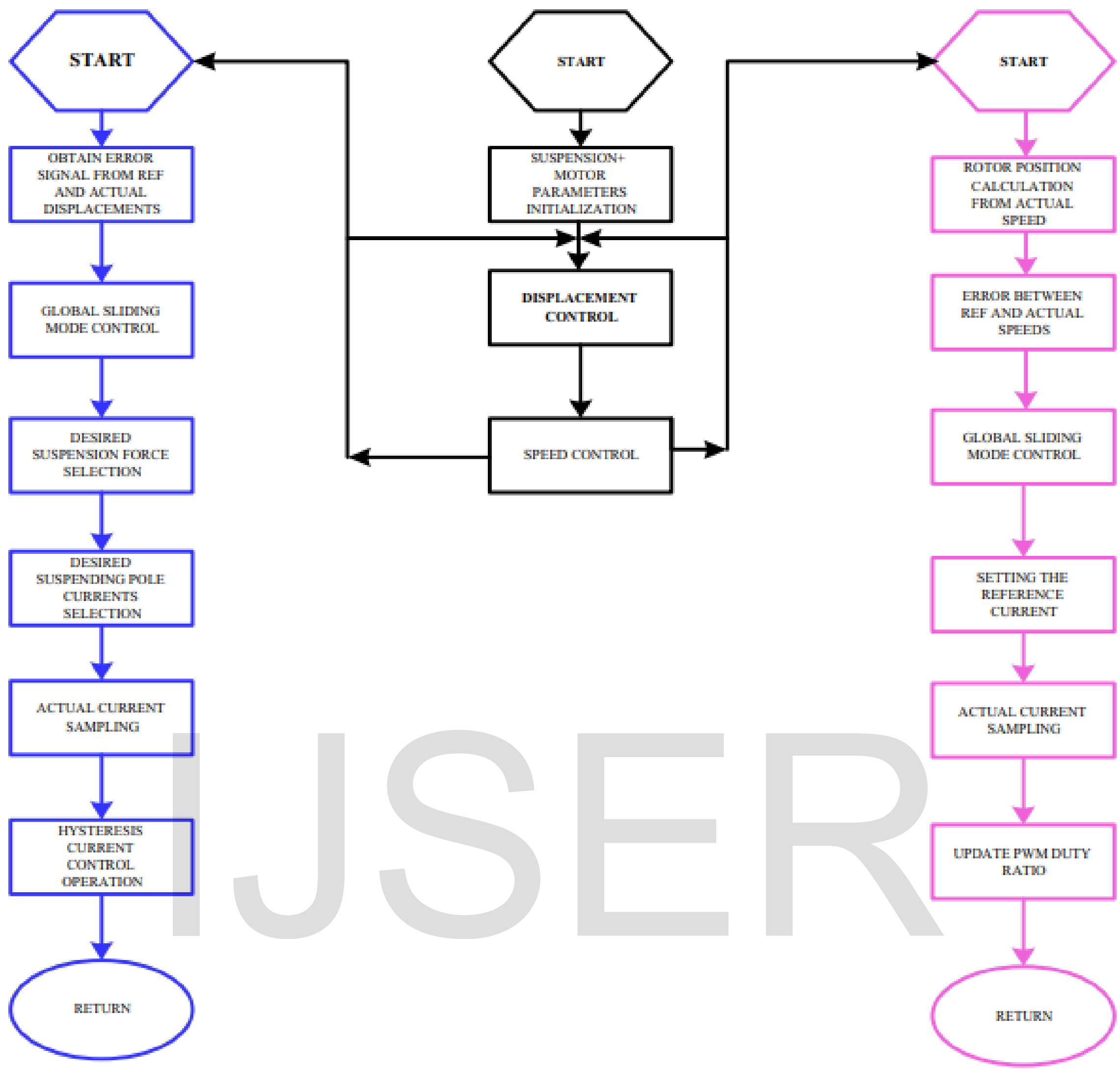


Figure 2. Global sliding mode control flow chart for regulation of speed and displacement of 12/14 BSRM

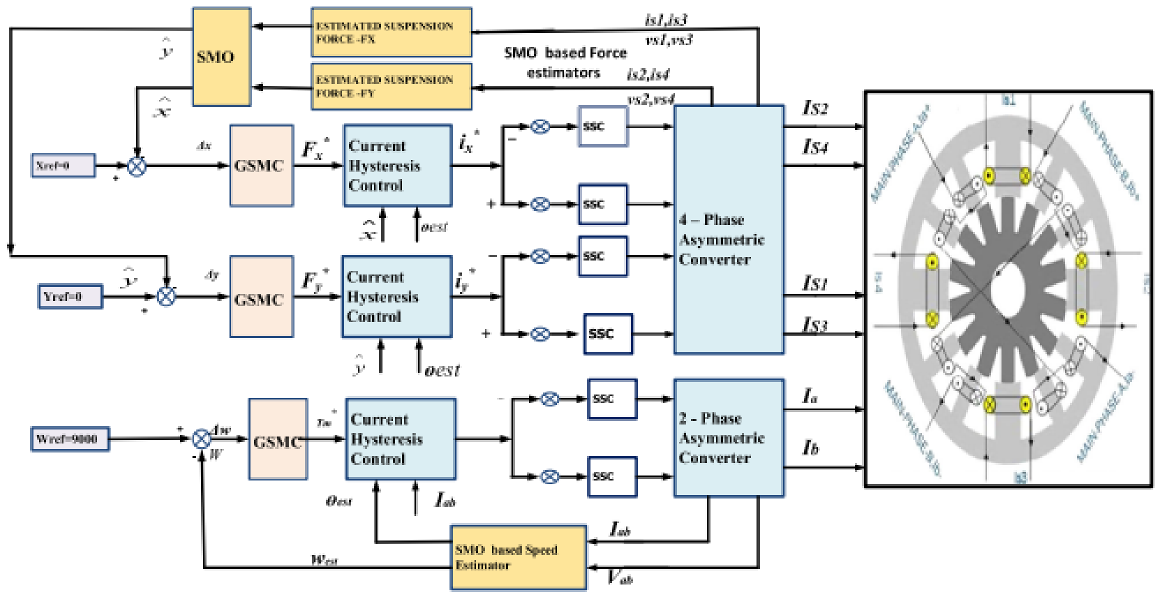


Fig. 3 Proposed sliding mode observer and control block diagram of BSRM

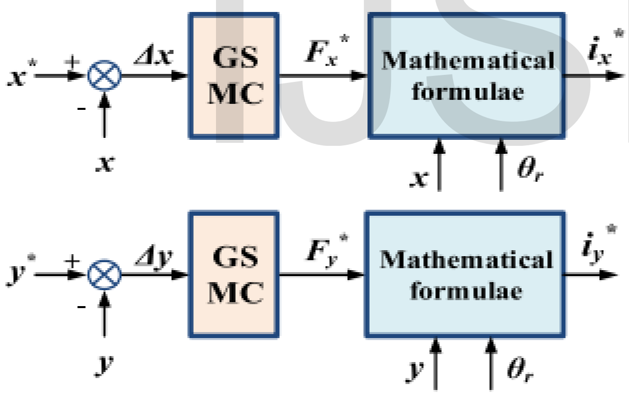


Fig. 4 Control strategy of suspension forces

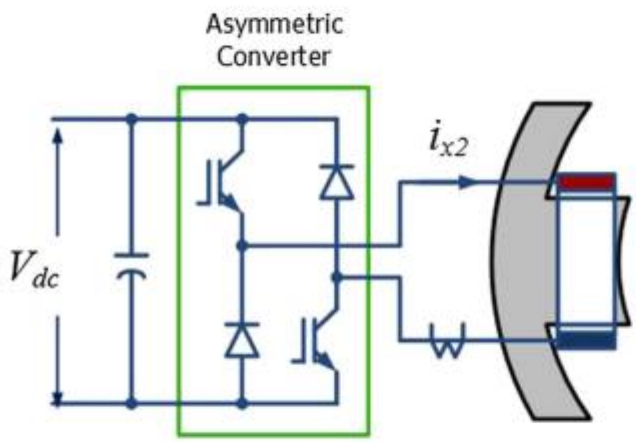


Fig. 5 Asymmetric converter configuration

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