Evolution of a Non-Invasive Method for Providing Assistance to the Heart

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The primary function of the ventricular chambers of the heart is to provide the proper volume of blood to the entire body that fulfills its energy requirements under a wide variety of normal and pathologic settings. If the ventricles are unable to perform this task properly, and the functions of the body deteriorates despite optimal medical management, mechanical methods are utilized to either complement or replace the pumping function of the cardiac ventricles. This presentation will describe the evolution of a non-invasive method of assisting the circulation called "counterpulsation," and the current state of the development of an "External Left Ventricular Assist Device" (XLVAV). In this method, in the first part of the cardiac cycle, when the heart is relaxed, cardiac diastole, the device exerts a positive pressure external to the lower extremities. This increases coronary artery blood flow and cardiac output. Then when the ventricle contracts, cardiac systole, the device exerts a negative pressure, thus drawing blood away from the heart into the lower extremities, resulting in a reduction of the work and energy requirement of the left ventricle. Experimental and clinical data will be presented that describe the following successive stages of development: 1. The initial experience of Osborn in 1962 using a pressure suit and air actuation was tested in a canine model and in normal volunteers, but was not successful since sufficient pressure was not exerted on the vascular bed of the lower extremities. 2. The initial experimental experience of Birtwell and Soroff in a canine model in 1962 using water as the actuating medium. 3. The construction of a device by Birtwell with cuff-type actuators around the legs, thighs and buttocks that were inflated with water. The cuffs had rigid shells to allow pressure to be exerted to the limbs. The device was successful in increasing diastolic pressure and coronary blood flow and was used successfully in a multicenter study as an initial treatment of patients with acute myocardial infarctions. However, since the device could only apply positive pressure, it could not be used to reduce systolic pressure. 4. The device was then modified to also apply negative pressure during cardiac systole, a major step forward, and tested in a multicenter study in patients with cardiogenic shock following myocardial infacrtions with an impressive increase in the survival rate from 15% to 45%. However, the device presented logistical and patient movement problems. 5. The next evolution in the device design was the use of air to inflate the actuator cuffs. This represented a significant breakthrough, and has been successfully used in the treatment of angina pectoris by increasing coronary blood flow and the promotion or creation of collateral circulation in the myocardium. The serious shortcoming of this device is that is cannot produce negative pressure during cardiac systole, i.e., the only means of assisting the left ventricle in patients with Congestive Heart Failure. 6. The device to be described can apply negative as well as positive pressure to the lower extremities using air as the actuating medium. The device is mobile and compact, and should be effective in the treatment of patients with Congestive Heart Failure both in the hospital setting and in the home, Acute Myocardial Infarction as well as Angina Pectoris.

A Wireless Insufflation System for Capsular Endoscopes

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Swallowable capsule-based cameras (e.g., the Given Imaging PillCam and competitors) are rapidly becoming the gold standard for diagnosis in the gastrointestinal (GI) tract. However, definitive diagnosis is still often precluded by the inability to control capsule position and orientation. This has inspired a number of active positioning strategies including augmenting the capsule with legs or other appendages, or incorporating magnets which can apply forces and torques in response to an external magnetic field. Furthermore, the loose, mucous coated, elastic intestine is generally deflated during capsule passage, making it challenging to view the entire internal surface adequately without the insufflation that is relied upon in traditional endoscopy. To address these challenges, we propose a new fluid-powered system that permits insufflation from a wireless capsule platform. This is accomplished by carrying a small reservoir of biocompatible liquid onboard the capsule which vaporizes and expands when released through a small onboard solenoid valve. The internal components of the capsule consist of two 3V Lithium coin cell batteries (VL621, Panasonic, Inc.) which charge 3 Tantalum capacitors (TAJB157M006R, AVX Corporation, Inc.) that fire the solenoid valve (S120, Lee Company, Inc.). In our initial proof-of-concept study, we have packaged all components in a 26 mm long by 11 mm diameter capsule. The fluid used in initial experiments is biocompatible Perfluoropentane, although any of a variety of biocompatible fluids that can be liquefied with light pressurization may be used. Perfluoropentane, developed for lung lavage, is a liquid at room temperature and becomes gaseous at body temperature. We note that pneumatic pressure produced in this way may be used for a variety of objectives, including powering biopsy collection devices or other mechanisms within the capsule, or being vented to inflate the intestine. In initial experiments, we have harnessed the pressure to inflate a balloon at the front of the capsule which can distend tissue and thereby improve image quality. In experimental tests, only 0.2 ml of fluid was consumed in inflating the balloon to sufficient pressure to distend porcine intestine (see http://research.vuse.vanderbilt.edu/MEDLab for images of these experiments). Optimization of the capsule body and electrical components is currently underway. Including a wireless camera, all components are expected to fit within the dimensions of a commercial PillCam.

