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Design and analysis of a minimally invasive and ECG controlled Ventricular Assistive Device

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***Abstract*— A novel electromechanical design to assist pumping of weak heart is proposed. The prototype is designed as a feasible alternative to the existing ventricular assistive device (VAD). The conventional device used primarily in the medical practice, suffers from infection, blood clotting, and internal bleeding problems, that are not easily diagnosable. In this paper, a minimally invasive VAD prototype is designed to assist in the pumping of the heart by inflating and deflating a balloon wrapped around the heart. The inflation and deflation cycle of the balloon is setup in synchronous to the ECG signal via a real time feedback subsystem. The real time feedback unit is designed in a view to promote blood flow in phase with that of the varying ECG signal, based on the heart activity of the user. The designed prototype was verified on a 3D modeled heart integrated with a pressure sensor and signal analysis was performed to further verify the working of the design. The proposed design is suggested to work better than the existing device and avoid other undesirable effects.**

Keywords*— *VAD, ECG, feedback-circuit, minimally-invasive

I. Introduction

Ventricular Assistive Device (VAD) is designed mechanically to assist pumping action of a weak heart [1]–[3] Traditional VAD consists of a pump, controller, power source, and an external drive line connecting either aorta to left atrium or pulmonary artery to right atrium [1]. Although VADs are expected to significantly improve life expectancy, they present complications and side-effects. The most common post-operative complication that arises from implanting VAD is internal bleeding, considered fatal to the patients under treatment, since blood flows over non-biological surfaces and tend to coagulate on insertion of VADs [4]. In this paper a minimally invasive VAD is proposed to maintain the original blood flow path from the heart chamber and yet maintain the optimum blood flow rate required for normal functioning of the heart. This is possible by electromechanically applying pressure on the lower ventricles of the heart and releasing pressure in accordance with ECG signal presented by the subject. A device with a balloon is designed to engineer the additional pumping of the heart. This paper also presents a feedback circuit incorporating variations in the heart rates observed from delayed or high frequency ECG signals, and controls the inflation deflation of the balloon accordingly.

II. Design

The proposed device consists primarily of a wrapped balloon, and an Electrocardiography (ECG) sensor. As shown in the Figure 1, the biocompatible wrapped balloon assists in the pumping operation of the heart and controls the adequate blood volume to transude to the body, outside the heart. The ECG controlled VAD is proposed to offer real time inflation and deflation action and maintain a suitable blood flow rate. As shown in Figure 2, the ventricles of the heart contracts in systole period during which the blood is ejected from pulmonary trunk towards aorta and the ventricles relaxes in diastole period during which the heart muscle relaxes and refills the heart chambers with blood [6]. Hence the proposed VAD is designed to inflate and impart pressure on the ventricles during systole event, and deflate balloon to relax ventricle during diastole span. The systole period occurs between R and T peaks of the ECG signal where balloon is inflated and diastole event occurs from T to R peaks where balloon is deflated, as shown in Figure. 2.

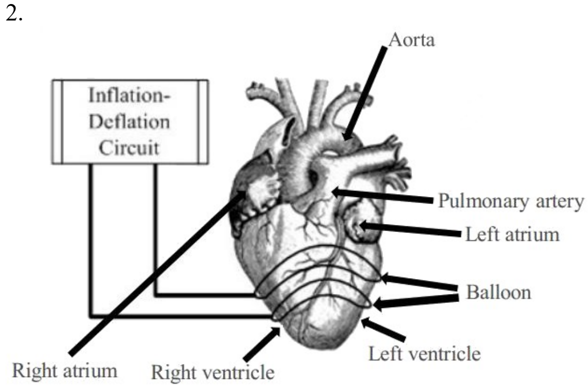

Figure 1. Schematic showing the connections of the balloon, that is wrapped around the human heart. The human heart was reproduced from [5].

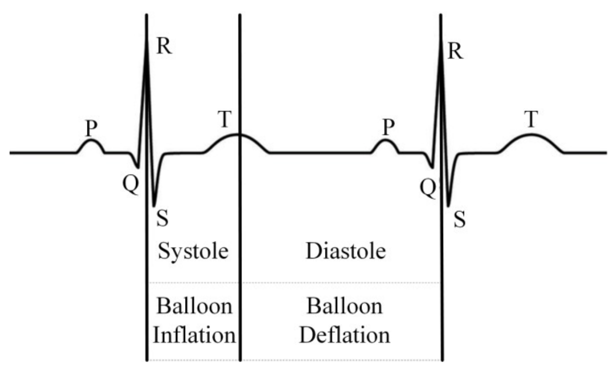

Figure 2. The proposed device operations in reference to a sample ECG signal. The ECG signal is reproduced from [6].

A circuit to inflate and deflate the balloon consists of an air compressor, vacuum pump and solenoid valves. Switched Mode Power Supply (SMPS) drives air compressor that requires 12V and 15A supply, along with the 12 V rated vacuum pump and solenoid valves. The balloon is connected

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to air compressor and vacuum pump via a T-joint and solenoid valves. Solenoid valve are electrically controlled using L293D motor driver IC, which is interfaced to the controller as shown in Figure. 3. Signal acquisition circuit to capture ECG signal was designed and interfaced with an Arduino Uno controller. Each ECG cycle was represented by 90 samples in the range of 0 to 1024. Solenoid valve referred to as *valve-A*, is tied to the tube connecting balloon and the reservoir, and *valve-B* is fastened to the tube connecting balloon and vacuum pump. During the diastole event, *valve-B* is opened to deflate the balloon, and *valve-A* is closed. In Systole duration, *valve-A* is opened, and *valve-B* is closed to inflate the balloon. In the proposed design, a slower heart rate proliferates the balloon and exerts additional pressure than recommended, hence a sensory system is integrated in the VAD device. The velostat pressure sheet is sandwiched between two aluminum foils [7], and is encased around the heart. The balloon is wrapped over the sensor and around the heart. The sensor continuously monitors the pressure applied by the balloon on the ventricles of the heart and switches off the balloon inflation mechanism when the pressure reaches a pre-defined value, above which the heart fails to withstand. The sensory system switches off the air compressor and closes *valve-A* thereby blocking the inflow of the air from the reservoir to the balloon, and stopping the inflation process.

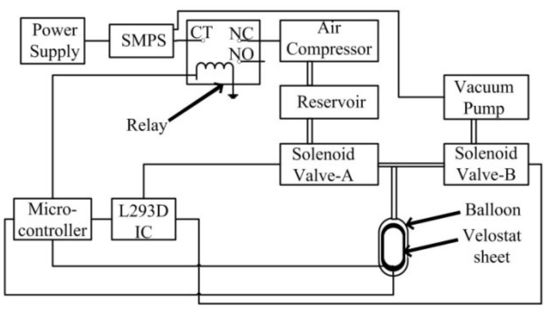

Figure 3. Block diagram of experimental setup showing feedback circuit and balloon wrapped around velostat sheet sensor.

III. EXPERIMENTS AND RESULTS

The prototype device was examined with a real time ECG signal acquired from a subject. Figure 4 shows the alternate switching of solenoid valves connected to vacuum pump and to air reservoir in accordance with ECG signal. Figure 4 also includes the relative pressure measured around the 3D modeled heart from the velostat sheet sensor, confirming the balloon pulsation cycle timing in accordance with ECG signal. A higher heart rate from the subject post routine exercise activity was captured and fed to the feedback controlled VAD system. An adequate pressure was maintained on the walls of the heart, due to an increased switching rate of the two solenoid valves as shown in Figure 4.

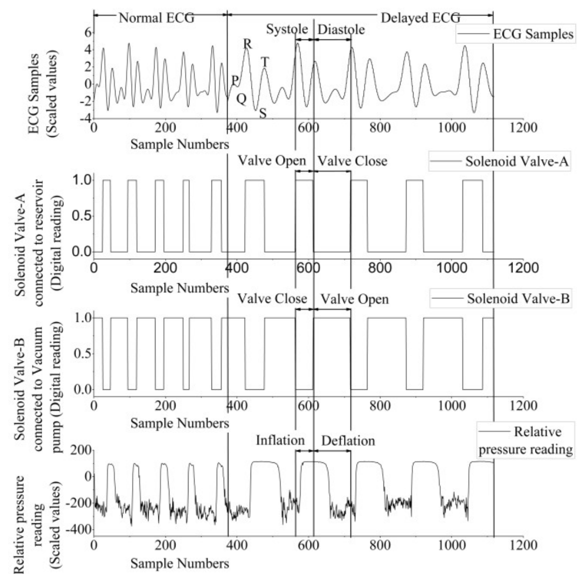

Figure 4. Transient graph showing relative pressure measured from velostat sheet sensor and voltage level measured at controller pins that are interfaced to solenoid valves, for optimal and lower heart rate.

IV. CONCLUSION

A minimally invasive Ventricular Assistive Device was designed and the working was demonstrated in accordance with offline acquired ECG signal. Possibility of achieving high pressure in the balloon due to a prolonged systole event, observed in slower heart rate is undesirable, hence an ECG based feedback control module was designed and integrated to the VAD system. The prototype working of a novel minimally invasive and ECG controlled VAD is described and analyzed. The design and demonstration of a novel prototype is a step closer to realize an ECG controlled VAD system in medical practices.

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