ANATOMY AND PHYSIOLOGY BASED MOCK LOOP FOR CARDIAC IMPLANT DEVELOPMENT

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Introduction

The integration of biological organs into *in vitro* mock loops is essential to simulate the operating conditions of medical devices under realistic testing conditions in the development phase which usually requires animal testing. A multifunctional mock loop connected to a porcine heart has been developed to mimic the natural movement of the heart. The current focus of this test bench is on the anchoring of pacemaker electrodes. The current focus of this mock loop is to support the development of cardiac electrodes.

Methods

The operating principle of the *in vitro* mock loop is to drive the movement of the ventricular walls throughout the cardiac cycle, mimicking the pulsatile pumping function of the heart. To achieve this, the system is able to pressurize the ventricles while excluding the atria from external loads. The system consists of a fluid-filled chamber that houses the ventricles and is sealed to isolate the atria from external stress loads. The heart is held in place by two thermally molded polyurethane foils supported by radially shiftable pins pointing towards the coronary sulcus. The thermoformability of the foils allows the mock loop to handle the high variability of the hearts. In between those foils a vacuum is generated. The chamber is connected a computer-controlled piston pump that cyclically injects and withdraws fluid in and out of the chamber, hence directly actuating the ventricular walls. The atriae and the large arteries are connected to the two circuits (cardiac and pulmonary circulation) with silicone tubes and 3D printed connectors. Each circuit consists of an open and a closed reservoir, a pressure sensor, a flow sensor, and a resistor. The current state of the test bench is shown in Figure 1.

Results

An initial pilot experiment was conducted to demonstrate the functionality of the mock loop. A representative example of the pressure and flow measured in the mock loop was recorded, which was consistent with typical systemic in vivo waveforms. It was possible to generate pressure and flow conditions corresponding to the diastole and systole of the beating human heart.

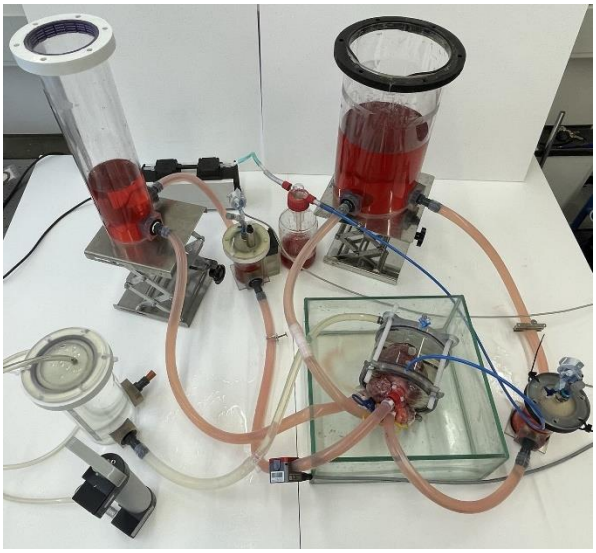

Figure 1: Mock loop for the development of cardiac implants using a slaughterhouse porcine heart, showing the heart housed in the fluid-filled chamber.

Discussion

From a technical point of view, the main challenge of the approach is to seal the pressurized fluid chamber around the coronary sulcus and to fix the heart within the mock loop In this regard, the design of two thermally molded vacuum sealing foils together with shiftable pins allowed a simple, efficient and reliable sealing and mounting of the heart, allowing physiological ventricular stroke volumes. Together with the hydraulic modules used in the mock loop this results in the achievement of appropriate hemodynamic conditions in the setup. Further improvements to the mock loop are required and will be implemented in the coming months.

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